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Feasibility of implementing a mobile phone-based telemonitoring programme to support pregnant women at high-risk for pre-eclampsia in Karachi, Pakistan: protocol for a mixed-methods study

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ABSTRACT

Introduction High maternal mortality from pre-eclampsia/eclampsia results from lack of early identification and management of pregnant women at high-risk for pre-eclampsia. A potential tool to support pregnant women at high-risk for pre-eclampsia is telemonitoring. There is limited evidence on the use and effectiveness of telemonitoring for pregnant women in low-income and middle-income countries (LMICs) which limits the understanding of the process and mechanisms through which the intervention works in LMICs. This study will explore the feasibility of implementing a mobile phone-based telemonitoring programme for pregnant women at high-risk for pre-eclampsia in Karachi, Pakistan.

Methods and analysis A convergent mixed-methods study will be conducted at the Jinnah Postgraduate Medical Center (JPMC) in Karachi, Pakistan. This study will recruit 50 pregnant women at high-risk for pre-eclampsia to assess clinical feasibility across the five foci of Bowen's framework including acceptability, demand, implementation, practicality and limited-efficacy testing. Data sources will include semi-structured interviews with the enrolled women, caregivers and clinicians, as well as quantitative data from paper medical records, research logs and server data. The quantitative and qualitative data will be analysed separately and then integrated at the interpretation and reporting levels to advance our understanding of the telemonitoring programme's feasibility across the five areas of Bowen's framework.

Ethics and dissemination Ethics approvals have been obtained from JPMC, the National Bioethics Committee of Pakistan, University Health Network, Aga Khan University and the University of Toronto. The study results will be disseminated to the scientific community through publications and conference presentations. Findings of the study will provide evidence on the feasibility of using a telemonitoring programme where pregnant women at high-risk for pre-eclampsia in Pakistan will take their own blood pressure readings at home. Lessons learnt in this feasibility trial will be used to determine the appropriateness of a future effectiveness trial.

Trial registration number NCT05662696

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of a mixed-methods research design will enable a comprehensive understanding of the feasibility of the telemonitoring programme through a range of qualitative and quantitative data collection methods.
⇒ The involvement of caregivers will provide insights into the sociocultural factors influencing the uptake and the use of the telemonitoring programme among high-risk pregnant women.
⇒ This study will use a theoretical framework, namely Bowen's framework, to guide the study including the development of interview guides as well as data analysis and interpretation.
⇒ This study focuses on a single setting (Jinnah Postgraduate Medical Center), which could limit the transferability of the findings to other settings. However, this study may provide insights into other similar public hospitals across Pakistan and in other low-income and middle-income countries.
⇒ It is anticipated that the women enrolled in this study will be relatively younger and more confident in using digital technology, which might limit the generalisability of the results to other groups.

INTRODUCTION

Hypertension is the most common medical condition encountered during pregnancy, occurring in approximately 6–8% of the pregnancies.[1] The spectrum of hypertensive disorders of pregnancy includes chronic hypertension, gestational hypertension, pre-eclampsia, eclampsia and pre-eclampsia superimposed on chronic hypertension.[2] In particular, pre-eclampsia affects between 3–5% of the pregnancies and is one of the main causes of maternal and neonatal mortality in low-resource settings.[3] Pre-eclampsia is a disorder of pregnancy that is characterised by high blood pressure and

protein in the urine after 20 weeks of gestation. It is associated with high maternal mortality, preterm birth, pregnancy loss and stillbirth.[1] Pregnant women with pre-eclampsia are at increased risk for stroke and damage to vital organs such as kidneys, liver and brain.[1] In severe cases, pre-eclampsia can lead to eclampsia which is the presence of seizures.[1] This condition could also lead to the separation of the placenta from the uterus (referred to as placental abruption).[1] In addition, the risk for anxiety and depression is increased in pregnant women with high-risk pregnancies.[4 5] Infants born preterm due to pre-eclampsia are at higher risk of mortality and long-term health issues including learning disorders, cerebral palsy, epilepsy, deafness and blindness.[1 6]

Pregnant women in low-income and middle-income countries (LMICs) are seven times more likely to develop pre-eclampsia compared with those living in high-income countries, and their mortality rates are much higher, with 10–25% of these cases resulting in maternal death.[7 8] Pakistan has one of the highest maternal mortality ratios worldwide at 178 per 100 000 live births[9] and neonatal mortality ratios at 42 per 1000 live births.[7] Eclampsia accounts for more than 12% of the direct maternal deaths in Pakistan.[10] Deaths from pre-eclampsia/eclampsia represent one-third of the maternal deaths reported at tertiary care hospitals.[11] High maternal mortality from pre-eclampsia/eclampsia results from: (1) lack of early identification and treatment of high-risk pregnant women, (2) difficulties in reaching treatment centres and (3) poor health-seeking behaviours linked with low patient health education.[11]

A potential tool to support pregnant women at high-risk for pre-eclampsia (HRPE) is telemonitoring, which refers to the use of information technology to monitor patients at a distance.[12] Women at HRPE would take home blood pressure readings and record self-reported symptoms related to pre-eclampsia/eclampsia, and the data would be sent to clinicians in real-time.[6 13–22] Telemonitoring is a promising tool to improve pregnant women's health outcomes from pre-eclampsia, as well as quality and coordination of care in a cost-effective and scalable manner.[10 12 16 17 20 23] Through telemonitoring, clinical alerts can be generated based on the patient's blood pressure values and symptoms as appropriate, and patients can be sent tailored self-care messages. This could lead to the earliest possible detection of alarming increases in blood pressure, resulting in an early intervention such as through medications, hospitalisation or delivery of the baby.[24 25] In addition, telemonitoring may provide pregnant women at HRPE with the reassurance of clinical oversight and self-care support that may reduce anxiety and stress related to pregnancy and hospitalisation.[20]

Most telemonitoring interventions have been implemented in high-income countries such as the UK, the USA and Belgium,[10 13–19 23] as part of clinical trials and feasibility studies. These studies have reported potential benefits of telemonitoring during pregnancy including fewer hospital visits, better blood pressure control and cost savings.[14 15 21 22] However, there is scarce evidence on the use and effectiveness of telemonitoring of pregnant women in LMICs.[16] Previous studies in LMICs have implemented telemonitoring by community health workers as part of the Community-Level Interventions for Pre-eclampsia (CLIP) trial[10] and Control of Blood Pressure and Risk Attenuation—Bangladesh, Pakistan and Sri Lanka (COBRA-BPS) studies.[26] These telemonitoring interventions relied on community health workers to record vital signs on a mobile application during in-person visits, which can miss signs of health issues between physical visits by the community health workers and can also introduce white coat hypertension or masked hypertension.

This will be the first study to explore the feasibility of using a mobile phone-based telemonitoring programme in an LMIC, where pregnant women at HRPE take their own blood pressure readings at home between antenatal visits. This study aims to explore the following research question: *What is the feasibility of implementing a mobile-based telemonitoring programme in Pakistan to support pregnant women at HRPE?* The objective of this study is to enable early risk detection, diagnosis and treatment of pregnant women at HRPE between antenatal visits and to provide more frequent data than what can be achieved with home visits by community health workers, such as in CLIP and COBRA trials. If this study finds that the telemonitoring programme is feasible, the intent is to conduct a future effectiveness trial. Therefore, this proposed feasibility trial will also include an evaluation of the feasibility of potential metrics and evaluation methods of a future effectiveness trial.

METHODS AND ANALYSIS

Study design overview

A convergent mixed-methods design[27] will be used to comprehensively understand the feasibility of the telemonitoring programme. It is anticipated that the feasibility study will be conducted between December 2022 and February 2024, at the obstetrics and gynaecology (OB-GYN) outpatient department of Jinnah Postgraduate Medical Center (JPMC), which is a 1650-bed tertiary-level public sector hospital in Karachi (the largest city in Pakistan). A vast majority of high-risk pregnant women of low-socioeconomic status within the region, seek care at JPMC, where annual admissions exceed 26 000, and 19 000 deliveries take place per year.

The study will recruit approximately 50 pregnant women at HRPE in the telemonitoring programme to assess clinical feasibility across the five foci of Bowen's framework. A range of qualitative and quantitative measures will be used to determine telemonitoring programme feasibility including telemonitoring adherence rate, recruitment rate, drop-out rate and interviews with enrolled women, caregivers and clinicians to explain quantitative results such as positive and negative exemplars (high and low telemonitoring adherence), outliers and significant findings (telemonitoring efficacy). The results of the

quantitative and qualitative data will be integrated at the interpretation and reporting levels.[28]

Study intervention: mobile phone-based telemonitoring programme named 'Raabta'

The study intervention will be the telemonitoring programme for high-risk pregnant women, which will be delivered using the telemonitoring platform. The telemonitoring programme is named 'Raabta' which means 'a connection' in Urdu. The Raabta technology has been developed at the Centre for Digital Therapeutics, University Health Network in Toronto, Canada. Hosting of the telemonitoring platform and storage of the study data will be at the Centre for Digital Therapeutics.

The patient-facing technology includes the Raabta smartphone application (app) and Bluetooth-enabled blood pressure device that is validated for use in pregnancy. The app will enable pregnant women to take daily blood pressure readings at home with a provided Bluetooth-enabled home blood pressure monitor and to receive automated alerts (ie, self-care messages) via the app. The app will use a rules-based algorithm (online supplemental appendix 1) which was developed using National Institute for Health and Care Excellence (NICE) guidelines and consultations from expert clinicians. The algorithm includes settings to trigger alerts and self-care messages for high-risk pregnant women with or without antihypertensives and symptoms of pre-eclampsia such as taking additional blood pressure readings, calling the medical officer (ie, a medical doctor with postgraduate training completed in OB-GYN field) or visiting the OB-GYN emergency department. Other features of the Raabta app include the use of the local language (Urdu), illustrations for daily symptom monitoring questions (for pregnant women who cannot read), an easy-to-understand green–yellow–red alert system that uses the well-known traffic lights analogy and voice message alerts in conjunction with the text. The features of the technology have been informed by our previous needs assessment study with pregnant women at HRPE and their caregivers.[29]

The clinician-facing technology includes the web-based Raabta dashboard. To support clinical decision-making, the medical officer and research nurse situated at the JPMC OB-GYN outpatient department will receive alerts from the telemonitoring system if the patient's blood pressure trends are out of the target and/or if the patient is reporting symptoms. The medical officer will act as a central point person to communicate with the patients (via phone calls or using the asynchronous telemonitoring system chat feature) and with the rest of the participant's care team as needed.

Preparations for the programme launch will include the development of training materials (user manual and training checklist) for patients as well as for clinicians. The medical officer and research nurse will be trained on the use of the web-based Raabta dashboard prior to recruitment of patients. A full-day training session will be organised for the clinicians to train them on using the Raabta web-based dashboard and the study procedures. Context-specific training plans will be designed to train pregnant women and caregivers on how to use the technology.

The medical officer and research nurse will train recruited pregnant women at HRPE and their caregivers, if appropriate, on the use of the telemonitoring system at the same antenatal visit at which they have consented to participate in the study. The training session for pregnant women and caregivers will last approximately 1 hour. If the participant owns a compatible smartphone (ie, an Android phone operating a minimum of Android V.5.1.1.), the app will be downloaded onto their phone. Otherwise, a mobile phone will be provided for the duration of the study. Technical support will be available to all participants by the research nurse and the medical officer via a provided phone number. Once at home, participants will be asked to take their blood pressure every morning, and answer symptom questions using the app to receive auto-alerts and self-care messages (figure 1). If the participant develops hypertension (systolic between 140 and 154 mm Hg inclusive and diastolic between 90 and 104 mm Hg inclusive), they will be prompted by the app to immediately call a medical officer (ie, the trained physician in Pakistan) and take a second blood pressure measurement in 4–6 hours. If the participant develops severe hypertension (systolic >155 mm Hg and diastolic

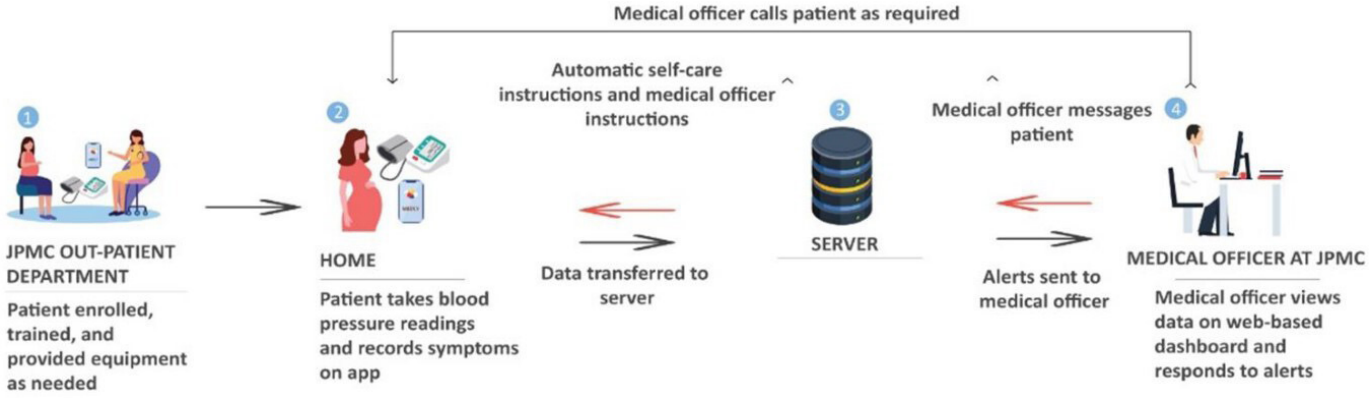

Figure 1 Patient and clinician workflow for the telemonitoring programme at Jinnah Postgraduate Medical Center (JPMC).

Box 1 Definition of pregnant women at high-risk for pre-eclampsia as per the National Institute for Health and Care Excellence (NICE)

Definition

NICE guidelines define pregnant women at high-risk for pre-eclampsia as those who have one high-risk factor or greater than one moderate risk factor for pre-eclampsia.

High-risk factors

⇒ Hypertensive disease in a previous pregnancy.
⇒ Chronic kidney disease.
⇒ Autoimmune diseases, such as systemic lupus erythematosus or antiphospholipid syndrome.
⇒ Type 1 or type 2 diabetes.
⇒ Chronic hypertension.

Moderate risk factors

⇒ First pregnancy.
⇒ Aged ≥40 years.
⇒ Pregnancy interval of >10 years.
⇒ Body mass index of ≥35 kg/m^2 at the first visit.
⇒ Family history of pre-eclampsia .
⇒ Multifetal pregnancy.

>105 mm Hg), they will be prompted by the app to immediately visit the emergency department.

Eligibility criteria and recruitment

Following the guidance from Browne[30] and Sim and Lewis[31] on the suggested sample size for feasibility studies, we will recruit 50 pregnant women at HRPE to implement the telemonitoring programme. It is anticipated that this sample size would provide sufficient data to explore the evaluation metrics as described below. The definition of HRPE will follow that of the NICE guidelines[32] that define pregnant women at HRPE as those who have one high-risk factor or more than one moderate risk factor for pre-eclampsia (box 1). Participants will only be included if they or their caregiver can speak and read (at least at a rudimentary level) the Urdu language for ease of communication with the research team and to be able to use the telemonitoring system. Pregnant women who meet these criteria will be asked by someone in their circle of care if they would be willing to speak to the medical officer or research nurse who are not involved in their circle of care, about participating in the telemonitoring study.

Data collection

Bowen *et al*'s feasibility framework[33] will be used to help guide the feasibility study. Bowen *et al*'s framework include eight general areas of focus for feasibility studies, which are *acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing*.[33] For our study, five of the areas suggested by Bowen *et al* will be explored: *acceptability, demand, implementation, practicality and limited-efficacy testing*. The areas of expansion and integration were excluded as they are not relevant to the aim of this study. Table 1 provides the five focus areas of Bowen *et al*'s feasibility framework used for this study and the corresponding outcome measures and data sources.

The data sources for the quantitative measures include: JPMC paper-based medical records, research logs and telemonitoring server data. Specific information within the five foci that will help inform a future effectiveness trial will include: recruitment rate and reason for declining participation (Demand); drop-out rate, resources needed for technical support and system stability (Implementation); clinical human resources required for the effectiveness trial (Practicality); estimate of efficacy for sample size calculations, reported adverse events and perceived safety from post-study interviews that may indicate safety concerns (Limited Efficacy). The challenges and facilitators to collecting the data for the Limited Efficacy area of focus will be noted for a potential future effectiveness trial.

In addition, pre-study questionnaires will be used to collect data on demographics, maternal characteristics, obstetric history and existing access to technology. The pre-study questionnaire will be completed by the medical officer and/or nurse at the time of enrolment of pregnant women into the feasibility study. The post-study questionnaire will be used to collect data on the management of the women's pre-eclampsia condition during pregnancy, as well as maternal and child health outcomes. The post-study questionnaire will be completed after childbirth while the women are admitted to the postnatal ward or during their first postnatal visit. The data on maternal and child health outcomes will be collected from the hospital's paper-based medical records and by the on-call clinician who will be providing care to the women.

The qualitative measures will include semi-structured, post-study, in-person interviews with enrolled women, caregivers and clinicians who participated in the Raabta programme to understand the programme's feasibility across the five areas of focus (table 1). Women enrolled in the study will be interviewed in Urdu during a normally scheduled JPMC clinic visit post-delivery. Enrolled women will be purposively sampled for interviews in order to explore perspectives of the following groups: pregnant women with different home supports, age groups, number of pregnancies, positive and negative exemplars (ie, high, and low telemonitoring programme adherence) and significant results (high or low telemonitoring programme efficacy indicated by different health outcomes).[27] Separate or combined post-study interviews will also be conducted with their partners (almost always male husbands in the Pakistani culture) and/or other caregivers (eg, mother and mother-in-law) in the Urdu language, at the preference of the woman and the caregiver. The interviews with partners and the caregivers will provide insight into the sociocultural barriers and facilitators influencing pregnancy care, which can further current research reporting that the inclusion of male partners in Pakistan resulted in a substantial increase in antenatal care uptake.[34] Post-study clinicians' interviews will be conducted in English

Table 1 Areas of focus for the feasibility study and corresponding outcome measures and data sources

Area of focus	Outcome measure	Quantitative data source	Qualitative data source
Acceptability: To what extent the telemonitoring programme is judged as suitable, satisfying or attractive to pregnant women at high-risk for pre-eclampsia and their clinicians?	Patient and provider satisfaction; intent to continue to use the programme; perceived appropriateness and organisational culture fit	Data on telemonitoring system server (eg, adherence to taking measurements)	Enrolled women (n=20–25), caregivers (n=20–25) and clinicians (n=5–7) interviews
Demand: To what extent the telemonitoring programme is likely to be used?	Actual use; expressed interest and perceived demand	Research logs (eg, recruitment rate, declined participation)	
Implementation: To what extent the telemonitoring programme can be successfully delivered to pregnant women at high-risk for pre-eclampsia?	Success or failure of execution; amount and type of resources needed to implement the telemonitoring programme; efficiency, speed or quality of implementation	Research logs (eg, drop-out rate); logs of support calls (eg, technical support calls); system downtime (eg, system stability); resources (eg, costs of resources, clinical human resource required)	
Practicality: To what extent can the telemonitoring intervention be carried out with intended participants using existing means, resources and circumstances?	Positive/negative effects on patients and clinicians; ability to carry out programme activities	Paper medical records and research logs (eg, patient/provider issues)	
Limited Efficacy: Does the new telemonitoring programme show promise of being successful with the intended population	Gestational age at delivery; baby weight; maternal complications; maternal and neonatal mortality; % of babies admitted to neonatal intensive care unit; delivery mode; the number of clinic visits; perceived benefits to health outcomes; adverse events	Paper medical records (eg, an estimate of efficacy for sample size calculation): research logs (eg, reported adverse events)	

to explore the experience of the implementation of Raabta.

Interviews with enrolled women and their caregivers will be conducted in a separate room which will be identified near the outpatient area to ensure participants' privacy,[35] while the clinician interviews will be conducted in their offices. We anticipate conducting approximately 45–57 interviews (20–25 enrolled women, 20–25 caregivers and 5–7 clinicians) to achieve data saturation. All interviews are expected to last between 45 and 60 mins[36] and will be audio-recorded. The interviews will use semi-structured interview guides (online supplemental files 2, 3 and 4) and will be guided by Bowen *et al*'s framework.[33] Separate interview guides have been designed for pregnant women, caregivers and clinicians. Interviews with enrolled women will explore the overall experience of using a telemonitoring programme, while caregiver interviews will explore the influence of the telemonitoring intervention on caregiver roles and responsibilities. Clinicians' interviews will focus on identifying facilitators and barriers to implementing the telemonitoring programme. Each of these interview guides will include open-ended questions and probes to facilitate discussion.

Data analysis

Descriptive analysis will be conducted for demographic information, maternal characteristics and obstetric history including the quantitative data related to the limited efficacy focus and telemonitoring programme adherence (eg, adherence to taking the home blood pressure measurements). In addition, monthly telemonitoring adherence rates will be examined to identify any patterns in the increase or decrease of pregnant women's adherence to the telemonitoring programme over time. The metrics relevant to the Limited Efficacy focus will be compared with values the year before the launch of the Raabta programme to provide an indication if the programme is worsening, improving or having no effect on the outcome metrics. In addition, general linear mixed model procedures will be performed to determine if pregnant women's characteristics predict dependent variables (telemonitoring adherence, and measures associated with limited efficacy). General linear mixed model procedures will also be performed to determine if there are any trends toward the programme adherence predicting the efficacy of the telemonitoring programme. The statistical analyses will be performed using a statistical software application such as R (V.4.2.2). Statistical significance will be considered at $p<0.05$ unless otherwise specified.

For the qualitative data, audio recordings of the interviews will be translated into English and transcribed for two-stage data analysis. In the first stage, the interviews will

be analysed inductively using an open coding approach to capture themes and codes that provide insights into the feasibility of the programme and a future randomised controlled trial. The transcripts will be uploaded to NVivo software and analysed by two researchers independently who will later discuss the themes and subthemes until consensus is achieved. To gain a more complete understanding of the telemonitoring programme feasibility, the themes from all the interviews will be compared by the primary investigator with the help of the research team to seek convergence and corroboration through data triangulation between the enrolled women, partners, caregivers and provider interviews. In the second stage, the identified themes and subthemes will be mapped to the focus areas of Bowen's feasibility framework. The study will also highlight themes and sub-themes that were identified through inductive analysis and do not fit under the focus areas of the framework.

Finally, the qualitative and quantitative data will be merged.[28] At this stage, the integration will occur at the interpretation and reporting level, whereby we will use a joint display technique for analysing the data and presenting the integrated data.[28 37 38] The integrated data will help advance our understanding of the programme's feasibility across the five areas of Bowen's framework.[27 37] The analysis of the qualitative and quantitative data within the five foci of Bowen's feasibility framework will also help inform a future effectiveness trial of the Raabta programme.

Study timeline

The intent is to launch the mobile phone-based telemonitoring programme in April 2023. We anticipate that the recruitment of 50 pregnant women at HRPE from JPMC will take approximately 3–5 months. Pregnant women will be followed until the 42 days postpartum. Post-study interviews with enrolled women, caregivers and clinicians will be conducted in the December 2023. The primary analysis is expected to be conducted by early 2024.

Patient and public involvement

Patients and caregivers informed through interviews, the design of the Raabta programme, which is the intervention in this study, as well as the study protocol.

ETHICS AND DISSEMINATION

The research ethics board approvals have been obtained from JPMC (2022-GENL/142), the National Bioethics Committee of Pakistan (NBC-781), University Health Network (22–5220), Aga Khan University (2022-7705-22204) and the University of Toronto (43159). Informed consent will be obtained from women, caregivers and clinicians who agree to participate in the telemonitoring programme feasibility trial. Findings of the study will be disseminated to the scientific community through publications and conference presentations.

DISCUSSION

This is the first study investigating the feasibility of using a mobile phone-based telemonitoring programme in an LMIC, where pregnant women at HRPE will take their own blood pressure readings at home between antenatal visits for real-time monitoring by their clinicians. The insights gained through this study will help determine the feasibility of implementing a mobile phone-based telemonitoring programme and may help justify and guide an intended future, large effectiveness trial, as well as provide knowledge on how to implement such a programme in other LMICs and even underserved populations in high-income countries. This study could be a foundational step toward a new model of care, with the aim to lower maternal and neonatal mortality rates.

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Contributors ES and ASF conceptualised and designed the study. ASF prepared the first draft of the manuscript and revised the manuscript based on the feedback. ES, SS and ZAB critically reviewed and edited the manuscript. All authors (ASF, ES, SS, HY, ZAB) approved the final version of the manuscript.

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