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Phone-based Intervention under Nurse Guidance after Stroke (PINGS): Concept for Lowering Blood Pressure after Stroke in Sub-Saharan Africa

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Abstract

Over the last four decades, rates of stroke occurrence in low-and middle-income countries (LMIC) have roughly doubled, whereas they have substantively decreased in high income countries (HIC). The majority of these LMIC are in Sub-Saharan Africa (SSA) where the burden of stroke will probably continue to rise over the next few decades due to an ongoing epidemiological transition. Moreover, SSA is circumstantially distinct: socioeconomic obstacles, cultural barriers, under-diagnosis, uncoordinated care, and shortage of physicians impede the ability of SSA countries to implement CVD prevention among people with DM in a timely and sustainable manner. Reducing the burden of stroke in SSA may necessitate an initial emphasis on high-risk individuals motivated to improve their health, multidisciplinary care coordination initiatives with clinical decision support, evidence-based interventions tailored for cultural relevance, task shifting from physicians to nurses and other health providers, use of novel patient-accessible tools, and a multi-level approach that incorporates individual- and system- level components.

This article proposes a theory-based integrated blood pressure self-management intervention called Phone-based Intervention under Nurse Guidance after Stroke (PINGS) that could be tested among hospitalized stroke patients with poorly controlled HTN encountered in SSA. PINGS would comprise the implementation of nurse-run BP control clinics and administration of health technology (personalized phone text messaging and home telemonitoring), aimed at boosting patient self-efficacy and intrinsic motivation for sustained adherence to antihypertensive medications.

Keywords

Secondary Prevention; Stroke; Vascular Events; Africa; Hypertension; Mobile health; Nurses; Task shifting

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INTRODUCTION

Hypertension is a major risk factor for cardiovascular disease.¹ Of all cardiovascular disease clinical entities, none is more strongly linked to hypertension than stroke.¹ Fortunately, with control of hypertension,² incidence of and mortality from stroke can be greatly reduced,³ as seen recently in several high-income countries (HIC).⁴⁻⁷ However, for low and middle income countries (LMICs) that disproportionately bear the global burden of stroke (death from stroke in LMICs accounted for 85.5% of stroke deaths worldwide, and the disability adjusted life years lost in these countries was almost seven times those lost in HIC),⁸ these gains have not materialized.⁹ Moreover, given the healthcare transition from primarily infectious conditions to chronic non-communicable diseases,¹⁰ the burden of stroke in Sub-Saharan Africa (SSA),¹¹ is likely to increase substantially over the next several decades,⁸ a situation likely to be compounded by the low prevalence of awareness, treatment, and control of HTN in SSA.^{12,13}

Achieving and sustaining blood pressure (BP) control is a particular challenge in SSA.^{9,11} Key factors responsible for uncontrolled HTN are medication non-adherence & failure to intensify therapy in a timely manner (i.e., therapeutic inertia).¹⁴⁻¹⁷ Systematic reviews of randomized controlled trials (RCTs) involving uncontrolled hypertensives indicate that BP self-monitoring, medication reminder tactics and use of case managers each improve adherence, therapeutic inertia and BP levels.¹⁸⁻²¹ However, no medication adherence/BP self-monitoring RCTs have been designed specifically for people in SSA, especially those at high risk for future stroke. Occurrence of prior stroke is the strongest predictor of future stroke, and risk is greatest during first 3 months post stroke.³ Initiation of prevention strategies are most effective when implemented early, monitored frequently, and maintained long-term after an index stroke.^{22,23} As such, culturally-sensitive, efficacious BP control programs which are acceptable, feasible, timely, & sustainable are needed, especially among hypertensive stroke survivors, the group at highest risk for future stroke.²⁴ Mobile health (mHealth) technology offers a promising approach to address this need.²⁵⁻³² Most adults in SSA own a cell phone (~73%),^{33,34} smart phone ownership is burgeoning (~25%),³⁵ & mHealth has produced promising results in chronic disease management (e.g., HIV) in SSA.³⁶⁻³⁸ This article proposes a theory-based framework for conceptualizing an integrated protocol-driven BP management strategy that could be adapted into an intervention for future study testing among hospitalized stroke patients encountered in SSA.

STROKE BURDEN IN SUB-SAHARAN AFRICA

Stroke is a leading cause of death, disability, dementia, and depression in SSA.^{8,11} Among stroke survivors, recurrent vascular events including secondary stroke and myocardial infarction (MI) lead to functional decline and subsequent mortality,³⁹⁻⁴³ which has led to the formation of multidisciplinary partnerships to explore ways to mitigate this immense burden in SSA.^{44,45} It is increasingly clear that the greatest opportunity for enhanced stroke outcomes is through prevention.⁴⁶ Aggressive efforts in reducing stroke risk factors will be crucial in preventing an impending stroke epidemic in SSA,⁴⁷ and since the greatest risk of recurrent stroke or MI is within 3 months of an index stroke, timeliness is also crucial.⁴⁸ The

most powerful modifiable stroke risk factor is hypertension (HTN),^{49,50} and uncontrolled HTN at the time of discharge from the hospital is a major predictor of recurrent stroke.⁵¹ Therefore, optimal blood pressure (BP) reduction needs to be at the center of any serious effort to lessen the burden of stroke in SSA.

HYPERTENSION CONTROL IN SUB-SAHARAN AFRICA

Hypertension is increasingly becoming a major public health issue in SSA.⁵²⁻⁵⁵ A survey of 47,443 adults in 6 middle-income countries, showed rates of hypertensives not receiving treatment ranged from 35% (Russia) to as high as 87% (Ghana).⁵⁶ Moreover, various surveys have demonstrated very low control (BP <140/90 mmHg) in SSA:

- Among patients with HTN, 18% were treated and only 4% were controlled.⁵⁷
- HTN treatment and control rates were low in both genders (men 7.8% and 4.4%; women 13.6% and 1.7%) and among elderly persons.⁵⁸⁻⁶⁰

While cost of drugs is a contributor to inadequate treatment rates, even in settings where anti-hypertensive drugs are provided free of charge, BP control rates are low.⁶¹ Sustained adherence to HTN medications can control HTN and reduce stroke events,⁶²⁻⁶⁵ but is actually the leading modifiable barrier to BP control.^{14,15,17,66} Indeed, sub-optimal HTN control poses a serious challenge to stroke prevention in SSA,⁶⁷⁻⁶⁹ A survey of HTN patients in SSA found only 5% had BP control (<140/90mmHg), 25% of respondents reported HTN had no long term effects, and 58% indicated it was curable.⁷⁰ The latter misconception of HTN being an acute condition and curable is a major barrier to long-term treatment adherence. Patients whose beliefs are discordant with conventional biomedical concepts of HTN tend to have poorer BP control than those with concordant beliefs.⁷¹⁻⁷⁵ A survey of Nigerians with HTN found 40% could not define HTN; 65% indicated no longer requiring use of anti-hypertensive drugs once they achieved initial BP control; and 21% opined they would achieve a permanent cure only from alternative medical practitioners and intended to solely utilize them in the future.¹³ Given all of the aforementioned, any strategy to improve adherence to anti-hypertensive drugs in SSA must address patients' beliefs, and more information from SSA is needed about the role of poor planning/forgetfulness to fill scripts/take meds, language barriers, as well as other intentional contributors to low medication adherence.

Therapeutic Inertia (TI) plays a significant role among adherent patients whose BP remains uncontrolled.⁷⁶⁻⁷⁸ A study in Nigeria found a major reason for non-adherence to anti-hypertensive drugs was that clinicians didn't provide appropriate guideline based treatment plans (60%),⁷⁹ while separate Nigerian study suggested that consistent health education and patient counseling by providers improved adherence to anti-hypertensive drugs.⁸⁰ Strategies to boost adherence to anti-hypertensive drugs in SSA should assist care providers in providing closer supervision of their patients and ensuring adherence to established guidelines.⁸¹ In fact, systems-level barriers seem to have an even more adverse impact on people with chronic diseases,^{82,83} and inadequate health workforces are perhaps the most serious of all such challenges in SSA: poor working conditions and low salaries have

triggered a wave of migration of health professionals especially physicians from SSA to developed nations.^{84,85}

Finally, there is a dearth of published BP control RCTs in SSA.⁶⁸ Three reviews of 133 RCTs ([37 RCTs],²¹ [78 RCTs],¹⁹ [18 RCTs],²⁰) conducted outside of SSA involving HTN patients concluded BP self-monitoring, med reminder tactics (live or automated phone calls) and education/counseling, individually and/or in combination, often improve adherence, reduce therapeutic inertia and result in small but significant BP declines. A search of the literature (in PubMed) and clinical trial registration sites (including ClinicalTrials.gov) did not reveal any published study or BP control RCT in SSA using real time medication reminder tactics and BP self-monitoring guided by behavioral change theory to enhance stroke outcomes.

MOBILE HEALTH AND BP CONTROL

Treiber and colleagues administered a 10-item questionnaire to predominantly African American renal transplant patients regarding attitudes toward remote monitoring and mHealth, along with a Perceived Stress Scale and Med Adherence Scale; and also conducted a demonstration of a prototype mHealth self-management program using electronic med tray and Bluetoothed BP/glucometer.⁸⁶ Patients were comfortable using mobile phones, felt mHealth could enhance self-efficacy and provider-driven medical management, and were confident their privacy could be protected.⁸⁶ Another study by Treiber et al. examined perceptions of mhealth among one of the most underserved populations in the US, Hispanic migrant farm workers.⁸⁷ They found 81% owned cell phones capable of sending and receiving health-related messages. 79% were highly receptive to a mHealth technology demonstration and felt it would be helpful in enhancing medication adherence, self-monitoring of health conditions, and receiving quicker medication changes from providers.⁸⁷ A subsequent randomized trial performed by the same group assessed feasibility, acceptability, and outcomes of a 3-month mHealth medication adherence and BP self-management system for predominantly African American kidney transplant patients with uncontrolled HTN in South Carolina. Subjects were randomly assigned to a smart phone medication adherence stops hypertension (SMASH) program or standard care (SC).⁸⁸ Participation and retention rates were 75% and 91%, respectively; and the system was safe, highly acceptable, and useful to patients and providers. Compared to the SC group, the mHealth group had significant improvements in medication adherence, as well as reductions in clinic-measured systolic BP. All SMASH subjects exhibited clinic BP control (<140/90 mmHg) from 1 month onwards vs. 20% in the SC group. Providers made more anti-hypertensive drug adjustments in the mHealth group based on information provided in weekly reports.⁸⁸ In another study, among Hispanics with uncontrolled HTN, 100% of subjects randomized to SMASH exhibited BP control at months 1-3 in resting clinic vs. 16.6% of SCs.⁸⁹ While there seem to have been no similar studies in SSA, all of the aforementioned studies indicate that a SMASH-based intervention is efficacious among typically disadvantaged populations of minority race-ethnic extraction, and suggest that there might be a reasonable chance of efficacy if tested in SSA.

GUIDING THEORETICAL FRAMEWORKS TO CONTROL BP AFTER STROKE IN SSA

Given the myriad of barriers to management of HTN at various levels in SSA, and evidence from HIC that chronic care interventions are most successful when they simultaneously target several levels in a multidimensional manner,⁹⁰⁻⁹³ it is anticipated that an effective intervention to improve outcomes among stroke patients with poorly controlled BP in SSA will require a multimodal intervention based in solid theoretical constructs tailored to the unique health care situation. In fact, a lack of theoretical development has been suggested as a major reason why several complex interventions in preventive care after stroke have failed to demonstrate efficacy.⁹⁴ Table 1 depicts two key theoretical frameworks that may underlie a possibly successful mhealth based intervention to enhance outcomes for stroke patients with poorly controlled HTN in SSA.

POTENTIAL INTERVENTION TO CONTROL BP AFTER STROKE IN SSA

A review of evidence regarding effectiveness of patient, provider, and health system interventions to improve care among socially disadvantaged populations revealed that intervention features with consistently favorable effects included cultural tailoring, one-on-one interventions with individualized assessment and reassessment, incorporating treatment algorithms, focusing on behavior-related tasks, and providing feedback.⁹⁵ Table 2 provides a detailed breakdown of promising strategies based on a literature review and the justification for their consideration. While any of these interventions could individually be tested in a clinical trial, multilevel strategies that include individual- and system- level components, have been consistently been shown to have better efficacy than individual interventions.

MIXED METHODS RESEARCH

Prior to conducting any study of a mhealth-based intervention to improve stroke outcomes in SSA, the components of the intervention(s) will need to be refined in iterative fashion using mixed methods research. Objectives that should serve as a boundary for such pre-trial investigation are:

- To explore help-seeking attitudes and beliefs among stroke patients and their understanding about symptoms and risks
- To integrate suggestions for improving and implementing the SMASH intervention
- To understand patients and caregivers knowledge about clinical trial research design and purpose and how this may affect a subject's decision to enroll in a study.

After completion of the actual clinical trial, an examination of utilization/cost of the intervention for the healthcare system will be useful to convince policy makers in SSA that the intervention is financially worthwhile. Furthermore, to promote potential scalability and sustainability of the intervention timely and ongoing involvement of local government agencies, private sectors, non-government organizations, academic institutions and communities will be necessary.

PHONE-BASED INTERVENTION UNDER NURSE GUIDANCE AFTER STROKE (PINGS)

Consideration might be given to developing a uniquely tailored multi-level SMASH-based intervention to reduce the risk of recurrent vascular events among stroke survivors in SSA, by promoting sustained BP control especially during the highest period of recurrence, i.e. the first 3 months after an index stroke. The efficacy of the developed intervention (PINGS) on 3 month post-stroke systolic BP could be tested in a pilot randomized trial vs. usual/customary care. A few details pertaining to the PINGs possible participants and process are briefly noted below.

Potential Participants

- Recent (within one month of symptom onset) stroke and transient ischemic attack patients in SSA with uncontrolled HTN, and modified Rankin Scale score ≥ 3 , and mini-mental state score ≥ 26 . This would include patients with SBP ≥ 140 &/or DBP ≥ 90 mmHg at the last clinical encounter post-stroke, and prior to recruitment. Conceivably no more than a 50 patients in each randomization arm (total study participants ≤ 100 patients).

Potential Process

- Patients (termed PINGSters) would be given an inexpensive simple pillbox and blue-toothed UA-767Plus BT BP device along with app for their smart phone for automatic relay of BP data to a central server.
- A PINGs nurse navigator and PINGSter would establish times the medications will be taken daily for programming SMS reminder messages. PINGSters (and/or caregiver) will show they can properly load the pill tray, take 3 consecutive BPs using 5 min protocol, and view the feedback chart and/or hear their BP data from that session on their phone.
- PINGSters would receive written & oral information on adherence criteria: take medications within 2 hours of designated times; and take BP every 3 days in morning & evening.
- PINGSters would be given a brief beliefs, values and life goals questionnaire. Responses will be used in a tree structured algorithm to generate personalized motivational and reinforcement messages guided by self-determination theory constructs of competence & autonomous regulation.^{96,97} These tailored brief SMS or voice mail messages would be based on previous day's reported med adherence levels & BP data every 3 days. After 2 consecutive weeks of 100% adherence (e.g., med intake reports & BP data scored using established algorithm based upon proximity to pre-established times for pill intake and BP measurements using time stamps of when data sent via phone).^{88,89} Typically during first 2-3 weeks, messages will be tapered to several times per week and cumulative adherence graphs will be sent during the 3 month trial unless adherence drops $< 90\%$.

- After each BP session, PINGSters would receive visual and auditory BP feedback on their phone, and could select charts showing cumulative averages across weeks/months compared to BP control threshold lines.
- In addition to personalized messages described above, PINGSters would receive 30-45 sec auditory or text messages 2 times per week on HTN/stroke facts, importance of med adherence, tips on expressing questions/ concerns with physician.
- Since patients will return BP monitors (and smart phones) at end of the 3 month trial, those who experience delayed monthly refill (> 3 days from designated time) or uncontrolled BP or missed appointment on 2 occasions at standard 3 month clinic visit will be called by the nurse navigator.
- The nurse navigator will be trained to conduct a motivational interview to help patients identify barriers/issues and develop an action plan. This may include patient restarting some PINGS components (e.g., med intake reminder alert app or text delivery system reactivation, motivational messages, etc.), get referrals for help (e.g. mental health), etc.
- PINGS physicians would receive PINGster summary reports every 2 weeks. They would also receive summary charts of prevailing expert consensus BP management guidelines. If a PINGster's mean BP exceeds thresholds, the PINGS nurse navigator will call patient and conduct BP protocol again, and initiate follow-up action as needed.

Potential Measures

- Key outcomes would include recruitment/retention rates; patient /provider Satisfaction,^{98,99} proportion of patients with systolic BP within control (<140/90 mmHg) at 3 months post-stroke.
- Other outcomes could include patient adherence (med possession ratio, Morisky med adherence score),^{100,101} and competence & autonomous self-regulation scores.^{102,103,101} Information on including sociodemographics, health literacy,^{104,105} and HTN/stroke knowledge, would also be collected.

CONCLUSIONS

A PINGS intervention in SSA could: 1) represent a culturally-sensitive multi-level mHealth self-management program for stroke patients; 2) apply synergistic constructs from behavioral and technology application theories, and direct guidance from stroke patients, caregivers and providers; 3) use real time adherence measurements of BP data and medication intake to facilitate immediate feedback, automated motivational/reinforcement messages & HTN/stroke educational messages, all aimed to enhance self-determination theory constructs of competence (akin to self-efficacy) and autonomous regulation (sustained internally driven motivation); 4) give healthcare providers individually tailored automated reports to enable faster changes in medication regimens and earlier sustained BP control.

A feasible and preliminarily efficacious PINGS intervention: 1) could lead to a larger more definitive efficacy/effectiveness RCT powered to look at clinical events, with the potential to reduce HTN-related stroke morbidity, mortality, and associated costs in SSA; 2) by utilizing a task-shifting strategy, which incorporates nurses to primarily direct BP control, could potentially mitigate the critical shortage of physicians in the region; 3) by leveraging the high (and rising) mobile phone penetration in SSA could integrate care systems, and improve overall patient-provider communication; and 4) by using an iterative behavioral change theory guided design process, assess post-trial acceptability, satisfaction, usability, salience & aids/barriers to sustainability among patients, caregivers, providers and other key stakeholders.

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Table 1

Guiding Theoretical Frameworks

Model/Theory	Description	Justification
<i>Self Determination Theory (SDT)</i>	<ul style="list-style-type: none"> • Competence & autonomous regulation are critical components • Building sustained motivation in SDT involves development of autonomous regulation, fostered by inculcating a sense of ownership and meaning in one's behavior changes consistent with personal values, beliefs or life goals.⁹⁶ 	<ul style="list-style-type: none"> • Confidence to engage in desired behaviors is increased when motivation is high • Behaviors are more likely to be sustained than those resulting from controlled motivation via external (e.g., "doctor's orders") or negative internal (e.g., shame, guilt) pressures.⁹⁷
<i>People, Activity, Context & Technology</i>	<ul style="list-style-type: none"> • Users must feel at ease with and perceive the technology as helpful in reaching desired goal.^{106,107} 	<ul style="list-style-type: none"> • Obtaining input from patients, caregivers, and providers in development of tailored culturally sensitive motivational messages for patients and circumstances is imperative for intervention sustainability

Table 2

Intervention Strategies

Strategy	Region	Description	Results
<i>Task shifting</i>	Cameroon	• Effectiveness of integrating care for HTN by task shifting to “non-physician” clinician facilities	• Decreased systolic BP and diastolic BP. ¹⁰⁸
	Nigeria	• Pharmacist-managed HTN clinics	• Improved BP control, reduced treatment failure, increased patient satisfaction. ¹⁰⁹
	Nigeria	• WHO launched a task-shifting evidence-based clinical decision support program targeted at CVD risk reduction at the primary health care level ¹¹⁰	• Decreased systolic and diastolic BP. ¹¹¹
	South Africa	• Nurse-led program for patients with HTN	• Enhanced early detection, referral of poorly controlled patients, & improved nurses’ knowledge. ¹¹²
Nurse-led Risk Reduction	South Africa	• Nurse-led program for patients with HTN	• Nurse-run care systems in SSA based on protocol/education are feasible. ¹¹³ • Local health system-wide nurse-led program used to follow patients with HTN in improved overall early detection and referral of high risk patients. ¹¹²
<i>mHealth Technology</i>	Nigeria	• Survey to determine number of SSA clinic patients with mobile phones	• ~67% of clinic patients had mobile phones. ³³ • Smart phone penetration in SSA is currently ~25%, ³⁵ and rising rapidly each successive ³⁴ year.
	Kenya	• Task-shifting strategy with technology (tablet-based electronic Decision Support & Integrated Record-Keeping)	• Approach was highly usable. ¹¹⁴
	World	• Home tele-monitoring of chronic diseases	• Empowers patients, influences behaviors, improves medical conditions. ^{91,115} • More effective when “augmented” with nurse-management.

HTN=hypertension; SSA=Sub-Saharan Africa; BP=Blood Pressure; mhealth=mobile health