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Protocol for a mixed-methods study to explore implementation outcomes of the Phone-based Interventions under Nurse Guidance after Stroke (PINGS-II) across 10 hospitals in Ghana

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ABSTRACT

Background Stroke survivors are at a substantially higher risk for adverse vascular events driven partly by poorly controlled vascular risk factors. Mobile health interventions supported by task shifting strategies have been feasible to test in small pilot trials in low-income settings to promote vascular risk reduction after stroke. However, real-world success and timely implementation of such interventions remain challenging, necessitating research to bridge the know-do gap and expedite improvements in stroke management. The Phone-based Interventions under Nurse Guidance after Stroke (PINGS-II) is a nurse-led mHealth intervention for blood pressure control among stroke survivors, currently being assessed for efficacy in a hybrid clinical trial across 10 hospitals in Ghana compared with usual care. This protocol aims to assess implementation outcomes such as feasibility, appropriateness, acceptability, fidelity, cost and implementation facilitators and barriers of the PINGS-II intervention.

Methods and analysis This study uses descriptive mixed methods. Qualitative data to be collected include in-depth interviews and FGDs with patients who had a stroke on the PINGS-II intervention, as well as key informant interviews with medical doctors and health policy actors (implementation context, barriers and facilitators). Data will be analysed by thematic analysis. Quantitative data sources include structured questionnaires for clinicians (feasibility, acceptability and appropriateness), and patients who had a stroke (fidelity and costs). Analysis will include summary statistics like means, medians, proportions and exploratory tests of association including χ^2 analysis.

Ethics and dissemination Ethics approval was obtained from the Committee for Human Research Publication and Ethics at the Kwame Nkrumah University of Science and Technology, Kumasi, Ghana. Voluntary written informed consent will be obtained from all participants. All the rights of the participants and ethical principles guiding scientific research shall be adhered to. Findings from the study will be presented in scientific conferences and published in a peer-reviewed scientific journal. A dissemination meeting will be held with relevant agencies of the Ghana Ministry of Health, clinicians, patient group representatives, and non-governmental organisations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a comprehensive mixed-methods approach with diverse participants including clinicians, health policy actors and patients who had a stroke.
⇒ The study will be situated within 10 hospitals in Ghana, providing valuable insights on stroke care from different authentic settings.
⇒ The protocol is grounded in established theoretical frameworks for a robust theoretical foundation.
⇒ Purposive sampling for the key informant interviews may introduce bias and limit generalisability.
⇒ Recall bias is also a concern, especially in the assessment of measures like costs to patients and implementation fidelity.

In Africa, there are an estimated 1460 persons living with stroke for every 100 000 with an annual incidence of 316 per 100 000.[1] A systematic review and meta-analyses across Sub-Saharan Africa showed stroke fatality of 24.1%, 33.2% and 40.1% at 1 month, 1 year and 3 years, respectively.[2] As a leading cause of death worldwide second only to ischaemic heart disease, stroke is globally pervasive, but in low-income and middle-income countries this burden is disproportionately high and continues to rise.[3] This trend is also observed in Ghana and is attributable at least partially to a rising incidence of poorly managed hypertension.[4–6] A prospective study among Ghanaians with hypertension and type II diabetes revealed 14.19 stroke events per 1000 person-years.[7]

The Phone-based Interventions under Nurse Guidance after Stroke, 'PINGS-II', is an mHealth intervention designed for blood pressure (BP) control among stroke survivors currently being evaluated in a randomised phase III clinical trial in Ghana. The study is being conducted in 10 hospitals:

Komfo Anokye Teaching Hospital, Korle Bu Teaching Hospital, Cape Coast Teaching Hospital, Agogo Presbyterian Hospital, Kumasi South Hospital, Ankaase Methodist Faith Hospital, Manhyia District Hospital, KNUST Hospital, Kwadaso SDA Hospital and Tafo Government Hospital. It is a hybrid design consisting of four main components, namely home-based self-monitoring of BP, medication reminders using phone alerts, patient education on cardiovascular risk reduction via interactive voice recordings in their preferred language and a 'nurse navigator' on call to guide and support patients while using the intervention. Patients will report to the hospital at specified follow-up intervals for physician review including physical examination, laboratory testing and recording of relevant data. The follow-up duration of the trial is 1 year. A detailed description of the PINGS-II intervention has been published by the investigators.[8] An earlier single-centre pilot of the intervention, called PINGS I, showed a significant reduction (p=0.035) in systolic BP control compared with usual care.[5] A systematic review of other randomised controlled trials of telemedicine and mHealth interventions for hypertension among stroke survivors showed a significant reduction of systolic BP (average of 5.49 mm Hg) as compared with usual care.[9]

Despite this potential, real-world success in implementing interventions like PINGS requires comprehensive efforts to plan, execute and evaluate outcomes.[10] However evidence-based innovative health interventions could take up to two decades to be adopted into mainstream public health systems,[11 12] and with about half of them failing at implementation,[13] research is crucial. To expedite potential improvements in health outcomes, implementation research as part of clinical and public health research is important for narrowing research-to-practice gaps,[14–16] including observing stronger effect sizes.[17] This study, although complementary to the main PINGS-II study, is a separate protocol outlining a strategy to assess specific implementation outcomes of PINGS-II, and to help develop strategies for successful real-world implementation and scale-up.

THEORETICAL AND CONCEPTUAL FRAMEWORKS UNDERPINNING THE STUDY

This protocol is guided by the Consolidated Framework for Implementation Research (CFIR), a comprehensive synthesis of implementation theories synthesised into a metatheory, as the overarching model driving the research. It identifies the following five domains: 'intervention characteristics' which examine the features of the innovation, 'individual characteristics' which deals with the perceptions, beliefs and knowledge of stakeholders, 'inner setting' which deals with organisational context such as culture, leadership and infrastructure affecting the intervention, 'outer setting' which focusses on the external context including broader social, political and economic factors and 'process' which examines the actual implementation including planning, execution, and feedback mechanisms.[18]

As this research agenda is more closely aligned with 'evaluating implementation', which is one of the three overarching aims for using theoretical approaches in implementation science,[19] we used the outcome evaluation framework developed by Proctor *et al*,[20] which includes implementation outcome measures such as feasibility, acceptability, appropriateness, fidelity and costs. Our proposed conceptual framework, figure 1, therefore represents a conceptualisation of how the PINGS-II design and process may interplay to yield the implementation outcomes. The PINGS II intervention components, comprising home BP checks, educational text messages, medication reminders and nurse navigation, interact with key elements of the CFIR to shape implementation outcomes. Ease of use of home BP checks for instance may influence adoption and adherence, reflecting CFIR's Intervention Characteristics, while adaptability of nurse navigation impacts acceptability and feasibility. Organisational support and resource availability reflect CFIR's Inner Setting and can shape implementation success. Patient characteristics and engagement strategies, aligning with CFIR's Individual Characteristics and Process, influence acceptability and engagement, are

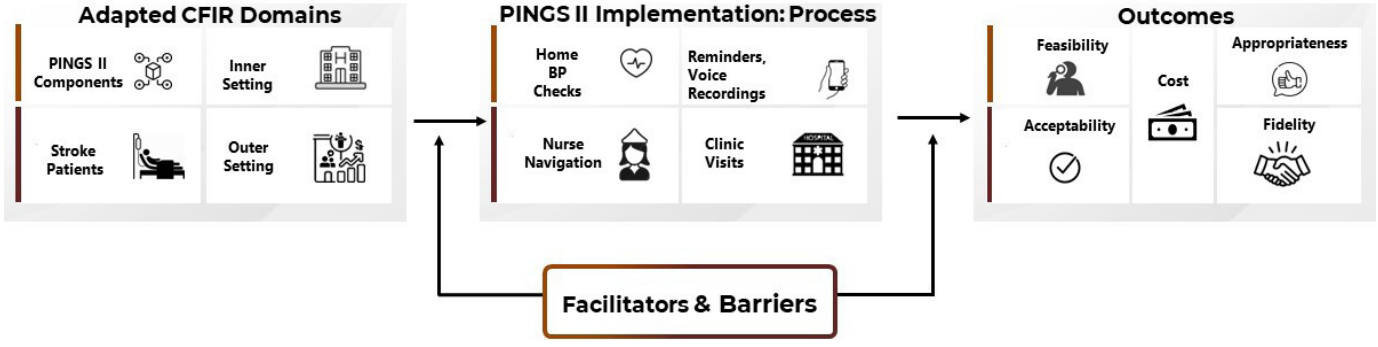

Figure 1 'Conceptual framework for the study'. 'The framework depicts how the implementation outcomes are conceived, as dependent on the components of the intervention, the relevant contextual factors, and how these may interplay within the Consolidated Framework for Implementation Research(18) to yield the implementation outcomes'. BP, blood pressure; CFIR, Consolidated Framework for Implementation Research; PINGS-II, Phone-based Interventions under Nurse Guidance after Stroke.

crucial for implementation success. By integrating these elements with CFIR, implementation strategies may be optimised to enhance patient outcomes effectively.

Study aims

1. To assess the feasibility, acceptability and appropriateness of the PINGS-II intervention.
2. To assess fidelity and out-of-pocket patient costs of the PINGS-II intervention.
3. To explore the contextual barriers and facilitators that may affect the PINGS-II intervention.

METHODS

Design

This mixed-methods descriptive exploratory study assesses specific implementation outcomes and contextual factors affecting the PINGS-II intervention.

Study setting and participants

This research will be conducted across 10 district-level and teaching hospitals where the PINGS-II intervention is being implemented. The PINGS II study is a phase III randomised controlled trial involving 500 recent stroke survivors, seeking to assess the efficacy of an mHealth technology-centred, nurse-led, intervention on BP control among stroke survivors. It consists of the following components: (1) home BP monitoring, (2) use of phone alerts to set medication reminders and (3) patient education on hypertension, cardiovascular risk management and stroke, all over 12 months of follow-up. The patients will also have access to a **nurse navigator,** who is the trial study nurse, the participants can call for medical advice regarding their blood pressure if needed.[8]

This implementation research protocol is however a separate observational enquiry which will be deployed in the 10 study sites where the PINGS-II intervention is being implemented. Three population groups are involved: (1) hypertensive patients who are using the PINGS-II intervention will be engaged in in-depth interviews, focus group discussions (FGDs) and will respond to a structured questionnaire, (2) health workers to be surveyed using an online questionnaire, (3) medical doctors involved in PINGS-II at each implementing site of PINGS-II for key informant interviews and (4) actors in the health policy domain such as the focal person for the non-communicable diseases in the Ghana Health Service, other relevant Ministry of Health agencies, academic research institutions and non-governmental organisations. The sampling is purposive although participants will be selected to maximise variation across demographics, severity of hypertension, facility location, socioeconomic factors and level of the healthcare facility as far as feasible.

To identify relevant questions and the most appropriate and feasible strategies for participant recruitment into this implementation study, we worked with the site investigators for the PINGS-II trial and engaged participants who had a stroke and their caregivers at the various study sites. The insights generated from these background activities were further reviewed by the research team to transform them into relevant questions to investigate strategies for recruitment, data collection and potential analyses. These actions were deemed important to ensure alignment of the study aims to the interests of patients as well as health workers involved in the care of patients who had a stroke, without compromising the scientific rigour of the study, while also complying meaningfully with the need to involve patients in study design and execution. Findings will be communicated to relevant stakeholders such as clinicians, policymakers and patient groups via appropriate forums such as dissemination workshops. Table 1 shows the inclusion and exclusion criteria for the study.

Study timelines

The online questionnaire with health workers was conducted in August 2021 as a preimplementation study to gauge feasibility, acceptability and appropriateness of the PINGS II intervention from the perspective of health workers. Results of this baseline assessment were published in August 2022.[21] Data collection for the assessment of fidelity, costs to patients, and interviews with policymakers, interviews and FGDs with patients who had a stroke have been on-going since June 2022. Transcription of all qualitative data collection finally concluded in June 2024. Quantitative data collection on 'costs' and 'fidelity'

Table 1 Inclusion and exclusion criteria for the study

Inclusion criteria for the different groups		
Patient recruitment	**Online health worker survey**	**Key informant interviews**
Patients enrolled on the PINGS-II clinical trial	Medical doctors, nurses, midwives, physician assistants and pharmacists working in Ghana	Medical doctors involved in the conduct of PINGS-II; health policy actors from government health agencies, research institutions, academia and non-governmental organisations
Exclusion criterion for all groups		
Unwillingness or inability to provide voluntary informed consent		

PINGS-II, Phone-based Interventions under Nurse Guidance after Stroke.

from patients is expected to conclude in September 2024, with write up of all results expected to be completed by December 2024, for onward peer-review submission.

Sample size and recruitment for the FGDs with patients

Patients enrolled on the PINGS-II intervention will be invited to voluntarily participate in the FGDs. One FGD will be conducted in each of the 10 health facilities with each discussion involving 6–10 participants.

Sample size for the quantitative data collection from patients

An anticipated 250 patients will be enrolled on the PINGS-II intervention within the PINGS-II clinical trial with sample size calculation and rationale already provided for the trial.[8] These patients will be invited to respond to the structured questionnaire to collect data on measures including implementation fidelity and costs. We will also include approximately 250 patients who were assigned to the control group to serve as a comparator population for analysis.

Sample size for the interviews with clinicians and policymakers

Creswell[22] indicates that between 5 and 25 interviews are sufficient for enquiries where participants have experienced the phenomenon under study. Thus, 10 key informant interviews are planned, comprising one clinician from each of the 10 health facilities. In addition, five health policy actors would also be interviewed.

Sample size for the online health worker survey

The survey will be deployed via various social media groups for health workers in Ghana, including medical doctors, nurses, pharmacists and physiotherapists. The hyperlink to the survey will be shared widely to maximise participation and representation of the different health worker groups.

We used the Cochran formula at the 0.95 CI (Z=1.96) and 5% level of precision (e). Since the population proportion was unknown for any of the measures that is, 'Feasibility', 'Acceptability' and 'Appropriateness', a proportion of p=0.5 was chosen assuming maximum heterogeneity, to calculate the minimum sample size (n). $n = \frac{z^2 p(1-p)}{e^2} = 385$,adjusted by an additional 10% to a final sample of 423, for non-response.

Assessing feasibility, acceptability and appropriateness outcomes

Feasibility is the extent to which an intervention can be deployed successfully in a given setting while appropriateness refers to the perceived fit, compatibility or relevance of the intervention for implementation.[23] Acceptability, also referred to as adoptability, is concerned with how well the target population will receive the intervention and how their needs might be met by the intervention.[24] Weiner and colleagues developed and validated three measures: Acceptability of Intervention Measure, Intervention Appropriateness Measure and Feasibility of Intervention Measure. These measures will be adapted for assessing these outcomes under this protocol, and were designed to be pragmatic, and demonstrated validity across several domains, including content, structure and responsiveness to change.[25] Table 2 summarises the relevant data types and study populations. The adapted tools for assessing feasibility. acceptability and appropriateness have been added as online supplemental information.

Assessing fidelity

Fidelity is the extent to which an intervention is implemented as intended.[26] This will be assessed using data from the structured patient questionnaire supported by the FGD with patients, and the routine administrative and operational data from the project implementation. The instruments for data collection will capture different dimensions of fidelity such as content, process, exposure and responsiveness.[27 28] A summary of the relevant data strategy and study population is presented in table 1. The set of items to assess fidelity are shown in the online supplemental information.

Assessing costs

Under this protocol, downstream costs such as self-reported additional personal costs incurred by patients who had a stroke partaking in the PINGS-II intervention will be assessed. This includes data on expenses made for related laboratory tests and other investigations, therapeutic agents, transportation, BP monitoring devices, among others. Downstream costs are those arising further after the implementation. Many interventions measure intervention and implementation costs but not costs incurred further downstream. These additional costs are an important factor when evaluating the overall intervention for cost-effectiveness.[29] This protocol will assess some of these additional costs to patients such as transportation costs to the hospital for follow-up, costs of purchasing items like batteries for home BP measurements, phone call credit to contact the nurse navigator, and so on. The complete set of cost items of interest is shown in the online supplemental information.

Assessing facilitators and barriers to PINGS-II implementation

Contextual factors that may impact PINGS-II implementation will be explored from the perspective of patients, clinicians and other relevant stakeholders in the health policy space. This will be done via interviews and FGDs with these target populations. It is necessary to account for the influence of context to explain why implementation outcomes are achieved. Failure to do this may result in limited generalisability of the findings to different circumstances.[30–32] Data to be gathered will include patients' demographic details, health status and accessibility issues, among others. Clinicians' professional backgrounds and attitudes towards technology that provide insights into individual and organisational challenges will be explored. Meanwhile, stakeholders' perspectives on the care delivery ecosystem and healthcare priorities

Table 2 Summary of the implementation outcome measures and processes

Outcomes	Participants/data	Process/description
(1–3) Feasibility, Appropriateness and Acceptability (FAA)	A cross-section of health workers in Ghana	Assessed via feasibility, acceptability and appropriateness[20] using a structured online health worker questionnaire based on the measures developed by Weiner et al.[25] To be done before or within Year 1 of PINGS-II implementation.
	Purposively sampled health policy actors	To be assessed as part of in-depth interviews using a semi-structured interview guide within Year 1 of PINGS-II implementation.
	Participants in the PINGS-II intervention	To be assessed via the structured patient questionnaire administered at month 3 and repeated at month 12. To be done simultaneously with 'Fidelity' and 'Cost'.
(4) Fidelity	Participants in the PINGS-II trial	To be assessed via the structured patient questionnaire at month 3 and repeated at month 12. Other supporting data include patient interviews and routine project operational data.
(5) Cost (self-reported)	Participants in the PINGS-II trial	Patients' self-reported costs of care to be done using the structured patients' questionnaire at month 3 and repeated at month 12. To be done simultaneously with 'Fidelity' and 'FAA'.
(6) Implementation facilitators and barriers (context)	Trial site clinicians	In-depth interviews using semi-structured interview guide for clinicians and policy actors to explore enablers and barriers to PINGS-II.
	Participants in the PINGS-II intervention	In-depth interviews and focus group discussions using patients' semi-structured interview guide exploring enablers and barriers to using PINGS-II.
	Policy actors within the health sector in Ghana	In-depth interviews using semi-structured interview guide for clinicians and policy actors to explore enablers and barriers to PINGS-II.

PINGS-II, Phone-based Interventions under Nurse Guidance after Stroke.

will offer a broad contextual understanding. Integrating these diverse viewpoints through interviews and focus groups is expected to enhance implementation strategies. The guides for the interviews and FGDs are provided in supplementary materials.

Data collection, management and analysis

The data collection and analysis team comprises five research scientists (including two lead physician researchers) with training and experience in mixed-methods research who are not directly involved in the PINGS-II clinical trial, and supported by other research physicians who are directly involved in the PINGS-II trial. The quantitative data will be collected using the REDCap software. All data will be kept password-secure and confidential with access restricted only to the investigators.

Descriptive summaries will be obtained for sociodemographic characteristics and other relevant domains using means, medians and proportions. Where appropriate, measures of dispersion such as SD and IQRs will be shown. The Likert type responses obtained for the feasibility, appropriateness and acceptability measures as described will be used to calculate a composite score for each measure. Relevant techniques such as χ^2 analysis will be used to explore associations between various physician characteristics and their ratings of the PINGS II initiative, regarding feasibility, acceptability or appropriateness. Cronbach's alpha will be calculated to determine the internal consistency of the data collection tools. The different dimensions of fidelity measured in PINGS implementation will also be analysed descriptively to show how PINGS II was implemented with reference to the planned procedures.

The qualitative data will be collected by digital audio-recording and stored on a password-protected personal computer with access available only to the investigators. Qualitative data will be analysed by thematic analysis, which is a process of identifying themes or patterns within qualitative data,[33] and an appropriate method for seeking to understand experiences, thoughts and behaviours across a dataset.[34] By this approach, the transcripts will be read and re-read to familiarise with the data and then labels or codes assigned to segments of text that represent the key concepts. The codes will then be iteratively refined and grouped into broader themes and mapped onto the CFIR domains,[18] for example, themes related to the Intervention Characteristics domain may include ease of use and perceived effectiveness. The Inner Setting domain may include resources, culture, leadership support while the Outer Setting will include community resources, patient needs and policy context.

The Individual Characteristics domain will also include factors like patient preferences and clinician attitudes to the intervention, while themes affecting the implementation process for example, barriers and facilitators will be classified under the Process domain of the CFIR. The codes will then be iteratively refined and grouped into broader themes related to implementation outcomes (feasibility, acceptability, appropriateness, fidelity and cost) and contextual factors. Once the data have been coded according to CFIR constructs, they will then be iteratively organised under the specific implementation outcomes of interest. This will allow exploration of the contextual factors identified through CFIR analysis and how they influence the achievement of these outcomes, that is, feasibility, acceptability, appropriateness, fidelity and costs, to provide valuable insights into the implementation. Such deeper and integrated use of the CFIR has been advocated in a systematic review that considered the application of the framework across diverse settings and objectives.[35]

Ethics and dissemination

Ethics approval for the study has been granted by the Committee for Human Research and Publication Ethics at the Kwame Nkrumah University of Science and Technology, Ghana (CHRPE/AP/117/22). Voluntary written informed consent will be obtained from the participants. All the rights of the participants and ethical principles guiding scientific research shall be adhered to. Findings from the study will be presented in scientific conferences and published in a peer-reviewed scientific journal. A dissemination meeting will be held with relevant agencies of the Ghana Ministry of Health, clinicians, patient group representatives, and non-governmental organisations.

Patient and public involvement

The study was developed with consideration of patients' priorities, experiences and preferences. Through informal consultation sessions, stroke survivors provided invaluable insights that guided the formulation of the research question and the selection of meaningful outcome measures.

Patients' input influenced the design to ensure that the research approach resonates with their convenience, needs and preferences to enhance the study's effectiveness. While not directly involved in recruiting other patients, stroke survivors will continue to influence the implementation and evaluation of PINGS-II through ongoing feedback sessions.

The study results will be disseminated to participants through clear, accessible means such as stakeholders' engagements with patient groups. Participants will also have opportunities to engage with researchers to discuss implications for their care and future interventions.

DISCUSSION

Despite ample evidence pointing to the potential for mHealth approaches to augment clinical management of hypertension,[36–38] many low-income and middle-income countries including Ghana are yet to reap its benefits as compared with developed regions like Europe.[39] This study will employ several complementary data collection strategies and sources to provide a comprehensive assessment of PINGS-II implementation in Ghana in order to facilitate real-world implementation.

While determining what implementation outcomes would be most suitable for any particular implementation research can be challenging,[26 28 40] choices can be guided by the nature of the intervention and the implementation setting.[20] The outcomes of interest in this protocol are selected for their relevance to PINGS-II implementation in Ghana, the relative ease of assessment and general recognisability of the constructs within implementation research. Other clinical level outcomes such as improvement of BP and other cardiovascular risks will be assessed within the PINGS-II clinical trial and not under this protocol. It is possible for the operational elements of an intervention to be fully implemented, even with high fidelity, without necessarily achieving the expected clinical outcomes; the converse is also true. Thus, identifying relevant non-alignments in the PINGS-II implementation research outcomes relative to the PINGS-II clinical trial outcomes might provide a further opportunity to understand factors and mechanisms which determine desired outcomes.

Recruitment into the study is expected to be facilitated by the availability of patients who had a stroke and clinicians working with the PINGS-II clinical trial, a convenient online deployment for the health worker survey, and strategic unbiased purposive sampling of the health policy actors. Due to the cross-sectional nature of the data collection, setbacks from participant loss to follow-up are non-applicable. The study tools are also simple and streamlined to encourage full completion by participants.

By expanding on the proof of concept already demonstrated by PINGS I and furthering the evidence base with more diverse participant demographics, study site contexts and other external factors, it is anticipated that future real-world implementation of PINGS-II will be more efficient and effective in enhancing BP control among stroke survivors.

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Contributors JA, MKA, FS, AB and BO developed the initial concept for the protocol. JA, MKA, AB, AA-A, PA and SN drafted the first version of the manuscript. JA, MKA, FS, AB, AA-A, PA, SN and BO refined and approved the final manuscript. JA is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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