Title of the project:

Addressing Provider Stress and Unconscious Bias to Improve Quality of Maternal Health Care: Caring for Providers to Improve Patient experience (CPIPE) study phase 2 in Migori County

ClinicalTrials.gov Identifier: NCT05019131

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This project is part of an NIH transition to independence (K99/R00) award. CPIPE1 was the K99 phase and CPIPE2 (this project) will be the R00 phase

Version 3.0 Sep 28, 2020

Contents

Abstract

Poor person-centered maternal health care (PCMHC) contributes to high maternal and neonatal mortality in sub-Saharan Africa (SSA), and disparities in PCMHC are driving disparities in use of maternal health services., However, little research exists on how to improve PCMHC and reduce disparities. We seek to fill this gap with this project. We propose targeting health provider stress and unconscious bias as fundamental factors driving both poor PCMHC and disparities in PCMHC. Health care provider stress and unconscious bias are important to consider because: (1) providers in low-resource settings often work under very stressful conditions; (2) unconscious bias is prevalent in every society including SSA; and (3) these factors are mutually reinforcing drivers of poor quality care and disparities in person-centered care. In the first phase of the project (CPIPE1), we conducted research to examine (1) the factors associated with PCMHC and identified provider stress and unconscious bias as key contributing factors. We also examined the levels of provider stress and unconscious bias and the types of stressors and biases in Migori County, Kenya. The results of that research will be used to inform this phase (CPIPE2), the aims of which are to: (1) design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias; (2) pilot the intervention to assess its feasibility and acceptability; and (3) assess preliminary effect of the intervention on: (a) provider knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) provider stress levels using a pretest-posttest control group design. We will use the results of the pilot to refine the intervention and develop an R01 proposal for a multi-site evaluation with a larger sample and longer follow up to assess impact on PCMHC. This study will yield valuable information to inform quality improvement efforts for PCMHC.

Lay summary

The activities described in this proposal are aimed at addressing health care provider stress and unconscious bias to improve quality of maternal health care, particularly related to the person-centered dimensions of care—i.e. care that is respectful and responsive to women's needs, preferences, and values. We focus on health provider stress and unconscious bias because they are key drivers of poor-quality care that are often not addressed in interventions designed to improve quality of maternal health care. We plan to (1) design an intervention that enables providers to identify and manage their stress and unconscious bias; (2) pilot the intervention to assess its feasibility and acceptability; and (3) assess preliminary effect of the intervention on: (a) provider knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) provider stress levels.

Introduction/Background

Of the estimated 800 pregnancy-related deaths that occur daily, about 99% occur in low- and middle-income countries (LMICs), with about two-thirds occurring in sub-Saharan Africa (SSA) alone.[1] Skilled care in health facilities is critical to reducing maternal mortality, as well as to improving neonatal outcomes. Yet, only about half of births in SSA occur in health facilities—with wide disparities, especially by socioeconomic status (SES).[2,3] For example, only 31% of women in the lowest wealth quintile in Kenya deliver in a health facility

compared to 93% among those in the highest wealth quintile. Poor Person-Centered Maternal Health Care (PCMHC) is a key factor driving both the low coverage for facility deliveries and high maternal mortality.[4–8] PCMHC refers to care that is respectful and responsive to individual women and their families' preferences, needs, and values.[9] PCMHC is an emerging concept in LMICs motivated by several studies in the last few years that have documented disrespectful, abusive, and neglectful treatment of women in facilities during childbirth.[10–13] Poor PCMHC has multiplicative effects, as it can directly lead to poor pregnancy outcomes, as well as decrease demand for services.[14,8] Yet, little research exists on effective interventions to improve PCMHC in low-resource settings like in SSA.[15,16]

High maternal mortality and morbidity in SSA: Maternal mortality and morbidity remains very high in SSA, despite progress in the last decade.[1,25] The estimated maternal mortality ratio for SSA is at a high 546 per 100,000 live births—with that of Kenya at 510—compared to about 12 per 100,000 live births in high-income regions.[25] For every woman who dies, about 20 others suffer from various disabilities.[26] These poor maternal outcomes go hand in hand with poor fetal outcomes including stillbirths, prematurity, and early neonatal deaths.[7] Various factors across the life course account for the poor MCH outcomes in SSA, hence a need for interventions across the life course. Skilled attendance at delivery is, however, critical to preventing maternal and neonatal mortality, as about three-quarters of maternal and fetal deaths occur from complications during labor, delivery, and the first 24 hours postpartum.[27] These complications are difficult to predict, but can be effectively managed and deaths averted if they are recognized and treated promptly.[27–29] Thus, there is the need for a *skilled birth attendant* (SBA)—a health professional who can identify and manage normal labor and delivery and who can identify and treat complications or provide basic care and referral—at every delivery.[27,28] In most of SSA, deliveries by SBAs only occur in health facilities.[2,3]

Poor coverage and quality of maternal health services contributing to poor outcomes: While many countries report increasing coverage for facility births, significant gaps in coverage, equity, and quality of care persists between and within countries.[30,31] For example, in Kenya, less than a third (31%) of women in the lowest wealth quintile give birth in a health facility, compared to almost all (93%) among those in the highest wealth quintile.[32] Until recently, many efforts in SSA to improve MCH outcomes focused on increasing coverage for use of MCH services. Documentation of poor quality care in many health facilities and evidence that increasing facility deliveries have not paralleled reductions in mortality have heightened attention on quality of care.[4,5,7,14,33] But efforts in SSA have focused on the technical aspects of quality of care. Fewer studies have addressed the person-centered dimensions.

The role of person-centered maternal health care: PCMHC refers to maternal health care that is respectful of and responsive to women and their families' preferences, needs, and values.[9] PCMHC thus includes system and provider responsiveness, patient-provider communication, interpersonal treatment, and related constructs.[14,8] Disrespectful, abusive, and neglectful treatment of women in facilities during childbirth reflect very poor PCMHC. Such mistreatment deters women from giving birth in health facilities.[10–13] The experience of poor PCMHC, even by a few women, leads to poor community perceptions of quality of care, which discourages many other women from delivering in health facilities.[6,34] Disparities in PCMHC are in particular driving the disparities in facility deliveries in SSA, as women of low SES, adolescents, minority tribes, and those with HIV are more likely to be mistreated and stigmatized in health facilities.[2,3,6,35] PCMHC also has direct effects on maternal and neonatal outcomes through pathways such as better clinical decision-making, improved provider-patient communication, increased adherence to treatments, and improved psychosocial health.[14,8,36,37] Poor PCMHC, therefore, leads to delayed, inadequate, unnecessary, or harmful care, minimizing health gains for both mothers and babies.[14,8]

This project seeks to extend knowledge in this area by examining two factors—provider stress and unconscious bias (UB)—that are driving poor PCMHC and contributing to disparities in PCMHC. Addressing provider stress and UB has not yet received attention in the quality of care dialogue in SSA, although it is well-

recognized that providers in SSA work under very stressful conditions and UB is prevalent in every society.[17,18] Our initial focus on these factors stemmed from the theory that disrespectful behavior towards patients results from characteristics of providers and their responses to stressful environments. Additionally, disrespect thrives in a culture that tolerates disrespect and individual biases may reinforce patterns of abuse.[19,20] Thus, in hierarchical societies where people of low status are more likely to be disrespected,[21] providers may be unconsciously mistreating women of low status. Our research in the first phase of the project provided support for this theory.[57,82] In this phase, we hypothesize that a multicomponent intervention that enables providers to identify and manage their stress and to be conscious of their biases and how their actions affect women's experiences will improve PCMHC and reduce disparities in PCMHC (Figure 2). The knowledge, skills, and the evidence from the first phase, will be used to develop this intervention. Addressing stress and UB together acknowledges both the vulnerability and the power of providers, and highlights outcomes not just for the patient, but also for the provider.

Justification for the study

Despite increasing recognition of the importance of PCMHC, little empirical research exists on effective interventions to address it in low-resource settings.[17] Two recent systematic reviews on interventions to improve PCMHC yielded only a handful of papers addressing some dimensions of PCMHC in SSA.[38,39] These interventions focus on educating women to advocate for themselves, labor support, and training providers on respectful care, and to improve patient-provider communication.[15,40] One intervention also involved working with policymakers to encourage greater focus on disrespect and abuse of women and strengthening linkages between the facility and community for accountability and governance.[40] These efforts, while important, fail to address some of the fundamental factors that may be driving poor PCMHC, particularly among poor and other marginalized groups in health facilities. This project seeks to help bridge this gap by examining two interrelated but under explored factors contributing to poor PCMHC and to disparities in PCMHC.

There are currently no evidence-based interventions to improve PCMHC in SSA that address health provider stress and unconscious bias (UB). While it is recognized that providers in SSA work under very stressful conditions, provider stress is hardly considered in interventions to improve quality of care in SSA.[17,41,42] This is even more so the case for UB, which is hardly acknowledged in this setting, although it is a prominent topic in developed settings like the US.[43–47]

Stress is the psychological and physiological response to environmental stressors.[48] Prolonged stress without adequate coping mechanisms leads to burnout, which manifests as overwhelming exhaustion, feelings of cynicism, detachment from the job, lower productivity and effectiveness, decreased job satisfaction, and reduced commitment to the job.[49,50] This leads to poor quality of care with risks to patient safety and poor attitudes towards patients.[51–53] Provider stress and burnout is also associated with poor health outcomes such as depression, cardiovascular disease, and premature mortality, and is expensive for the health system as it leads to absenteeism and high staff turnover.[49,51,54] Addressing provider stress is therefore important from a broader public health perspective, beyond improving PCMHC.[49] The potential stressors providers in SSA have to deal with are numerous: including feelings of inadequacy in the face of high maternal and newborn mortality; an overwhelming work load from staff shortages; not being able to provide best practice due to lack of drugs, supplies, and equipment; being required to manage complications beyond their competency; financial strain from poor remuneration; poor working conditions with insufficient basic resources, including scarcity of water and sanitation; and disrespectful and violent behavior from patients.[17,55,56] Disrespectful behavior towards patients is a response to these stressful work conditions.[57] Yet, few of providers have had training on how to cope or deal with stress—only about 10% of the providers we interviewed in Migori, Kenya had received any form of training on how to reduce stress.

Bias is the negative evaluation of one group relative to another. It can be explicit/conscious or implicit/ unconscious.[45] UB operates at an unintentional level and so does not require a person to endorse it or devote attention to its expression. Instead, it can be activated quickly and unknowingly by situational cues such as a person's skin color, accent, or low status clothes.[45,58] UB is prevalent in every society, although the type of biases may differ in different contexts.[18,44] In the US, where racial bias has been extensively studied, greater pro-White bias among physicians is associated with disparities in quality of care, with lower likelihood of prescribing thrombolytics for Black compared to White patients with acute coronary syndrome;[59] lower inclination to prescribe pain medications for Black versus White children;[60] and poorer ratings of interpersonal care among Black versus White patients.[43] Our work in Kenya supports the critical role of UB in PCMHC disparities by SES, age, tribe, and HIV status.[57]

The way people are treated in healthcare settings is a reflection of the broader societal norms and behaviors.[17] In societies where gender-based violence, disrespect of the poor, tribalism, and differential treatment based on SES are normative—and providers are higher in the social hierarchy than patients—providers are more likely to (unconsciously) treat patients with disrespect.[17,21] Providers are, however, more likely to be conscious of their actions and to treat patients with respect when they meet someone who challenges their social standing. Low SES women hardly challenge how they are treated, reinforcing mistreatment towards them. This supports the idea that disrespect thrives in a culture that tolerates disrespect, and individual biases may reinforce patterns of abuse.[19,20] Addressing biases against marginalized groups is especially important in Migori County given the poor status of women, the high rates of teenage pregnancy, and the high prevalence of HIV in the area.[32,61,62]

Research suggests that deeply felt biases are more likely to emerge when people are stressed.[58] In addition, interventions such as mindfulness practices have been shown to have direct effects on implicit bias as well as indirect effects through stress reduction.[63] Furthermore, addressing provider stress and UB together acknowledges both the vulnerability and power of providers, and highlights outcomes not just for the patient, but also for the provider. As a result, providers are less likely to feel blamed and more likely to support such an intervention. This research is timely, given the increasing evidence of poor PCMHC in SSA, but a lack of evidence-based interventions to improve it. It is also innovative as it addresses factors rarely considered in MCH quality improvement efforts in SSA and bridges disciplines that have traditionally worked independently. The focus on stress is particularly relevant in the current pandemic given the increasing stress providers are experiencing. The proposed intervention will be among the first, if not the first, rigorously designed and evaluated intervention to improve PCMHC that addresses provider stress and UB as underlying factors.

General Objective:

To develop and test a locally delivered intervention for addressing provider stress and unconscious bias among maternal health providers in Migori, Kenya.

The specific objectives are:

To design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias in Migori County

To pilot the intervention developed in Aim 1 to assess its feasibility and acceptability

To assess preliminary effect of the intervention on: (a) Providers' knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) Provider stress levels.

METHODOLOGY:

(a) Study site (Geographical)

The intervention will be implemented in the county hospital and one sub-county hospital in Migori County. The sub-county hospital will be selected together with the advisory board after the initial formative work. Migori County is the primary site of the Preterm Birth Initiative (PTBi)-Kenya and the site of our current project CPIPE (SERU 3682). It has eight sub-counties, each of which has a sub-county hospital. There is also one county referral hospital and several health centers and faith-based and private health facilities. There are 32 nurses, 19 clinical officers, and four doctors per 100,000 people in the county. The county population is approximately one million, with an estimated 40,000 births annually. The estimated maternal mortality ratio is high at 673 deaths per 100,000 live births compared to 495/100,000 nationally. Based on the most recent Kenya demographic and health survey, 53% of births in the county occurred in health facilities, compared to the national average of 61%.

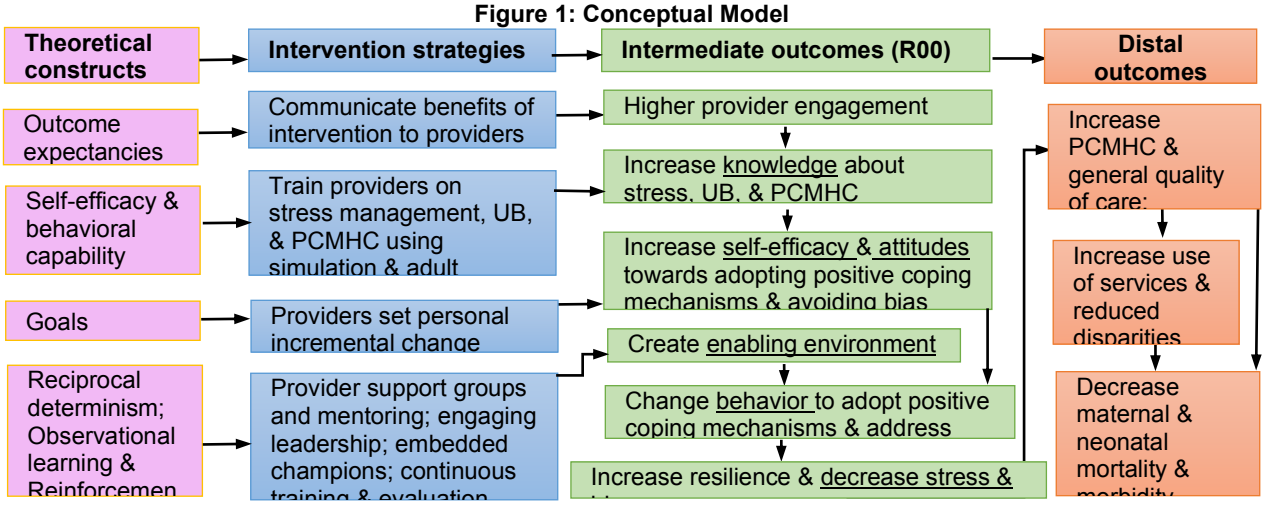
(b) Study design

AIM 1: Design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias. The intervention design will be an iterative process informed by formative research and continuous feedback in consultation with key stakeholders and experts. About 20 stakeholders including county and sub-county health officials, facility and unit heads, and different cadres health care providers will be interviewed. Qualitative research will inform the adaptation of the intervention using implementation science methodology. The intervention will be informed by the Social Cognitive Theory,[22] Trauma Informed System framework,[23] and the Ecological Perspective.[24] It will include provider training using adult learning concepts and simulation to engage providers, increase self-efficacy, and stimulate behavior change; as well as foster leadership engagement, and use of embedded champions to create an enabling environment for individual behavior change. The curriculum will be short to be taught in less than a day (to avoid taking providers away from their work for prolonged periods), but with subsequent booster sessions. It will be easy to understand and apply so that it can be taught to all cadres of health providers and disseminated using a training of trainers' approach.

AIM 2: Pilot the intervention developed in Aim 1 to assess its feasibility and acceptability: We will pilot the intervention with about 40 health workers **(doctors, clinical officers, nurses, and midwives)** in Migori County, Kenya. **In the formative phase, we will assess the feasibility and acceptability of including maternity support staff such as ward aids.** We will collect data on process measures and document all steps of the implementation process to assess feasibility and acceptability of various components of the intervention, and to assess intervention fidelity. We will use quantitative and qualitative methods to evaluate the implementation process.

AIM 3: Assess preliminary effect of the intervention on: (a) Providers' knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) Provider stress levels. We will use a *pretest-posttest control group design* with quantitative measures of

Figure 1: Conceptual Model



provider knowledge, attitudes, and behaviors related to stress and unconscious bias to assess the preliminary effect of the intervention on these intermediate outcomes (Figure 1). We will also assess preliminary effectiveness on provider stress levels using validated psychological measures of stress and biomarkers.

(c) Study populations

The main study populations are health care providers in the health facilities in Migori County

Criteria for inclusion of subjects

Providers working in maternity units of the intervention facilities
Willing and able to provide informed consent

Criteria for exclusion of subjects

Inability to attend scheduled training.

(d)Sampling

(i) Sample size determination

For the qualitative formative research, a sample size of 20 is estimated to achieve saturation. For the evaluation, we expect to enroll 80 providers, with 40 in the intervention group and 40 in control group. This is a pilot study and the sample size of 80 is based on feasibility: on an assumption that about 50% of providers in the selected sub-counties are likely to participate in the intervention. This sample size is powered (at 80%) to detect an effect size of about 0.5. The results will be used to determine the sample size for the R01 clinical trial

(ii) Sampling procedure

About 20 people, including providers and county leadership, will be recruited for the formative research which will use in-depth interviews and 80 providers for the evaluation, which will use both structured and in-depth interviews. 40 providers will be assigned to the intervention group and another 40 in the control group. Assignment will be at the facility level, based on which facilities are selected as the intervention and control facilities. Thus, all providers in the two intervention facilities will be assigned to the intervention group. Providers from other facilities will be assigned to the control group. All 80 providers will be asked to participate in the baseline and end line surveys. We will collect contact information at baseline to follow up for the end line survey for the evaluation data. Providers will be purposively selected based on their position in the facility and involvement in maternity care. Providers will include both male and female clinical and support staff such as ward aids and community health workers who assist in various roles on the ward. We will assess the feasibility and acceptability of including the support staff in the formative phase.

(e) Procedures

AIM 1 (Year 1): Design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias. We will develop a theory and evidence-based intervention that is relevant and acceptable in Kenya and can be easily implemented and scaled up. The target population for this project is health workers in maternity units as well as other support units in Migori County—the primary site of the Preterm Birth Initiative (PTBi)-Kenya and the site of my current project. We intend to build off the PTBi infrastructure including existing relationships for the next phase of the research. Given that the sources of stress are difficult to avoid in the life of a provider in a low resource setting, our approach focuses on the factors that influence the stress response—which is providers' perceptions of the stressors, coping strategies, and their general wellbeing.[48] For UB, a first step towards creating structures to minimize it is recognizing it.[18] Additionally, people have to be *concerned* about the effects of UB, to be motivated to learn when biased responses are likely to occur, and to learn how to replace biased response with responses more consistent with their goals.[64]

In CPIPE 1, we reviewed existing interventions to address stress and UB and identified some that could be adapted for Kenya. The results of the previous CPIPE1 will serve as the initial formative research for the intervention. Additionally, at the beginning of this study, we will conduct in-depth-interviews with key stakeholders including providers, hospital heads, and the county health director, as well as with experts on stress and UB, to help select and refine the intervention. This process will involve presenting potentially useful interventions identified from the literature to stakeholders and asking them to assess the interventions in terms of feasibility, relevance, and potential for impact, and to suggest changes to improve the intervention.

We will establish a local advisory board to inform this process, with a goal of developing a sense of local ownership—a critical component to the sustainability of the project. The formative research and intervention development will be an iterative process. Initial interviews will yield preliminary data to inform the type of intervention and subsequent interviews will help refine and improve the quality and acceptability of the intervention. Consistent with qualitative methods, we will use an evolving semi-structured guide, whereby information from prior interviews will inform future interviews. Interviews will be recorded, transcribed, and analyzed using thematic analysis.[65]

The formative work using qualitative methods within an implementation science framework will inform the final intervention. We will use the PRECEDE PROCEED implementation science framework, which guides the identification of predisposing, enabling, and reinforcing factors that facilitate the success of a health intervention. The intervention will also be informed by the Social Cognitive Theory (SCT),[22] Trauma Informed Systems (TIS) framework,[23] and the Ecological Perspective.[24] SCT describes a dynamic process in which personal factors, environmental factors, and human behavior exert influence upon each other (reciprocal determinism). SCT posits that, if individuals have a sense of self-efficacy, they can change their behavior even when faced with obstacles. Also, people are more likely to change if they believe the activity has benefits to them (outcome expectancy), and if there are tangible goals, positive role models (observational learning), and reinforcement.[22] These SCT constructs will inform the intervention strategies (Figure 1). For example, to decrease resistance and increase their engagement, the intervention will emphasize benefits of stress reduction and coping strategies for the provider, as well as for women and their babies. The training will also use simulation, a technique of choice in training professional teams, to evoke real life scenarios in an interactive fashion to increase self-efficacy,[66] and adult learning techniques such as self-directed inquiry.[67]

Figure 2: Ecological approach

The TIS framework recognizes stress as a source of trauma to the system, and which if not addressed leads to numbing, reactivity, depersonalization.[23,68] TIS supports "reflection in place of reaction, curiosity in lieu of numbing, self-care instead of self-sacrifice, and

collective impact rather than siloed structures."[23] Potential TIS curriculum content is included in Table 1. The curriculum will also include content on UB, PCMHC, mindfulness, quality improvement methodology, being good mentors and mentees, and developing provider support groups. We anticipate a curriculum that will be delivered within one day to avoid keeping providers away from their work for extended periods for training. Recognizing, however, that stress and UB are deep-seated and difficult to change, we will plan for shorter booster sessions that may be delivered in-person or through a mobile-based technology platform. We will assess which components are relevant and acceptable, as well as appropriate length of training in the formative research.

Training providers is important, but not enough. Thus, the intervention will employ an ecological perspective (Figure 2), which recognizes that behavior is affected by *multiple levels of influence*,[24] to create an enabling environment for individual behavior change efforts. Potential strategies at each level include: (1*) Engaging leadership* to align the goals of addressing provider stress and UB with other system goals, to increase buy in and sustainability. (2) *Using embedded champions* who will help transmit ideas, pilot changes, and inspire others to adopt the principles and practices learnt. This will be achieved with a *"Train the Trainer" approach*, with potential trainers selected from within the health system, to create a flexible and efficient model for generating embedded and sustained support. (3) *Peer Support and mentorship:* Finally, we will facilitate the formation of support groups and a mentorship program. This operates at the interpersonal level and will help increase motivation, reduce sense of isolation among providers, and provide reinforcement for individual behavior change.

Table 1: Intervention strategies

1. Training

We will develop a training for providers that addresses the following topics

- Stress & positive coping mechanisms
- Unconscious bias awareness and mitigation
- Person-centered maternity care
- Dealing with difficult situations
- Teamwork and communication; Supportive supervision
- Assertiveness; problem solving and growth mindset
- Cultural humility & responsiveness; Compassion & dependability
- Resilience & recovery; Safety & stability; Collaboration & empowerment

As part of the PTBi work in Migori, providers were introduced to simulation training for the management of obstetric and neonatal emergencies as well as teamwork and communication. We are thus working with PRONTO international to integrate new content into their curriculum that addresses the above issues. This will lead to the development of an integrated curriculum that will improve quality of care by addressing the key drivers of poor person-centered care as well as the technical aspects of care. We anticipate an initial large group training (about 20 providers per group) in a one- or two-day training followed by monthly updates provided through smaller groups such as the peer support groups.

2. Peer support and mentorship

In the formative research, we will identify what works best for these groups in terms of group composition, size, and how the groups want to interact. In addition, we will work with providers to identify mentor/mentee pairs, based on on what providers said they will like in mentorship relationships

3. Leadership engagement

To ensure leadership buy in, support and sustainability of the intervention, we will engage leadership of the County from the beginning. This will include sharing findings from CPIPE1 with them and sharing our intervention in response to the findings as well as discussing issues identified from that are beyond the capability of our study. In addition, we will invite some of

them to serve on the advisory board. We will also plan to provide periodic updates during county health management meeting for ongoing engagement.
4. Embedded champions To facilitate ongoing engagement, we will identify potential local leaders, and invite them to training where they will be taught how to facilitate peer support groups and serve as champions within their facilities

AIM 2 (Year 2): Piloting the intervention in Aim 1 to assess its feasibility and acceptability: We will implement the intervention in two high or medium delivery volume facilities in two sub-counties in Migori County. All providers working in maternity units in selected facilities and lower level facilities that refer to them will be eligible for the pilot intervention. We anticipate about 20 providers per sub-county (based on estimates from the PTBi work in Migori), giving about 40 providers in the intervention group. We will recruit health workers through letters to county, sub-county, and facility leadership, and fliers at health facilities. The ability to implement the intervention will be the first assessment of feasibility.

In addition, we will document all steps of the implementation process to assess feasibility of various intervention components, implementation challenges and successes, and lessons learnt. To assess acceptability, we will interview providers who participate in the intervention on their experiences, their assessment of its relevance, engagement, and their interest, delivery. We and satisfaction with the content and perceptions of will also interview leaders on their improvement. the intervention and suggestions for We will conduct a process evaluation to assess intervention delivery, coverage, and integrity. Proctor's framework will be used to evaluate implementation outcomes, using both quantitative and qualitative methods.[69,70] We will assess intervention fidelity—adherence, exposure, quality of delivery, competence, participant responsiveness, and program differentiation—through interviews with participants, observations, and review of project documents, logs and attendance sheets (example of measures in Table 2).[71,72]

Table 2: Potential evaluation measures
Feasibility: Challenges, successes, lessons learnt
Acceptability: Experiences with the training, assessment of its relevance, satisfaction with content and delivery, suggestions for improvement
Fidelity: Number of providers trained, number trained as trainers, number of leaders engaged, hours of training, content delivered, etc.
Knowledge: Practical questions based on the foundational learning related to stress, coping, and resilience; UB; PCMHC
Attitudes: Attitudes towards coping with stress, support for suggested changes to reduce stress and UB, IAT scores, commitment to change, and attitudes towards providing PCMHC
Behavior: Implementing coping mechanisms to reduce stress; vignettes with scenarios that may be influenced by individual bias
Stress: Psychological and biological measures of stress and burnout: e.g., Stress score-based Cohen stress scale and hair cortisol levels
Controls: *Individual*: Age, sex, education, marital status, income; position in facility, working hours per week, years of service, etc.; *Institutional:* adapted organizational climate surveys.

AIM 3 (Yrs 2&3): Assess preliminary effect of the intervention on: (a) Provider knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) Provider stress levels. We will use a pretest-posttest control group design, with the two intervention facilities matched to the two control facilities, to assess the preliminary effect of the intervention. Matching criteria will include delivery volumes and staffing capacities of the facilities, as well as other relevant factors. We will recruit about 40 providers from the selected control facilities in addition to the 40 providers in the intervention group for the evaluation (about 80 total). Randomizing individual providers is not ideal for this pilot because of a high potential for contamination. The pretest-posttest control group design allows us to address common threats to internal validity.[73] If the intervention is shown to be effective and providers in the control group wish to participate in the intervention, we will consider offering the intervention to the control group after completing the post-test. This will be decided after the implementation of the pilot.

Data management

(a) Data collection procedures and measures:

We will use or adapt existing tools as well as develop additional questions to measure provider knowledge, attitudes, and behaviors (Table 2). Given the deeply seated nature of UB, it may not change in the six-month period for the evaluation. Providers behavior may, however, change with awareness of their biases.[58,64] To measure how bias affects care, we will use the Implicit Association Test (IAT) and vignettes with different scenarios that require judgment that may be influenced by individual bias, as has been used in other studies and in CPIPE1.[59,60] We will use

the validated psychological stress measures (Cohen stress scale[74] and Shirom-Melamed

Burnout scale[75]) used in CPIPE1 to measure provider stress.[74] These measures will be included in a questionnaire and administered through surveys before and after the intervention for both the intervention and control arms. We will also measure heart rate variability (HRV) and collect hair samples before and after the intervention to analyze for hair cortisol levels. HRV is a non-invasive measure of stress, but readings are easily affected by physiological factors.[76–78] Hair cortisol, on the other hand, is a more stable measure.[79,80] It has less diurnal variation and does not require multiple samples a day. Different segments of hair will enable us to examine monthly changes in provider stress levels before and after the training.[79] We assessed the feasibility of both measures in CPIPE1. We found that although both could be obtained, it was not always possible to get hair samples from all providers because some of them have their hair cut too short. Using the two measures helps ensure we have some physiologic measure for each person. We will also collect demographic and work-related data from all participants, as well as measures of organizational climate, to control for individual and organizational factors that might explain intervention outcomes. The pretest (T1) will be right before the intervention start and the posttest (T2) in about the 6th month, with other intervention activities in the intervening period.

(b) Data collection and storage

Interviews

All data collection will occur in private spaces to ensure confidentiality during data collection. Quantitative survey data will be collected using tablets and the RedCap application and uploaded to secure UCSF servers, which will provide long-term storage for research data. This data is then downloaded and merged with other data described below for analysis. Qualitative data will be tape-recorded, and recorders stored in secured cabinets till transferred to encrypted box folders, after which data will be deleted from tapes. An experienced transcriptionist will transcribe the qualitative data, and all identifying information will be excluded from the transcription files. Only the study staff will have access to the data. All paper records, including consent forms, will be kept under lock and key with restricted access.

I*mplicit association test (IAT)*

Following each interview, providers will be asked to fill out the IAT. The IAT is a test that has been validated to measure implicit biases, and has been used in many different settings.[83,84] It measures the strength of associations between concepts (e.g., black people, poor people) and evaluations (e.g., good, bad) or stereotypes (e.g., athletic, clumsy). The main idea is that making a response is easier when closely related items share the same response key. When doing an IAT people are asked to quickly sort words into categories that are on the left and right hand side of the computer screen by pressing the "e" key if the word belongs to the category on the left and the "i" key if the word belongs to the category on the right. In this study, we will be using the IAT to examine evaluations and stereotypes based on people's socioeconomic status, which we developed as part of CPIPE 1. The IAT is programmed with a software called Inquisit Lab that stores the data generated together with a respondent ID which is entered before the initiation of the test. A spreadsheet containing the HRV by ID numbers is then downloaded from the app and merged with the survey data for analysis.

Heart rate variability

HRV will be measured using a heart rate variability monitor (polar H10 heart rate sensor) which is strapped to the chest or worn on the wrist. We will obtain 5-minute HRV measurements with the provider in the seated position. The readings are transmitted via blue tooth to a secure phone app (Elite HRV app) and a respondent ID entered for each reading. No identifying information is entered in the app. A spreadsheet containing the HRV by ID numbers is then downloaded from the app and merged with the survey data for analysis.

Hair cortisol

For the hair samples, a few strands of hair (about 30 strands which is very little and respondents will be shown picture to get a sense of what 30 strands look like) will be taken from the scalp at back of the head. The hair samples will be wrapped in foil and labelled and put in envelopes or ziplock bags, and then be stored in in a locked cabinet until transported for analysis. The Hair samples will be labeled with unique codes and stored securely until transported for hair cortisol analysis in a laboratory capable of such analysis, and appropriately disposed after the analysis. To our knowledge there is no certified lab doing the hair cortisol analysis in Kenya at the moment. Thus, we plan to take the samples to US where there are labs for such analysis. We will provide the lab with deidentified samples labelled by respondent IDs, which they will analyze and provide us with the hair cortisol levels for each respondent in a spreadsheet which we will merge with the other quantitative data for analysis.

(c)Data management and analysis plan

Aims 2&3*:* We will record all in-depth interviews and transcribe them verbatim. We will use the REDCap application to conduct the quantitative surveys. The data collected with this application is uploaded directly to a secure online server and immediately available for analysis. This will enable us to do data quality checks while the data is being collected to address any issues in a timely manner. We will ensure confidentiality of all participants in the data collection and storage.

We will use thematic analysis to analyze the qualitative data on feasibility and acceptability. We will use Braun and Clarks' approach to thematic analysis. This is an iterative process getting familiar with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report. We will use the Dedoose software for coding the data.

For the quantitative data, the merged dataset will be imported into Stata for analysis. We will examine the univariate and bivariate distributions of all variables and conduct appropriate multivariate analysis: logistic regressions for categorical outcomes and linear regression for continuous outcomes. We will use a difference in differences approach to assess intervention effects: for a given outcome, the intervention effect is the outcome change from baseline to end line for the intervention group (T2i -T1i) minus that for the control group (T2c - T1c).[73] Where applicable, we will use mediation and moderation analyses to examine intervening and conditional effects. We will use intent to treat design, which is recommended for understanding intervention effectiveness.

Ethical considerations

Ethical approvals will be sought from the KEMRI Scientific and Ethics Review Unit (SERU) and the UCSF Committee for Human Research. Furthermore, authority to carry out research will be sought from the Migori County, Department of Health and participating facilities.

Human Subjects:

"First, do no harm": We do not anticipate any harm to participants, as the risk that may be experienced is minimal. Participants may feel anxious about answering questions about stress and bias or having their physiological stress levels measured. We will train interviewers to be compassionate and sensitive.
Direct Benefit: We think participation in the intervention might benefit providers by helping them to better manage stress which can improve their work experience. However, there may be no direct, immediate benefits to participants. But, the project will provide information that may inform future quality improvement efforts that address provider's concerns. There also is no compensation for participation, as they will only receive a token—300KES in appreciation for their participation.
Informed Consent: For all participants, the interviewers will provide information about the study and obtain their written consent before initiating data collection. We will let them know that participation in the study is voluntary and will not affect their positions in any way. Participants will be given adequate information will have the option to participate in the surveys but decline to have their heart rate variability measured and or give their hair samples. Informed consent documents for interviews are attached.
Confidentiality: All data collection will occur in private spaces to ensure confidentiality during data collection. Electronic data will be stored on secured computers and UCSF servers. All paper records, including consent forms, will be kept under lock and key with restricted access.

Study limitation
A limitation of this intervention is that it does not address structural factors such as shortage of health workers and essential supplies that affect provider stress and PCMHC. These are important but beyond the scope of an individual intervention. This intervention is to help providers cope and provide better care in the midst of the structural deficiencies. It will complement efforts by government and other organizations to address the structural issues. Additionally, the problem-solving strategies learnt from the intervention will help address artificial shortages such as due unbalanced scheduling. Furthermore, reducing burnout has the potential to reduce shortages from burnout related absenteeism.

Expected application of the results
We will use the pilot data to refine the intervention and develop an R01 proposal for a rigorous multisite evaluation with a larger sample and longer follow up, to assess the effect of the intervention on PCMHC (measured from the perspective of women with the PCMHC scale).[81] If the curriculum is proven to be effective, it will be disseminated to the Kenyan Ministry of Health for continuous workforce training through refreshers and as part of the formative training for health trainees. This research will address a major gap in the efforts to improve MCH outcomes and reduce disparities.

Time frame/duration of the project
The intervention design will be in year 1, pilot testing and evaluation in year 2, and analysis and revisions for the R01 in year 3 (Figure 3).

Figure 3: Timeline for Research activities by quarter (Q)

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Formative research												
Intervention design												
Pretest												
Piloting												
Posttest												
Analysis of pilot data												

R01 preparation												
Writing & Dissemination												

Role of Investigators

Patience Afulani: Principal Investigator
Dr. Afulani is an Assistant Professor at UCSF and the recipient of this transition to independence (K99/R00) grant. She is a Ghanaian trained physician with an MPH and PhD. She will lead all aspects of the project including the scientific and administrative conduct of this award. She will lead the development of the protocol, the data collection tools, and the intervention. Additionally, she will have responsibility for data analysis and interpretation, and dissemination of the research results. Dr. Afulani will ensure ethical conduct of the research and oversee the international subcontract.

Linnet Ongeri: Co-PI
Is a mental health researcher working at KEMRI. She will serve as the site PI and point of contact for KEMRI and facilitate obtaining local approvals for the project. In addition, she supports all project activities in Kenya including helping to identify and coordinate communication with key stakeholders in Kenya, participate in planning meetings, implementation activities, and dissemination activities. As a health care professional in Kenya, she will help advocate for uptake of the intervention, if successful, to improve provider wellbeing as a means to improving quality of care.

Joyceline Kinyua: Co-investigator
She is a scientist at KEMRI. She has an MPH in epidemiology and an interest in social science research. She will support Dr. Ongeri in obtaining local approvals for the project. She will also support all project activities in Kenya including helping to identify and communicate with stakeholders and participating in planning meetings, implementation activities, and in dissemination activities.

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STATISTICAL REPORT AND ANALYSIS PLAN

Study Title: *Addressing Provider Stress and Unconscious Bias to Improve Quality of Maternal Health Care: Caring for Providers to Improve Patient experience (CPIPE) study phase 2 in Migori County* *Sep 28, 2020 V3 Protocol*
Study Acronym: *CPIPE 2*
ClinicalTrials.gov Identifier*: NCT05019131*

Summary

Poor person-centered maternal health care (PCMHC) contributes to high maternal and neonatal mortality in sub-Saharan Africa (SSA), and disparities in PCMHC are driving disparities in use of maternal health services., However, little research exists on how to improve PCMHC and reduce disparities. We seek to fill this gap with this project. We propose targeting health provider stress and unconscious bias as fundamental factors driving both poor PCMHC and disparities in PCMHC. Health care provider stress and unconscious bias are important to consider because: (1) providers in low-resource settings often work under very stressful conditions; (2) unconscious bias is prevalent in every society including SSA; and (3) these factors are mutually reinforcing drivers of poor quality care and disparities in person-centered care. In the first phase of the project (CPIPE1), we conducted research to examine (1) the factors associated with PCMHC and identified provider stress and unconscious bias as key contributing factors. We also examined the levels of provider stress and unconscious bias and the types of stressors and biases in Migori County, Kenya. The results of that research will be used to inform this phase (CPIPE2), the aims of which are to: (1) design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias; (2) pilot the intervention to assess its feasibility and acceptability; and (3) assess preliminary effect of the intervention on: (a) provider knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) provider stress levels using a pretest-posttest control group design. We will use the results of the pilot to refine the intervention and develop an R01 proposal for a multi-site evaluation with a larger sample and longer follow up to assess impact on PCMHC. This study will yield valuable information to inform quality improvement efforts for PCMHC.

General Objectives: To develop and test a locally delivered intervention for addressing provider stress and unconscious bias among maternal health providers in Migori, Kenya.

Specific objective

1. To design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias in Migori County
2. To pilot the intervention developed in Aim 1 to assess its feasibility and acceptability
3. To assess preliminary effect of the intervention on: (a) providers' knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) provider stress levels.

Target Population: Health care providers and support staff in maternity units in health facilities in Migori County.

Inclusion criteria: All providers working in maternity units, inclusive of clinical staff (nurses, midwives, doctors, clinical officers) and support staff (nurse aides, cleaners), in the selected study facilities in Migori County

Exclusion criteria: Intend to leave study facility within intervention period; and Inability to participate in intervention activities.

Study Design: A *pretest-posttest non-equivalent control group design*

Number of Participants: 80 participants in total; 40 from control health facilities and 40 from intervention facilities.

Study aims

AIM 1: Design a multicomponent theory and evidence-based intervention that enables providers to identify and manage their stress and unconscious bias. The intervention design will be an iterative process informed by formative research and continuous feedback in consultation with key stakeholders and experts. About 20 stakeholders including county and sub-county health officials, facility and unit heads, and different cadres health care providers will be interviewed. Qualitative research will inform the adaptation of the intervention using implementation science methodology. The intervention will be informed by the Social Cognitive Theory,[22] Trauma Informed System framework,[23] and the Ecological Perspective.[24] It will include provider training using adult learning concepts and simulation to engage providers, increase self-efficacy, and stimulate behavior change; as well as foster leadership engagement, and use of embedded champions to create an enabling environment for individual behavior change.

AIM 2: Pilot the intervention developed in Aim 1 to assess its feasibility and acceptability: We will pilot the intervention with about 40 health workers (doctors, clinical officers, nurses, and midwives) in Migori County, Kenya. In the formative phase, we will assess the feasibility and acceptability of including different cadres of health providers. We will collect data on process measures and document all steps of the implementation process to assess feasibility and acceptability of various components of the intervention, and to assess intervention fidelity. We will use quantitative and qualitative methods to evaluate the implementation process.

AIM 3: Assess preliminary effect of the intervention on: (a) Providers' knowledge, attitudes, and behaviors related to stress and unconscious bias; and (b) Provider stress levels. We will use a *pretest-posttest non-equivalent control group design* with quantitative measures of provider knowledge, attitudes, and behaviors related to stress and unconscious bias to assess the preliminary effect of the intervention on these outcomes. We will also assess preliminary effectiveness on provider stress levels using validated psychological measures of stress and biomarkers.

The Statistical Analysis Plan below pertains to Aim 3/objective 3.

Definition of Study Variables

a. Primary outcomes

We have four primary outcomes; 1) perceived stress, 2) burnout, 3)Stress knowledge, and 4) unconscious bias knowledge and attitude score. These variables are described in box 1

b. Secondary outcomes

We also have four secondary outcomes: 1) Hair cortisol levels, 2) Hair rate variability, 3) IAT, and 4) explicit bias score. A brief description of these outcome variables are provided in Box 2.

Box 1: Study Primary outcome measures	
Perceived	The 10-item Cohen Perceived Stress Scale (PSS) on people's feelings and thoughts

Stress	in the past month.[3] The PSS has undergone substantial testing for validity and reliability in different populations including in the study setting.[4–7] These questions capture how nervous or stressed, unpredictable, uncontrollable, and overloaded respondents find their lives; response scales are 0 (never) to 4 (very often). Summative scores will be created after recoding all response to the same direction. Scores range from 0 to 40; higher scores indicate higher perceived stress.
Burnout	The14-item Shirom-Melamed Burnout Measure (SMBM) on feelings at work in the past month.[8] The SMBM has undergone psychometric testing in various populations with strong evidence for its validity and reliability in the study setting. [4–6,8–10] Questions capture three domains: physical fatigue, emotional exhaustion, and cognitive weariness, with responses ranging from 1 (never or almost never) to 7 (always or almost always). Mean scores will be generated and will range from 1 to 7; higher scores indicate higher burnout.
Stress knowledge and attitudes	A 14-question knowledge of stress and stress management assessment adapted from existing questions.[1] Each multiple-choice question has one correct answer; responses will be coded into binary (right or wrong) and summed to create a composite stress knowledge score. Scores range from 0 to 14; higher scores indicate higher stress knowledge.
Unconscious bias knowledge and attitude	A 17-question assessment of unconscious bias adapted from existing questions [2]. Each multiple-choice question has one correct answer; responses will be coded into binary (right or wrong) and summed to create a composite implicit bias knowledge and attitude score. Scores range from 0 to 17; higher scores indicate higher implicit bias knowledge.

Box 2: Secondary outcome measures

Hair cortisol levels	Hair cortisol reflect cumulative secretion of cortisol within the hair growth period, with high levels indicative of chronic or sustained stress.[11,12]We will obtain hair samples from providers who have enough hair (at least 2cm long) and willing to provide hair samples. Hair samples will then be processed to obtain cortisol levels. There are no specified cut-offs for cortisol levels, but, on average, higher cortisol levels indicate higher stress.
Hair rate variability	HRV is a measure of the beat-to-beat interval between consecutive heart beats to estimate cardiac vagal tone.[13,14] HRV will be measured using the CorSense finger monitor by Elite HRV,[15] and the natural log of the root mean square of successive differences in RR intervals (lnRMSSD) calculated.[13] The LnRMSSD reflect parasympathetic nervous system activity. Higher LnRMSSD is thus more adaptive and associated with relaxation and calm states, while low levels are associated with anxiety, high stress, and burnout [14,16].
IAT	Two situationally specific vignettes assessing providers' perceptions of women's PCMC expectations and behaviors based on SES [17,18]. One vignette describes a woman with low SES and the other vignette a high SES woman; vignettes were read in counter-balanced orders to providers and followed by 8-questions assessing providers' perceptions of the woman's expectations for introductions, consenting, companionship, potential to cooperate, understand explanations, and exaggerate pain; and provider behavior needed to convey seriousness and gain patient cooperation. The vignettes and questions were informed by measurement of explicit bias in prior literature [19,20] and prior research in this setting [21–23,19,20]. Response options

	range from strongly disagree to strongly agree on a 4-point scale. Summative scores are created after recoding all responses to the same direction; higher scores indicate higher bias towards the woman in the vignette. Scores range from 0 to 27. *Cronbach alpha for the 8 items in the study sample at baseline was 0.70 for the low SES vignette and 0.80 for the high SES vignette.*
Explicit bias score.	Situationally specific vignettes assessing providers' perceptions of women's PCMC expectations and behaviors based on SES will be used to measure explicit bias [17,18]. One vignette describes a woman with low SES and the other vignette a high SES woman; vignettes were read in counter-balanced orders to providers and followed by 8-questions assessing providers' perceptions of the woman's expectations for introductions, consenting, companionship, potential to cooperate, understand explanations, and exaggerate pain; and provider behavior needed to convey seriousness and gain patient cooperation. The vignettes and questions were informed by measurement of explicit bias in prior literature [19,20] and prior research in this setting [21–23,19,20]. Response options range from strongly disagree to strongly agree on a 4-point scale. Summative scores are created after recoding all responses to the same direction; higher scores indicate higher bias towards the woman in the vignette. Scores range from 0 to 27..

Statistical Methods

Number of subjects planned to be enrolled: About 80 providers will enrolled.

Justification of Sample Size

The sample size of 80 is based on feasibility: on an assumption that about 50% of providers in the selected facilities are likely to participate in the intervention. This sample size is powered (at 80%) to detect an effect size of about 0.5. The length of the pilot study might, however, be too short to see such an effect size. Thus, the pilot is likely not powered for formal significance testing. The effect size estimates from the pilot will be used to inform the sample size estimation for the R01 trial.

Description of the study

Characteristics of study facilities

We will provide a summary table showing the capacity of each maternity unit in terms of beds, number of deliveries per year, and number of providers for in different cadres: doctors, clinical officers, nurses/midwives, and other staff.

Table 1: Characteristics of Study facilities

Facility	Maternity Bed capacity	Deliveries Per year	Number Providers in Maternity Unit			
			Doctors	Clinical Officers	Nurses/ midwives	Support staff

Baseline characteristic of the study participants

We will provide a summary of participants characteristics by study group. The summary will be presented in Table 2

Table 2: Baseline characteristic of the study participants

Characteristics	**Category**	**Control (N=40)**	**Intervention (N=40)**	**P value**
		Frequency (%)	**Frequency (%)**	

Analysis of primary outcomes at baseline and endline for control and intervention groups

We will generate descriptive statistics (both mean with standard deviation, and median with the range) to understand the distribution of each of the outcome variable at both baseline and end line for control or intervention groups. We will use a Wilcoxon paired signed-rank test to determine whether changes in the outcome measures are different between baseline and endline for control or intervention group. These results will be presented in a Table 3.

Table 3: Estimates of primary outcomes at baseline and endline

Outcome measure	Statistic	Overall estimates		P
		Baseline	End line	
Control Group (N=40)				
Intervention Group (N=40)				

We will then use a difference in differences approach to assess intervention effects: For a given outcome, the intervention effect is the outcome change from baseline to end line for the intervention group (T2i -T1i) minus that for the control group (T2c - T1c).

Analysis of secondary outcomes at baseline and endline for control and intervention groups

We will adopt a similar analysis plan like for the primary outcomes in sections **5.3 and 5.4**. Briefly, we will generate descriptive statistics to understand the distribution of these outcomes at both baseline and end line for control and intervention groups, and we will use a Wilcoxon paired signed-rank test to determine whether changes in the outcome measures are different between baseline and endline for the control or intervention groups. We will finally use a difference in differences approach to assess intervention effects.

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