RESEARCH PLAN

Effects of telerehabilitation on occupational performance of stroke patients treated by the Occupational Therapy service: a randomized clinical trial.

Principal Investigator: André Tadeu Sugawara

Associate Researchers: Paulo Vitor Rodrigues da Silva, Gracinda Rodrigues Tsukimoto, Denise Rodrigues Tsukimoto, Tatiana Amodeo Tuacek

Department/Institute: Department of Legal Medicine, Bioethics, Occupational Medicine, and Physical Medicine and Rehabilitation / Institute of Physical Medicine and Rehabilitation of the Hospital das Clínicas

CAAE: 86185525.8.0000.0068
Version: 3
Opinion Number: 7.441.169
Location: São Paulo, Brazil
Date of approval: August 21, 2025

RESEARCH PLAN

SUMMARY

Stroke represents a health problem with increasing incidence in the world population. The consequences of the injury are not limited to physical deficits, but also encompass significant biopsychosocial changes. This study aims to evaluate the effect of using telehealth, specifically telerehabilitation, correlated with the practice of Occupational Therapy for the population affected by stroke. To this end, a randomized study will be conducted, which will involve data collection through a structured sociodemographic questionnaire and standardized scales: Scale of Instrumental Activities of Daily Living, Katz Scale, and the Motor Activity Log, which will be applied to the intervention group and the control group. Participants will be users of the Unified Health System (SUS) who are on the waiting list, with an indication for Occupational Therapy services in an outpatient or inpatient setting at the Institute of Physical Medicine and Rehabilitation of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (IMREA FMUSP). The intervention group is expected to show improved occupational performance in response to the guidance provided to patients and caregivers.

Keywords: Stroke (D020521), Digital Public Health (DDCS060401), Telemedicine (D017216), Occupational Therapy (D009788).

INTRODUCTION

A stroke is a significant neurological injury, characterized by an abrupt change in brain function, and is currently the leading cause of disability worldwide (Steinmetz et al., 2024). It can be caused by two distinct pathophysiological mechanisms: ischemic, accounting for 85% of cases, and hemorrhagic, accounting for 15%(Vieira et al., 2020). In 2020, the total costs to the public health system for stroke in Brazil amounted to 416 million Brazilian Reais (BRL) (Reis; Chaoubah, 2024). The estimated incidence of this pathology in the country is 232,000 to 344,000 new cases per year (Ministry of Health, 2021). The sequelae caused by stroke can lead to loss of autonomy and independence for the individual, making it impossible to perform Basic Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL), impacting their family and social interactions, due to the need for assistance, in many cases, to perform various tasks (Vieira et al., 2020; Castro; Martins; Colto; Reis, 2018).

Post-stroke treatment involves a wide range of care and should be intensive, timely, and multidisciplinary (Langhorne; Sandercock; Prasad, 2009). Therefore, efficient treatment has a significant impact on costs, making access to specialized post-stroke treatment services important (Fonseca et al., 2018). Ensuring access to rehabilitation services is fundamental to the recovery process, as it contributes to social reintegration and the resumption of occupational performance (Platz, 2021). However, several barriers impede access, ranging from the organization of health services, due to a lack of material or human resources, to financial resources and the family dynamics of the stroke victim (Santos et al., 2022). In this context,

telehealth is a service modality that has been used to address these shortcomings (Luz, 2022; Silva et al., 2023).

The term telehealth is comprehensive, encompassing teleconsultation, telemonitoring, teleconsulting services, telemedicine, telerehabilitation, among others, to provide remote health services through telecommunications and digital information technologies (COFFITO, 2020; Cason, 2012). Telerehabilitation, specifically, is a field of telehealth correlated with the provision of remote rehabilitation services to users, using Information and Communication Technologies (ICTs) (Noorani, Picot, 2001). This type of care was boosted by the global health crisis of the COVID-19 pandemic, becoming promising for cost reduction and optimization of access to health services (Garfan et al., 2021). Thus, it enables the provision of health care in remote areas, regions with a shortage of professionals, without the need for a robust care infrastructure. In the context of post-stroke rehabilitation, telerehabilitation can overcome significant barriers, such as dependence on caregivers, financial problems, lack of regional medical resources, and transportation challenges, by making rehabilitation feasible for stroke survivors in adverse settings (Chumbler et al., 2012; Sarfo et al., 2018).

In the context of telerehabilitation, multidisciplinary intervention is also a fundamental factor in ensuring the quality of treatment in stroke services (Clarke; Forster, 2015). The multidisciplinary team for post-stroke treatment is composed of multiple health professionals, many of whom include an occupational therapist. Occupational Therapy is a field of knowledge and profession focused on occupation and aimed at strengthening support for the individual to achieve performance, aiming at the acquisition of "new patterns that meet their personal needs and desires" (Kielhofner, 2006, p. 66). In the context of physical rehabilitation and post-stroke treatment, this objective translates into the recovery of skills necessary for performance in ADLs and IADLs.

It is estimated that 22.6% of healthcare costs are allocated to musculoskeletal dysfunctions (Briggs et al., 2018), indicating the significant demand for rehabilitation services. However, there is a mismatch between supply and demand, resulting in extensive waiting lists in healthcare services (Meneses; Silva; Silva, 2020). From this perspective, the importance of specific strategies for managing, regulating, and optimizing waiting lists is evident, since early intervention for individuals affected by stroke is essential for a good prognosis (Zeiler, 2019). It is also important to consider that the post-stroke recovery process is multifactorial, with genetic, pathophysiological, environmental, and therapeutic factors determining the overall course of recovery (Wlodarczyk et al., 2021).

There is still no formal structure for telehealth, so access to this type of service can occur in various ways (Galea, 2019), and studies on its applicability are needed. It is also important to consider that access to specialized care is still a major bottleneck; the average waiting time for care in universal systems can exceed 10 months (Edwards; Hensher, 1998; Katz et al., 2020). Given the increasing use of telehealth by occupational therapists in the Brazilian Unified Health System (SUS) and the incorporation of digital technologies in the health field, it presents a potentially effective strategy to optimize the efficiency of rehabilitation services (Eroğlu et al., 2020).

RESEARCH PLAN

HYPOTHESES

This study will examine the effect of using telerehabilitation as an occupational therapy intervention strategy for stroke patients, as clinically indicated, who are awaiting in-person care from this same professional category, whether outpatient or inpatient, at the Institute of Physical Medicine and Rehabilitation of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (IMREA HCFMUSP).

GENERAL OBJECTIVE

To determine the effects of Occupational Therapy services provided through telerehabilitation for the population with sequelae from CVA who are awaiting outpatient or inpatient inpatient care.

SPECIFIC OBJECTIVES

To establish the occupational performance of participants through the application of specific scales, using occupational therapy intervention via telerehabilitation;

To demonstrate and analyze the challenges and limitations during the application of telerehabilitation services to stroke patients participating in the study;

To identify telerehabilitation as a strategy for optimizing care and access to public rehabilitation services.

METHODS

In order to answer the research objectives, a randomized controlled trial study was chosen. This is a pilot study that will be developed through the proposal of telerehabilitation sessions for patients on a waiting list, with a medical prescription, for Occupational Therapy care at the IMREA FMUSP, linked to the Lucy Montoro Rehabilitation Network.

A convenience sample will be used (20 users, divided equally into two groups), considering that patients awaiting care will be subject to the research eligibility criteria and will be selected in descending order (selected in reverse chronological order from the waiting list) to allow sufficient time for the intervention. If a study participant, regardless of the group to which they belong, is called to begin in-person Occupational Therapy care, a final assessment will be applied, concluding the follow-up.

Data collection for initial and final assessments will be conducted by an independent researcher, not involved in the study, allowing for a single-blind study. Participants will be divided into two groups using randomization: intervention and control. The first group (intervention) will participate in one 45-minute session per week for eight weeks. During this

time, participants will receive guidance and perform therapeutic activities to improve occupational performance. The second group (control) will remain on the waiting list, without a specific intervention, as they were already waiting for care. Both groups will undergo initial assessments in the first session and final assessments in the last session. Jerry Dallal's randomization tool (Dallal, 2020) will be used to classify participants into the first and second groups. Allocation, at a 1:1 ratio, will be conducted by an independent researcher who will not participate in data collection or statistical analysis. The concealed allocation will be implemented using sequentially numbered, opaque, and sealed envelopes. A blind evaluator will open the sealed envelopes after the Informed Consent Form (ICF) has been signed and will conduct the evaluation of the participant in person. Those participants selected by lottery, belonging to the intervention group, will be given a schedule with the dates and topics that will be addressed in each session. Participants in the control group will sign the ICF and complete the structured questionnaire and rating scales.

The following research protocols will be used as data collection instruments: Katz Scale (Lino et al., 2008) for assessing ADLs; Scale of Instrumental Activities of Daily Living (Dos Santos; Júnior, 2008) for measuring performance in IADLs; and Motor Activity Log (MAL) for assessing hand motor function (Saliba et al., 2011). The study will be conducted according to the Consolidated Standards of Reporting Trials (CONSORT) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Participants will also be given a structured sociodemographic questionnaire, developed by the researcher, to collect demographic data, including age, sex, educational level, and other data. Similarly, clinical data will be collected, such as the duration of hemiplegia, laterality of the affected body, etiology, hand preference, risk factors, and motor stages according to the Brunnstrom model (Naghdi, 2010). The questionnaire will be administered by the independent researcher at the time of randomization.

Thus, based on the research instruments presented, the research will be structured in five stages: i) recruitment of eligible patients; ii) randomization; iii) application of scales and structured questionnaire (intervention and control groups); iv) occupational therapy intervention via telerehabilitation (intervention group); v) final evaluation (intervention and control groups); vi) data processing and analysis.

Inclusion criteria

Adult patients, clinically stable, regardless of sex, race/color, aged 18 years or older, who present with sequelae of stroke, regardless of the Rankin scale score (Rankin, 1957), on a waiting list and according to medical indication for Occupational Therapy care at IMREA HCFMUSP. Individuals must also have access to a computer, tablet, and smartphone with an internet connection that allows for video calls, understand the Portuguese language, and have the assistance of a caregiver during therapy sessions, if necessary.

Exclusion criteria

RESEARCH PLAN

Clinically unstable patients, such as frail elderly individuals with decompensated chronic diseases and high-risk pregnant women **and individuals** under 18 years of age who are not on a waiting list for Occupational Therapy at IMREA HCFMUSP, in accordance with medical indication. Individuals who do not have access to a computer, tablet, or smartphone with an internet connection, and who do not have a caregiver when needed during therapy sessions, will also be excluded.

RISK ANALYSIS

The research presents a low risk of harm to participants, as it involves remote guidance, not exposing the user to any type of invasive procedure or risk associated with travel for appointments. However, the nature of stroke can result in significant variations in the cognitive and physical abilities of patients, which may interfere with adherence to and development of therapeutic interventions through telerehabilitation. Regarding the proposal to conduct remote appointments via video call platforms, there is a risk that sessions may be compromised due to technical and connection problems at the time of the sessions, potentially leading to difficulties in understanding and hindering the visualization and interpretation of instructions, inhibiting or hindering participation. Interruption of remote appointments will occur due to health problems and personal issues of the patient that prevent their participation; recurring technical issues that prevent the patient from accessing sessions; lack of interest from the research participant in continuing treatment; as well as the start of in-person Occupational Therapy appointments. To minimize such risks, a set of measures and/or procedures will be taken to ensure the privacy, confidentiality, and security of participants and their information. These are: i) data collection through scales and the structured questionnaire will be carried out manually, and only the researchers involved in the research will have access; ii) data collected manually will be digitized and stored on institutional servers; iii) personal information of participants related to the information provided will not be part of the research records, including any information that could be used to establish, identify, or reveal the participant's identity, or any other data that may be requested by the participant will be discarded from the research records; iv) depending on the degree of difficulty the patient has in performing the activities through telerehabilitation, it will be necessary for them to have a family member or caregiver present during the session; v) the participant will have complete freedom not to participate or to withdraw their consent at any time, even after the conclusion of the research, without any penalty, and will have confidentiality and privacy. vi) Nevertheless, in the event of harm or distress, the researcher is committed to providing support and referring participants to the physician responsible for the patient, without any expenses for the participants.

BENEFITS

The benefit of this research to individuals diagnosed with stroke and to occupational therapists working in the rehabilitation field within the Brazilian Unified Health System (SUS) is direct. For patients, it represents a possible structuring of another healthcare pathway in the

rehabilitation process. For professionals, the research is linked to expanding knowledge about the use of telehealth for rehabilitation interventions within the SUS. The benefits for other professional categories are indirect, through support for research aimed at developing and improving the skills necessary for providing virtual healthcare services.

DATA ANALYSIS

The data collected through assessments and the structured questionnaire will be organized and classified according to their variables in digital spreadsheets. Subsequently, this data will be stratified using STATA software for statistical analysis. The effects of telehealth and the occupational performance of the participants will be determined by comparing the means between the intervention and control groups, as observed in the study assessments. The analysis method will be defined as either the Student's t-test or the Wilcoxon test, depending on whether the data are parametric or non-parametric, after normality tests using Shapiro-Wilk and evaluation of histograms or q-q plots. The other objectives will be analyzed descriptively. The information obtained will be correlated with the bibliographic material collected, aiming to integrate the results and draw conclusions about the use of telerehabilitation by occupational therapists.

FINANCIAL RESOURCES

The research will not receive direct public or private funding. Expenses related to equipment, personnel, materials and supplies, among other costs necessary for the project, are already integrated into the routine of the health service. Thus, these costs will not represent an additional burden on the institution's operation.

TIMELINE

The planned research schedule will be executed, as per Table 1, if the project is approved by the CEP/CONEP System. The same will occur within a period of 11 months.

Stage Identification	**Month**										
	01	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**
Field research - participant recruitment and randomization	X	X									
Field research - initial application of questionnaires and scales (group, intervention, and control)	X	X									
Field research - occupational therapy intervention via telerehabilitation (intervention group)		X	X	X	X						
Field research - application of final assessments (group, intervention, and control)				X	X						
Bibliographic research					X	X					

Data analysis					X	X	X				
Research report							X	X	X		
Development of Residency Completion Project							X	X	X	X	X

PROCEDURES AFTER COMPLETING THE RESEARCH

Following the conclusion of the research, the researchers commit to the public dissemination of the results, whether favorable or unfavorable, either through the development of a scientific article or presentations at academic events such as congresses, symposia, and others. This commitment relates to the dedication to scientific dissemination so that the research has a significant impact on the advancement of knowledge and the improvement of healthcare for patients with stroke sequelae.

REFERENCES

1. BRASIL. Conselho Federal de Fisioterapia e Terapia Ocupacional. Dispõe sobre teleconsulta, telemonitoramento e teleconsultoria [Internet]. COFFITO. Resolução nº 516, de 20 de content/uploads/2020/03/Resolucao516_2020.pdf

2. BRIGGS, Andrew M. et al. Reducing the global burden of musculoskeletal conditions. **Bulletin of the World Health Organization**, v. 96, n. 5, p. 366, 2018.

3. CASON, Jana. Telehealth opportunities in occupational therapy through the Affordable Care Act. **The American Journal of Occupational Therapy**, v. 66, n. 2, p. 131-136, 2012.

4. CHAN, An-Wen et al. SPIRIT 2013 Statement: defining standard protocol items for clinical trials. **Revista Panamericana de Salud Pública**, v.38, p. 506-514, 2015.

5. CLARKE, David J.; FORSTER, Anne. Improving post-stroke recovery: the role of the multidisciplinary health care team. **Journal of multidisciplinary healthcare**, p. 433-442, 2015.

6. DALLAL, G. E. Randomization Plans: Randomizing Subjects to a Single Treatment, 2020 (acesso 19 novembro 2024), http://www.jerrydallal.com/random/assign.htm.

7. DE OLIVEIRA, P. et al. Terapia por caixa de espelho e autonomia no autocuidado após acidente vascular cerebral: programa de intervenção. **Revista de Enfermagem Referência**, v. 4, n. 17, p. 95-105, 2018.

8. DOS REIS, M. F.; CHAOUBAH, A.. Gastos do Sistema Único de Saúde e do Regime Geral de Previdência Social com o acidente vascular cerebral: Brasil, 2020. **Revista Eletrônica Acervo Saúde**, v. 24, n. 2, p. e14884-e14884, 2024.

9. DOS SANTOS, A. R. T. et al. Barreiras de acesso a reabilitação física pós acidente vascular cerebral: uma revisão integrativa. Research, Society and Development, v. 11, n. 4, p. e4911427224-e4911427224, 2022.

10. DOS SANTOS, R. L.; JÚNIOR, J. S. V. Confiabilidade da versão brasileira da escala de atividades instrumentais da vida diária. **Revista Brasileira em Promoção da Saúde**, v. 21, n. 4, p. 290-296, 2008.

11. EDWARDS, N.; HENSHER, M. Managing demand for secondary care services: the changing context. **BMJ**, v. 317, n. 7151, p. 135-138, 1998.

12. EROĞLU, M. et al. Occupational therapy assessment and treatment approach in patients with subacute and chronic stroke: A single-blind, prospective, randomized clinical trial. **Turkish journal of physical medicine and rehabilitation**, v. 66, n. 3, p. 316, 2020.

13. FONSECA, A. R. R. et al. Impacto socioeconômico do Acidente Vascular Cerebral no estado de Roraima: um estudo de coorte de base hospitalar. **Revista Brasileira de Neurologia e Psiquiatria**, v. 22, n. 2, 2018.

14. GALEA, M. D. Telemedicine in rehabilitation. **Physical Medicine and Rehabilitation Clinics**, v. 30, n. 2, p. 473-483, 2019.

15. GARFAN, S. et al. Telehealth utilization during the Covid-19 pandemic: a systematic review. **Computers in biology and medicine**, v. 138, p. 104878, 2021.

16. KATZ, N. et al. Access and regulation of specialized care in Rio Grande do Sul: the RegulaSUS strategy of TelessaúdeRS-UFRGS. **Ciência & Saúde Coletiva**, v. 25, p. 1389-1400, 2020.

17. LANGHORNE, P.; SANDERCOCK, Peter; PRASAD, Kameshwar. Evidence-based practice for stroke. **The Lancet Neurology**, v. 8, n. 4, p. 308-309, 2009.

18. LINO, V. T. S. et al. Adaptação transcultural da escala de independência em atividades da vida diária (Escala de Katz). **Cadernos de saúde pública**, v. 24, p. 103-112, 2008.

19. LUZ, L. S. Telessaúde em tempos de pandemia da covid 19: percepção de fisioterapeutas e de terapeutas ocupacionais do estado de São Paulo. 2022. march 2020.

20. MENESES, A. S. et al. Perspectiva financeira sobre regulação de filas de espera para fisioterapia na Atenção Primária à Saúde. In SciELO Preprints. 2020.

21. MINISTÉRIO DA SAÚDE. Datasus. Brasília, DF: Ministério da Saúde, 2021. Disponível em: http://tabnet.datasus.gov.br/cgi/deftohtm.exe?sim/cnv/obt10uf.def. Accessed on October 6, 2024.

22. NAGHDI, S.et al. A neurophysiological and clinical study of Brunnstrom recovery stages in the upper limb following stroke. **Brain injury**, v. 24, n. 11, p. 1372-1378, 2010.

23. NOORANI, H. Z.; PICOT, J. Assessment of videoconferencing in telehealth in Canada. Ottawa, Ontario: Canadian Coordinating Office for Health Technology Assessment, 2001.

24. PLATZ, T. Caminhos clínicos na reabilitação de AVC: Recomendações de prática clínica baseadas em evidências. 2021.

25. RANKIN, J. Acidentes vasculares cerebrais em pacientes com mais de 60 anos: II. Prognóstico. **Revista médica escocesa**, v. 2, n. 5, p. 200-215, 1957.

26. SAFANELLI, J. et al. The cost of stroke in a public hospital in Brazil: a one-year prospective study. **Arquivos de neuro-psiquiatria**, v. 77, n. 6, p. 404-411, 2019.

27. SALIBA, V. A. et al. Adaptação transcultural e análise das propriedades psicométricas da versão brasileira do instrumento Motor Activity Log. **Revista Panamericana de Salud Pública**, v. 30, n. 3, p. 262-271, 2011.

28. SARFO, F. S. et al. Tele-rehabilitation after stroke: an updated systematic review of the literature. **Journal of stroke and cerebrovascular diseases**, v. 27, n. 9, p. 2306-2318, 2018.

29. SCHULZ, K. F.; ALTMAN, D. G.; MOHER, D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. **Journal of Pharmacology and pharmacotherapeutics**, v. 1, n. 2, p. 100-107, 2010.

30. SILVA, L. K. C.et al. Acesso de pacientes com AVC à telessaúde: quais são as principais barreiras e como são explicadas pelo modelo teórico UTAUT? Uma revisão sistemática. **Fisioterapia e Pesquisa**, v. 30, p. e22009023en, 2023.

31. STEINMETZ, J. D. et al. Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. **The Lancet Neurology**, v. 23, n. 4, p. 344-381, 2024.

32. URBANIAK, G. C.; PLOUS, S. Research randomizer [Computer software]. **Social Psychology**. Retrieved from https://www. randomizer. org, 2020.

33. VIEIRA, I. P. et al. Funcionalidade e qualidade de vida em pacientes pós acidente vascular cerebral. **Brazilian Journal of Developmen**t, v. 6, n. 4, p. 17391-17403, 2020.

34. WLODARCZYK, L. et al. Biomarkers of angiogenesis and neuroplasticity as promising clinical tools for stroke recovery evaluation. **International journal of molecular sciences**, v.22, n. 8, p. 3949, 2021.

35. WOLF, S. L. et al. The HAAPI (Home Arm Assistance Progression Initiative) trial: a novel robotics delivery approach in stroke rehabilitation. **Neurorehabilitation and neural repair**, v. 29, n. 10, p. 958-968, 2015.

36. ZEILER, S. R. Should we care about early post-stroke rehabilitation? Not yet, but soon. **Current neurology and neuroscience reports**, v. 19, p. 1-9, 2019.

APPENDICES

1. Scale of Instrumental Activities of Daily Living (Brazilian version)

This interview aims to identify your functional status level by assessing possible difficulties in performing activities of your daily life. Please try to recall for each activity if you perform it without help, with some assistance, or if you do not perform it at all.

Regarding telephone use...
a) Telephone
[ ]³ receives and makes calls without assistance
[ ]² requires assistance to make telephone calls
[ ]¹ does not have the habit or is unable to use the telephone

Regarding travel…
b) Travel
[ ]³ travels alone
[ ]² only travels when accompanied
[ ]¹ does not have the habit or is unable to travel

Regarding shopping...
c) Shopping
[ ]³ does shopping, when transportation is provided
[ ]² only does shopping when accompanied
[ ]¹ does not have the habit or is unable to go shopping

Regarding meal preparation...
d) Meal preparation
[ ]³ plans and cooks full meals
[ ]² prepares only small meals or when receiving help
[ ]¹ does not have the habit or is unable to go shopping* *(Note: The original text in the image repeats "unable to go shopping" instead of "unable to prepare meals").*

Regarding housework...
e) Housework
[ ]³ performs heavy tasks
[ ]² performs light tasks, requiring help with heavy ones
[ ]¹ does not have the habit or is unable to perform housework

Regarding medication use...
f) Medications
[ ]³ takes medications without assistance
[ ]² requires reminders or assistance
[ ]¹ is unable to manage medication use alone

Regarding money management...
g) Money
[ ]³ fills out checks and pays bills without assistance
[ ]² requires assistance using checks and bills
[ ]¹ does not have the habit of dealing with money or is unable to manage money, bills...

Classification
[ ] Total dependence = ≤5 (P_{25})
[ ] Partial dependence = >5 < 21 (>P_{25} < P_{100})
[ ] Independence = 21 (P_{100})

2. Motor Activity Log (Brazilian version)

Dominant side:_____ Affected side:_____

RESEARCH PLAN

	Quantitative Scale	Qualitative Scale	
1) Turn the light on using the switch	_____	_____	If not, why? (use code)__ Comments _____
2) Open a drawer	_____	_____	If not, why? (use code)__ Comments _____
3) Taking a piece of clothing out of the drawer	_____	_____	If not, why? (use code)__ Comments _____
4) Take the phone off the hook	_____	_____	If not, why? (use code)__ Comments _____
5) Wipe down (clean) the kitchen countertop	_____	_____	If not, why? (use code)__ Comments _____
6) Exiting the car (includes only the movement necessary to get up from the seat and stand outside the car after the door is open)	_____	_____	If not, why? (use code)__ Comments _____
7) Open the refrigerator	_____	_____	If not, why? (use code)__ Comments _____
8) Open a door by turning the doorknob	_____	_____	If not, why? (use code)__ Comments _____
9) Using the TV remote control	_____	_____	If not, why? (use code)__ Comments _____
10)Washing hands (includes lathering and rinsing hands; opening/closing a hand tap)	_____	_____	If not, why? (use code)__ Comments _____
11) Opening and closing a screw or lever tap	_____	_____	If not, why? (use code)__ Comments _____
12) Dry your hands	_____	_____	If not, why? (use code)__ Comments _____
13) Put on the socks	_____	_____	If not, why? (use code)__ Comments _____
14) Take off your socks	_____	_____	If not, why? (use code)__ Comments _____
15) Putting on the shoes (includes tying the laces and adjusting the Velcro or straps)	_____	_____	If not, why? (use code)__ Comments _____
16) Taking off your shoes (includes untying laces and loosening Velcro or straps)	_____	_____	If not, why? (use code)__ Comments _____
17)To stand up from a chair with armrests	_____	_____	If not, why? (use code)__ Comments _____
18) Move the chair away from the table before sitting down	_____	_____	If not, why? (use code)__ Comments _____
19) Pulling the chair towards the table after being seated	_____	_____	If not, why? (use code)__ Comments _____
20) Raise a glass, bottle (glass or plastic) or can (does not need to include drinking)	_____	_____	If not, why? (use code)__ Comments _____
21) Brushing your teeth (does not include preparing the toothbrush or brushing dentures, unless the dentures are brushed inside the mouth)	_____	_____	If not, why? (use code)__ Comments _____
22) Applying foundation, lotion, or shaving cream to the face	_____	_____	If not, why? (use code)__ Comments _____
23) Using a key to unlock a door	_____	_____	If not, why? (use code)__ Comments _____
24) Writing on paper (if the hand used for writing before the stroke is the most affected, score the item; if the hand that did not write before the stroke is the most affected, skip the item and mark N/A)	_____	_____	If not, why? (use code)__ Comments _____

RESEARCH PLAN

25) Carrying an object in your hand (hanging an item over your arm is not acceptable)	_____	_____	If not, why? (use code)__ Comments _____
26) Using a fork or spoon to eat (refers to the action of bringing food to the mouth with a fork or spoon)	_____	_____	If not, why? (use code)__ Comments _____
27) Comb your hair	_____	_____	If not, why? (use code)__ Comments _____
28) Lifting a cup by the handle	_____	_____	If not, why? (use code)__ Comments _____
29) Buttoning a shirt	_____	_____	If not, why? (use code)__ Comments _____
30) Eating half of a sandwich, appetizer, or snack (any food that is eaten with your hands).	_____	_____	If not, why? (use code)__ Comments _____
TOTAL:	_____	_____	

Codes for recording "no" responses

1. "I used my unaffected arm the entire time" (check "0").
2. "Someone else did it for me." (mark "0").
3. "I never do this activity, with or without help from others, because it's impossible." For example, combing hair on bald people. (mark "N/A" and remove from the list of items).

4. "I sometimes do this activity, but I haven't had the opportunity since the last time I answered these questions." (repeat the last value assigned for this activity).
5. Non-dominant hand hemiparesis. (only applicable to question 24; mark “N/A” and remove from the list of items).

QUANTITATIVE SCALE	QUANTITATIVE SCALE
0 - I didn't use my weaker arm (I didn't use it).	0 - The weaker arm was never used for that activity.
0.5	0.5
1- I occasionally used my weaker arm, but only very rarely (very rarely).	1 - The weaker arm moved during that activity, but it wasn't helpful (too weak).
1.5	1.5
2 - Sometimes I used my weaker arm, but I did the activity mostly with my stronger arm (rarely).	2 - The weaker arm was of some use during this activity, however, it needed help from the stronger arm or moved very slowly or with difficulty (weak).
2.5	2.5
3- I used my weaker arm approximately half as often as I did before the stroke (half as I did before the stroke).	3- The weaker arm was used for the intended purpose, but the movements were slow or performed only with some (good) effort.
3.5	3.5
4- I used my weaker arm almost as much as before the stroke (3/4 pre-stroke).	4- The movements made by the weaker arm were almost normal, but they weren't as fast or precise as normal (almost normal).
4.5	4.5
5- I used my weaker arm with the same frequency as before the stroke (even before the stroke).	5- The ability to use the weaker arm for this activity was as good as before the stroke (normal).

3. Katz Scale (Brazilian version)

For each functional area listed below, check the description that applies (the word "help" means supervision, guidance, or personal assistance).

Functional Area — Independent (I) / Dependent (D)

Taking a bath (bed, bathtub or shower)
[ ] does not receive assistance (gets in and out of the bathtub alone, if this is the usual way of bathing) (I)
[ ] receives help to wash only a part of the body (such as the back or a leg) (I)
[ ] receives help washing more than one part of the body, or cannot bathe alone (D)

Getting dressed (retrieving clothes, including underwear, from closets and drawers, and handling fasteners, including those of orthotics and prosthetics, when used)
[ ] The patient picks up their clothes and dresses completely without help (I)
[ ] The patient picks up their clothes and dresses without help, except for tying shoes (I)
[ ] receives help to get clothes or get dressed, or remains partially or completely unclothed (D)

Use of the toilet (going to the bathroom or equivalent place to defecate and urinate; personal hygiene and tidying clothes)
[ ] Goes to the bathroom or equivalent place, cleans himself/herself and adjusts his/her clothes without help (may use objects for support such as a cane, walker or wheelchair and may use a bedpan or urinal at night, emptying it in the morning) (I)
[ ] receives assistance to go to the bathroom or equivalent location, or to clean themselves, or to adjust their clothes after defecation or urination, or to use a bedpan or urinal at night. (D)
[ ] does not go to the bathroom or equivalent for physiological eliminations. (D)

Transfer
[ ] Gets out of bed and lies down, sits down and stands up from a chair without assistance (may be using an object for support, such as a cane or walker) (I)
[ ] lies down and gets out of bed and/or sits down and gets up from a chair with help. (D)
[ ] doesn't get out of bed (D)

Continence
[ ] It completely controls urination and defecation (I) [ ] There are occasional "accidents". (D)
[ ] needs help to maintain control of urination and defecation; uses a catheter or is incontinent. (D)

Food
[ ] The patient feeds themselves without help (I)
[ ] The patient feeds themselves, but receives help cutting meat or spreading butter on bread (I)
[ ] receives assistance with feeding, or is fed partially or completely through the use of catheters or intravenous fluids. (D)

Interpretation (Katz & Apkom):

0: independent in all six functions; **1:** independent in five functions and dependent in one function; **2:** independent in four functions and dependent in two; **3:** independent in three functions and dependent in three; independent in two functions and dependent in four; **5:** independent in one function and dependent in five functions; **6:** dependent in all functions.

4. Structured questionnaire

I - Identification

1) Name: _____
2) Date of birth: ___ / ___ / ___
3) Medical record number:
4) Age: _____
5) Nationality:
6) Sex: ( )Male ( )Female
7) Race/color: ( )Asian ( )Indigenous ( )White ( )Black ( )Others
8) City of residence: _____
9) Neighborhood: _____
10) Profession: _____
11) Current occupation: _____
12) Telephone: _____
13) E-mail: _____
14) Reference physician: _____
15) Caregiver/responsible family member: _____
16) Dominance: ( )Right ( )Left-handed ( )Ambidextrous

II - Family

17) Marital status: ( )Single ( )Married/Living with partner ( ) Divorced/Separated ( )Widow(er) ( )Others
18) Do you have children?: ( )Yes ( )No
19) Number of Children: _____
20) Currently, where and how do you live?: ( )At home or in an apartment, alone ( ) At home or in an apartment, with parents and/or relatives ( )Living in a house or apartment with a spouse ( )In another type of housing
21) Can you move around between the rooms of the house? ( )Yes ( )No
22) Do you have a caregiver or family member who assists with daily tasks? ( )Yes ( )No
23) Do you have a family history of stroke? ( )Yes ( )No

III - Education

24) Level of education: ( )Illiterate ( )Can read and write ( )Elementary education ( )High School ( )Higher education ( )Postgraduate studies

IV - Income

25) Do you have health insurance? ( )Yes ( )No
26) Income: ( )less than minimum wage ( )up to one minimum wage ( )between 2 and 3 minimum wages ( )4 to 5 minimum wages ( )more than 6 minimum wages

V - Assistive Technology

27) Assistive technology: ( )Wheelchair ( )Walker ( )Single-point cane ( )Forearm crutch ( )Shower chair ( )Hearing aid ( )Orthosis ( )Other - Specify
28) Do you wear corrective lenses?: ( )Yes ( )No
29) Uses dentures: ( )Yes ( )No

VI - Health condition

30) Injury time:_____
31) Date of injury: _____

32) Type of stroke: ( )Ischemic ( )Hemorrhagic
33) Medications: ( )Antihypertensive ( )Antiplatelet agent ( )Anti-inflammatory ( )Antidepressant ( )Antipsychotic ( )Antidiabetic ( )Anticonvulsant ( )Sedative ( )Analgesic ( )Diuretic ( )Other - Specify
34) Associated diseases: ( )Rheumatological ( )Genitourinary ( )Endocrine ( ) Gastrointestinal ( )Cardiovascular ( )Respiratory ( )Other - Specify
35) Current pain?: ( )Yes ( )No
36) Pain location: _____
37) Presence of sensory alterations: ( )Yes ( )No
38) Location of sensory alteration: _____
39) Currently smokes: ( )Yes ( )No
40) Former smoker: ( )Yes ( )No
41) Consumes alcoholic beverages: ( )Yes ( )No

5. Schedule of appointments (intervention group)

Service Number	Intervention Focus	Duration (min)	Description	Responsible
1	Initial assessment (in person)	60	Application of the structured questionnaire, and the scales Instrumental Activities of Daily Living Scale, Katz Scale, and Motor Activity Log.	Independent researcher
2	Guidelines on the importance of mobility/positioning/posture of the body and the affected upper limb (telehabilitation)	45	To provide guidance on the importance of body and affected upper limb mobility/positioning/posture for: prevention and treatment of muscle contractures; improvement of joint mobility; improvement of blood circulation; reduction of spasticity; prevention of secondary injuries; improvement of neuromuscular function and coordination; prevention of muscle atrophy.	Researcher responsible
3	Nutrition; Mobilization; Cognitive/recreational activity (telerehabilitation)	45	Guidelines on techniques for independent feeding (opening packages, preparing and serving food).	Researcher responsible
4	Self-care; Mobilization; Cognitive/recreational activity (telehabilitation)	45	Guidance on independent personal hygiene techniques (combing and tying hair, brushing teeth, shaving, applying makeup), positioning of the affected upper limb, and possible adaptations.	Researcher responsible
5	Leisure; Mobilization; Cognitive/recreational activity (telerehabilitation)	45	Guidance and discussion about possible leisure activities.	Researcher responsible
6	Bathing and toilet use; Mobilization; Cognitive/recreational activity (telerehabilitation)	45	Guidelines on techniques and adaptations for independent bathing and toilet use.	Researcher responsible

7	Upper Clothing; Mobilization; Cognitive/Recreational Activity (telerehabilitation)	45	Guidelines on techniques and adaptations for autonomy in dressing upper limbs.	Researcher responsible
8	Lower garment; Mobilization; Cognitive/recreational activity (telerehabilitation)	45	Guidelines on techniques and adaptations for independent dressing of lower limbs.	Researcher responsible
9	Final instructions (for family/caregiver when necessary). Reinforcing safety aspects during activities (telerehabilitation).	45	Guidelines regarding finals, questions, and safety aspects.	Researcher responsible
10	Final assessment (in person)	60	Final application of the Scale of Instrumental Activities of Daily Living, Katz Scale, and Motor Activity Log.	Independent researcher

6. Informed Consent Form

RESEARCH DATA

Research Title: Effects of telerehabilitation on the occupational performance of stroke patients treated by the Occupational Therapy service: a randomized clinical trial

Principal Investigator: André Tadeu Sugawara

Department/Institute: Department of Legal Medicine, Bioethics, Occupational Medicine and Physical Medicine and Rehabilitation / Institute of Physical Medicine and Rehabilitation of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo

According to resolution 466/2012, the following content should be included in the explanations about the research

1. Participation

Invitation to participate – We invite you to participate in this research. The text below presents all the necessary information about what we intend to do. Your collaboration in this study will be very important to us, but if you withdraw at any time, this will not cause you any harm. The name of this document you are reading is the Informed Consent Form (ICF). Before deciding whether you wish to participate (of your own free will), you should read and understand all the content. At the end, if you decide to participate, you will be asked to sign it and you will receive a copy of the form. Before signing, ask questions about anything you did not understand well. The study team will answer your questions at any time, before, during and after the study.

2. Justification and Objectives of the Study

This study was designed to understand the effects of using remote healthcare services, specifically telehealth, specifically the telerehabilitation modality, performed by occupational therapy professionals with patients with sequelae from stroke (CVA), who are awaiting in-person care at the Institute of Physical Medicine and Rehabilitation of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (IMREA HC-FMUSP).

This study is justified by the lack of a formal structure for telerehabilitation. In addition, access to specialized care, such as post-stroke rehabilitation, remains a major challenge for the Brazilian Unified Health System (SUS), and the incorporation of digital technologies in healthcare emerges as a potentially effective strategy to optimize the efficiency of care.

3. How will your participation in this study be?

RESEARCH PLAN

During your participation in this study, you will be invited to perform some activities related to telerehabilitation in Occupational Therapy. Your name and any identifying information will not be disclosed, maintaining confidentiality. Research participants will be divided, by lottery, into two groups: the first, called the intervention group, and the second, the control group. The first group (intervention) will undergo initial and final assessments (to measure their health status for performing daily activities before and after the completion of all appointments) and will also receive telerehabilitation care, performed by an Occupational Therapy professional. The second group (control) will undergo initial and final assessments with the same purpose as the first group, however, they will not receive telerehabilitation care and will remain on the waiting list. Thus, your participation will be divided into different phases, as described below:

I. **Initial Assessment (Intervention Group and Control Group):** You will undergo an initial assessment, in which information about your current condition will be collected, including medical history, Physical function of the upper limbs, and performance in carrying out daily activities. This assessment will help the research team understand your health condition and, if you are allocated to telerehabilitation, this information will be important for better structuring the treatment plan, initially common to all participants.

II. **Telerehabilitation (intervention group):** If you are allocated to this group, you will receive the telerehabilitation intervention, and will be guided through virtual sessions with an occupational therapist. The sessions will take place at pre-arranged times, using the Hospital das Clínicas' video conferencing platform, and will aim to train and develop motor and cognitive skills necessary for carrying out basic and instrumental activities of daily living. During these sessions, you will also be guided to perform mobility and stretching exercises for the upper limbs, which can help improve your occupational performance, that is, in carrying out tasks in your daily life.

III. **Control (control group):** If you are allocated to the control group, you will follow the standard treatment, without participating in telerehabilitation sessions, without changes to the waiting list order. In this case, you will also be monitored throughout the study to assess your occupational performance, in order to compare the results of the assessments between the intervention group and the control group.

IV. **Final assessments (intervention group and control group):** Throughout the study, you will be invited to undergo periodic assessments to measure your progress and any changes in your occupational performance. These assessments may include questionnaires, functional tests, and interviews. This information will help the research team understand the effects of telerehabilitation and compare the results between the groups.

V. **Duration of Participation:** The study will last approximately 3 months (to be specified), during which you will participate in telerehabilitation sessions (if allocated to this group) and will be monitored to track the progress of your occupational performance.

4. Could your participation pose any risks?

Participation in this study may generate a certain degree of discomfort due to the disclosure of information, related to aspects of personal history, such as descriptions and perceptions about your cognitive, physical, and social condition. However, in general, the research presents minimal risk, as the services are provided remotely, without invasive procedures or the need for travel. However, stroke can cause variations in the cognitive and physical capacity of participants, affecting adherence and the development of interventions. There is also the risk of technical problems during video calls, which may impair understanding of the instructions.

Interruption of services may occur due to health issues, recurring technical problems, lack of interest, or the start of in-person services. To minimize these risks, security measures will be adopted, such as manual data collection, secure storage, and confidentiality of participants' personal information. In addition, if necessary, a family member or caregiver may accompany the patient. The participant may withdraw at any time without penalty and, in case of harm or embarrassment, will be referred to the responsible physician, free of charge.

Thus, it is necessary to clarify their autonomy in the process, highlighting respect for the patient's personal limits and their willingness to continue participating or terminate it at any time. If there is any direct or indirect, immediate or subsequent harm caused by participation in the research, their family member may be compensated in accordance with CNS Resolution No. 466 of 2012, items II.6 and II.7. In accordance with items II.3.1 and II.3.2 of CNS Resolution No. 466 of 2012. In line with CNS Resolution No. 251 of 1997, access to the evaluation results will always be available. The participant will be required to participate in the study whenever requested and/or indicated. If this procedure may cause any type of embarrassment, you will not need to do it.

5. What will be the benefits of your participation in this study?

The expected benefits of your participation in this study lie in the possibility of improved performance in carrying out daily activities, and also in the possible structuring of another pathway (telerehabilitation) of health care in the rehabilitation process. This can result in significant improvements in your quality of life, physical and cognitive functionality, among other aspects. In addition, upon completion of this study, and in case of positive results, it is expected to contribute to the development of best practices in care for post-stroke patients.

6. Withdrawal from the study

RESEARCH PLAN

Participation is voluntary. You may withdraw from this research at any time by contacting one of the responsible researchers or the Ethics Committee, CAPPesq.

7. Confidentiality of your information

The information collected will be handled only by the researchers and access by other people will not be permitted. The data and instruments used will be kept under the responsibility of the researchers with the guarantee of maintaining secrecy and confidentiality, and archived for a period of 5 years; after this time they will be destroyed. The results of this work may be presented at scientific meetings or journals. However, it will only show the results obtained in their entirety, without revealing your personal data or any information related to your privacy.

8. Clarification on the form of follow-up and assistance to which participants in the research will be entitled

We clarify that your participation in the research will not be an obstacle to your access to the in-person services of IMREA HC-FMUSP, regardless of the group to which you were allocated (intervention group or control group). Your participation will take place during the period in which you await in-person appointments, whether outpatient or inpatient. If you are called to start in-person appointments before the end of telerehabilitation, the final assessments will be applied, and then you will continue with in-person appointments. All data collected will be treated with maximum confidentiality, respecting the highest ethical and regulatory standards. Guarantees of full freedom for the participant to refuse to participate or withdraw their consent at any stage of the research without any penalty, of secrecy and privacy.

9. Guarantee that the participant will receive a copy of the consent form

To ensure transparency and respect for participants' rights, a copy of the informed consent form (ICF) will be provided in duplicate during the consent process. The ICF will be prepared in two original copies, one for the participant and the other for the research records, under the responsibility of the researcher. Both copies will be initialed by the responsible researcher and the participant, indicating mutual consent and understanding of the terms of the study.

10. Explicit statement of guarantees for reimbursement of expenses arising from the research and explicit statement of the guarantee of compensation for any damages arising from the research.

To ensure the protection and well-being of research participants, clear guarantees of reimbursement for expenses arising from participation in the study will be provided, as recommended by Resolution 466/2012. In addition, the research will guarantee comprehensive coverage for any damages arising from participation, as established by ethical and regulatory protocols. In case of physical, psychological or other damages, participants will be supported and will receive adequate medical assistance at no cost to them.

11. Information on the study results

At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The principal investigator is Prof. Dr. André Tadeu Sugawara, who can be found at IMREA-HCFMUSP, at Rua Domingo de Soto, 100 – 3rd floor, Clinical Research Center - Vila Mariana - CEP 04116-030, São Paulo - SP, Brazil, telephone (011) 5180-7887, from 8 am to 5 pm, Monday to Friday, or by email: andre.sugawara@hc.fm.usp.br

If you have any considerations or questions about the ethics of the research, you can contact the local Ethics Committee, CAPPesq, which approved this study. The Ethics Committee is an independent and non-profit entity that safeguards ethics in research with human beings and defends the interests of research participants, such as yourself, in their integrity and dignity, contributing to the development of our research within globally established ethical standards. CAPPesq is located at R. Dr. Ovídio Pires de Campos, 225, 6th floor - Cerqueira César, São Paulo - SP, 05403-010, opening hours: 7am - 4pm; Tel.: (11) 2661-1548 or (11) 2661-7585; Email: cappesq.adm@hc.fm.usp.br

I have been sufficiently informed about the study “Effects of telerehabilitation on the occupational performance of stroke patients treated by the Occupational Therapy service: a randomized clinical trial”.

I discussed the above information with the principal investigator, Prof. Dr. André Tadeu Sugawara, or person(s) designated by him _____ about my decision to participate in this study. The objectives, procedures, potential discomforts, risks, and guarantees were made clear to me. I voluntarily agree to participate in this study, sign this consent form, and receive a copy initialed by the researcher.