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Clinical study

Secondary prevention of stroke by a primary health care approach: An open-label cluster randomised trial

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ABSTRACT

Background and aim: Increasing stroke burden in developing countries necessitates measures to strengthen health systems. We aimed to evaluate whether a Community Health Worker (CHW) based educational intervention will improve risk factor control among stroke survivors and enhance behavior change communication.

Method: An open-label, cluster-randomized trial was conducted in rural area of Thiruvananthapuram district, Kerala from December 2017 to December 2018. A CHW-based educational intervention in addition to standard of care was provided in intervention arm and compared to standard clinical care in the control arm with follow-up at three and six months. The primary outcome measures were risk factor control and quality of behavior change communication provided by CHWs.

Results: Of the 234 Stroke/TIA survivors enrolled, the mean age (SD) was 59.43 (11.07) years. At 6-month follow up, all patients with smokeless tobacco consumption had quit in the intervention arm (5 at baseline and 0 at six months) and no relapse in smoking was found (as compared to control arm wherein 9 at baseline and one at 6 months). The control of hypertension and diabetes was not significant at 3 months and 6 months in both intervention and control groups. Home visits as well as health education on risk factors by CHWs in the intervention arm were significantly higher.

Conclusion: Community health worker-based intervention is feasible in resource constrained settings for secondary stroke prevention. Training of CHW on risk factor control and lifestyle modifications for stroke survivors enhances quality of health education provided by health services.

1. Introduction

The Global Burden of Disease study has demonstrated that low- and middle-income countries (LMICs) bear the largest burden of cerebrovascular disease. Further, more than 90% of stroke burden has been attributed to modifiable risk factors. It is estimated that control of these risk factors can potentially reduce the burden of the stroke to less than a quarter of existing DALY loss across the globe [1].

Stroke survivors are at high risk of future stroke and other vascular events [2]. Aggressive control of the risk factors reduces the risk of these vascular events by 80 percent over a decade [3]. However, prior studies demonstrate reduced adherence to pharmacotherapy and lifestyle measures such as smoking cessation, healthy diet, and physical activity, among individuals with established cardiovascular disease. The PURE study demonstrated disparities between LMICs and high-income countries (HICs). Over 5 years of follow-up, only 38% had quit smoking in LMICs compared to 75% in high-income countries and only 26% adhered to a healthy diet in LMICs compared to 43% in high-income countries [4,5].

Among stroke survivors, risk factor control and medication adherence are poor in HICs. This is even more limited in LMICs secondary to the shortage of primary care providers and neurologists [6–8]. Limited geographic access and financial barriers pose additional challenges in accessing appropriate health services among stroke survivors living in rural areas as compared with urban

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patients. This inequity in accessing service manifests as an increase in the rural post-stroke disability and short-term mortality [9,10].

The increasing burden of non-communicable diseases, including stroke, in LMICs necessitates measures to strengthen health systems [11]. According to the World Health Organization (WHO) report 2006, task-shifting and skill delegation is considered a proven approach to enhance workforce productivity and improving health system effectiveness in combating chronic diseases [12]. Emerging health systems, in India and other LMICs, have incorporated community health workers (CHWs) to address the shortage of physicians and allied healthcare professionals [13]. Task-shifting interventions for cardiovascular disease prevention to non-physician health workers may help address this gap in LMICs, [14,15] but few efficacy and implementation studies have been conducted targeting stroke survivors [16,17]. Therefore, the present study was undertaken to evaluate whether a Community Health Worker (CHW) based education intervention to improve risk factor control among stroke or transient ischemic attack (TIA) survivors as well as enhance behavior change communication in health services to improve secondary stroke prevention measures in a rural LMIC setting.

2. Material and methods

The present study was an open-label cluster-randomized trial conducted in the rural health blocks of Thiruvananthapuram district, Kerala from December 2017 to December 2018. The intervention included training of CHWs on secondary prevention of stroke. The study hypothesis was that among stroke survivor patients residing in the community, an intervention such as training on stroke management for CHWs when compared with those receiving routine care will improve outcome measured in terms of improved risk factor control as well as enhanced behavior change communication provided through CHWs in the health services. Since the overall administrative control and field practice area of the health workers is at the block level, cluster randomization was carried out instead of randomization at the individual level to prevent contamination. A flow diagram depicting enrollment, allocation, and follow-up details of the study is represented in Fig. 1.

2.1. Ethics clearance

The study was carried out after obtaining ethics clearance from the Institutional Ethics Committee. Also, permissions from the state health authorities were obtained before the conduct of the study. During the conduct of the study, informed consent was obtained from all the patients enrolled in the study.

2.2. Study setting

Thiruvananthapuram district in the state of Kerala has 23 administrative blocks. Among these blocks, 16 are rural health blocks and seven are urban health blocks. In each block, health services are delivered through District hospitals as a tertiary care centre, Community Health Centres (CHC) at the block level, and Primary Health Care centres (PHCs) and sub-centres at the village level. Multiple health professionals (doctors, nursing staff, paramedical staff, and auxiliary health care workers) are located at these centres and provide team-based clinical care. In the field, community health workers include health supervisors, health inspectors, Junior Public Health Nurses (JPHN), palliative care nurses, and activists such as Accredited Social Health Activists (ASHA). The administrative control of health care professionals and auxiliary health care workers is maintained at the block level.

2.3. Study design

In the present study, a cluster was defined as a geographical region depicting administrative rural blocks of the district. Each cluster included health care workers located throughout the various public health care establishments in the block. All the rural health blocks were randomized into an intervention and control arm in the ratio of 1:1 using the lottery method. Subsequently, all the patients fulfilling inclusion criteria, who underwent treatment at the Comprehensive Stroke care center at Sree Chitra Tirunal Institute for Medical Sciences and Technology during the first three months of the study were recruited. The patients were allocated to either of the study group based on their place of residence. All the patients were assessed using a pre-structured questionnaire, clinical, and laboratory-based examination at recruitment, 3 months, and 6 months. An illustrative map of the study location and selected sites in the present study is represented as Fig. 2.

2.4. Unit of study and participant recruitment

The present study had CHWs as unit of study for estimating the direct effect of training sessions provided on the quality of health education being imparted by CHWs. To estimate the indirect or resulting effect of training sessions for health workers, stroke survivors were considered as the unit of study. For recruitment of patients as well as CHWs, the geographical clusters were randomly grouped into intervention and control health blocks. All the CHWs working in the selected intervention blocks were provided training at the start of the study period and all patients receiving treatment from the Comprehensive Stroke Centre of the institute during the first three months of the study period and having residence in the intervention blocks were considered as part of intervention arm. On identification of the stroke survivor from the intervention block, a call was placed to the respective CHW intimating details about the patient. The CHWs from the control health blocks were also provided training at the end of the study period.

2.5. Participant characteristics

The study participants included stroke patients aged $\geq$ 18 years with the previous history of ischemic or hemorrhagic stroke or transient ischemic attack (TIA) regardless of its etiological subtype (guideline-based definitions [2] using clinical and neuroimaging evidence) and residing in the rural areas of Thiruvananthapuram district. Exclusion criteria included a depressed level of consciousness, Modified Rankin scale 5, and expected life expectancy $\leq$ 6 months due to co-morbidities or disease severity.

3. Intervention

A formal training program (in local language Malayalam) on symptoms of acute stroke and its management, nursing care of stroke survivor, control of vascular risk factors, and caregiver-based rehabilitation was conducted for CHW posted in the intervention clusters (health blocks) at the start of the study. The training was designed and provided by the neurologist, nurse, and physiotherapist working in the comprehensive stroke center. Considering the supervisory role of physicians towards CHWs, a special training session was also given to primary care physicians working in CHC/PHC of intervention blocks. Also, during this training, health workers were educated on the benefits of making regular visits to the home of stroke survivors and education of the patient and the family regarding risk factor control, lifestyle modifications, medication adherence, and blood pressure monitoring. As part of the training program, the project staff (medical social worker and

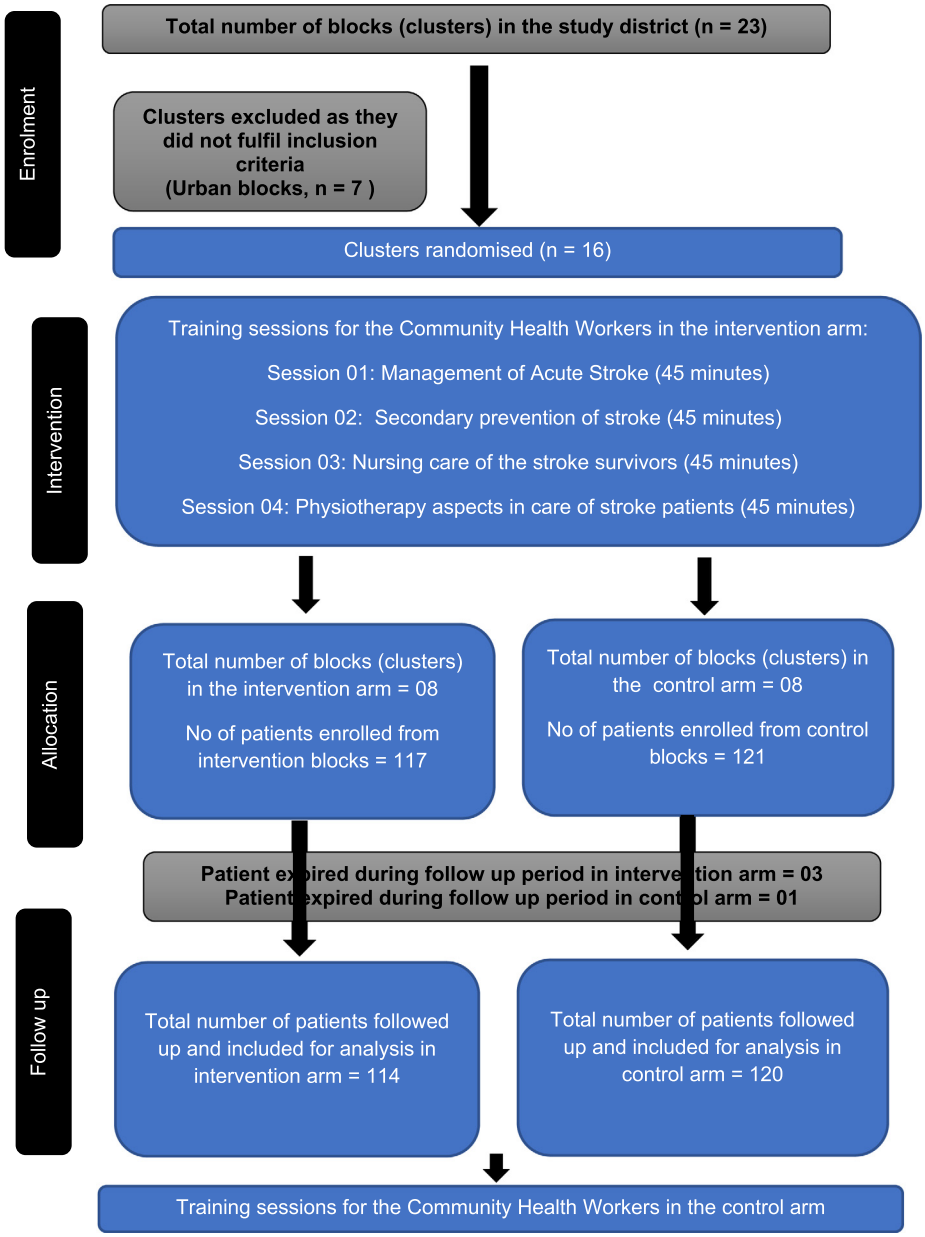

Fig. 1. Schematic presentation of study protocol.

trained nurses) undertook community visits to support the activities of the CHWs in the field. Whenever required, hands-on training of the health workers was also imparted to CHWs in the field itself.

Standard medical care was provided to all the patients in both the arms. Additionally, each enrolled patient and their families were provided with a list of vascular risk factor goals and targets at the time of recruitment. Workbooks were also provided to all the patients and they were advised to record any health and medication updates in the workbook. Training of health workers and primary care physicians in the control blocks were provided training sessions at the end of the study period.

3.1. Outcome(s)

The outcomes in the present study were

1. Control of selected risk factors for secondary prevention of stroke (blood pressure, blood sugar levels, cholesterol levels, tobacco and alcohol consumption) among stroke survivors.
2. The quality of behaviour change communication provided by CHWs as assessed through feedback from patients/ caregivers. All the study participants were asked to provide their feedback on a structured interview schedule regarding the number of health visits being undertaken by CHWs, and health education provided by CHWs on medication adherence, lifestyle changes, rehabilitation, and dietary modifications.

3.2. Statistical analysis

The data was entered into excel and analyzed using SPSS version 21.0 (IL, Chicago, US). Descriptive measures were calculated for both groups. Chi-square test, independent samples *t*-test, and paired *t*-test were applied to determine the difference between

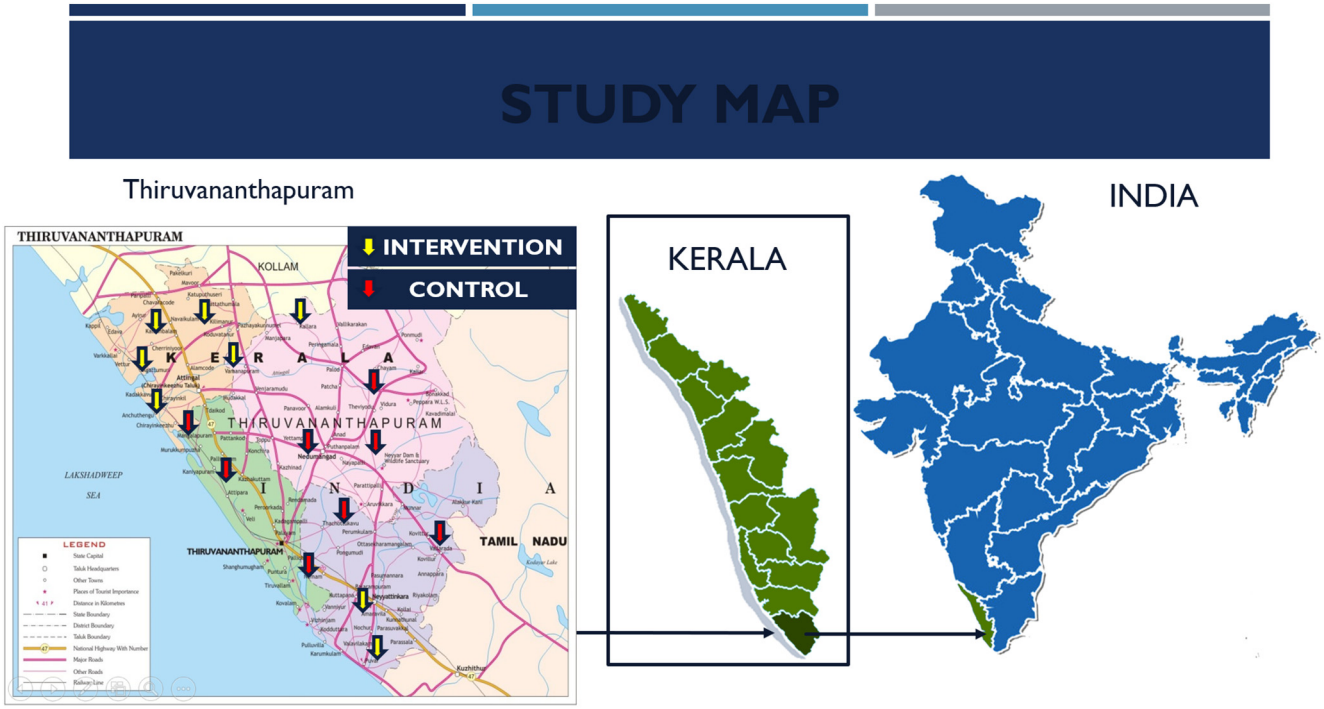

Fig. 2. Study map showing the rural health blocks that were randomized in the intervention and control arms.

proportions, the difference between means in independent and paired observations, respectively. A p-value of less than 0.05 was considered statistically significant.

4. Results

A total of 234 Stroke/TIA patients participated in the study. Intervention and control clusters comprised 114 and 120 patients, respectively.

4.1. Participant characteristics

The mean (SD) age of study participants from the control and intervention groups was 59.43 (11.07) and 59.77 (12.17) years (p = 0.820). The majority of participants were male; 69.3% in the intervention group and 71.7% in the control group (p = 0.691). All the participants were literate, with at least primary education in 64.1% and 72.7% in interventional and control groups, respectively. Study participant baseline sociodemographic characteristics and vascular risk factors are shown in Table 1.

4.2. Control of risk factors in intervention and control groups

The control of risk factors in intervention and control groups is demonstrated in Table 2.

The mean (SD) Systolic Blood Pressure (SBP) in intervention and control groups at baseline was 140.79 (19.51) and 135.59 (16.52) mm Hg, respectively (p = 0.029). As compared to baseline, the control of systolic blood pressure at 3 and 6 months follow up demonstrated significantly lower SBP in both the intervention (135.15 (18.19) and 135.71 (17.03) mm Hg at 3 and 6 months respectively) and control group (130.28 (15.41) and 128.66 (12.64) mm Hg at 3 and 6 months respectively).

The mean (SD) fasting blood sugar values in the intervention and control group at baseline was found to be 121.33(44.47) and

Table 1
Participant characteristics.

Characteristics	Intervention (n = 114)	Control (n = 120)	p-value
Age (Mean, SD)	59.77 (12.17)	59.43 (11.07)	0.820
Gender			
Male	79 (69.3)	86 (71.7)	0.691
Female	35 (30.7)	34 (28.3)	
Marital Status			
Married	103 (90.4)	106 (88.3)	0.618
Other (Separated/ Widower/ Unmarried)	11 (9.6)	14 (11.7)	
Education status			
Primary	75 (64.1)	88 (72.7)	0.062
Secondary	27 (23.1)	14 (11.6)	
Graduate and Above	15 (12.8)	19 (15.7)	
Place of Recruitment			
Outpatient	97 (85.1)	107 (89.2)	0.351
Hospitalised	17 (14.9)	13 (10.8)	
Presence of risk factors			
Tobacco consumption (Smoking/ Smokeless)	09 (7.9)	17 (14.2)	
Alcohol	30 (26.3)	34 (28.3)	0.729
CAD	18 (15.8)	19 (15.8)	0.993
Valvular Heart Disease	7 (6.1)	10 (8.3)	0.518
Prosthetic valve	04 (3.5)	04 (3.3)	0.941
Hyperlipidaemia	79 (69.3)	85 (70.8)	0.798
AF	08 (7.0)	03 (2.5)	0.103
h/o prior stroke	16 (14.0)	12 (10.0)	0.342
DM	68 (59.6)	70 (58.3)	0.838
HTN	95 (83.3)	89 (74.2)	0.087
NIHSS at recruitment			
Mean Score	1.6	2.3	0.068
MRS at recruitment			
Mean Score	1.1	1.2	0.529
Classification of stroke			
Ischemic stroke	100 (87.7)	102 (85.0)	0.545
Haemorrhagic stroke	14 (12.3)	18 (15.0)	
Median number of days since stroke	805	517	0.513

Table 2
Control of selected risk factors in intervention and control groups.

Risk factor		N	Mean	SD	Percent change	P-value
	Systolic Blood Pressure (SBP)					
Intervention	Baseline	114	140.79	19.51	Ref	
	At 3 months		135.15	18.19	−4.02	<0.001*
	At 6 months		135.71	17.03	−3.61	<0.001^
Control	Baseline	120	135.59	16.52	Ref	0.029$
	At 3 months		130.28	15.41	−3.92	<0.001*
	At 6 months		128.66	12.64	−5.11	0.005^
	Fasting Blood Sugar (FBS)					
Intervention	Baseline	81	121.33	44.47	Ref	
	At 3 months		120.22	36.88	−0.91	
	At 6 months		123.48	40.53	1.77	
Control	Baseline	86	122.58	46.81	Ref	0.847$
	At 3 months		119.93	38.67	−2.16	0.961$
	At 6 months		118.93	32.89	−3.68	0.426$

* Paired sample *t*-test for difference between mean values at baseline and 3 months; ^ Paired sample *t*-test for difference between mean values at baseline and 6 months; $ Independent sample *t*-test for difference between mean values between intervention and control arms.

122.58(46.81) mg/dl respectively (p = 0.847). At three months follow up, the mean (SD) fasting blood sugar was significantly lower than baseline in both the intervention and control groups (120.22 (36.88) and 119.93(38.67) mg/dl respectively (p < 0.001 in both groups). At six months follow up, the decline in mean blood sugar level was seen only in the control group. However, the difference between mean blood sugar levels was not statistically significant between the intervention and control groups (p = 0.426).

Considering tobacco consumption behaviour, in the intervention arm, out of five smokers at the baseline, one each had quit smoking by the end of three months and six months follow up. Smokeless tobacco consumption was stopped by all the participants in the intervention arm. In comparison, in the control arm, out of nine smokers at baseline, five had stopped smoking at the end of 3 months and one restarted by 6 months follow up. Similarly, there was a relapse seen in smokeless tobacco consumption

Table 3
Behaviour Change Communication by CHWs in intervention and control groups.

Variable	N	Frequency	Percentage	p-value	OR (95%CI)
At 3 months follow up					
Health worker visited at least once in the past three months					
Intervention	114	70	61.4	<0.001	11.14
Control	120	15	12.5		(5.76–21.54)
Health worker visit quality assessment					
Advised Medication Adherence					
Intervention	70	57	81.4	<0.001	28.5
Control	15	02	13.3		(5.72–142.01)
Advised dietary modification					
Intervention	70	54	77.1	<0.001	12.56
Control	15	02	13.3		(3.04–51.91)
Advised benefits of exercise/ rehabilitation					
Intervention	70	31	44.3	0.026	5.17
Control	15	02	13.3		(1.08–24.63)
Advised blood pressure control					
Intervention	70	58	82.9	<0.001	7.25
Control	15	06	40.0		(2.17–24.21)
Advised blood sugar control					
Intervention	70	56	80.0	0.002	6.00
Control	15	06	40.0		(1.83–19.67)
At 6 months follow up					
Health worker visited at least once in past three months					
Intervention	114	75	65.8	<0.001	12.50
					(6.50–24.02)
Control	120	16	13.3		
Health worker visit quality assessment					
Advised Medication Adherence					
Intervention	75	63	84.0	<0.001	8.75
Control	16	06	37.5		(2.67–28.63)
Advised dietary modification					
Intervention	75	62	82.7	<0.001	7.95
					(4.25–25.75)
Control	16	06	37.5		
Advised benefits of exercise/ rehabilitation					
Intervention	75	35	46.7	0.259	1.93
Control	16	05	31.3		(0.61–6.08)
Advised blood pressure control					
Intervention	75	63	84.0	0.013	4.08
Control	16	9	56.3		(1.27–13.09)
Advised blood sugar control					
Intervention	75	62	82.7	0.005	4.77
Control	16	8	50.0		(1.51–15.03)

in the control group as compared to none in the intervention group. The proportion of participants in the intervention and control groups consuming alcohol at baseline (26.3% and 28.3% respectively) reduced to 4.4% and 5.0% by 3 months of follow up respectively. In the intervention arm, alcohol consumption further reduced to 3.5% by the end of 6 months of follow up as compared to no change at 5.0% in the control group.

4.3. Home visits and behaviour change communication by CHWs

At three months follow up period, 70 (61.4%) of study participants in the intervention arm were visited by a health worker as compared to 15 (12.5%) of the study participants in the control arm and the difference was found to be statistically significant ($p < 0.001$). Among those who were visited by a health worker, there was a significant difference between intervention and control groups regarding advise provided by the health worker during the visit on medication adherence ($p < 0.001$), dietary modification for secondary prevention of stroke (<0.001), benefits of exercise in secondary prevention of stroke including rehabilitation measures ($p = 0.026$), blood pressure control ($p = <0.001$), and blood sugar control ($p = 0.002$). Also, at end of six months follow up, there was a marginal increase in the proportion of study participants being visited by a health worker in both intervention and control arms (n = 75 (65.8%) and 16 (13.3%) respectively), and among those who were visited by a health worker, there was a significant difference between intervention and control groups regarding advise provided by the health worker during the visit on medication adherence (<0.001), dietary modification for secondary prevention of stroke ($p < 0.001$), blood pressure control ($p = 0.013$), and blood sugar control ($p = 0.005$) (Table 3).

5. Discussion

The present study showed that it is feasible to train CHWs and give education for improving risk factor control among stroke survivors. In addition, there was an improvement in the quality of behaviour change communication by health services in rural settings for secondary prevention of stroke, though we could not demonstrate any significant change in the risk factor control for the stroke survivors

Secondary prevention of stroke is largely based on rigorous monitoring of the risk factors at regular intervals and education regarding control of risk factors through behavioural and lifestyle modifications [18]. In developing countries such as India, the patient consultations are usually limited by time constraints and lack of adequate counselling and advice to the patient by busy hard-pressed outpatient departments. Despite the ongoing arguments regarding the doctor population ratio gap in India [19], a paradigm shift in policy implementations to reduce the doctor-population ratio inequity gap in rural and urban areas is required. Thus, to handle the human resource shortage, the WHO recommends task shifting as a sustainable solution [12], which requires training of the auxiliary workers. The present study showed that trained CHWs in the intervention arm were more likely to undertake home visits. At 3 months, 61.4% of participants in the intervention arm were visited by a CHW as compared to just 12.5% in the control arm. Also, the quality and content of home visits being undertaken by a health worker showed significant improvements. Among those who were visited by a CHW, there was a significant difference between intervention and control groups regarding advice provided by the health worker during the visit on medication adherence, dietary modification for secondary prevention of stroke, benefits of exercise in secondary prevention of stroke, blood pressure control, and blood sugar control. The potential of CHW based interventions to improve health outcomes has been demonstrated in more than 25 countries in the African subcontinent [12]. However, randomized control trials from the Indian subcontinent on secondary prevention of stroke using CHW based intervention is limited. CHWs are trusted representatives from and for the community. Their informal, but well-informed behaviour change communication at timely intervals has been shown to successfully improve risk factor control for chronic disease prevention and inculcate healthy behaviours in the community [20].

This study also reflects the potential of CHW based interventions in risk factor control and improved tobacco cessation among stroke survivors. The study also brings forward the need for impetus on measures to improve physical activity post-stroke in the communities. In a study by Olaiya et al of community-based intervention in stroke survivors at 24 months, there were no significant changes in cardio-metabolic targets.

Limitations of the study. The present study had a follow-up period of only six months; therefore the long-term sustainability of these measures could not be ascertained. The assessment of the quality of home visits by a health care worker was questionnaire-based, a qualitative component in the study would have given an in-depth assessment. Lastly, lifestyle changes such as alcohol consumption and use of tobacco products were self-reported which are known to be underreported. The enrolment of the patients were from a single hospital and hence not representative of the community.

The study focused on training community health workers on risk factor control and lifestyle modifications for stroke survivors in the community and documents a positive impact of the intervention. It has a potential for enhancing stroke care in the community but larger studies assessing the opportunity cost and assessment of impact such novel approaches on already existing other health intervention programs need to be ascertained before policy decisions.

6. Conclusion

The CHW based intervention is feasible to be delivered in the community. The present study has developed and assessed the feasibility of a novel method to improve secondary prevention among stroke survivors. Engagement of multiple stakeholders will help maximize the sustainability and scalability of our developed intervention. Further study is required to understand which risk factors can be targeted with this approach. It will enhance understanding of the challenges faced by stroke survivors in obtaining optimal medical therapy, sustaining lifestyle changes, and obtaining appropriate medical care. A successfully developed CHW-based intervention is likely to be of interest and high value in multiple settings, including other parts of India and other LMIC's where stroke remains a significant public health problem.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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