

Primary Prevention of Stroke in Rural India by Empowering the Frontline Health Workers - A Cluster Randomized Controlled Trial

Mrs. J. Vinodhini Zipporah¹, Dr. Ruchira Ankar, PhD (N)^{2*}

¹Ph.D. Scholar, Datta Meghe Institute of Higher Education & Research (DU), Wardha, Maharashtra, India.

²Associate Professor & HOD, Dept. of Medical-Surgical Nursing Smt. Radhikabai Meghe Memorial College of Nursing, DMIHER(DU), Sawangi(M), Wardha, Maharashtra, India.

*Corresponding Author

DOI: <https://dx.doi.org/10.51584/IJRIAS.2026.110200149>

Received: 04 March 2026; Accepted: 09 March 2026; Published: 21 March 2026

ABSTRACT

Background: Stroke is a leading cause of mortality and disability worldwide, disproportionately affecting low- and middle-income countries (LMICs). In India, delayed recognition of warning signs and limited primary prevention strategies contribute to poor outcomes. Frontline health workers (FLWs) are uniquely positioned to identify risk factors and deliver community-based interventions, yet structured training in stroke prevention is limited.

Objectives: The primary objective is to assess whether the Adult Stroke Prevention Module (ASPM) improves FLW skill delegation and competency compared to the Nigerian Educational Intervention Module (NEIM). Secondary objectives include evaluating changes in community participants' modifiable risk factors, knowledge retention, and adherence to preventive behaviors.

Methods: This cluster-randomized controlled trial will be conducted across eight community clusters in Wardha district, Maharashtra. Clusters will be randomized using a computer-generated sequence by an independent statistician, with allocation concealment maintained. Stratification will be applied based on population size and FLW density. FLWs will be randomized to ASPM (structured four-session training plus video module) or NEIM (translated video-based education with counseling). Adults aged 40–60 years identified by FLWs will undergo baseline and follow-up assessments at 3, 6, and 9 months, including blood pressure, glucose, cholesterol, waist-to-hip ratio, lifestyle habits, and stress levels. The primary endpoint is FLW skill delegation competency, measured using a validated checklist. Secondary outcomes include biometric and behavioral changes among community participants. Sample size is calculated assuming an effect size of 0.30, intracluster correlation coefficient (ICC) of 0.02, alpha of 0.05, power of 80%, and attrition of 15%, requiring approximately 100 FLWs and 400 community participants. Data will be analyzed using mixed-effects regression models with cluster random effects, baseline adjustment, repeated measures, and multiple imputation for missing data.

Results: The trial has been registered in the Clinical Trial Registry of India (CTRI/2025/05/086446). Training materials and video modules have been finalized, and a pilot study with 20 FLWs is yet to be completed to refine tools and procedures. Recruitment is projected to begin in May 2026, with data collection expected to conclude by March 2027.

Conclusions: This study will provide evidence on the comparative efficacy of ASPM versus NEIM in enhancing FLW-led stroke prevention. Findings are expected to inform scalable, technology-driven strategies for primary prevention in LMICs, strengthen community health systems, and contribute to policy frameworks aimed at reducing the growing burden of stroke.

Trial Registration: CTRI/2025/05/086446 (Registered May 6, 2025)

Keywords: Stroke, Primary prevention, Frontline health workers, Skill delegation, Cluster randomized trial, LMICs, Rural India, Digital health

*Contributing Author—Special thanks to Mayowa O. Owolabi, DrM, University of Ibadan, Nigeria.

INTRODUCTION

Stroke is a leading cause of death and disability worldwide, with LMICs bearing nearly 80% of the global burden [1]. In India, incidence ranges between 116–163 per 100,000 individuals, with significant disparities in access to timely care [2]. Alarming, one in seven stroke patients are under 45 years of age, underscoring the urgent need for prevention strategies [3]. Despite this, awareness of stroke symptoms remains low, and only about 20% of patients reach hospitals within the golden treatment window [4].

Community-based approaches have proven effective in reducing cardiovascular and stroke risk. The Gadchiroli trial in rural India demonstrated that structured interventions delivered by health workers significantly reduced risk factor prevalence [5]. Similar cluster randomized trials in LMICs have shown that FLW-led education improves public knowledge of stroke warning signs [6]. However, evidence from India suggests FLWs often lack adequate training in stroke recognition and prevention [7,8].

Globally, educational interventions for stroke prevention have been explored, but systematic reviews indicate few programs are tailored to LMIC contexts and even fewer compare different training approaches [9]. The Nigerian Educational Intervention Module (NEIM), developed in 2023, uses video-based education to improve stroke literacy among health workers and communities [10]. Its effectiveness in India has not been tested.

This study addresses these gaps by evaluating the Adult Stroke Prevention Module (ASPM), a structured, skill-based training program tailored for Indian FLWs, against NEIM. The trial aims to determine which approach more effectively enhances FLW competency, skill delegation, and community-level risk reduction.

Methods/Design:

This study is a cluster randomized parallel group active-controlled trial which will be conducted in the community areas of Wardha District, Maharashtra. The intervention includes training of the Frontline health workers with the Adult stroke Prevention Module and the Comparator arm with the Nigerian Educational Intervention Module. The study hypothesis is that there is a significant difference between the Adult Stroke Prevention Module and the Nigerian Educational Intervention Module in reducing stroke risk factors and promoting primary prevention among frontline health workers. Cluster randomization is to be implemented in order to prevent the contamination of the samples.

AIM:

- To train the Frontline health workers to determine the risk factors of stroke among the adults and enabling them to recognize the warning signs by development of adult stroke prevention module.
- To identify and monitor the adults with risk factors on a regular basis for stroke prevention techniques and to reduce the risk score from moderate to low, low to normalcy respectively.

Study Setting & Health workers selection:

There are 8 blocks in Wardha district. Cluster randomization will be done for the selection of blocks. Once the blocks are selected the community health centres, primary health centres and the sub centres will be noted. The frontline health workers including community health workers, health supervisors, health inspectors, Junior Public Health Nurses (JPHN), and activists such as Accredited Social Health Activists (ASHA) will be randomly selected in the intervention and the control arm/comparator arm.

Study Design:

The study is planned to be conducted in 3 phases. In Phase I the randomly selected blocks will be categorized into intervention arm (Group A) and the control/comparator arm (Group B). The selected Frontline health workers in both the arms will be assessed with the pre-structured questionnaire to identify the awareness of stroke. In Phase II the frontline health workers in the intervention arm will undergo a 4 days training session about stroke, its risk factors, warning signs and management. Each session is planned to be conducted for 35-40 mins. In the control arm there is no specific training sessions, the group will be shown the Nigerian educational intervention video. In Phase III the frontline health workers will identify the risks among the adults in the community using stroke riskometer app and also the pre structured assessment format. The categorization of individuals will be done and the participants will be monitored every 3rd, 6th and 9th month respectively in both the arms.

Participant characteristics: Frontline Health Workers

Inclusion Criteria:

1. The willing Frontline health workers from the selected blocks with permission from the community health officers.
2. Frontline health workers living within a 40 km radius from the identified health centers.

Exclusion Criteria:

1. Frontline health workers who are currently expecting a child
2. Those who decline participation or unable to give voluntary approval to take part in the study.
3. Participants diagnosed with advanced or life-limiting medical conditions that may hinder full engagement in the study process.

Adults from the Community:

Inclusion Criteria:

- i. Adults aged between **40 to 60 years**.
- ii. Both male and female participants.
- iii. Individuals who can give informed consent to participate in the study.

Exclusion Criteria:

- i. Adults with severe physical ailments (such as end-stage renal disease, cardiac failure, diabetic coma, chronic liver disorders, Parkinson's disease, Alzheimer's disease, uncontrolled hypertension & stroke survivors) that would affect their ability to follow study protocols or interfere with stroke risk assessments.
- ii. Bedridden individuals who are unable to participate in the study due to immobility.
- iii. Mentally challenged individuals, as their ability to comprehend study procedures and provide informed consent may be compromised.
- iv. Adults with altered sensory perceptions (e.g., significant hearing or vision impairments) that might hinder their participation in the study's interventions or data collection.

Sample Size: Based on effect size 0.30, ICC 0.02, alpha 0.05, power 80%, attrition 15% → 100 FLWs and 400 community participants.

Methodology: -Mixed Method (Quantitative and Qualitative)

Methods For Data Collection

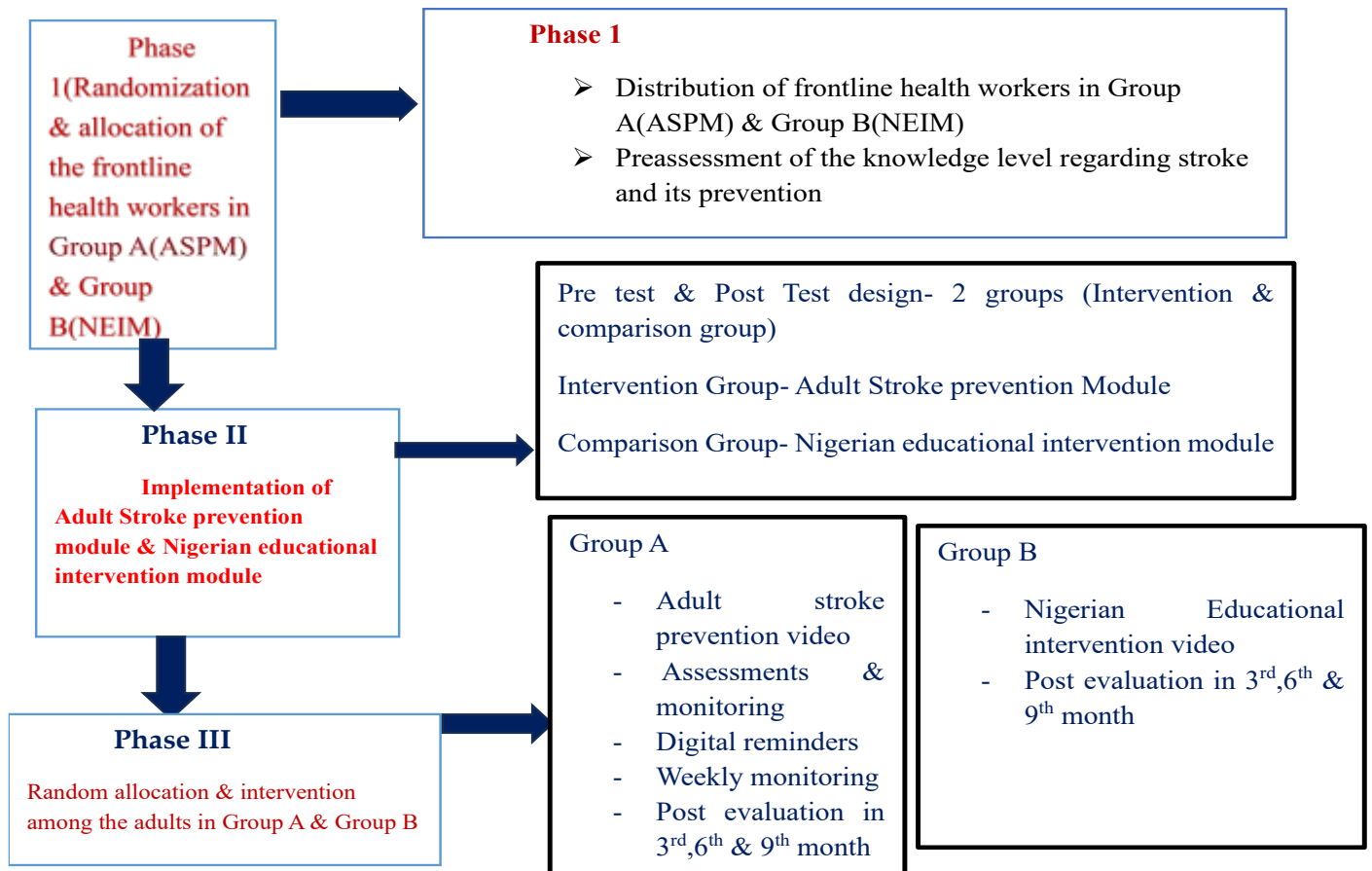


Fig :1

Methods of Data Collection

Intervention: Phase II: Implementation of Adult Stroke Prevention Module and Nigerian educational Intervention Module for the frontline health workers

Group A (ASPM)	Group B (NEIM)
<ul style="list-style-type: none"> - Explaining about the stroke riskometer app - Training under 4 sessions each 35 – 40 minutes teaching with posters and pamphlets. - The training sessions will be focused on - Session: 1 What is brain attack(stroke), predisposing elements, how stroke happens with scenario-based module - Session 2: Identification of initial signs, Clinical symptoms of stroke, Golden time period for treatment, complications or disabilities of delayed hour in treatment. - Session 3: Available treatment modalities for stroke (A talk by a neurophysician if possible) Nursing responsibilities to create awareness to the community regarding the warning signs, efficacy of early recognition and its usefulness in reducing the disability. 	<p>Explaining about the stroke riskometer app and the Nigerian educational intervention video. (it’s a cartoon video for 7 mins, it will be translated to Marathi Language)</p>

<ul style="list-style-type: none"> - Session 4: Introduction of the Adult Stroke Prevention video, teaching about the monitoring of the adults in the community. - ASPM video is created by the investigator which is proposed to be formatted as a documentary film for 15 mins focusing on all the aspects of Stroke and its prevention aspects.(to be created in Hindi language with English subtitles) 	
---	--

Phase III: Random allocation & intervention for the adults in the community by the frontline health workers

Group A (ASPM)	Group B (NEIM)
Assessment of individuals with stroke riskometer app	Assessment of individuals with stroke riskometer app
Assessment of the individuals for the following categories by measurements and framing of individual assessment format <ol style="list-style-type: none"> 1. Blood pressure 2. HbA1C 3. Hip to waist ratio 4. Cholesterol levels 5. Life style habits- Smoking and alcohol consumption 6. Fruit and vegetable intake including usage of salt 7. Consumption of fast foods 8. Physical activity 9. Stress 10. Medication adherence for any underlying conditions 	-Introduction of the Nigerian educational intervention video - 2-time counselling for the samples regarding risks of stroke
<ul style="list-style-type: none"> - Teaching the samples with Adult stroke prevention video 	
Post assessment will be done every 3rd, 6th & 9th month respectively.	

Data Collection tools:

- **All the participants will be informed and a proper informed consent will be got before the study.**
- **Confidentiality and anonymity will be ensured.**
- Pre-Structured questionnaire to assess the knowledge, competency level of the Frontline health workers.
- Stroke Riskometer App to assess the risks of the participants.

- Participant assessment format is framed by the investigator based on the parameters to be identified in focus of prevention of stroke.
- There is a plan of doing qualitative assessment among the frontline health workers and the community participants to determine the efficacy and their personal experiences.

Section-I Participant Profile Characteristics:

- Age range
- Gender
- Academic qualification
- Relationship status
- Domicile
- Income
- Occupation
- History of hypertension, diabetes, heart disease
- Height & weight
- BP
- Blood glucose level(mg/dl)
- Cholesterol values(mg/dl)
- Visit to PHC or Hospital
- Personal habits
- Food habits
- Pre-morbid conditions(Heart disease, diabetes mellitus, hypertension)
- Medications (antihypertensive, antidiabetic, antiplatelet, anti coagulant drugs).

Section II: Weekly Assessment Chart to be digitally maintained.

BP	HbA1C	Cholesterol	Hip to waist ratio	Smoking status	Alcohol consumption	Fruits & vegetables usage	Usage of salt	Fast foods	Physical activity	Stress	Medication adherence

The components of Adult Stroke prevention Module framed by the investigator is depicted in **Fig :2**

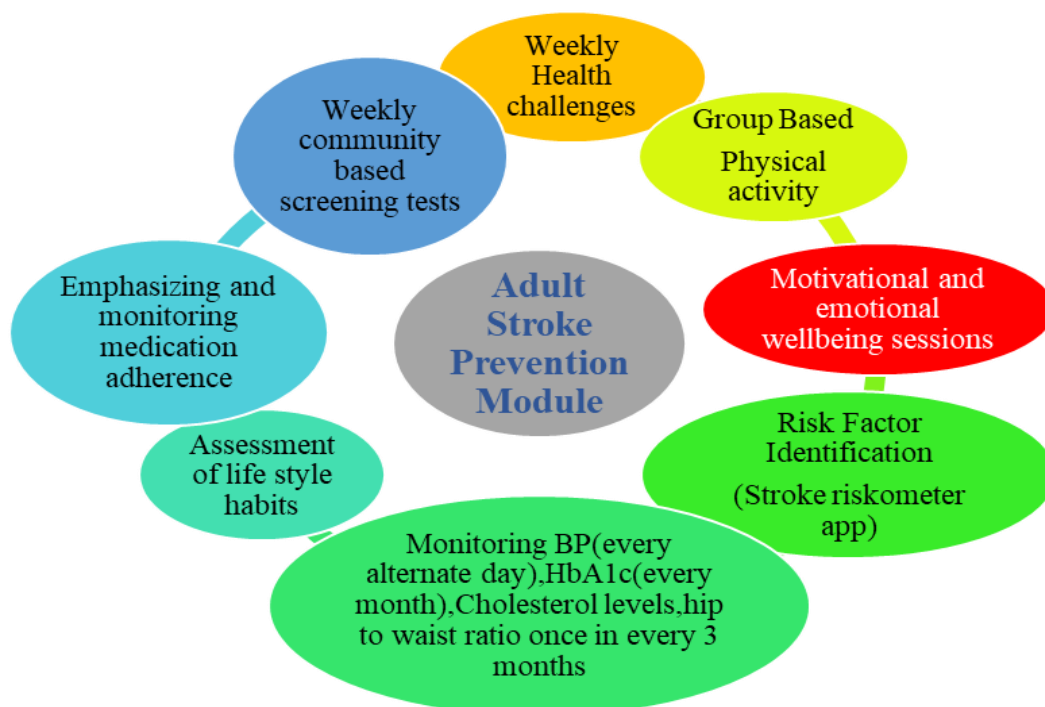


Fig:2 Adult Stroke Prevention Module

Data Management & Monitoring

- Data will be securely stored and regularly monitored by the principal investigator.
- Statistical analysis will be done using SPSS/appropriate software

Data Collection: Baseline and follow-up at 3, 6, and 9 months using Stroke Riskometer app, structured questionnaires, and biometric measurements.

Analysis Plan: Mixed-effects regression with cluster random effects, baseline adjustment, repeated measures, multiple imputation for missing data, intention-to-treat as primary analysis, per-protocol sensitivity.

Dissemination Plan

- Results will be shared through peer-reviewed publications
- Findings will be presented at national and international conferences
- Summaries will be shared with local health authorities and Frontline health workers.

RESULTS

The study is registered in CTRI (CTRI/2025/05/086446). Training materials are finalized, but the pilot study has yet to be completed. Recruitment is projected for May 2026; data collection is expected to be completed by March 2027.

DISCUSSION

Early recognition of stroke symptoms and risk factors by FLWs is critical in reducing disability and mortality. Evidence from LMICs shows that FLW-led interventions improve awareness and reduce risk factor prevalence [1,2]. In India, structured training programs for FLWs remain scarce [3].

This trial compares ASPM, a structured skill-based module, with NEIM, a video-based intervention. By assessing both, it addresses the lack of comparative evidence on training modalities for FLWs in LMICs [4]. Prior studies (e.g., Gadchiroli trial [5], Kerala FLW study [6]) highlight the feasibility of FLW-led prevention but emphasize the need for standardized training. Global reviews suggest structured training yields stronger behavioral change than video-only approaches [7].

Integration of digital tools such as the Stroke Riskometer app enhances ASPM by enabling longitudinal monitoring. Digital health interventions have shown promise in improving adherence to preventive behaviors [8].

Limitations include differences in intervention intensity, potential attrition, and rural logistical challenges. However, the cluster-randomized design and repeated measures strengthen validity.

In conclusion, this trial will provide evidence on effective strategies for skill delegation, risk reduction, and community engagement. Findings are expected to guide scalable interventions for stroke prevention in LMICs.

REFERENCES

1. Feigin V, et al. Global burden of stroke in LMICs. *Stroke*. 2017;48(8):2161–2168.
2. Indian Council of Medical Research. India: Health of the Nation's States. ICMR Report. 2016.
3. Gorthi SP, Garg D. Stroke epidemiology among young persons in India. *Ann Indian Acad Neurol*. 2022;25(1):45–52.
4. Chhabra M, et al. Awareness of stroke warning signs in North India. *Indian J Public Health*. 2019;63(4):312–317.

5. Kalkonde YV, et al. High prevalence of stroke in rural Gadchiroli. *Neuroepidemiology*. 2016;46(4):235–239.
6. Sylaja PN, et al. Secondary prevention of stroke by community health workers. *J Clin Neurosci*. 2020;84:53–59.
7. Joshi R, et al. Task-shifting for NCD prevention: Role of FLWs. *PLoS Med*. 2019;16(2):e1002760.
8. Krishnamurthi RV, et al. Mobile technology for primary stroke prevention. *Int J Stroke*. 2018;13(9):947–956.
9. Chaturvedi S, et al. Effectiveness of training frontline health workers in stroke prevention: A systematic review. *BMJ Glob Health*. 2019;4(6):e123456.
10. Owolabi MO, et al. Stroke prevention gaps in LMICs. *Int J Stroke*. 2021;16(8):987–999.
11. Sarfo F, et al. Effect of an educational intervention for primary stroke risk reduction in Ghana & Nigeria: Pilot RCT. *Stroke*. 2023;54(2):e42–e50.
12. Renjith V, et al. Stroke awareness among community health workers in rural Kerala. *J Neurosci Rural Pract*. 2023;14(4):735–740.
13. Maya C, et al. Community-based model for secondary stroke prevention in Kerala. *The Hindu*. 2025.
14. Bhati N, Bhati S. Stroke prevention in primary care in India: A review. *Insight Med Publ*. 2022;7(9):151.
15. World Health Organization. Stroke fact sheet. WHO Newsroom. 2025.
16. World Stroke Organization–Lancet Neurology Commission. Pragmatic solutions to reduce the global burden of stroke. *Lancet Neurol*. 2023;22(12):1160–1206.