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Development of a Social-Media–Based Tele-Rehabilitation and Caregiver Education Protocol for Stroke Survivors Stratified by Functional Independence Measure Levels: Pilot Randomized Study Protocol

1. **Trupti Deshmukh,** Faculty of Physiotherapy, Parul University, Waghodia, Vadodara, Gujarat,391760, India
2. **Amal Bhattacharya,** Department of Medicine, Parul University of Medicine, Faculty of Medicine, Parul University, Waghodia, Vadodara, Gujarat,391760, India
3. **Bhavana Gadhavi,** PhD, Dean and Principal, Faculty of Physiotherapy, Parul University, Limda, Vadodara

Corresponding Author: Trupti Deshmukh, tkulkarni1110@gmail.com

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ABSTRACT

Background: Stroke remains a leading cause of long-term disability worldwide. Despite the proven benefits of structured rehabilitation, many stroke survivors—particularly in resource-limited settings—lack access to continuous facility-based therapy due to geographical, economic, and infrastructural barriers. Tele-rehabilitation, delivered through accessible platforms such as Zoom or WhatsApp, has emerged as a promising approach to bridge these gaps. Caregivers play a crucial role in stroke recovery, yet caregiver education is rarely integrated into digital rehabilitation programs.

Objective: To describe the design of a pilot randomized controlled trial evaluating the feasibility, acceptability, and preliminary efficacy of a social-media–based tele-rehabilitation plus caregiver education (SM-TR+CE) protocol stratified by Functional Independence Measure (FIM) levels, compared with conventional in-center neurorehabilitation.

Methods: This pilot RCT will enroll 20 participants (10 per arm) within one year of ischemic stroke or TIA, stratified by FIM dependency level. Participants will be randomized to either SM-TR+CE or conventional care. The intervention will last 12 weeks, comprising three supervised sessions per week supplemented by caregiver training modules, brochures, and digital reinforcements. Primary outcomes are feasibility metrics (recruitment, retention, adherence, and adverse events). Secondary outcomes include changes in FIM, Fugl-Meyer motor scores, caregiver burden, and caregiver quality of life.

Discussion: This pilot trial is designed to assess feasibility and provide variance estimates for future sample size calculations. While not powered for definitive efficacy conclusions, it will inform the refinement of a scalable tele-rehabilitation framework that integrates caregiver education tailored by functional dependency levels.

Conclusion: The study protocol represents a step toward developing an accessible, cost-effective, and stratified tele-rehabilitation model for stroke survivors and their caregivers, with potential to guide a future definitive RCT.

INTRODUCTION

Stroke is one of the foremost causes of long-term disability worldwide and often results in profound impairments in mobility, self-care, and social participation. Rehabilitation plays a central role in optimizing recovery, yet access to structured programs is highly variable across regions. Recent systematic reviews have highlighted that telerehabilitation can improve functional recovery and reduce disability when appropriately delivered (Laver et al., 2020; Chumbler et al., 2012).[1,2] Validated outcome measures such as the Barthel Index and the Functional Independence Measure (FIM) provide robust frameworks for evaluating functional outcomes in stroke rehabilitation (Quinn et al., 2011; Keith et al., 1987).[3,4]

The involvement of caregivers in the rehabilitation process has received increasing attention in the literature. Training programs for informal carers have demonstrated significant improvements in patient recovery and caregiver competence (Kalra et al., 2004).[5] Updates to the evidence base confirm that dyadic and caregiver-focused interventions contribute positively to outcomes for both survivors and carers (Bakas et al., 2017).[6] Nonetheless, caregiving is often associated with high burden and stress, with systematic reviews emphasizing the considerable physical, emotional, and financial toll borne by informal carers (Rigby et al., 2009; Cameron et al., 2013; Greenwood et al., 2009).[7–9]

Telerehabilitation has emerged as a promising strategy to overcome geographic and financial barriers to care. A randomized trial demonstrated that home-based telerehabilitation can achieve outcomes comparable to in-clinic therapy, thereby supporting its clinical viability (Cramer et al., 2019).[10] The American Heart Association has also recognized the importance of telemedicine as part of integrated stroke systems of care (Schwamm et al., 2009).[11] Beyond clinical outcomes, psychoeducational frameworks have been developed to support clinicians in adopting telehealth and delivering safe, scalable interventions (Panzeri et al., 2021).[12] The broader healthcare

landscape has also embraced telehealth, recognizing its potential to transform chronic disease management and extend specialist services to underserved populations (Dorsey & Topol, 2016).[13]

Caregiver training within telerehabilitation frameworks is an emerging area of study. Evidence suggests that caregiver burden and quality of life are influenced by multiple determinants, including preparedness and access to support (McCullagh et al., 2005).[14] Programs such as liaison workers and structured education sessions have been tested with positive impacts on patient–caregiver dyads (Ellis et al., 2010; Forster et al., 2012).[15,16] More recent systematic reviews have specifically highlighted the benefits of digital caregiver training modules, demonstrating reductions in stress and improvements in coping strategies (Sun et al., 2023).[17] Empirical evidence from quasi-experimental and randomized studies in Asia has reinforced these findings, with caregiver training improving functional recovery and reducing burden (Islam et al., 2023; Sukwatjanee & Rujipong, 2024; Ding et al., 2024).[18–20] Dyadic interventions, where patient and caregiver are supported simultaneously, have also been found to improve psychosocial outcomes (Zhang et al., 2023; Deepradit et al., 2023).[21,22]

Despite these advances, gaps remain in the integration of functional stratification and caregiver education within tele-rehabilitation protocols. Patient outcomes such as quality of life during subacute recovery are influenced by caregiver support and psychosocial environment (Nichols-Larsen et al., 2005).[23] Tools such as the Zarit Burden Interview have been used for decades to quantify caregiver strain (Zarit et al., 1980),[24] while clinical reviews reaffirm the multifactorial nature of caregiver burden (Adelman et al., 2014).[25] Predicting long-term independence after stroke remains challenging, but early assessments using validated scales can help tailor rehabilitation more effectively (Veerbeek et al., 2011; Winstein et al., 2016).[26,27]

Innovations such as video-based caregiver education and tele-supporting programs are being tested to bridge gaps in transitional care (Bartoli et al., 2025).[28] Similarly, recent reviews confirm that structured caregiver interventions, whether digital or face-to-face, reduce stress and improve overall caregiving capacity (Luck & Hildebrand, 2023; Pashmdarfard et al., 2023).[29,30] Randomized trials and meta-analyses further support the feasibility and acceptability of caregiver-directed interventions (Jammal et al., 2024; Yi-En et al., 2023).[31,32] Qualitative studies continue to highlight the crisis-like experience of stroke for patients and their families, reinforcing the importance of ongoing education and support (Lutz et al., 2011).[33] Moreover, self-management principles widely applied in chronic disease contexts may also be relevant for empowering stroke caregivers (Lorig et al., 2001).[34]

Against this background, there is a clear need for structured, evidence-based, and scalable models of tele-rehabilitation that integrate both patient stratification and caregiver education. The current pilot randomized controlled trial has been designed to address this gap by evaluating the feasibility and preliminary efficacy of a social-media–based tele-rehabilitation plus caregiver education (SM-TR+CE) protocol stratified by FIM levels, compared with conventional neurorehabilitation. This protocol aims to generate essential feasibility data and preliminary effect-size estimates to inform the design of a larger definitive trial.

Methods

Study Design

This study is a two-arm, parallel, pilot randomized controlled trial comparing a social-media–based tele-rehabilitation plus caregiver education program (SM-TR+CE) with conventional in-center neurorehabilitation. The primary aim is to evaluate feasibility outcomes including recruitment, retention, adherence, and safety. The secondary aim is to provide preliminary estimates of treatment effects on functional and caregiver-related outcomes to guide the design of a future definitive trial. Pilot trials with small samples are recognized as essential for testing feasibility before scaling to larger randomized studies.[10,23]

Study Setting and Duration

The trial will be conducted at a tertiary-care rehabilitation facility in India. Recruitment is planned over a 6-month period, with each participant enrolled for 12 weeks of intervention and follow-up. The overall study duration is expected to be one year.

Participants

Inclusion Criteria – Patients

1. Adults with ischemic stroke or transient ischemic attack (TIA) within the past 12 months.
2. Mini-Mental State Examination score ≥24.
3. Modified Ashworth Scale < grade 2 in both upper and lower limbs.
4. Pre-stroke independent living status.
5. Willingness to appoint a caregiver.
6. Ability to provide informed consent (or via legally authorized representative in cases of motor impairment).

Exclusion Criteria – Patients

1. Serious comorbidities (cardiac, respiratory, endocrine, orthopedic, or neurological).
2. Vestibular deficits or vertigo.
3. History of seizures in the past 6 months.
4. Severe perceptual or cognitive impairments interfering with participation.

Inclusion Criteria – Caregivers

1. Aged 18–60 years.
2. Ability to understand Marathi, Hindi, or English.
3. Motivated to participate in caregiver-mediated rehabilitation.
4. Access to a smartphone or computer with internet connectivity.

Exclusion Criteria – Caregivers

1. Presence of major comorbidities.
2. Diagnosed depression or psychiatric illness.

Sample Size

As this is a pilot trial, the sample size is guided by feasibility objectives rather than hypothesis testing. A total of 20 participants (10 per arm) will be recruited. Pilot studies with 10–15 participants per group are widely recommended to evaluate feasibility, adherence, and preliminary effect sizes.[10,23]

Randomization and Allocation Concealment

Participants who meet eligibility criteria will be randomized in a 1:1 ratio to the experimental or control group using a computer-generated sequence with permuted block sizes of four. Allocation concealment will be maintained using sequentially numbered, sealed, opaque envelopes prepared by an independent statistician not involved in recruitment or intervention delivery.

Intervention

Experimental Group (SM-TR+CE)

Participants in the experimental arm will undergo 12 weeks of structured tele-rehabilitation delivered via the Zoom platform, supported with WhatsApp reminders and caregiver-focused video clips. Sessions will be conducted three times per week, lasting approximately 30 minutes each. Exercises will include bed positioning, mobility training, transfers, strengthening, task-oriented activities, postural control, balance, and gait training. The intervention will be stratified according to Functional Independence Measure (FIM) levels to ensure tailored progression.[4] Caregivers will receive structured brochures, weekly video reinforcements, and will actively participate in each session to ensure safe and correct practice.

Control Group (Conventional Neurorehabilitation)

Participants randomized to the control arm will receive conventional in-center neurorehabilitation, comprising mobilization, strengthening, balance training, and functional task practice under direct supervision of physiotherapists.

Intervention Proctocol

Table 1.Protocol for Maximally (FIM) Dependent Patients

Exercise / Technique	Frequency & Duration	Tools Required	Safety Precautions	Expected Outcomes

Bed positioning (supine, side-lying, prone) on affected and non-affected side	Every 2 hours/day	Bed, pillows for support	Caregiver must ensure proper limb alignment and avoid pressure sores	Prevention of contractures, improved comfort
Shoulder care during transfers (preventing shoulder dislocation)	During all transfers	Manual support	Support affected arm at elbow and wrist during transfers	Reduce risk of shoulder subluxation
Environmental modifications (reduce falls)	Daily as required	Grab bars, commode chair, nonslip mats	Ensure environment is clutter-free	Fall prevention
Bed transfers	Daily as required	Bed sheet, transfer board	Use proper caregiver body mechanics	Safer transfers
Tone optimization (icing, brushing, weight-bearing)	2–3 times/day	Ice pack, brush, firm surface	Avoid prolonged icing, monitor skin	Tone regulation
Passive exercises & stretching	3–4 times/day	None	Do not overstretch, monitor pain	Maintain joint ROM
Facial exercises & oral care	5–6 times/day if affected	Mirror, toothbrush	Ensure oral hygiene, avoid aspiration	Improved oral motor control
Breathing exercises (spirometer, segmental, pursed-lip)	2–3 times/day	Spirometer, chair support	Monitor SpO_2, stop if breathless	Maintain lung capacity
Dressing techniques (upper/lower limb)	Daily as required	Clothing, dressing aids	Avoid fatigue, caregiver assistance	Independence in ADLs
Bedpan/toileting techniques	Daily as required	Bedpan, hygiene materials	Maintain dignity, caregiver support	Improved hygiene management
Use of assistive devices for transfer	Daily as required	Walker, cane, sliding board	Ensure device stability	Safer mobility transitions

Table 2. Protocol for Moderately (FIM) Dependent Patients

Exercise / Technique	**Frequency & Duration**	**Tools Required**	**Safety Precautions**	**Expected Outcomes**
Bed positioning (all postures)	Every 2–3 hours	Bed, pillows	Ensure proper support	Prevention of contractures
Tone optimizing (icing, brushing, weight-bearing)	2–3 times/day	Ice pack, brush	Monitor for skin irritation	Tone regulation
Active-assisted exercises (Theraband, pulleys)	1–2 sessions/day	Theraband, pulley	Avoid overexertion	Improved muscle strength
Task-oriented functional rehab (sit-to-stand, bottle holding, combing)	Daily repetition required	Household items (bottle, comb)	Caregiver assistance initially	Functional independence
Self-care activities (dressing, grooming, bathing)	Daily as required	Personal care tools	Supervision to prevent falls	ADL independence
Trunk & postural control (sitting, standing)	Daily practice	Chair, wall, ball	Supervision to avoid imbalance	Improved stability
Balance training	Daily	Household supports	Ensure fall precautions	Fall risk reduction

Table 3.Protocol for Minimally (FIM) Dependent Patients

Exercise / Technique	Frequency & Duration	Tools Required	Safety Precautions	Expected Outcomes
Tone optimization (icing, brushing, weight-bearing)	As needed	Ice pack, brush	Monitor skin condition	Maintain tone balance
Task-oriented functional rehab (PNF, NDT, bottle holding, vegetable cutting, device holding)	Daily	Household items, vegetables, assistive devices	Safe work surface	Functional independence
Trunk & balance training (sitting/standing)	Daily	Chair, wall support	Avoid unsafe environments	Core strength, stability
Preparation for standing & walking (orthosis donning/doffing)	Daily	Orthosis, walker	Caregiver supervision initially	Improved gait readiness

Coordination exercises (upper/lower limb)	Daily	Household objects	Avoid fatigue	Motor coordination improvement
Use of assistive device for transfer/walking	Daily	Cane, walker	Proper fitting of device	Independent ambulation
Indoor/outdoor gait training	Daily	Safe walking space	Ensure fall precautions	Community ambulation

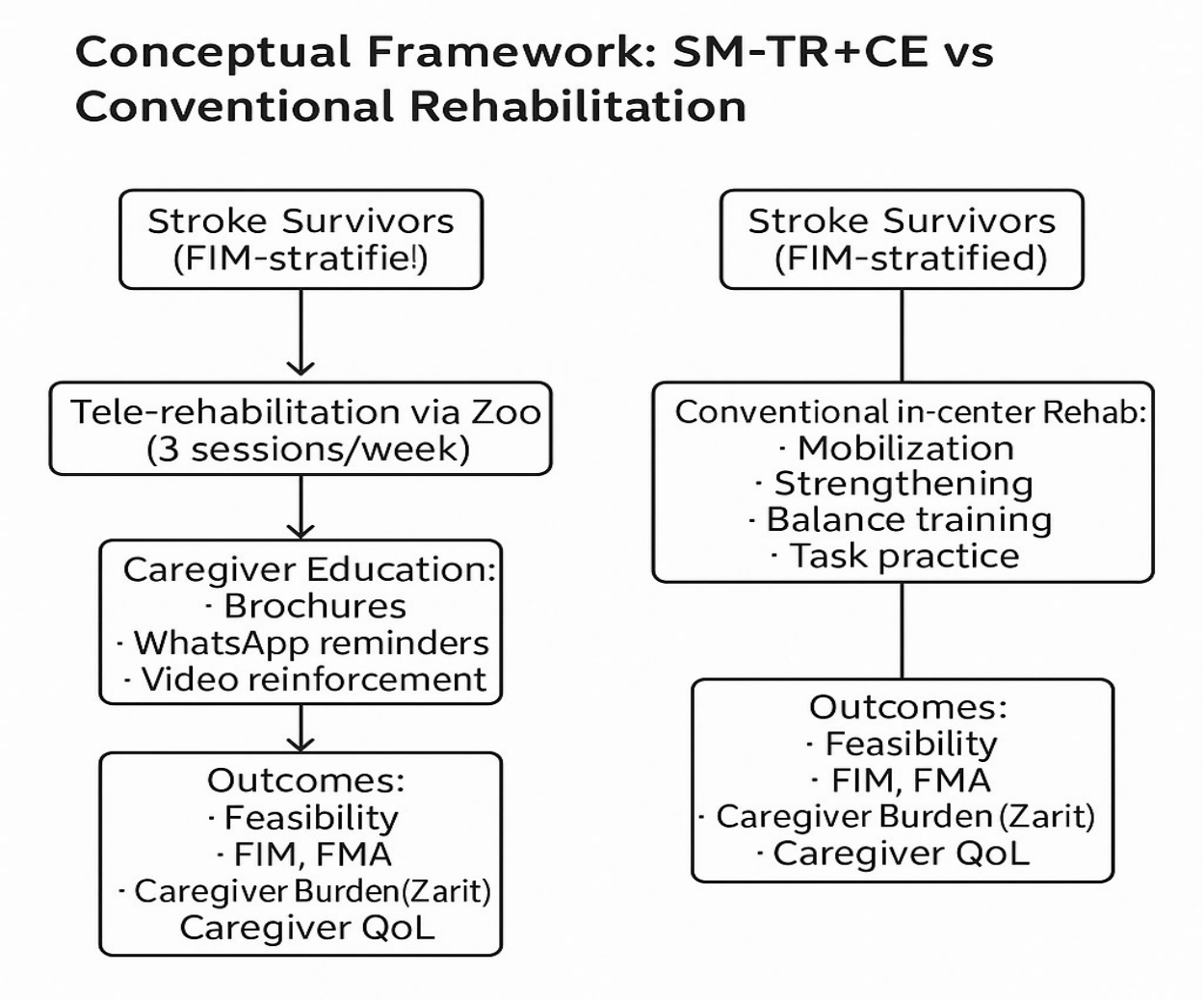
Table 4 Caregiver Education Module Schedule (12 Weeks)

Week	Session Topic	Content Focus	Delivery Method
1	Basics of Stroke & Recovery	Stroke overview, warning signs	Zoom lecture + handout
2	Positioning & Transfers	Safe bed mobility, transfers	Demo + video clips
3	Oral & Facial Care	Oral hygiene, facial exercises	Live demo + brochure
4	Breathing & Pulmonary Care	Spirometer, breathing control	Interactive session
5	Home Environment Modifications	Fall prevention, safe environment	Photo-based guidance
6	Tone Management	Icing, brushing, WB	Video + caregiver practice
7	ADL Support	Dressing, grooming, feeding	Live demo
8	Sensory Re-education	Tactile tasks, pusher correction	Interactive demo
9	Functional Task Training	Sit-to-stand, combing, object holding	Video + caregiver feedback
10	Mobility & Gait	Indoor/outdoor gait prep, orthosis	Live demo
11	Assistive Devices	Walker, cane, adaptive kitchen tools	Demo + checklist
12	Caregiver Well-being	Stress management, motivation	Group discussion

Table 5 Safety & Monitoring Checklist

Before Session	During Session	After Session
Patient stable (BP, HR, SpO_2 if available)	Caregiver present	No falls or injuries
No chest pain, dizziness, or shortness of breath	Therapist supervises via Zoom	Caregiver submits logbook
Environment safe (clutter-free, proper lighting)	Proper technique ensured	Feedback to therapist

Figure 2. Conceptual framework illustrating the integration of Functional Independence Measure (FIM)-stratified social-media-based tele-rehabilitation with caregiver education (SM-TR+CE) compared with conventional neurorehabilitation.



Outcome Measures

Primary Outcomes (Feasibility)

- **Recruitment rate:** number enrolled vs. approached.
- **Retention:** proportion completing the 12-week intervention.
- **Adherence:** percentage of prescribed sessions attended.
- **Safety:** incidence of adverse events (falls, medical complications).

Secondary Outcomes (Preliminary Efficacy)

- **Functional status:** Functional Independence Measure (FIM).[4]
- **Motor recovery:** Fugl-Meyer Assessment (FMA).[10]
- **Caregiver burden:** Zarit Burden Interview.[24]
- **Caregiver quality of life:** validated caregiver QoL scale.[25]
- **Satisfaction:** self-reported feedback from participants and caregivers on program acceptability.

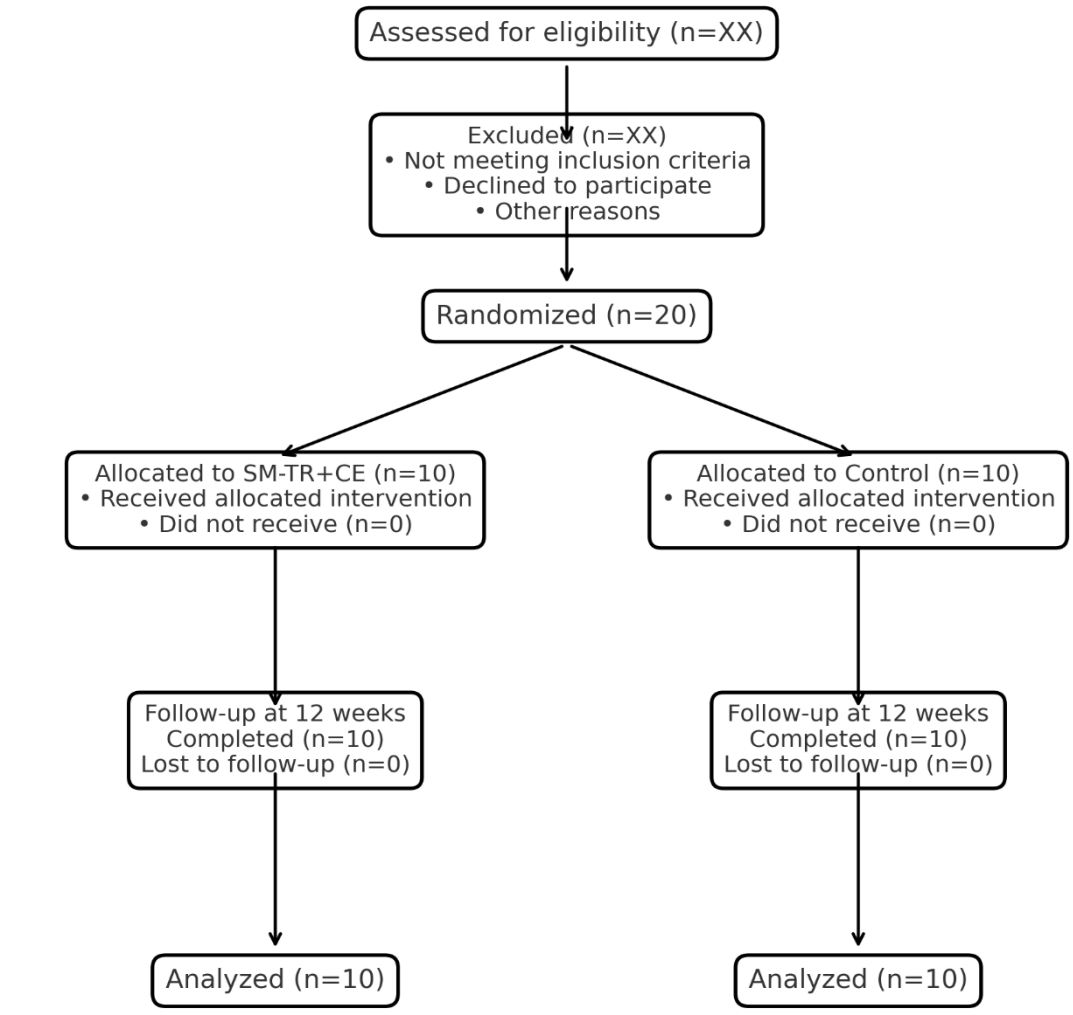
Data Management and Privacy

Data will be stored in password-protected digital spreadsheets with access restricted to study investigators. Social media groups will remain private, with participation by invitation only. Identifiable personal health information will not be shared in group settings. All participants will sign specific consent forms covering the use of social-media platforms for rehabilitation.

Statistical Analysis

Analyses will follow the intention-to-treat principle. Feasibility outcomes will be reported descriptively with means, proportions, and 95% confidence intervals where appropriate. For preliminary efficacy, mean changes from baseline to 12 weeks will be presented for each outcome, along with between-group mean differences and 95% confidence intervals. No formal hypothesis testing will be conducted, as the study is not powered for definitive efficacy conclusions.[23] Variance estimates obtained from this pilot will inform the sample size calculation of a subsequent full-scale randomized trial.

Figure 1. CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis for the pilot randomized controlled trial.



Ethics and Trial Registration

The study was approved by the Sai Ethics Committee (SAI/EC/17122023/06) Written informed consent was obtained from all patients and caregivers prior to participation. Participants were informed of their right to withdraw at any time without penalty.

DISCUSSION

The present protocol outlines a pilot randomized controlled trial designed to evaluate the feasibility, acceptability, and preliminary efficacy of a social-media–based tele-rehabilitation combined with caregiver education (SM-TR+CE) program. The rationale for developing such a protocol is supported by existing evidence highlighting both the unmet rehabilitation needs of stroke survivors and the central role of caregivers in long-term recovery. Stroke remains a leading cause of disability globally, and although rehabilitation can substantially improve functional independence, barriers such as geographical distance, limited resources, and insufficient workforce capacity restrict access to consistent in-center rehabilitation services (Laver et al., 2020; Chumbler et al., 2012).[1,2]

Telerehabilitation has gained prominence as a strategy to overcome these challenges, offering comparable functional outcomes to in-person therapy while extending the reach of services (Cramer et al., 2019).[10] The American Heart Association has emphasized its role within integrated stroke systems of care, acknowledging its potential to improve equity in service delivery (Schwamm et al., 2009).[11] Importantly, social-media platforms such as Zoom and WhatsApp provide cost-effective and user-friendly options for delivering telerehabilitation in low- and middle-income countries, thereby enhancing scalability. Panzeri

et al. (2021)[12] further highlighted the necessity of clinician preparedness and psychoeducational approaches to ensure the effective adoption of telerehabilitation in clinical practice.

The inclusion of caregiver education within rehabilitation protocols is critical. Kalra et al. (2004)[5] demonstrated that training carers of stroke patients through structured programs significantly improved patient outcomes and reduced healthcare utilization. Similarly, Bakas et al. (2017)[6] emphasized in their evidence update that caregiver- and dyad-focused interventions yield measurable benefits in both functional recovery and psychosocial outcomes. However, caregiving responsibilities are often associated with emotional strain, physical burden, and decreased quality of life (Rigby et al., 2009; Cameron et al., 2013).[7,8] Systematic reviews also reveal that unmet support needs are prevalent among informal carers and evolve throughout the care continuum (Greenwood et al., 2009).[9]

Evidence from recent trials and systematic reviews demonstrates that caregiver-directed interventions can reduce burden and enhance coping skills. Islam et al. (2023)[18] reported that caregiver training in Bangladesh improved functional outcomes in stroke survivors, while Sukwatjanee and Rujipong (2024)[19] confirmed reductions in caregiver burden following a structured preparation program. Likewise, Ding et al. (2024)[20] showed that nurse-led rehabilitation training involving caregivers contributed to better patient motor function recovery. Digital and dyadic programs have also demonstrated effectiveness in improving caregiver stress, self-efficacy, and dyadic psychosocial well-being (Zhang et al., 2023; Deepradit et al., 2023).[21,22] These findings collectively highlight the relevance of embedding caregiver education into rehabilitation frameworks, particularly in resource-limited settings.

The current protocol incorporates stratification of patients according to the Functional Independence Measure (Keith et al., 1987),[4] ensuring that exercises and support strategies are tailored to individual dependency levels. Stratification is expected to improve safety, optimize progression, and enhance caregiver engagement, given that caregivers will be actively involved in sessions matched to the patient's functional stage. As noted by Veerbeek et al. (2011)[26] and Winstein et al. (2016),[27] early identification of functional prognosis and personalized rehabilitation are key to improving long-term outcomes.

Pilot trials are essential precursors to definitive randomized controlled trials, as they allow for the assessment of feasibility parameters including recruitment, retention, adherence, and adverse events (Jammal et al., 2024).[23] The small sample size of this trial is therefore not a limitation but rather an intentional design feature to ensure rigorous evaluation of feasibility. By capturing recruitment and retention rates, adherence to prescribed sessions, and technical or logistical challenges, the present study will generate critical data to refine the intervention and calculate appropriate sample sizes for a full-scale trial. Similar pilot work has been instrumental in establishing feasibility benchmarks for telehealth interventions in other rehabilitation domains (Panzeri et al., 2021; Bartoli et al., 2025).[12,28]

An additional strength of the SM-TR+CE protocol is its use of widely accessible technologies, which may facilitate rapid translation into practice if proven feasible and effective. Furthermore, the integration of caregiver education has the potential to reduce burden and improve caregiver quality of life, aligning with the recommendations of recent systematic reviews (Luck & Hildebrand, 2023; Pashmdarfard et al., 2023).[29,30] The inclusion of standardized outcome measures such as the FIM, Fugl-Meyer Assessment, and Zarit Burden Interview enhances the methodological rigor and comparability with existing literature.

As a pilot study, limitations are inherent, particularly the small sample size and short duration of follow-up. Nevertheless, such limitations are characteristic of feasibility trials and do not diminish their value. Instead, findings will inform the refinement of study procedures, highlight technical challenges, and provide preliminary estimates of variability and effect sizes required for powering a future definitive randomized controlled trial.

CONCLUSION

This pilot randomized controlled trial protocol has been developed to evaluate the feasibility, acceptability, and preliminary efficacy of a social-media–based tele-rehabilitation combined with caregiver education program for stroke survivors. By stratifying participants according to Functional Independence Measure levels and actively involving caregivers in structured digital rehabilitation, this study aims to address key gaps in current rehabilitation practice. The findings will provide essential feasibility data, identify logistical and technical challenges, and generate preliminary estimates of outcome variability. These insights will guide the design of a larger definitive randomized trial with adequate power to assess efficacy. Ultimately, the protocol has the potential to contribute to scalable, cost-effective, and caregiver-inclusive rehabilitation strategies for stroke survivors in diverse healthcare contexts.

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