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Tailored Hospital-based Risk reduction to Impede Vascular Events after Stroke (THRIVES) study: qualitative phase protocol

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Abstract

Background—There is an urgent need to develop effective strategies to improve stroke outcomes in Sub-Saharan Africa (SSA), where use of evidence-based therapies among patients receiving conventional care is poor. Designs of behavioral interventions to improve stroke care in SSA need to be sensitive to both individual and community factors (including local perceptions

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and public policies) contributing to the likelihood of compliance with recommended therapeutic goals. This article presents a community-based participatory research protocol that will evaluate systems and processes affecting the continuum of stroke preventive care in a SSA country.

Methods/Design—Phase 1 of the Tailored Hospital-based Risk Reduction to Impede Vascular Events (THRIVES) study will be implemented from 2013 to 2014 at four different types of hospital settings in Nigeria. Six adult stroke survivor and six stroke caregiver focus groups, comprising ~ 8 participants per group, and lasting 120 minutes each, will be conducted; as well as 22 semi-structured key informant interviews (informed by the Theoretical Domains Framework) with several types of providers and hospital administrators. Purposive and maximum variation sampling will be used to identify and recruit participants from participating hospitals. Transcript data will be analyzed by reviewers in an iterative process to identify recurrent and unifying themes using a constructivist variant of the grounded theory methodology, and will involve participatory co-analysis with key stakeholders to enhance authenticity and veracity of findings.

Discussion—Based on the results of THRIVES Phase 1, we intend to develop a culturally-sensitive, system-appropriate, multipronged intervention whose efficacy to boost adherence to evidence-based stroke preventive care will be tested in a future randomized trial (Phase 2).

Keywords

chronic care model; stroke; secondary prevention; low and middle income countries; patient report card; hypertension

INTRODUCTION

In 2001, stroke mortality in low-income and middle-income countries (LMIC) accounted for 85.5% of stroke deaths worldwide, and the disability adjusted life years (DALYs) lost in these countries was almost seven times those lost in high-income countries.¹ Most of these LMIC are in Africa where the burden of stroke is likely to increase substantially over the next few decades due to ongoing epidemiological transition.² Unfortunately, reliable high-quality data on the epidemiology, prevention, and bedside-to-community management of stroke are sorely lacking in this region.³ However, limited data from Sub-Saharan Africa (SSA) suggest an annual stroke incidence rate of up to 316 per 100 000, a prevalence rate of up to 315 per 100 000 and a 3-year fatality of up to 84%.⁴⁻⁶

Use of evidence-based therapies for the prevention of stroke in patients receiving conventional care remains inadequate, despite the available data and the current national guidelines that support their use.⁷ Longitudinal epidemiologic studies have identified a number of modifiable stroke risk factors including hypertension, cardiac disease, diabetes mellitus, hyperlipidemia, cigarette smoking, alcohol abuse, physical inactivity, and prior stroke or transient ischemic attack,⁸ which if properly modified or controlled could substantially lessen the burden of stroke.

The most pre-eminent of these is hypertension, a condition, which strongly confers elevated risk for both primary and recurrent stroke.^{9, 10} In Nigeria, the most populous nation of individuals of Black race, up to 36.6% of adult Nigerians are hypertensive,¹¹ and up to 98% of stroke patients have hypertension.¹² With rising rates of hypertension in these countries,

there is an urgent need to develop effective strategies to improve outcomes for those at high risk for stroke and its recurrence. Indeed optimal blood pressure reduction (BP) needs to be at the center of any serious effort to lessen the burden of stroke in SSA.

In SSA, studies on multidimensional post-stroke intervention measures aimed at modifying these factors based on preliminarily identified barriers and facilitators for effectiveness of such measures are sparse.

CHRONIC CARE MODEL

Systematic reviews and large cohort studies have shown poor utilization rates^{13, 14} for variety of medical and lifestyle modification measures in patients with stroke or other chronic diseases. A number of programs have been developed to promote secondary stroke prevention strategies.¹⁵⁻¹⁸ Successful quality care programs tend to incorporate elements of the Chronic Care Model (CCM) into their design and algorithms.^{19, 20}

CCM comprises 6 major components: self-management support, clinical information systems, delivery system redesign, decision support, healthcare organization, and community resources. A majority of CCM-based interventions have shown improvement of a care process²¹⁻²³ or outcome measure and reduction of healthcare costs as a result.²⁴ Reinforcing patient self-management enhances self-efficacy, i.e. the belief in one's ability to behave in a manner that produces the desired outcome.²⁴

Lessons from Previous Application of CCM in Secondary Stroke Prevention

Development of Preventing Recurrence of Thromboembolic Events Through Coordinated Treatment (PROTECT) goals were guided by CCM. An important component of this program was the use of a “report card” aimed at improving patient self-management and tailored to that individual's risk factors.¹⁶⁻¹⁸ The program, was associated with high post-discharge compliance rates with treatments, lifestyle modification and target biomarker goals as well as a substantially lower early vascular event rate in the first 3 months after index stroke.¹⁶⁻¹⁸

A similar CCM-based stroke program utilized the Spanish Stroke Patient Report Card.²⁵ It showed that it was feasible to conduct qualitative investigation to improve care among ethnic minority, non-English-speaking stroke patients, and their caregivers encountered within an under-resourced local government healthcare system.²⁵

Barriers to stroke prevention in SSA

To design an efficient CCM-based stroke prevention program for a resource limited setting such as SSA, it is crucial to understand the prevailing barriers. An example of such barriers is very low prevalence of hypertension awareness and control (BP <140/90 mmHg) demonstrated by several surveys in Africa.²⁶ A study in Nigeria among hypertensive patients showed that 40% of the study population could not define hypertension,²⁷ while 65% indicated that they would no longer require further long-term use of antihypertensive drugs once they achieved control of their blood pressure.²⁷ Twenty-one percent of respondents opined that they would only achieve a permanent cure only from alternative medical

practitioners and would avail themselves of complementary and alternative medicine in the future.²⁷ Barriers hindering adequate BP control in another Nigerian study²⁸ included patient's knowledge, attitudes and beliefs (60%), consultation failure on the part of clinicians (60%), lack of finances (23.8%) and side effects of medications (16.2%). Stroke awareness is also poor.²⁹ Any approach to better control of elevated BP in this region, will first require an in-depth exploration of these perceptions, and then development of a strategy to overcome them in a culturally-sensitive manner.

ROLE OF QUALITATIVE RESEARCH

Experimental and quantitative methods are inadequate for this sort of in-depth exploration. Qualitative research, “a form of systematic empirical inquiry into meaning”, is gaining momentum as an additional mode of clinical research inquiry.³⁰ It has been recommended during earlier phases of research projects because it permits sensitivity to contextual factors and the opportunity to develop empirical theories of relevance to a target group of interest.³⁰ Qualitative research would seem an ideal way to develop and refine an intervention for an understudied population unfamiliar with many aspects of Western Medicine being treated in an under-resourced medical system with unique challenges.³⁰

There are extremely few studies that have explored patient and caregiver views in developing secondary stroke prevention tools, and no published studies we are aware of have incorporated the views and recommendations of stroke patients in SSA into the crafting of a tool to promote treatment adherence.

RATIONALE AND SIGNIFICANCE

The need to improve stroke preventive care is particularly pressing in developing countries where resources are few and the burden of stroke is disproportionately heavy. This study focuses on design of sustainable self-care management that leads to good control of blood pressure and other stroke risk factors for individuals with recent stroke and transient ischemic attacks (TIA) with proven lifestyle, diet and pharmacological interventions to prevent recurrent stroke. We propose to combine lessons from the successful Stroke PROTECT and Spanish report card tool programs, results of qualitative research among stroke survivors and practitioners treating stroke patients in a LMIC, together with major components of the CCM to formulate an innovative multipronged intervention.

Indeed a successful program could serve as a model to be implemented in Nigeria, SSA, and other LMICs. We plan to share all aspects of our protocol with the Global Alliance for Chronic Diseases and also make it available to the research and public health community.

METHODOLOGY

a. Aims and Hypothesis

Specific Aim—To obtain information about barriers and facilitators (mediators & moderators) of adherence to guideline recommended biomarker goals for vascular risk reduction after stroke and develop an intervention comprising a patient report card, phone text messaging from providers, and in-clinic educational video sessions, based on input from

stroke patients, caregivers, providers, and hospital administrators that can be tested in a subsequent randomized controlled clinical trial of secondary stroke risk reduction.

Primary Hypothesis: Within a LMIC, it is feasible to conduct qualitative research investigation and craft a secondary stroke prevention intervention that incorporates local barriers/facilitators.

b. Study sites

Nigeria, the most populous Black nation, provides an ideal setting for this initiative to develop and test the efficacy of a tool to reduce BP levels among stroke survivors in a LMIC. The middling designation of its economy by the World Bank could mean outcomes there are more generalizable to other LMICs.

Four distinct hospital types are involved in this study. The University College Hospital Ibadan, the first *teaching hospital* in Nigeria, receives referral from all over Nigeria and SSA. It has 850 bed spaces and 163 examination couches. The Blossom Center for NeuroRehabilitation, Ibadan, was established in 2010 through the support of the World Federation for Neurorehabilitation as the first *center for Neurorehabilitation* in East, West and Central Africa. The Federal Medical Center, Abeokuta is a 250-bed *regional tertiary center* which receives patients from Ogun and neighbouring states and countries, and relates closely with community care clinics within and outside the Abeokuta metropolis. Established in 1895, the Sacred Heart Hospital, Abeokuta, was the first Catholic *missionary secondary medical care center* in Nigeria and continues to meet the growing health needs of the community.

Design Overview—This study is designed with the aim of utilizing qualitative research for the development of the intervention and pathways of implementing it (Figures 1 and 2).

Eligibility Criteria—Patients aged ≥ 18 years, with stroke-onset within one year, and access to mobile phone will be included. We will exclude those with severe aphasia or difficulty with communication, any medical condition that would limit participation in follow up assessments such as severe cognitive impairment/dementia (modified CSID score ≥ 20, Appendix 1), or severe global disability (modified Rankin Score ≥ 3). However, these exclusionary criteria will apply only to participation in the patient focus groups, while caregivers of these excluded patients will participate in the caregiver focus group.

c. Qualitative Methodology

As a guide for this phase, we plan to: explore help-seeking attitudes and beliefs among subjects with regard to stroke disease and what they understand about the symptoms and ramifications of symptom risks; integrate suggestions for enhancing and implementing the post-discharge THRIVES intervention; examine what patients and caregivers know about clinical trial research design and purpose and how this may affect a subject's decision to enroll in a study; and illustrate the feasibility and utility of gathering qualitative data to understand the challenges of clinical trial research participation on people's daily lives in a developing country.

Training will be coordinated for interview leaders prior to the execution of the study. Staff personnel from University College Hospital, Ibadan, Nigeria will carry out all focus group discussions and semi-structured interviews.

For this phase, subjects will be recruited using a “purposive” sampling design, composed of participants who best represent or have knowledge and experience with the research topic. Actual sample size is important simply as it relates to evaluating the extent to which issues of “theoretical saturation” have been carefully considered and specifically addressed in the interview guides.³¹ During the data coding process, the size of the sample may be increased in order to collect additional data until there is redundancy of information being provided. In qualitative analysis it should be noted that it is the data or data categories that should be saturated; the research should not ‘saturate’ the study participants.³¹

Focus Group Discussions (FGD)—FGDs will be carried out with patients and caregivers to systematically explore potential barriers and facilitators that influence adherence to guideline recommended biomarker goals for vascular risk reduction after stroke. Each focus group will include approximately 6-8 participants to sustain a meaningful but controlled discussion.³¹ A potential of 12 focus groups will be conducted for patients and for caregivers also allowing for important cohort distinctions by age (young adult, middle age, and elder) and gender status that are recognized in Nigerian culture. A focus group interview guide will be developed to ensure that the same areas of information are collected from each of the groups in a systematic manner. This guide will identify major areas of discussion including beliefs about stroke risk factor control and prevention; existing self-management skills, strategies, experiences; expectations/preferences; literacy/reaction to/perceived use of written health information; and impressions of patient report card tool.

The translation of study materials into Yoruba will be conducted using standard techniques involving three bilingual translators. A fourth person, blind to the original survey, will then back-translate the new survey into the source language and compare it with the original document to check the validity of the translation.

The translated instrument will then be pretested in a sample of 30-40 persons from the target population using standard cognitive interviewing techniques. Focus group participants will be encouraged to speak freely in their own native Yorùbá language and will be audio-recorded for the purpose of documenting important comments verbatim. Interviews will be transcribed first into the Yorùbá language with strikeouts of any named individual or location that might breach the confidentiality of the subject. Transcriptions will then be translated to English for the purpose of conducting the content analysis and identifying and summarizing important content themes emerging from the interviews.

Semi-Structured Individual Interviews—Approximately 22 participants will be recruited for individual interviews representing different departments from the main teaching hospital and also personnel from surrounding community clinics. The hospital departments represented will include primary care physicians, social work, nursing administration, ambulatory care, pharmacy, information technology, diet/nutrition, and neurology. A semi-structured interview guide will be developed to address major areas

current approaches to vascular risk factor control; perceived gaps in care; cultural competence/communication; knowledge of treatment guidelines; and impressions of patient report card tool. Another interview guide will be designed for hospital administrators covering existing care coordination personnel and models for other conditions/populations; available risk factor control programs; information technology systems support/assessment of accessibility/adequacy of administrative databases and systems for use in intervention; and impressions of patient report card tool. Interviews will be transcribed verbatim with strikeouts of any named individual or location that might breach the confidentiality of the subject. Transcriptions of audio recordings will be translated to English for interviews conducted with non-English speaking personnel for the purpose of identifying and summarizing important content themes emerging from the interviews.

Data Coding Plan—For this study, final transcript data will be analyzed using a *constructivist* variant of the widely used grounded theory methodology,³² found in the writings of Charmaz.³³ Charmaz approaches the data with a more reflexive focus on subjectivism, multiple realities, hidden situations and relationships, and an emphasis on the complexities of different beliefs, feelings, and ideologies reproduced in the words of the individual.

The process of coding qualitative data consists of several important steps. The first step involves reading through the transcripts at a very general level in order to condense the data into analyzable units.³⁴ Segments of text ranging from a phrase to several sentences may be assigned codes a priori through a process known as memo-ing. Selected research staff from both Nigeria and the U.S. will assist Dr. Hurst to carry out an initial reading of approximately 10% of the transcripts to establish inter-rater reliability for the final coding hierarchy that will be used to analyze the text. Disagreements in the description or assignment of attribute codes will be resolved through mutual consensus among the study team. A thematic codebook will be specified for content differences in the focus group and semi-structured interviews. Transcripts of all interviews will be scrupulously read and coded with the aid of a web-based qualitative data management software (i.e. Dedoose), frequently checking the model against the text as a constant measure for rigor.³⁵

From the final coded transcripts, the coded text segments and assigned code labels will be analyzed via a computational process of queries and comparisons. As such, the themes can be further sorted and transformed into theoretical models of practice displayed as sets of visual data patterns and graphical representations of the subjects' behaviors, beliefs, and ideas.

THRIVES Task Force—A THRIVES task force comprising physician investigators, statisticians, pharmacists, nurses, dietitians, physical therapists, administrators, health educators, and representatives of the Nigerian Stroke Society will be assembled. The task force will regularly meet to review the progress of the community participatory research process and make recommendations about any local adaptations to facilitate its effectiveness.

Pre-specified Features of the THRIVES Intervention—Following the qualitative analysis of Phase I interviews, major themes and subthemes emerging from participant discussions will be integrated and summarized to develop a conceptual action framework providing specific suggestions for the design and successful implementation of the THRIVES intervention. Implementing such evidence into practice requires a conceptual framework to identify elements and relations among those elements that must be considered at multiple levels of operation.

We have pre-specified that the THRIVES intervention (table 2) will contain key features that correspond to important components of the Chronic Care Model (CCM) including delivery system redesign (increased follow-up visits, pre-appointment phone texts), self-management support (patient report card, post-clinic follow-up phone texts, waiting room educational video), and clinical information systems (patient report card as part of medical chart, hospital registry). The intervention will last one year after stroke onset.

1. Pre-appointment phone text: asking patients to arrive an hour early for their appointment.
2. In-clinic educational video: While in the waiting room the patients will be asked to watch a stroke awareness educational video containing dramatized stroke scenarios, educational messages, and questions on the material taught with delayed responses. This video was developed based on information on stroke literacy and perception obtained from previous surveys of community residents and health workers in the cities of Ibadan and Abeokuta wherein the THRIVES study is being carried out. It consists of short narrative segments and expert interviews providing information on semantic stroke knowledge – causes, risk factors, warning symptoms, treatment options, primary and secondary prevention, and rehabilitation. In addition there were interview sessions with stroke survivors and their caregivers detailing salient experiences and factors that have facilitated their survival and recovery. Finally, selected health administrators spoke on their efforts to overcome systemic barriers in their center in order to facilitate efficient and effective stroke care. The content will be structured to be consistent with the content and sequence of material in checklist form on the patient report card. This is meant to enhance visual learning of the material in the checklist with people and in a setting that the subjects can readily identify with. The video will run for repeatedly every 30-45 minutes throughout the clinic.
3. Patient report card: When the patient meets with the physician the material of the video will be briefly discussed. The physician will then show the patient the customized report card and go over the patient's current vs. optimal control of key stroke risk factors. Following the discussion the patient or caregiver will sign the report card, and copy will be given to the patient and another placed in the medical chart. If this is a return visit, progress since the last visit will be queried, and specific difficulties in optimizing risk factor control discussed with a plan of action. Patients will be asked to bring back the updated cards to subsequent THRIVES sessions.

4. Post-clinic phone text: At the end of each THRIVES clinic, the physician who saw the patient will send a brief structured telephone text to the patient's mobile (cell) phone emphasizing the areas requiring better risk factor control.
5. Outpatient stroke registry: Each patient will be tracked in an electronic registry. The registry will contain data written on the report cards. It also will contain contact information on how the subject can be notified for care coordination telephone texts. As components of the chronic care model, we expect these interventions to have a synergistic effect.^{21-24, 26}

d. Ethical approval

Ethical approval has been obtained from the IRBs of Medical University of South Carolina, University of California at San Diego, University of Ibadan/University College Hospital (also covering WFNH-Blossom Specialist Medical Center) Ibadan, Federal Medical Center, Abeokuta, and Sacred Heart Hospital Abeokuta.

e. Timeline

The study is expected to last a total of 1.5 years (table 1) from initiation of the first study site for the qualitative research to completion of intervention development.

CONCLUSIONS

Several aspects of the project are innovative: 1) Conducting qualitative research work involving input from stroke patients, caregivers, multidisciplinary providers, and administrators, non-governmental organizations and industry to develop a culturally sensitive stroke risk factor intervention appropriate and sustainable for the local medical setting in a LMIC; 2) The iterative development of a multipronged intervention in the native LMIC tongue consisting of stroke patient report card tool, mobile (cell) phone technology, and applied theater. We anticipate that such an intervention will be potentially more effective on the outcomes being assessed (table 3) when compared to conventional care in a randomized control trial. A successful program may serve as a model of effective means of achieving guideline recommended goals among stroke survivors, which can be scaled up to other hospitals within Nigeria and perhaps other LMIC within Africa.

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APPENDIX 1

Cognitive Scores (COGscore) for the modified CSI-D for THRIVES

MAXIMUM SCORE = 30

1 POINT SCORE	DETAIL
[If 22 or more items are missing, score is not calculated]	
1 PENCIL	Identify pencil
2 WATCH	Identify watch
3 CHAIR	Identify chair
4 SHOES	Identify shoes
5 KNUCKLES	Identify knuckles
6 ELBOW	Identify elbow
7 SHOULDER	Identify shoulder
8 BRIDGE	Describe bridge
9 HAMMER	Describe hammer
10 CHURCH/MOSQUE	Describe church/mosque
11 BUYMED	Where buy medicine
12 IFANDBUT	Repeat "no ifs, ands, or buts"
13 REMNAME1, REMNAME2	Remember my name (either chance – ie item 14 or 34)
14 ANIMALS	Naming animals (scaled score divided by 5)* see details below
15 BOAT1, HOUSE1, FISH1	Repeat words (1/3 each)
16 BOAT2, HOUSE2, FISH2	Remember words (1/3 each)
17 NAMECITY	What is the name of this city / town/district
18 MJRSTREE	What are two major streets near your home
19 LANDMARK	Where is the Market
20 ADDRESS	What is your address
21 DAYWEEK	What day of the week
22 MONTH	What month
23 YEAR	What year
24 SEASON \ PARTDAY	What season
25 RAIN	Did it rain yesterday
26 NODHEAD	Please nod your head
27 WINDDOOR	Point to the window, then to the door
28 RTHAND, FOLDS, INLAP	Takes paper in rt hand, folds, puts in lap (1/3 each)
29 CHILD1, HOUSFIR1, BRAVE1, RESCUE1, MINOR1, WELL1	Repeat Story (1/6 each)
30 CIVILWAR	Leader during civil war

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Figure 1.
THRIVES Study Plan

Figure 2.
The Data Coding Spiral for Qualitative Interview Analysis

Table 1

THRIVES Qualitative Research Timeline

	Year	1				2	
	Quarter	1	2	3	4	1	2
1	THRIVES Task Force meetings			X	X	X	X
2	Development and translation of data gathering tools	X					
3	Training interviewers and focus group moderators	X					
4	Pretest of data tools in 2 external sites		X				
5	Finalization of instruments		X				
6	Recruitment and scheduling of participants		X	X			
7	Main data collection			X	X		
8	Transcription and translation of focus group discussions				X		
9	Transcription of in-depth Interviews				X		
10	Data analysis and summarization				X	X	
11	Development of multipronged intervention					X	X
12	Final report writing					X	X
13	Preparation for randomized control trial					X	X

Table 2

Interventions

	Category	Actual intervention
1	m-Health	Pre-appointment phone text and Post-clinic phone text
2	Applied theatre	In-clinic educational video
3	Self- management tool	Patient report card
4	Health system restructuring	Outpatient stroke registry

Table 3

Outcome measures

Endpoint Level	Endpoint Name
Primary	Systolic blood pressure (mmHg) *
Secondary	Smoking status
	Body mass index (kg/m ²)
	Waist circumference
	Diet
	Physical Activity
	Quality of life/functional status

* Mean change at 12-months