**Study Protocol**

# Impact of Interactive, Virtual Tele-Physiotherapy for Improving Motor Function and Quality of Life in Stroke Patients: A Study Protocol

***ABSTRACT:***

**Introduction:** Telephysiotherapy (TPT) is provision of physiotherapy services using telecommunication technology such as audio call or video call to facilitate the physiotherapy management of patients within their own homes. In the absence of which the patients may have to discontinue physiotherapy treatment that may result into poor motor outcomes leading to deterioration of the quality of life (QoL).

**Methodology:** This is a study protocol designed to study the effectiveness of TPT intervention in Stroke patients. The objective is to study whether TPT is effective for Stroke Rehabilitation in improving motor function and quality of life. An exercise protocol will be administered to patients suffering from mild to moderate stroke (mRS=<4). A total 40 patients will be recruited in the study, divided into 2 groups –Group A and Group B, where Group A will receive the exercise therapy through Tele Physiotherapy & Group B will receive OPD-based Physiotherapy. Participants of both the groups will be called to the OPD at the baseline and at the end of 6 weeks intervention. The patients shall be assessed at the baseline and at the end of intervention using Fugl-Meyer Assessment (FMA), Dynamic Gait Index (DGI), Functional Independence Measure (FIM) and Stroke Specific Quality Of Life scale (SS-QOL) to evaluate their motor function, gait, functional status and quality of life respectively.

**Ethical considerations:** Approval from the Institutional Ethics committee of the institute is obtained. Participation in study will be voluntary and only the patients willing to give the written informed consent will be recruited for the study.

**Results:** The results of the study will be published and disseminated in peer-reviewed journals.

***Keywords:*** Telephysiotherapy, Stroke, Virtual, Rehabilitation

## 1. INTRODUCTION:

Stroke is one of India's most common causes of death and disability. Early initiation of rehabilitation at the earliest helps to improve patient outcomes. The rehabilitation for stroke is an ongoing process and maybe given on in-patient or out-patient basis mainly to improve the physical function and quality of life.

## 1.1 NEED OF STUDY:

In low-income and middle-income countries like India where the resources for providing rehabilitative services are often limited, physical therapy approaches that can be implemented in low-resource settings need to be need to be devised, tested and promoted in the community.

Due of the pandemic and lockdown, the number of stroke patients coming for OPD follow-up and rehabilitation has considerably reduced. This could be due to decreased availability of public transport and fear of acquiring SARS- CoV- 2 infection. The abrupt interruption in rehabilitation may cause worsening of the functional outcomes of post-stroke patients. In order to maintain the continuum of care for stroke care and reduce morbidity and mortality, tele-health and tele-rehabilitation have been proposed and implemented as a remedial measure for the post-stroke rehabilitation. The TPT has already shown effectiveness in improving clinical outcomes in developed countries but such studies are lacking in the context of developing countries where there are limited resources and the literacy rate is low. Thus, this study is designed to be undertaken in the context of a developing country like India.

## 1.2 BACKGROUND:

**Stroke or Cerebrovascular accident (CVA**) is the sudden loss of neurological function caused by interruption to the blood flow to the brain. The **World Health Organization (WHO)** defines **Stroke** as "rapidly developing clinical signs of focal (or global) disturbance of cerebral function,

with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than vascular origin" [(1)]

Among 240 causes of death, globally stroke is the second leading cause of death worldwide [(2)] Globally, incidence of stroke is about 25.7 million with 6.5 million deaths from stroke and 113 million DALYs are lost due to stroke [(3)] Stroke is one of India's most common causes of death and disability. The average annual incidence rate of stroke in India currently is 145 per 100,000 population, which is higher than the western nations [(4)]

The growing burden of stroke-related disability and the unmet need for rehabilitation following stroke in India poses a major public health challenge. Rehabilitation training is the most effective way to reduce motor impairments in stroke patients and is an important aspect of the continuum of care in stroke. Physiotherapy forms an important component of stoke rehabilitation and can be started as soon as the patient vitals are stable, once the acute hospital care of the stroke patient is completed. Stroke rehabilitation is a goal oriented, progressive process which enable a person with impairment to achieve their optimal physical, social and restoration of normal functional level. Post stroke rehabilitation helps to improve the functional status and independence in activities of daily living of the individual suffering from stroke.[(5)]

The term 'Telehealth' refers to the application of electronic or digital information and communication technology to assist patient and professional health, as well as health education, public health, and health administration. The delivery of rehabilitation and habilitation services via information and communication technology (ICT) is referred to as tele-rehabilitation.[(6)]

Telephysiotherapy (TPT) is a provision of physiotherapy services at a distance, using telecommunication technology such as video conferencing or telephone meeting, when an in-person visit to the patient is not a feasible option. TPT can be implemented and used to provide

therapeutic exercise information to patients at home, allowing patients to skip long distance transport and undertake basic physiotherapy exercises in the comfort of their own house[7] TPT covers a wide variety of rehabilitation and habilitation services, including assessment, monitoring, prevention, intervention, supervision, education, consultation, and counseling on a clinical level[8]

Application of TPT can also ensure patient adherence to self-assessment and self-management, result in improved clinical outcomes. With the removal of barriers (distance to clinic, transportation expense, travel time, and waiting list), flexible scheduling, and enhanced patient choice, the TPT also aids in the timely delivery of interventions, resulting in a more patient-centered approach to care. [9]

## 2. MATERIAL & METHODS:

This is a study protocol for studying effectiveness of TPT intervention in Stroke patients.

**2.1 STUDY DESIGN:** Two-arm parallel group design.

**2.2 STUDY POPULATION:** Patients with mild to moderate stroke disability were considered for the study (mRS=<4) A total 40 patients were recruited in the study, divided into 2 groups – Group A and Group B, where Group A received Tele Physiotherapy & Group B received OPD-based Physiotherapy**.** The study will be conducted in OPD premises of Acharya Vinoba Bhave Rural Hospital (AVBRH) Sawangi for the OPD based Physiotherapy Group and for Tele-Physiotherapy Group the study setting will be respective patient's home. The patients will be selected using simple random sampling (using blinded chits). A sample size of 16 for each group was determined using the following formula.

Formula: $n1=\kappa n2$, $n2=(z\alpha+z\beta)^2 s^2(1+1/\kappa) / (\mu E-\mu C+\delta NI)^2$

where $\kappa=n1/n2$shows treatment allocations

$z\beta$ is the upper $\beta$th-quantile and $z\alpha$ is the upper $\alpha$th-quantile of the standard normal distribution.

$\mu E$ is the true mean response of the experimental treatment;

$\mu C$ is the true mean response of the control treatment

$\delta$ is the clinically meaningful difference

Considering 10 percent dropout rate with 80% power and a one-sided type I error level set to 5% a total of 40 patients, 20 in each group, the expected effect size is 0.33 units and the variance $\sigma 2=0.4$. [16]

## 2.3 STUDY PROCEDURE:

After receiving approval from the Institutional Ethics committee, the participants will be recruited from AVBRH physiotherapy OPD and screened for the inclusion and exclusion criteria. Once they meet the inclusion criteria, an informed ethical consent will be taken from the patients to participate in the study. Total 40 patients will be recruited in the study. The study participants were divided into 2 groups –Group A and Group B, where Group A received Tele Physiotherapy & Group B received OPD-based Physiotherapy. Participants of both the groups were called to the OPD prior to beginning the study and after 6 weeks.

The patient was assessed on the following scales at the baseline and at the end line.

1. **Fugl-Meyer Assessment (FMA)**
2. **The Dynamic Gait Index (DGI)**
3. **Functional Independent Measure (FIM)**
4. **The Stroke Specific Quality of Life scale (SS-QOL)**

The patients in both the groups shall be performing the exercises every alternate day. The TPT group shall perform the same at home (guided by the physiotherapist), while the OPD-based group shall provide at the hospital OPD (treated by the same physiotherapist). Hence, the participants in both the group shall perform 18 sessions in the total time period of 6 weeks. The duration for session is 60 minutes for both the groups. It will be ensured by the therapist that the exercises provided to both the groups shall be dose-matched.

**Group A- Telephysiotherapy group:**

An individualized exercise program will be prescribed and explained to the patient and their care-giver. The care-giver will be trained regarding various abnormal pattern/synergies that the muscles of the upper and lower limb could go into, post-stroke recovery phase. The care-giver will also be made aware regarding patient positioning, and the postures to be avoided. He will be taught to assist the exercises to be performed by the patient and monitor when the patient is performing the exercises in their home settings, and also to be present for the TPT sessions throughout.

The TPT session will be scheduled every alternate day. Both the patient and care-giver will be present while the tele-therapy. Demonstration of exercise will be done by the therapist on the whatsapp video call; followed by performance of the exercises by the patient / maybe assisted by the care-giver where required and this will also be monitored by the physiotherapist on the video call. Information regarding correction of exercise will be done simultaneously by the therapist. The TPT session will last for about 60 minutes. And each patient will be given a total of 18 such video-conferencing sessions conducted in the period of 6 weeks.

The patients will be asked to perform exercises by themselves on Sunday and record a video and send to the therapist; so that information regarding correction of exercise can be done by the therapist after assessing the video. A whatsapp group will be created for these TPT patients, where every patient will be asked to post after performing their exercises, with the help of their care-giver. The care-giver can be the spouse, sibling or children of the patient in most of the cases. Telephone calls will be made to these TPT patients from time-to-time so that they do not miss their TPT session to ensure adequate patient compliance. The exercise protocol shall be progressed on a weekly basis.

**Group B – OPD-based group:** The Group B participants will be given exercises directly by the physiotherapist at the OPD department of AVBRH. Patient and Care-giver education was provided. And same exercise protocol was followed as in group A but on one-on-one basis. The exercises protocol will be dose matched as in group A and will also be progressed on a weekly basis.



**Criteria for Selection:**

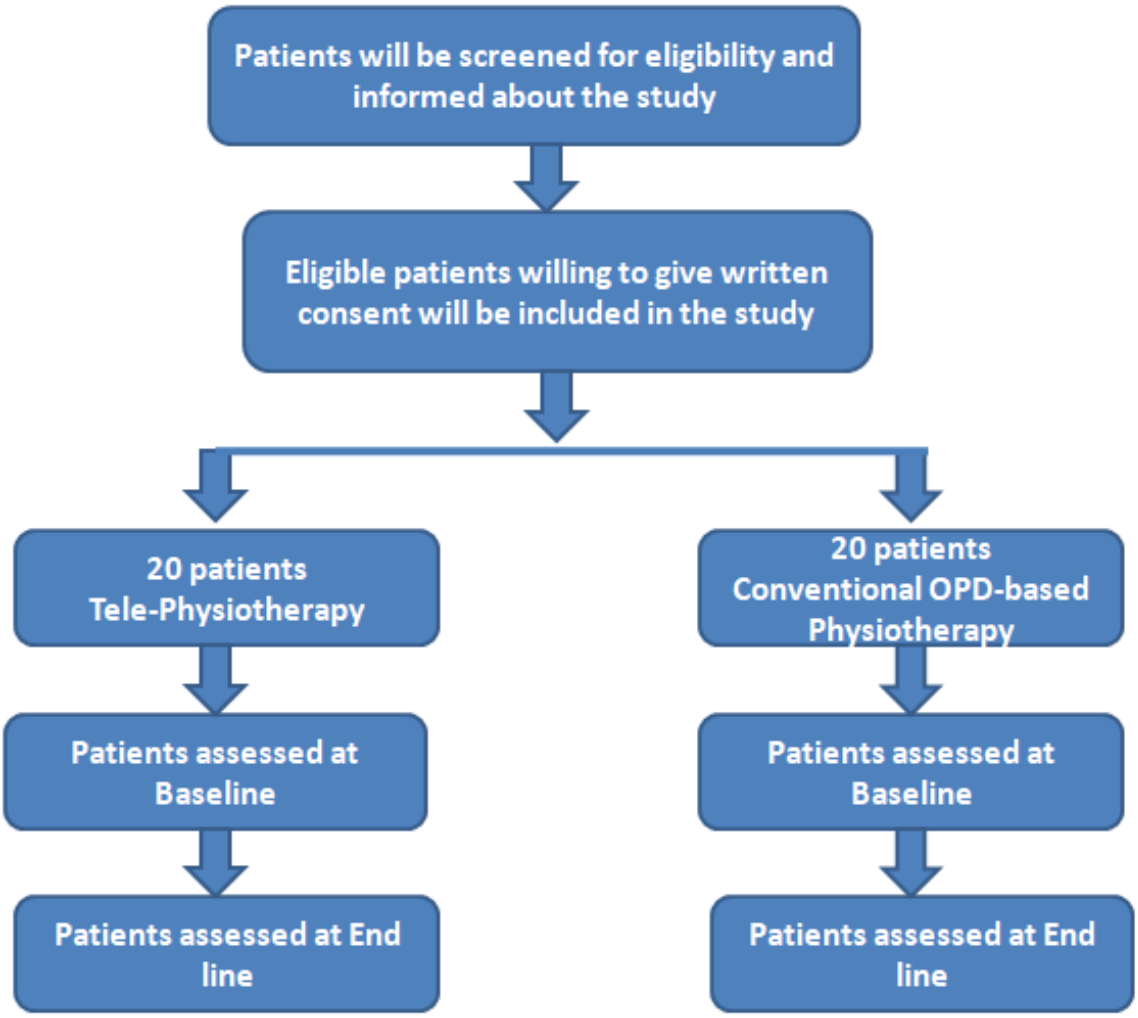
**Inclusion criteria –**

- Stroke patients aged between 40 years to 70 years
- Stroke patients with stable vital parameters (temperature, pulse, blood pressure)
- Patients suffering from hemiplegia or hemiparesis more than 1 month and less than 12 months.
- Patients with Voluntary control above Grade 2
- Patients with modified Rankin score (mRS) between Grade 1 to 4.
- Patients with an access to a multimedia android phone, with good internet connectivity.
- Patients willing to give informed consent and obeying instructions.
- Patient with a dedicated care-giver (could be any of the family member)

**Exclusion criteria** –

- Patients with stroke more than a year.
- Patients with uncontrolled diabetes mellitus, hypertension.
- Patients with Deep vein thrombosis.
- Patient with any other sensory or cognitive disability such as aphasia etc
- Patients who are unable to follow instructions
- mRS score greater than Grade 4

## 2.4 FLOWCHART OF THE STUDY:



## 2.5 DATA MANAGEMENT AND ANALYSIS:

Analysis of variance (ANOVA) was used to compare scores at baseline and at the end of 6$^{th}$ week of clinical intervention for the OPD-based group and telephysiotherapy group, respectively.

Also, independent Student's *t*-test was used to compare the progress of the two treatment groups (OG and TG) at baseline and at the end of 6$^{th}$ week of clinical intervention.

## 2.6 ETHICAL CONSIDERATIONS:

The approval from the Institutional Ethics committee of the institute will be obtained before proceeding for the study. The participation will be purely voluntary and all respondents will be given the choice whether or not to participate in the study; or withdraw from the study before its completion.

## 2.7 INFORMED CONSENT:

Only those respondents, who are willing to participate in the study and willing to give the written consent after being fully informed about the aim and scope of the study will be recruited for the study. The participation will be purely voluntary and all respondents will be given the choice whether or not to participate in the study; or withdraw from the study before its completion.

The name and address of the participants would be kept confidential, so that the identity of the patients is not revealed anywhere in the study findings.

## 2.8 FUTURE IMPLICATIONS OF STUDY:

- A New Model of Health Care that is both inexpensive and efficient can be devised and delivered to the communities affected by disability in the urban and rural setups.
- This technique of Telephysiotherapy can be effectively used in bed-ridden and immune-compromised patients
- Also, Telephysiotherapy can be effectively combined in-complement with the conventional physiotherapy.
- In times of existing pandemic, technique of Telephysiotherapy can be utilized as a boon, thus ensuring social distancing; without hampering patient recovery.



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