

Title: *Evaluating the Clinical Effectiveness and Implementation Outcomes of Nurse-Led Stroke Transitional Care Model in Tanzania*

Location: Muhimbili University of Health and Allied Sciences, Tanzania

Overall status: Recruiting

Actual start date: 1st August, 2025

Anticipated Completion: 30th March 2026

NCT Number: Pending assignment by ClinicalTrials.gov

Document Type: Submission Package for ClinicalTrials.gov Registry

Sponsor / Collaborator: Shandong University, China

Last Date of Approval: 24th June, 2025

1.0 Introduction

Stroke is a second leading cause of death and disability worldwide, with ischemic stroke accounting for more than half of all stroke types (1). The global prevalence, incidence and mortality rates of stroke are estimated to be 101 million, 12.2 million and 6.6 million respectively in 2019. On the same year, the disability adjusted life-years (DALYs) from stroke was estimated to be 143 million. This represents a substantial rise in stroke burden for 85% prevalence rate, 70% incidence rate, 43% death rate, and 32% DALYs in the past two decades (2). The observed stroke vital statistics are two times higher in Sub-Sahara African countries than those reported in high-income countries (2).

Therefore, there is a growing need to understand the burden of stroke and its associated treatment outcomes in Africa, a continent facing unique healthcare challenges. Stroke prevalence and incidence in Africa exhibits considerable variability, with a higher burden in Sub-Saharan Africa (SSA). Studies have reported the pooled crude incidence rate and one-month case-fatality rates of 106.49 per 100,000 and 24.5% respectively in SSA (3). While in Northern Africa the age-standardized point prevalence, death and DALY rates of stroke are estimated to be 1537.5 , 87.7 and 1826.2 per 100,000 respectively (4).

Limited access to stroke care services, late or underdiagnoses, and inadequate stroke-capable facilities remain the significant predictors of mortality due to stroke in Africa (5). Addressing the stroke burden in the continent requires a multifaceted approach that involve preventive strategies targeting risk factors, improving access to stroke care, establishing stroke units, and increasing rehabilitation services (6). Interestingly, number of efforts are underway in several countries to raise awareness about stroke risk factors, promote healthy lifestyles, and improving access to acute stroke care (7). However, efforts to address transitional care (TC) have not been widely realized in the current initiatives.

Transitioning from hospital to home is a critical phase for patients with chronic illnesses such as stroke. Stroke, being a sudden and often life-altering condition, requires a comprehensive TC approach to facilitate recovery, community reintegration, and long-term disease self-management (8). Owing the growing stroke burden in low-and-middle income countries (LMICs), it is crucial for the healthcare systems to establish a well-functioning TC pathway to enhance quality of stroke care. Lack of a seamless transition may leave stroke survivors susceptible to readmissions and suboptimal health outcomes (9).

The current TC for patients with stroke in SSA countries such as Tanzania is fraught with multifaceted challenges. Stroke survivors are discharged directly from hospital to home leading to a shift of locus of care from healthcare providers to untrained caregivers. Sometimes, hospital to home discharge is a surprise to stroke survivors and their caregivers because they are seldom involved in discharge planning. Furthermore, the transition process lacks a cohesive coordination among healthcare providers resulting in disjointed care, where essential post-stroke care and rehabilitation services are missed (10).

To improve TC, several strategies need to be piloted. First, establishing standardized protocols for information exchange between stroke survivors, caregivers and healthcare providers to ensure timely and complete transfer of patient data. Second, involving stroke survivors and their caregivers in discharge planning, offering clear and understandable instructions, and providing educational resources to empower patients to take an active role in managing their health. Third, designing and implementing locally validated evidence-based TC models to improve hospital-to-home transition. Since plenty of evidence is available in-favor of nurse-led stroke TC (11), adoption of these evidence-based models is worth to explore within the Tanzania's healthcare system.

The current study aims to evaluate the clinical effectiveness and implementation outcomes of a locally validated nurse-led stroke TC model among stroke survivors, caregivers and healthcare providers in Tanzania. Ideally, the nurse-led stroke TC model is informed by the philosophy of the end-user also known as user-centered design (12). The model intends to; (a) prepare stroke survivors to return home through involving them in discharge planning, and (b) foster a sense of patient self-efficacy through active participation in disease self-management.

1.1 Research objectives

1. Assess the effect of nurse-led transition care model on stroke survivors' discharge preparedness, disease self-management and quality of life
2. Assess the effect of a nurse-led transition care model on caregivers' resilience, self-efficacy and care satisfaction
3. Assess the effect of a nurse-led transition care model on healthcare providers' team convergence for discharge preparedness
4. Explore survivors, caregivers and healthcare providers' perceived benefits, barriers and facilitators of implementing, adopting and sustaining a nurse-led transition care model in Tanzania.

2.0 Materials and methods

2.1 Study design

This study uses a multi-stage mixed-methods approach with an effectiveness-implementation design hybrid type 1 that focuses predominantly on clinical effectiveness, and minimal implementation outcomes of the nurse-led stroke TC model (13).

2.2 Setting

The study will be conducted in Dar es Salaam: the most urbanized and commercial city in Tanzania, with a population of about 5.4 million people (14). Specifically, the study will be conducted at stroke units and neurology wards of Muhimbili National Hospital (MNH)-Mloganzila located at Ubungo district. The hospital has a bed capacity of 600 with an internal medicine department that has 108 beds (15). MNH- Mloganzila is a national stroke care center in Tanzania. About 50 stroke survivors are discharged from the stroke units per month after receiving specialty care from neurologists, trained stroke nurses, clinical pharmacists, clinical nutritionists and rehabilitation therapists (15).

2.3 Inclusion and exclusion criteria

2.3.1 Inclusion criteria

- Clinical nurses and physicians with six months of working experience in stroke care
- Clinical nurses and physicians with a minimum of diploma in their professions.
- Stroke survivors with 18 years old and above
- Stroke survivors admitted in the stroke units
- Stroke survivors with primary diagnosis of stroke confirmed by brain CT/MRI
- Stroke survivors who undergo usual discharge process
- Stroke survivors who live with their family caregivers
- Stroke survivors who have mobile phones
- Stroke survivors who can read and write
- Stroke survivors who are able to communicate
- Stroke survivors with National Institutes of Health Stroke Scale (NIHSS) < 6
- Stroke survivors with Modified Barthel Index (MBI) > 9
- Stroke survivors with Modified Rankin Scale (mRS) < 5

- Stroke survivors with Montreal Cognitive Assessment Test (MoCA) > 14
- Stroke survivors who are expected to stay in the ward for 3-5 days,
- Stroke survivors who are expected to survive for 3 months (16).
- Family caregivers with mobile phones
- Family caregivers who can read and write
- Family caregivers who are able to communicate
- Family caregivers who live with the patient after stroke

2.3 Exclusion criteria

- Healthcare providers who will be on leave during the study period.
- Stroke survivors with previous stroke who are not admitted in stroke units
- Stroke survivors who are discharged against medical advice
- Stroke survivors who have end-stage organ failure
- Stroke survivors who have family caregivers
- Stroke survivors who can't read/write
- Stroke survivors who have no mobile phones.
- Family caregivers without mobile phone that is accessible (16).

2.4 Development and validation of the Nurse-led Stroke Transition Care Model

The research team developed the nurse-led stroke TC model by conducting a systematic review and meta-analysis of randomized controlled trials, and rated the evidence by using GRADE recommendations (17). Then, in-depth interviews (IDIs) were conducted between June and September 2024, with a purposively sample of stroke survivors (n=15), caregivers (n=15) and healthcare providers (n=15). The qualitative phase aimed to explore barriers, facilitators and strategies to improve the current hospital-to-home stroke TC practices at the

local setting. Findings from the systematic review and IDIs were combined to form an initial draft of the nurse-led stroke TC model containing TC model bundle interventions, educational topics and nursing activities. Later, the nurse-led stroke TC model interventions and nursing activities were validated by using co-designing approach through three iterative Delphi rounds with academic experts, clinical experts, stroke survivors and informal caregivers between January and March, 2025 (18). Finally, the research team developed the educational materials from literature review of post-stroke guidelines and expert opinions on transitional care of stroke survivors and their caregivers.

2.5 Feasibility of the Nurse-led Stroke Transitional Care Model

Before implementation, we conducted a one-week in-house training with healthcare providers on the locally validated nurse-led TC model. Healthcare providers were assessed their competences in providing TC through observer rating by the principal investigator. After one week of in-house training, a 4-week pilot of 6-pairs of stroke survivors and their caregivers was conducted from April to July, 2025. End-point outcome data were collected at 3 months. Assessment of perceived barriers and facilitators for implementing the nurse-led stroke TC was also conducted using the Consolidated Framework for Implementation Research (19). Likewise, the researchers assessed the acceptability, appropriateness and feasibility of the nurse-led stroke TC model by using the 20-items Implementation Outcome measures developed by Weiner and colleagues (20).

2.6 Implementation of the Nurse-led Stroke Transitional Care Model

2.6.1 Implementation layout

The implementation of the nurse-led stroke TC model is informed by the Health Belief Model (HBM) and Social Cognitive Theory (SCT) (21). Stroke survivors and their caregivers will be recruited to participate in the study upon admission in the stroke units. The model has ten

interventions, each with two goals (Table 1). Two nurse champions will conduct the face-to-face sessions while other two nurse researchers will conduct the telephone call sessions between August and December, 2025. (Table 2). During hospitalization, the two nurse champions will conduct five face-to-face sessions (2 individual sessions at admission; and at discharge), and three group sessions with 2-4 dyads of patients and caregivers. After hospitalization, two nurse researchers will conduct seven follow-up sessions for three months via phone calls at day 3, week 1, week 3, week 5, week 7, week 9, and week 11. The face-to-face sessions and phone call sessions will take 40-60 minutes and 20-30 minutes respectively.

Table 1: Transition Care Model Interventions and Goals

Transition care intervention elements	Goals
1. Patient risk assessment	-To identify risks for hospitalization -To identify risks for poor recovery
2. Discharge planning	-To facilitate early discharge -To formulate transition care goals
3. Stroke specific education	-Identify stroke risk factors and warning signs -Identify stroke complication -To manage symptoms and seek care
4. Disease self-management education	-To modify health risks such as eating, smoking, alcoholism and sleeping -To develop culture of symptom self-assessment and management
5. Caregivers education	-To improve caring willingness -To enhance caregiver engagement in care
6. Education on patient health record	-To enhance patient health literacy -To facilitate care continuity and follow-up
7. Teaching problem solving skills	-To improve social adaptability -To develop coping skills
8. Medication reconciliation	- To prevent medication error -To enhance medication management
9. Rehabilitation education	-To enhance adherence to scheduled physiotherapy sessions -To equip caregivers with competence home-based exercises
10. Education on follow-up care	-To complete treatment schedule -Foster disease self-management

Table 2: Nurse-Led Transition Care Model Implementation Algorithm

Transition care nursing activity	Hospitalization face-to-face sessions					Post-hospitalization phone call sessions						
	1	2	3	4	5	1	2	3	4	5	6	7
-Conduct 8Ps of patient risk assessment -Reconcile pre-admission and admission medications -Conduct discharge home needs assessment -Formulate individualized long- and short-term goals	√											
- Teach about stroke risk factors - Teach about stroke warning signs - Teach about stroke complication		√										
-Teach about symptom self-assessment -Teach about managing anxiety and depression -Teach about managing change of body image -Teach about home-based physical exercises -Teach about support systems			√									
-Teach how to solve and complex simple problems -Educate on the importance of personal health records -Teach about vital signs data				√								
-Assess completion of short-term goals -Give customized discharge instructions -Reinforce on behavioral and emotional management -Teach on the need and importance of follow-up visit -Teach patient about medication use and side effects					√							
-Discuss issues related to general health and home care -Reinforce on stroke education -Reinforce on self-management -Reinforce caregivers' roles and responsibilities -Reinforce on dealing and managing anxiety -Reinforce on medication adherence -Reinforce on maintaining personal health records -Answer any questions related to follow-up visit						√	√	√	√	√	√	√

2.6.2 Purpose of nurse-led stroke educational program

The aim of this educational program is to enhance discharge preparedness and promote disease self-management among stroke survivors and caregivers. This program will equip stroke survivors and caregivers with the knowledge, skills and confidence to manage chronic illness, reduce hospital readmission and improve their quality of life after discharge.

2.6.3 Learning Objectives

Session 1: Patient assessment, Medication reconciliation, and Discharge planning (40-60 min)

1. Describe the risks for poor outcomes during hospitalization and discharge
2. Reconcile patient's medications and explain about medication use, and their side effects
3. Identify patient's discharge needs and preparedness

Pre-session Activity

- Review of current medications and potential discharge home concerns.

Post-session Activity

- Create a personalized medication schedule and discharge plan.

Session 2: Introduction to Stroke and Recovery Process (40-60 min)

1. Describe the basics of stroke, its types, risk factors
2. Explain the stroke related complications, and the recovery process.

Pre-session Activity

- Questionnaire to evaluate participants' knowledge of stroke and its impact.

Post-session Activity

- Journal on personal experiences or history of stroke.

Session 3: Disease self-management, rehabilitation and support systems (40-60 min)

1. Describe the role of nutrition and exercise in preventing further strokes.
2. Describe strategies to cope with physical, cognitive, and emotional challenges after stroke.
3. Explain the importance of social support and how to build a network of family, friends, and healthcare providers.

Pre-session Activity

- Log current eating habits and physical activity.
- Assess individual challenges post-stroke
- Identify current support system and gaps

Post-session Activity

- Develop a personalized nutrition and exercise plan.
- Practice coping strategies learned in the session.
- Create a social support plan.

Session 4: Health literacy and problem solving skills (40-60 min)

1. Demonstrate how to solve and complex simple problems
2. Explain the importance of personal health records and record keeping

Pre-session Activity

- Review problems related to healthcare access and stroke related physical and cognitive limitations.
- Obtain a patient mini-record booklet

Post-session Activity

- Assess individual ability to solve simple and complex problems
- Fill the patient mini-record booklet

Session 5: Long-term disease self-management and follow-up (40-60 min)

1. Explain the importance of medication adherence, lifestyle changes, diet adjustments, follow-up appointments, and self-assessment to manage the risk of stroke recurrence.

Pre-session Activity

- Review the medical follow-up schedule and individual goals.

Post-session Activity

- Set a personal schedule for long-term self-management.

Telephone call session 1 to 7: Reinforcement of health behaviors and self-management (20-30 min)

1. Discuss issues related to general health, clinical improvement, self-management practices and home care challenges

Pre-session Activity

- Review the medications, medical follow-up schedule and individual goals.

Post-session Activity

- Set a personal schedule for long-term disease self-management.

2.6.4 Teaching and Learning Strategies

- I. Interactive discussions: engage participants in conversations and peer interactions to reflect on their experiences and knowledge, ensuring participation and shared learning.

- II. Practical demonstrations: include demonstrations of medication management, exercise routines, and other practical skills.
- III. Role-playing: use role-playing scenarios to practice dealing with healthcare providers, family members, or peers.
- IV. Case studies: provide real-life case studies that reflect common post-stroke issues and challenges, followed by group discussions.
- V. Visual aids: use videos, infographics, and charts to explain complex topics in a simple and clear way.

2.6.4 Educational contents

1. Patient risk assessment

- 1.1 Identify the principal diagnosis
- 1.2 Identify the risk of poor health literacy
- 1.3 Identify the risk of fall
- 1.4 Identify the risk of DVT or bleeding
- 1.5 Identify the risk of pressure ulcer
- 1.6 Identify the risk of aspiration pneumonia
- 1.7 Identify the risk of physical limitations such as deconditioning, frailty and malnutrition
- 1.8 Identify the risk of poor social support
- 1.9 Identify the risk of psychological problems
- 1.10 Identify the risk of medication error or polypharmacy
- 1.11 Identify the risk of UTI, urosepsis and sepsis
- 1.12 Identify the risk of readmission
- 1.13 Identify the risk of palliative care
- 1.14 Identify the risk of contractures and spasticity

2. Medication reconciliation

- 2.1 Identify patient pre-admission medication
- 2.2 Compare pre-admission medication and admission medications
- 2.3 Importance of adhering to medications

3. Discharge planning

- 3.1 The hospital discharge process
- 3.2 Conduct discharge home needs assessment
- 3.3 Formulate individualized long- and short-term goals

4. Stroke specific education

- 4.1 Stroke types
- 4.2 Stroke risk factors
- 4.3 Stroke signs and symptoms
- 4.4 Brain MRI and CT- scan for stroke diagnosis
- 4.5 Stroke complications
- 4.6 Overview of stroke-related medications

5. Disease self-management

- 5.1 Role of diet in stroke prevention
- 5.2 Exercise recommendations for stroke survivors
- 5.3 Behavioral and lifestyle adjustments
- 5.4 Management of depression and anxiety
- 5.5 Management of change of body image
- 5.6 Importance of medication adherence

6. Rehabilitation after stroke

- 6.1 Home-based physical rehabilitation techniques (physiotherapy and occupational therapy)

6.2 Cognitive and emotional coping mechanisms

6.3 Speech and language therapy

7. Support Systems

7.1 Building and maintaining a social support or peer network

7.2 Encouraging peer support and family involvement

7.3 Living with stroke survivors: Roles and responsibilities of a caregiver

8. Health literacy

8.1 The importance of personal health records

8.2 Know your numbers: vital signs data

8.3 Keeping personal health records

9. Problem solving skills

9.1 Evidence-based process for problem solving

9.2 Solving and complex simple problems

10. Long-term disease self-management and follow-up

10.1 Customized discharge instructions

10.2 Importance of regular follow-up appointments and self-monitoring

10.3 Evaluating health goals and tracking progress

10.4 Reinforce on behavioral, medical and emotional management

2.6.5 Supporting structures from the organization

- I. Interdisciplinary team approach: collaboration between healthcare professionals (e.g., nurses, occupational therapists, physiotherapists, physicians, nutritionists, social workers, clinical pharmacists and hospital administrators) to ensure comprehensive content delivery.

- II. Patient education resources: availability of pamphlets, videos, and other educational materials for ongoing reference.
- III. Presence of equipped conference rooms and user-friendly environment with privacy

2.6.6 Post-training support materials

- I. Educational booklets: a comprehensive booklet containing all the contents from the sessions will be given to each patient-caregiver dyad.
- II. Online support group: participants will have access to WhatsApp group platform for continued learning and peer interaction.
- III. Follow-up reminders: SMS reminders will be sent to participants to encourage adherence to treatment plans and follow-up dates.

2.6.7 Training of instructors/implementers

- I. Evidence-based training: instructors will be trained in the principles of stroke recovery, as well as in adult learning theories.
- II. Refresher training: instructors will be up-to-date with the latest stroke research and management guidelines.
- III. Instructor support: instructors will be given continuous feedback and support during the program.

2.6.8 Methods used to decide the educational contents

- I. Review of current stroke guidelines: content is aligned with national and international stroke management guidelines (e.g., AHA/ASA, WSO).
- II. Feedback from stakeholders: obtained feedback from healthcare providers, stroke survivors and caregivers to inform the relevance and applicability of content.
- III. Expert consultations: solicited opinions from clinical experts, academic staff and stroke experts to develop evidence-based contents.

2.6.9 Possible barriers to implementation

- I. Limited resources: funding for materials, shortage of instructors, or facilities
- II. Cognitive and physical limitations: some stroke survivors may have difficulty with certain learning methods, requiring modifications to the curriculum.
- III. Logistical barriers: transportation, time constraints, and mobile/internet network could affect participation.
- IV. Readiness of healthcare providers: some healthcare providers maybe reluctant or sluggish to implement the new norm.

2.7 Intervention fidelity

The principal investigator will conduct face-to-face training and give printed materials and checklists to stroke TC program implementers to enhance intervention fidelity. Also the principal investigator will conduct participatory observations and peer ratings of implementers to assess adherence to the implementation algorithms. Implementers will be given feedback with regards to their adherence to implementation algorithm after finishing ward-rounds and clinical meetings. Poor adherence will imply a need for more education.

2.8 Sampling

The sample size is estimated by using statistical method with a G*power calculator to detect a mean difference between two groups for quality of life of stroke survivors as shown in a previous clinical trial of stroke transition care (22). The current study assumes a medium effect size of Cohen $d = 0.5$, 80% priori power, two tailed $\alpha = 0.05$, and allocation ratio of 1:1. This yields a total sample size of 128. After accounting for 20% attrition rate, a minimum of 154 dyads of patients and caregivers will be required in pre-implementation phase also known as historical control group ($n=77$) and implementation phase also known as intervention group ($n=77$). Similarly, a minimum of 154 dyads of registered nurses and

discharging physicians will be required to ascertain for patients' discharge preparedness events in historical control group (n =77) and intervention group (n = 77) respectively.

2.9 Data collection

In the historical control group, participants were recruited between September and December, 2024. However, in the intervention group, participants will be recruited between August and December 2025. In each group, baseline data will be collected upon admission in the stroke units (T0). Follow-up data will be collected at 3 months (T1), and 6 months (T2) after discharge. Patients' demographic characteristics will include age, sex, education level, insurance type, marital status, religion, and residence. Also, biodata such as blood pressure, blood sugar, lipid profile, body mass index, stroke type, comorbidity index, functional status, cognitive status, stroke severity, stroke onset, time metrics and medications will be collected. Caregivers' demographic characteristics will include age, sex, education level, residence, phone number and relationship with patient. While, healthcare providers' demographic characteristics will include age, sex, education level, profession, and years of work experience.

2.10 Evaluation of the Clinical Effectiveness of a Nurse-led Stroke TC Model

2.10.1 Stroke survivors' outcomes

The primary outcomes will be Quality of TC that will be measured by the Care Transitions Measure (CTM) Tool developed by Eric Coleman (23); Discharge preparedness that will be measured by the Short Forms of the Readiness for Hospital Discharge Scale (RHDS) developed by Weiss (24); Self-efficacy that will be measured by the Stroke Self-Efficacy Questionnaire ($\alpha=0.9$) developed by Jones and colleagues (25); and Quality of life that will be measured by the Stroke Specific Quality of Life (SSQoL) with ($\alpha=0.85$). The secondary outcomes will be resilience that is measured by the 10-items Connor–Davidson Resilience Scale (CD-RISC) validated by Laura (26) with $\alpha=0.85$; depression and anxiety that is measured by the locally

validated 10-items Kessler Psychological Distress Scale with $\alpha=0.85$ (27); readmission measured as a number of times an unplanned readmission occurs; mortality measured as death that occurs after a patient is discharged from the hospital; and length of stay measured as number of days spent in the hospital from admission to discharge.

2.10.2 Healthcare providers' outcomes

The outcome for healthcare providers will be discharge readiness as measured by the Short Forms of the Readiness for Hospital Discharge Scale (RHDS) developed by Weiss (24).

2.10.3 Caregivers' outcomes

Caregiver self-efficacy that will be measured by the 10-items Family Caregiver Activation Tool (FCAT) developed by Coleman (28) with $\alpha=0.6$; Resilience that will be measured by the 10-items Connor–Davidson Resilience Scale (CD-RISC) validated by Laura (26) with $\alpha=0.85$; and Depression and anxiety that will be measured by the locally validated 10-items Kessler Psychological Distress Scale with $\alpha=0.85$ (27).

2.10.4 Data analysis

Quantitative data will be analyzed using STATA software based on intention-to-treat analysis. At baseline demographic characteristics, and group differences between the historical control group and intervention group will be analyzed by the Independent Samples T-test and one-way ANOVA. The Chi-Square Test of Associations (χ^2) and Fisher's Exact Test will be conducted to compare association between categorical variables. To estimate, visualize and compare survival probabilities over time, Kaplan-Meier estimation and Log-rank test will be conducted. Also, Cox regression will be used to examine the relationships between predictor variables and the hazard rate or relative risk of experiencing an adverse event over time. A $p < 0.05$ and 95% Confidence Intervals (95% CI, excluding zero value) will be regarded as statistically significant indicators.

2.11 Evaluation of the Implementation Outcomes of the Nurse-led stroke TC Model

Descriptive qualitative explorations will be conducted to uncover the benefits, barriers and facilitators of implementing, adopting and sustaining the nurse-led stroke transition care model. Stroke survivors, caregivers and healthcare providers who participated during the implementation of the nurse-led stroke TC model will be purposeful selected (29) between January and March, 2026. Data collection will be done by using audio-recorded IDIs and Focus Group Discussions (FGDs). Initially 10-20 In-depth Interviews (IDIs) will be conducted, followed by 2-4 FGDs with 6-8 healthcare providers per group. Stroke survivors and caregivers will be recruited during their scheduled clinic visits at the out-patient department, while healthcare providers' will be recruited from the neurological wards.

2.11.1 Data analysis

Data analysis will be done using six-steps thematic analysis in Dedoose software. First, researchers will familiarize themselves with the data by reading transcripts multiple times. Second, one researcher competent in using the software will generate initial codes by identifying meaningful features in the data. Third, the researcher will search for themes by grouping related codes together. Fourth, themes will be reviewed to ensure they accurately represent the data. Fifth, the researchers will define and name each theme to clearly capture its essence. Finally, the research team will produce the report, where themes will be integrated into a coherent narrative that addresses the research questions. This qualitative phase will adhere to the established standards (credibility, confirmability, dependability, and transferability) for undertaking qualitative studies (30).

2.12 Quality control of the study

The study will use standardized and validated assessment tools that correspond to the study objectives and local context. Expert methodological opinions, suggestions, and

recommendations have been solicited to improve the current study. Regular team meetings, discussions, and training before and after data collection will be hold. Any deviations from the study protocol will be timely communicated and rectified. Also, any missing data will be noted and measures to input data either directly by contacting the study participant or using multiple imputation method with chained equation will be considered.

2.13 Ethical considerations

The study adheres to the ethical principles of conducting studies involving human subjects as outlined in the Helsinki Declaration. The ethical approval to conduct this study has been obtained from Muhimbili University of Health and Allied Sciences Institution Review Board (MUHAS-REC-04-2024-2139). Permission to enter the study site has been granted by the Executive Director of MNH. The participants are told that participation is voluntary and any person may wish to participate or drop out from the study at any time. Also, all participants are required to give an informed consent to participating in this study.

3.0 Discussion

Recently, nurse-led stroke TC models are increasingly recognized as effective strategies for improving various aspects of care, including discharge preparedness, and disease self-management (16). These TC models ensure that patients are adequately prepared for discharge. Nurses use their clinical expertise and patient-centered approach to assess patients' needs, addressing concerns, and coordinating TC. During transition, nurses deliver comprehensive education and training to patients and their caregivers on various aspects of care such as self-care, medication management, symptom recognition, rehabilitation exercises, and lifestyle modifications (31).

The nurse-led TC models have been shown to positively impact the quality of life of stroke patients by addressing their physical, emotional, and social needs (32). Nurses play a crucial

role in managing stroke-related symptoms and complications, such as pain, fatigue, depression, and anxiety. Through patient education, symptom monitoring, and timely interventions, nurses alleviate distressing symptoms and improve patients' overall quality of life. Also, nurses provide psychosocial support and counseling to patients in order to cope with the psychological and emotional impacts of stroke (33).

Evidence show that nurse-led TC models not only have positive impacts on patients' outcomes, but also have significant impacts on caregivers' resilience, self-efficacy, and activation. TC nurses offer caregivers education and training on assisting patients with activities of daily living, managing medications, and recognizing signs of complications (32). Similarly, TC nurses enhance caregiver self-efficacy by providing opportunities for skill development, fostering confidence in caregiving abilities, and promoting a sense of mastery over caregiving tasks. Also, during transition, caregivers are engaged as active partners in the care process that promotes a sense of ownership over caregiving responsibilities (34).

Moreover, nurse-led TC models facilitate effective communication and collaboration among healthcare providers from different disciplines involved in the care of stroke survivors (8). These models emphasize care coordination among healthcare providers to ensure seamless transitions for stroke survivors. Nurses serve as central coordinators, liaising between different disciplines and facilitating the exchange of information and resources. By promoting regular team meetings, multidisciplinary rounds, and family conferences, nurses ensure that all team members are informed about the patient's condition, progress, and discharge plan. To date, the adoption and integration of evidence-based nurse-led TC models has not been widely recognized within the Tanzania's healthcare system. There is lack of focus on TC and few healthcare professionals are trained in chronic illness care (35). Similarly, the healthcare system lacks structured and well-defined TC programs specifically designed to address the

needs of patients with chronic illnesses. To address these challenges, there is an urgent need to establish structured TC programs which addresses the healthcare needs of patients and their caregivers during hospital-to-home transitions.

3.1 Study limitation and mitigation

This study is prone to temporal changes, such as improvements or changes in care processes over time that might confound the observed before-and-after differences. Also, extreme values in the "before" measurement may regress toward the mean in the "after" measurement purely by chance, creating the illusion of improvement due to the intervention. However, we will use various mitigation strategies to address the limitations of this study. First, we will include multiple follow-up points to minimize the impact of short-term fluctuations that will help to differentiate sustained effects from transient effects of the intervention. Second, we will employ statistical techniques such as regression analysis to adjust for confounding variables and reduce biases. Third, we will maintain consistency in measurement tools, perform sensitivity and post-hoc analysis, and implement blinding procedures to reduce biases in outcome assessment, ensuring the outcome assessors are unaware of the participants' intervention status.

4.0 Conclusion

There is a need to critically consider TC as an absolute care need for stroke survivors and their caregivers. However, the current TC in Tanzania faces several challenges such as insufficient staff training in chronic care, limited access to post-stroke care services and low patients' health literacy. Similarly, there is a lack of structured and well-coordinated TC program that addresses the needs of stroke survivors. Thus, there's a need for further investments in structured and locally tailored stroke TC programs, and targeted interventions to address the unique needs of stroke survivors as they move from the hospital to their homes.

Conflict of interest: None

Acknowledgment: None

Funding source: National Natural Science Foundation of China. Grant number: 72274110

Reporting guideline: TIDieR (Template for Intervention Description and Replication) checklist.

References

1. Fan J, Li X, Yu X, Liu Z, Jiang Y, Fang Y, et al. Global Burden, Risk Factor Analysis, and Prediction Study of Ischemic Stroke, 1990-2030. *Neurology*. 2023;101(2):e137-e50.
2. Collaborators G, Feigin VL, Stark BA, Johnson CO, Roth GA, Bisignano C, et al. Global, regional, and national burden of stroke and its risk factors, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. 2021;20(10):795-820.
3. Mensah George A, Fuster V, Murray Christopher JL, Roth Gregory A, Mensah George A, Abate Yohannes H, et al. Global Burden of Cardiovascular Diseases and Risks, 1990-2022. *Journal of the American College of Cardiology*. 2023;82(25):2350-473.
4. Shahbandi A, Shobeiri P, Azadnajafabad S, Saeedi Moghaddam S, Sharifnejad Tehrani Y, Ebrahimi N, et al. Burden of stroke in North Africa and Middle East, 1990 to 2019: a systematic analysis for the global burden of disease study 2019. *BMC Neurology*. 2022;22(1):279.
5. Urimubenshi G, Cadilhac DA, Kagwiza JN, Wu O, Langhorne P. Stroke care in Africa: A systematic review of the literature. *International journal of stroke : official journal of the International Stroke Society*. 2018;13(8):797-805.
6. Walker R. Osuntokun Award Lecture 2021: Challenges of Measuring the Burden of Stroke in Africa. *Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association*. 2022;31(4):106386.

7. Tawa N, Rhoda AJ, Brink Y, Urimubenshi G, Giljam-Enright M, Charumbira MY, et al., editors. Stroke rehabilitation services in Africa – Challenges and opportunities: A scoping review of the literature 2021.
8. Duncan PW, Bushnell C, Sissine M, Coleman S, Lutz BJ, Johnson AM, et al. Comprehensive Stroke Care and Outcomes. 2021;52(1):385-93.
9. Matuja SS, Mlay G, Kalokola F, Ngoya P, Shindika J, Andrew L, et al. Predictors of 30-day mortality among patients with stroke admitted at a tertiary teaching hospital in Northwestern Tanzania: A prospective cohort study. *Frontiers in neurology*. 2022;13:1100477.
10. Mkoba EM, Sundelin G, Sahlen KG, Sörlin A. The characteristics of stroke and its rehabilitation in Northern Tanzania. *Global health action*. 2021;14(1):1927507.
11. Karen B. Hirschman MES, Kathleen McCauley, Mark V. Pauly, Mary D. Naylor. Continuity of Care: The Transitional Care Model. *OJIN: The Online Journal of Issues in Nursing*. 2015;20(3).
12. Salgueiro-Oliveira A, Rêgo ADS, Santos-Costa P, Bernardes RA, Filipe L, Sousa LB, et al. Design of Innovative Clothing for Pressure Injury Prevention: End-User Evaluation in a Mixed-Methods Study. *Int J Environ Res Public Health*. 2023;20(18).
13. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. 2012;50(3):217-26.
14. Statistics TNBo. Population and Housing Census: Administrative units Population Distribution and Age and Sex Distribution Reports. <https://sensaibsgotz/>. 2022.
15. Mloganzila MNH-. Directorates. mloganzilaortz. 2024.

16. O'Callaghan G, Fahy M, Murphy P, Langhorne P, Galvin R, Horgan F. Effectiveness of interventions to support the transition home after acute stroke: a systematic review and meta-analysis. *BMC health services research*. 2022;22(1):1095.
17. Michael NA, Mselle LT, Tarimo EM, Cao Y. The Effectiveness of Nurse-Led Transition Care on Post-Discharge Outcomes of Adult Stroke Survivors: A Systematic Review and Meta-Analysis. *Nursing open*. 2025;12(3):e70140.
18. Zogas A, Sitter KE, Barker AM, Fix GM, Khanna A, Herbst AN, et al. Strategies for engaging patients in co-design of an intervention. *Patient Educ Couns*. 2024;123:108191.
19. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation science : IS*. 2022;17(1):75.
20. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implementation science : IS*. 2017;12(1):108.
21. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. *Health education quarterly*. 1988;15(2):175-83.
22. Kam Yuet Wong F, Wang SL, Ng SSM, Lee PH, Wong AKC, Li H, et al. Effects of a transitional home-based care program for stroke survivors in Harbin, China: a randomized controlled trial. *Age and ageing*. 2022;51(2).
23. Coleman EA, Smith JD, Frank JC, Eilertsen TB, Thiaré JN, Kramer AM. Development and testing of a measure designed to assess the quality of care transitions. *International journal of integrated care*. 2002;2:e02.

24. Mehraeen P, Jafaraghaee F, Paryad E, Kazemnejad Leyli E. Comparison of Nurses' and Patients' Readiness for Hospital Discharge: A Multicenter Study. *Journal of patient experience*. 2022;9:23743735221092552.
25. Jones F, Partridge C, Reid F. The Stroke Self-Efficacy Questionnaire: measuring individual confidence in functional performance after stroke. *Journal of clinical nursing*. 2008;17(7b):244-52.
26. Campbell-Sills L, Stein MB. Psychometric analysis and refinement of the Connor-davidson Resilience Scale (CD-RISC): Validation of a 10-item measure of resilience. *Journal of traumatic stress*. 2007;20(6):1019-28.
27. Vissoci JRN, Vaca SD, El-Gabri D, de Oliveira LP, Mvungi M, Mmbaga BT, et al. Cross-cultural adaptation and psychometric properties of the Kessler Scale of Psychological Distress to a traumatic brain injury population in Swahili and the Tanzanian Setting. *Health and quality of life outcomes*. 2018;16(1):147.
28. Coleman EA, Ground KL, Maul A. The Family Caregiver Activation in Transitions (FCAT) Tool: A New Measure of Family Caregiver Self-Efficacy. *Joint Commission journal on quality and patient safety*. 2015;41(11):502-7.
29. Renjith V, Yesodharan R, Noronha JA, Ladd E, George A. Qualitative Methods in Health Care Research. *International journal of preventive medicine*. 2021;12:20.
30. Forero R, Nahidi S, De Costa J, Mohsin M, Fitzgerald G, Gibson N, et al. Application of four-dimension criteria to assess rigour of qualitative research in emergency medicine. *BMC health services research*. 2018;18(1):120.
31. Jee S, Jeong M, Paik NJ, Kim WS, Shin YI, Ko SH, et al. Early Supported Discharge and Transitional Care Management After Stroke: A Systematic Review and Meta-Analysis. *Frontiers in neurology*. 2022;13:755316.

32. Lin S, Xiao LD, Chamberlain D, Ullah S, Wang Y, Shen Y, et al. Nurse-led health coaching programme to improve hospital-to-home transitional care for stroke survivors: A randomised controlled trial. *Patient Education and Counseling*. 2022;105(4):917-25.
33. Camicia M, Lutz B, Summers D, Klassman L, Vaughn S. Nursing's Role in Successful Stroke Care Transitions Across the Continuum: From Acute Care Into the Community. 2021;52(12):e794-e805.
34. Lobo EH, Abdelrazek M, Grundy J, Kensing F, Livingston PM, Rasmussen LJ, et al. Caregiver Engagement in Stroke Care: Opportunities and Challenges in Australia and Denmark. *Frontiers in public health*. 2021;9:758808.
35. Rachlis B, Naanyu V, Wachira J, Genberg B, Koech B, Kamene R, et al. Identifying common barriers and facilitators to linkage and retention in chronic disease care in western Kenya. *BMC Public Health*. 2016;16(1):741.

CONSENT FORM IN ENGLISH

ID. NO

Consent Form for Participating in a Research Study

My name is **Nyagwaswa A. Michael**, Assistant Lecturer at Muhimbili University of Health and Allied Sciences (MUHAS) in the School of Nursing, currently pursuing PhD in Nursing Sciences at Shandong University in China. I am researching the effects of transition care experiences on the outcomes of patients with stroke at Muhimbili National Hospital.

The aim of the study

This study aims to explore the practices, barriers, and facilitators and effects of nurse-led transitional care among patients with stroke at Muhimbili National Hospital, Dar-es-Salaam, Tanzania. The findings of this study will provide will contribute to the improvement of quality of transitional care among patients with stroke and other chronic illness in Tanzania.

Procedure

You have been selected because you are among the patients, caregivers/healthcare providers who is involved in the transition care of patients with stroke. If you choose to participate you will be interviewed for about 50-60 minutes and will audio record the interview to ensure we don't miss any information.

Confidentiality

All information will be kept strictly confidential. This means that your responses will be recorded anonymously and shall be used only for research. I will ensure that any information included in my report does not identify you as the respondent. No names will be included both during the interview and reporting findings.

Right to refuse or withdraw

You have absolute choice to participate in this study. Moreover, you don't have to talk about something you don't want and you may stop the interview at any time for any reason without any consequences. However, I encourage you to participate because your experience is very important in improving the quality of transition care for patients with stroke in our country.

Benefits

Participating in this study may not benefit you directly, but will provide useful information that can benefit others and improve the quality of transition care for patients with stroke in our country. You will be given a flier that will help you to improve your knowledge on stroke.

Risks

There is no harm to you if you participate in this study. However, there are some questions that may be personal, but feel free to reply.

Whom to Contact

In case of any inquiry please contact the researcher, **Nyagwaswa A. Michael** from MUHAS, P. O. BOX 65001, Dar es Salaam, mobile number 0685005923. If you ever have questions about your rights as a participant, you may contact the Director of Research, Publications and Innovation, at MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania.

Signature

Do you agree to participate? Put a tick in the appropriate box

Participant agrees ☐ participant does NOT agree ☐

I, have read the contents of this form and understood. My questions have been answered; I agree to participate in this study.

Signature of participant..... Date.....

Signature of researcher Date.....