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Impact of a two-way short message service (SMS) to support maternally administered childhood mid-upper arm circumference monitoring and expand malnutrition screening in Kenya: the Mama Aweza trial protocol

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ABSTRACT

Introduction Over 52 million children under 5 years of age become wasted each year, but only 17% of these children receive treatment. Novel methods to identify and deliver treatment to malnourished children are necessary to achieve the sustainable development goals target for child health. Mobile health (mHealth) programmes may provide an opportunity to rapidly identify malnourished children in the community and link them to care.

Methods and analysis This randomised controlled trial will recruit 1200 children aged 6–12 months at routine vaccine appointments in Migori and Homa Bay Counties, Kenya. Caregiver–infant dyads will be randomised to either a maternally administered malnutrition monitoring system (MAMMS) or standard of care (SOC). Study staff will train all caregivers to measure their child's mid-upper arm circumference (MUAC). Caregivers in the MAMMS arm will be given two colour coded and graduated insertion MUAC tapes and be enrolled in a mHealth system that sends weekly short message service (SMS) messages prompting caregivers to measure and report their child's MUAC by SMS. Caregivers in the SOC arm will receive routine monitoring by community health volunteers coupled with a quarterly visit from study staff to ensure adequate screening coverage. The primary outcome is identification of childhood malnutrition, defined as MUAC <12.5 cm, in the MAMMS arm compared with the SOC arm. Secondary outcomes will assess the accuracy of maternal versus health worker MUAC measurements and determinants of acute malnutrition among children 6–18 months of age. Finally, we will explore the acceptability, fidelity and feasibility of implementing the MAMMS within existing nutrition programmes.

Ethics and dissemination The study was approved by review boards at the University of Washington and the Kenya Medical Research Institute. A data and safety monitoring board has been convened, and the results of the trial will be published in peer-reviewed scientific journals, presented at appropriate conferences and to key stakeholders.

Strengths and limitations of this study

► This is a large randomised controlled trial.
► Cell phone ownership and literacy in Kenya is high, suggesting that Kenya is an ideal setting to test mobile health (mHealth) programmes.
► The study population (children aged 6–18 months) are entering a period of childhood when the incidence of malnutrition is high.
► The maternally administered malnutrition monitoring system mHealth intervention cannot be blinded.
► Generalisability may be limited by exclusion of caregivers without access to a phone, or those who cannot read or write or do not have someone who can help them read or write, as well as those that are not able to complete mid-upper arm circumference training.

INTRODUCTION

Childhood wasting is a critical driver of paediatric mortality that must be addressed to achieve global child health targets.[1–4] Over 52 million children become wasted each year, costing the global economy an estimated $2.1 trillion annually.[1 5] Provision of ready-to-use therapeutic foods and nutritional counselling in the community is a highly effective method of preventing deaths among wasted children.[6–10] However, UNICEF estimates that only 17% of all children with wasting receive treatment.[11] Even in areas with active community-based management of acute malnutrition (CMAM) programmes, the mean treatment coverage is estimated

to be 38%.[12] Among children who are treated, the diagnosis of wasting is often made late in their disease when the risk of complications and death increases from 2.5% to 16%.[11 13 14] Increasing the coverage and frequency of nutritional screening to identify children with wasting earlier in the disease process is a critical step toward achieving global child health goals.

Studies from Niger have shown that caregivers can measure mid-upper arm circumference (MUAC) effectively, and that this leads to earlier identification of malnutrition in comparison to active and passive screening conducted by field workers.[15 16] However, developing a generalisable strategy to deliver caregiver MUAC training and provide support to parents while their child is most vulnerable, remains a challenge. Mobile health (mHealth) platforms capitalise on the proliferation of mobile phone coverage across low-resource settings and create efficient and reliable connections between families and healthcare providers. mHealth interventions have demonstrated effectiveness at increasing clinic attendance and health-relevant knowledge,[17] and supporting patients in accessing proven interventions such as facility delivery, exclusive breastfeeding, family planning, antiretroviral therapy, pre-exposure prophylaxis, early identification of neonatal and infant illnesses and peripartum depression care.[18–21]

The Mama Aweza trial aims to establish the efficacy and feasibility of a novel malnutrition screening approach called the maternally administered malnutrition monitoring system (MAMMS), in which caregivers attending immunisation clinics are taught to use MUAC tapes and are enrolled in a semiautomated mHealth short message service (SMS) system that provides health education and MUAC monitoring support in the 6 months following enrollment. The overarching aim is to improve early identification and linkage to care for malnourished children.

METHODS AND ANALYSIS
Objectives
Mama Aweza is a randomised controlled trial in western Kenya training caregivers to measure their infant's MUAC. The specific objectives are to:

1. Determine if MAMMS leads to earlier identification and recovery from childhood wasting (defined as MUAC <12.5 cm).
2. Demonstrate the accuracy of maternal administered MUAC assessments compared with trained field worker, and the ability of repeated maternal administered MUAC measurements to monitor early childhood growth.
3. Evaluate the acceptability, feasibility and fidelity of MAMMS relative to standard of care (SOC) nutrition programmes.
4. Determine the relationship between sociodemographic and health characteristics and childhood acute malnutrition.

Locations
The study will recruit caregiver–infant pairs in western Kenya at the Migori County Referral Hospital, Nyatike Sub-County Hospital and Isebania Sub-County Referral Hospital and Homa Bay County Referral Hospital. Kenya has an endemic level of moderate acute malnutrition (MAM, defined as weight-for-height z-score <−2, MUAC <12.5 cm if ≥6 months of age or nutritional oedema) among children under 5 years of age, with Migori County having an estimated MAM prevalence of 2%.[22] Due to the low prevalence of MAM, Migori County has not been prioritised in the national strategic plan for tackling malnutrition,[23] and consequently the coverage of local nutritional programming is low.

Eligibility
We aim to recruit 1200 caregiver–infant pairs attending clinic for 6-month and 9-month immunisations. Eligible children must have an MUAC between 12.5 and 14.0 cm.

Criteria for exclusion of caregiver–infant pairs:
► Infant is younger than 6 months or older than 12 months of age.
► Infant is currently on or requires treatment for malnutrition.
► Inability to provide a mobile phone number.
► Caregiver cannot read or write and does not have someone to help them read or write.
► Caregiver does not plan to reside in the catchment area (Migori County) for >6 months.
► Caregiver unable to complete MUAC measurement training.
► Previously enrolled in the study.
► Child's sibling or other household member is currently or was previously enrolled in the study.

Screening and recruitment
Caregivers of infants aged 6–12 months attending 6-month and 9-month immunisations will be identified by study staff. During this period of childhood, the incidence of childhood wasting begins to increase while engagement with routine medical services often wanes, suggesting this is a high-risk population for missed diagnoses of childhood wasting. Caregivers will be given a brief overview of the study and will provide verbal consent prior to formal screening. A screening log will capture all caregiver–infant pairs attending clinic for 6-month and 9-month immunisations and document reasons for exclusion. Eligible caregiver–infant pairs will be provided with full details of the study in their chosen language (English, Kiswahili, Luo, Kuria) and written consent will be obtained.

Enrollment and follow up
Consenting caregivers will be interviewed by study staff to capture the child's and caregiver's social, demographic, medical, obstetric, nutritional and household status. Contact information and household location will be recorded to facilitate home visits and participant tracing

for missed visits or for active screening visits in the SOC arm. Anthropometric measurements will be obtained in duplicate from all infants and caregivers (weight, length and MUAC). Caregivers and infants without a documented HIV test result will be referred for voluntary counselling and testing per Kenya National Guidelines. Newly diagnosed caregivers and HIV-exposed children will be referred to comprehensive care clinic (CCC) at each site for HIV care and treatment services.

After completion of the enrollment form, study staff will deliver a 10–15 min standardised training to caregivers on measuring their child's MUAC, using an insertion MUAC tape colour coded and numbered to 1 mm gradations. The field worker and caregivers will then measure a child's MUAC independently of each other. This validation serves as the first comparison between caregiver and field worker MUAC accuracy. Caregivers who do not pass the validation check, defined as a difference of ≥0.05 cm between the field worker and caregiver's MUAC measurement, will be provided further instruction. Satisfactory completion of the MUAC training will be defined as MUAC measurements of <0.05 cm difference between the caregiver and the field worker, using their own infant and/or other infants of similar age at the facility. Any caregiver not able to satisfactorily complete the MUAC training after receiving a second training will be excluded from the study.

To assess MAMMS feasibility and acceptability, caregivers who successfully complete MUAC training will be asked a series of short open-ended questions to assess their confidence in measuring MUAC and taking action on observed measures, their confidence that the tool can accurately assess the nutritional status of their child and their plan for how to integrate the tool into their household routine. These questions will be repeated at the 180-day visit to assess changes to the acceptability and feasibility of the MAMMS model associated with increased exposure to the MAMMS.

Randomisation

After completion of procedures above, including the MUAC training, each caregiver–infant dyad will be randomised to MAMMS (n=600) or SOC arms (n=600) (figure 1). Randomisation allocation codes have been generated by the study biostatistician using random block sizes. Allocation codes will be placed in sequentially numbered and sealed envelopes by participant ID. A subset of 33% of participants in the MAMMS arm will be further randomised to a 'colour and number' subgroup in which caregivers are asked to text both the colour and numeric value of their child's MUAC measurement. The remaining 67% only return the colour of their child's MUAC.
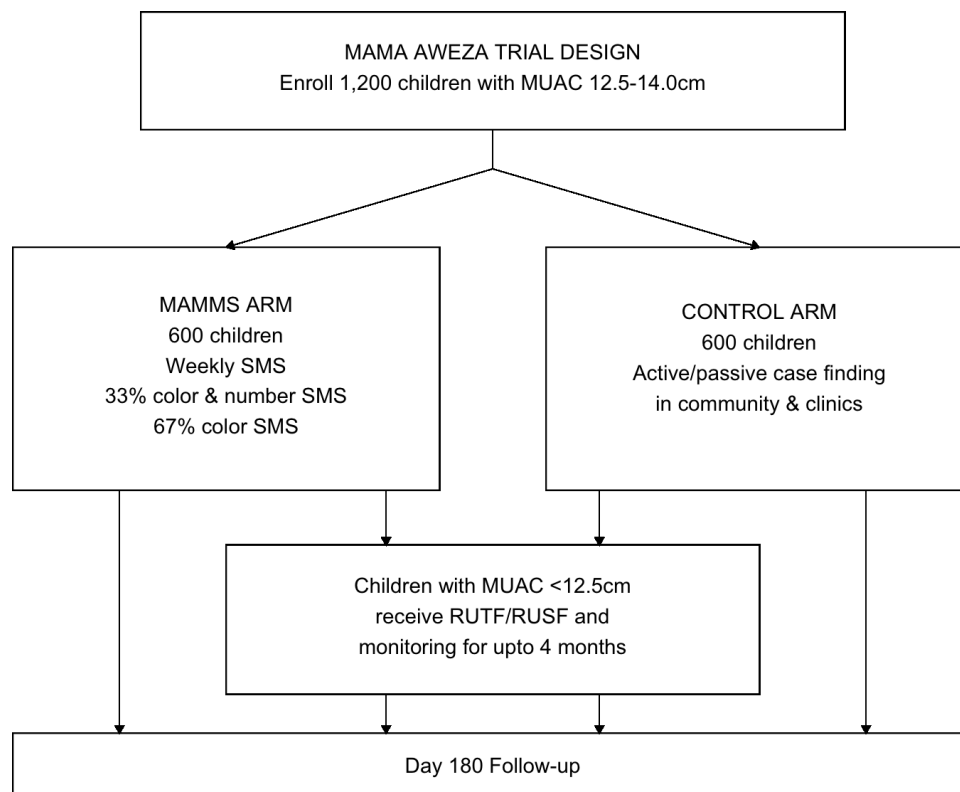

Figure 1 Randomisation schema for the MAMMS trial. Colour SMS request the caregiver sends the colour (green, yellow, red) of their child's MUAC, while colour and number requests that they send the colour and numeric value of the MUAC measurement. MAMMS, maternally administered malnutrition monitoring system; MUAC, mid-upper arm circumference; RUSF, ready-to-use supplementary food, RUTF, ready-to-use therapeutic food; SMS, short message service.

Table 1 Study flow for the intervention and standard of care arms

	MAMMS	SOC
Enrollment (study day 0)		
Screening for inclusion at maternal child health clinic	X	X
Enrollment questionnaire	X	X
Training on MAMMS, nutritional education and MUAC monitoring	X	X
Validation or mothers MUAC measurement versus fieldworkers	X	X
Randomisation	X	X
Intervention (study day 1–180)		
Returns home with MUAC tapes	X	
Weekly two-way SMS including age-specific health messages	X	
Wasting confirmation visit if MUAC <12.5 cm or colour yellow/red reported	X	
Quarterly study home visits to complement routine CHV visits		X
Routine medical services, including CHV home visits	X	X
Standardised management and follow-up if wasted*	X	X
Study conclusion (study day 180)		
Day 180 visit, study end unless still in malnutrition treatment follow-up	X	X
Acceptability and feasibility questionnaire and interviews	X	X

*Children will be followed for up to 4 months after diagnosis of wasting to assess their duration of treatment, indicating that maximum possible study follow-up would be 10 months if a child were diagnosed at the day 180 visit and followed for an additional 4 months.
CHV, community health volunteer; cm, centimeters; MAMMS, the maternally administered malnutrition monitoring system; MUAC, mid-upper arm circumference; SMS, ahort message service; SOC, standard of care.

Intervention

Caregivers randomised to the MAMMS arm will be provided with two colour coded insertion MUAC tapes, numbered to 1 mm gradations and enrolled in the mHealth platform. The mHealth platform sends a weekly automated SMS including a health education message and a request for the caregiver to respond with either the colour or the colour and numeric value of their child's MUAC measurement (table 1). Study staff will review all messages from caregivers and respond by either assuring the caregivers that the measurement appears to be normal or scheduling a clinic visit for any child whose MUAC is reported to be either <12.5 cm or in the yellow section of the tape.

The health education and support messages sent to caregivers in the MAMMS arm were developed from previously validated messages and new messages relevant to this age group.[18–20 24] The topics and content of these message were based on UNICEF's Guidance on Childhood Development and the Integrated Management of Childhood Illness recommendations,[25 26] and tailored to the cultural setting through a two stage consultation process. The first stage engaged with clinical and community workers and the second stage consisted of five focus group discussions (FGDs) with caregivers attending immunisation clinics at Migori County Referral Hospital. Final topics include education regarding developmental milestones, sanitation and hygiene practices, timing of vaccinations, the utility of a kitchen garden, prevention of malaria, recognition of fever, home management of diarrhoea,

recognition of ear infections and danger signs of severe infection. To avoid altering the underlying incidence of malnutrition in the MAMMS arm, messages concerning breastfeeding and nutrition were omitted. Messages have been translated into local languages (Kiswahili, Luo and Kuria) and caregivers will select their preferred language. Receipt of study SMS and messages sent to the MAMMS incur no cost to study participants.

SOC arm

Caregiver–infant dyads randomised to the SOC arm will receive the same MUAC training and nutritional education as caregivers in the MAMMS arm. To simulate the current 'gold standard' CMAM programme, both active and passive malnutrition identification will be conducted to identify children with the outcome (acute malnutrition defined as MUAC <12.5 cm as measured by a trained health professional) in the SOC arm. Active case identification will mirror community outreach programmes in which door-to-door nutritional screening is conducted by community health volunteers. To accurately simulate community outreach programmes, no SMS messages will be sent to the caregiver prior to these quarterly visits.

For passive case identification, study staff will work with hospital staff at each study site to monitor hospital admissions and identify any children in the SOC arm that are admitted to the paediatric ward. In such cases, nutritional status will be ascertained at the time of hospital admission. Passive identification will be strengthened by instructing caregivers to present to the study staff if they believe their

child requires hospitalisation, after which study staff will escort the caregiver to hospital staff to ensure the child receives proper clinical attention. To capture information on admission to non-study site hospitals or receipt of malnutrition diagnosis at a different health facility, we will ask the caregiver whether the child was admitted to a paediatric ward or received a diagnosis of malnutrition at the day 180 visit. If a hospitalisation or malnutrition diagnosis occurs, a field worker will visit the appropriate clinic or hospital and ascertain a copy of the patient's notes and confirm the diagnosis of malnutrition.

Post-randomisation day 180 visit

Caregiver–infant dyads in both study arms will return to clinic 180 days after enrollment. At day 180, study staff will obtain anthropometric measurements (weight, length and MUAC) and administer a standardised questionnaire to ascertain the child's current condition, any malnutrition diagnosis since enrollment and other illnesses and hospitalisations. Caregivers in the MAMMS arm will be asked to measure their child's MUAC to serve as a comparison with day 180 MUAC measurement taken by study staff. All participants will receive an SMS reminder prior to their scheduled day 180 visit. If the caregiver–infant dyad does not return at their scheduled time, study staff will attempt to contact the caregiver via mobile phone. If the caregiver cannot be reached, staff will trace the child to the household within 10 days of the scheduled visit. Caregivers in the MAMMS arm will complete an evaluation to determine acceptability of caregiver-led MUAC and optimal timing of SMS requests for MUAC measurements.

MUAC validation monitoring

Caregivers who report (via SMS) acute malnutrition (MUAC <12.5 cm) will be phoned by study staff and asked to attend clinic for confirmation of the child's status and treatment initiation, as needed. During the clinic visit, the trained field workers will measure and record the child's MUAC. The field worker MUAC validation will be used to evaluate the accuracy of the caregiver's report (via SMS) of their child's MUAC. All children with confirmed acute malnutrition (MUAC <12.5 cm) will be offered treatment in accordance with national guidelines. Any child identified with medical complications will be taken to the paediatric ward. If the caregiver is found to have reported an erroneous MUAC measurement they will be retrained. All contacts with study participants will be captured on a standardised study visit form to be reported in the primary manuscript. Data from these wasting confirmation visits will be complemented by MUAC validation data comparing the caregiver and field worker MUAC measures at enrollment and study discharge.

Outcomes assessment

The primary outcome of the study is time to diagnosis of acute malnutrition, defined as MUAC <12.5 cm as measured by a trained health professional. In the MAMMS arm, a trained field worker will confirm the child's MUAC when the caregiver has reported, via SMS, a MUAC <12.5 cm. In the SOC arm, children with MUAC <12.5 cm will be identified during home visits conducted by a trained field worker (as part of standard active screening), by clinical staff at hospital admission or during routine active or passive screening conducted by the county nutritional services. For the latter scenario, we will identify malnutrition diagnosis through personal communication with the county nutritionists and confirm the diagnosis through review of the child's medical notes during hospitalisation or clinic visit. Any child identified with acute malnutrition will be offered treatment according to national guidelines. Children in the MAMMS and SOC arms will receive the same nutritional treatment. Study staff will follow the clinical progress of these children for 4 months after identification of malnutrition to ascertain treatment recovery. Both arms will be sent SMS messages to remind them to pick up supplementary foods and return to the clinic for treatment follow-up visits. If a child recovers from malnutrition and is discharged from treatment within the 180-day follow-up period, they will continue with their regularly scheduled day 180 visit.

Acceptability, feasibility and fidelity

We will evaluate the acceptability, feasibility and fidelity of the MAMMS using a mixed-methods assessment of caregiver and nutritional programme worker experiences. Prior to programme launch, we conducted five FGDs with caregivers attending the immunisation clinic at Migori County Referral Hospital to understand baseline perceptions of mHealth programmes, child nutrition and healthcare preferences. These FGDs informed the design of a short questionnaire that will be administered to caregivers at enrollment as well as intervention design. Additionally, all caregivers in the MAMMS arm will be asked a series of questions at study completion (180 days) that will quantify key indicators of participant satisfaction, tool acceptability, appropriateness and feasibility. Caregivers in the SOC arm will be administered a short questionnaire at study completion to assess their satisfaction with SOC procedures, and desired level of engagement in nutritional monitoring of their children in the future.

At study completion, a subset of caregivers from each study arm will be invited to participate in summative FGDs. Participants will be randomly sampled from the pool of caregivers, with six to ten caregivers in each FGD. Eight FGDs will be conducted with two FGDs for each of the following (1) MAMMS participants whose child did not develop acute malnutrition, (2) MAMMS participants whose child became acutely malnourished, (3) SOC participants whose child did not develop acute malnutrition and (4) SOC participants whose child became acutely malnourished during the study. We will also conduct in-depth interviews with nutritional staff currently active at the study sites. Individual interviews will be conducted with purposively sampled health volunteers, including

10 community health volunteers, two nurses, three nutritionists and two nutrition programme managers. The individual interviews will be used to access health worker perceptions of the MAMMS model, potential barriers to sustaining or scaling the programme and opportunities to improve the programme moving forward. All FGDs and interviews will be conducted in the preferred local languages by a trained qualitative researcher and audio recorded for subsequent analysis.

Time-and-motion studies will be used in both arms to assess the personnel and beneficiary time and resources associated with each nutritional monitoring platform. During each MUAC validation visit in the MAMMS arm, study personnel will ask caregivers how much time they spend measuring and sending their child's MUAC each week. The opportunity costs of nutrition staff and caregivers in the SOC arm will also be assessed during time-and-motion studies to determine the amount of time that community members and health volunteers expend to deliver routine nutrition monitoring. A random sample of community visits in the SOC arm will be selected for inclusion in the time-and-motion study, during which project staff will accompany nutrition staff to monitor time and resources expended per activity. In both study arms, time-and-motion studies will be used in health facilities to assess time expenditures on caring for acutely malnourished children identified by the study.

Data collection

All data will be collected on standardised case report forms administered by trained study staff. The data will be held locally and uploaded to the secure central UW-KEMRI server housed at the University of Washington. This will be overseen by a data management team. Access to the study database will be password protected and restricted to study staff and investigators.

Provisions for data verification and validation

The data will be managed in accordance with Good Clinical Practice and Health Insurance Portability and Accountability Act requirements. The data management system, such as REDCap, will maintain an audit trail. Data queries will be generated on a weekly basis, and resolved by study staff, with an audit trail archive retained within the study's document management system. Implementation of the trial protocol and data validity will be monitored by an independent local trial monitor.

Sampling and analysis

Based on documented immunisation records across sites, we anticipate 133 children to attend 6-month and 301 to attend 9-month immunisations per month. Thus, we expect to enrol approximately 40 children per month across the study sites to reach the target enrollment of 1200 children in 12–14 months. Caregiver–infant pairs will be randomised to MAMMS (n=600) or SOC (n=600) following enrollment.

The total sample size was calculated to detect a difference in identification of acute malnutrition between randomisation arms, assuming 80% power and alpha=0.05. We require 553 children in each arm to detect a twofold increase in malnutrition identification, with a cumulative incidence of 4% identified malnutrition in children in the SOC arm.[22] This incidence rate is based on prevalence to incidence conversion formulas and assumes that we will identify 50% of children with acute malnutrition in the SOC arm. Thus, while the true incidence of acute malnutrition is expected to be 8%, the incidence of malnutrition detected in the SOC arm will be 4%. To account for loss to follow-up, we will recruit an additional 47 per group (94 total) for a total planned enrollment of 600 per arm (1200 total). Children who develop malnutrition will be followed for an additional 4 months from diagnosis of acute malnutrition and recovery rates will be compared between randomisation arms. Assuming 4% (n=24) malnutrition in SOC and 8% (n=48) malnutrition in MAMMS, we will have 80% power to detect a 43% increase or decrease in duration of treatment.

Primary analyses will be intent-to-treat (ITT) based on randomisation allocation to MAMMS or SOC arms. Reasons for exclusion will be clearly documented in the final analysis. To ensure randomisation was successfully balanced between arms, baseline characteristics will be compared using a χ^2 test for dichotomous variables and Mann-Whitney U test for continuous variables. While we anticipate successful randomisation to result in no important baseline differences between arms, should we identify any chance imbalance in baseline characteristics, we will evaluate these variables as potential confounders in a sub-analysis secondary to the ITT analysis. To determine whether the MAMMS arm can identify acute malnutrition earlier than the SOC arm, we will use Cox proportional hazard regression models to conduct a time-to-event analysis, with acute malnutrition being the event. An interim analysis will be conducted when 50% of the target sample size has completed the study.

To demonstrate the accuracy of maternal-led MUAC measures compared with trained field workers, and the ability of repeated maternal MUAC measurements to monitor early childhood growth, with a sample size of 553 in the MAMMS arm (accounting for attrition) at two time points (wasting confirmation visit and study conclusion), and conservatively assuming a weak correlation of r=0.35 between maternal and field worker MUAC measures, we will have 80% power at an alpha=0.05 to detect a 0.10 difference in correlation using a Fisher's z test. Assuming a moderate correlation of r=0.60, we will have at least 80% power to detect a 0.071 difference in correlation between maternal and field worker MUAC measures. Due to the exploratory nature of the phenotypic MUAC trajectories to predict acute malnutrition, we do not have preliminary data for a sample size calculation.

To evaluate the acceptability, feasibility and fidelity of MAMMS relative to SOC nutrition programmes, the sample size for the qualitative data collection is based on

the ability to reach data saturation by the re-emergence of key themes across data sources, time and resources. If we are not able to reach data saturation using the pre-specified sample sizes for FGDs and individual interviews, an additional four FGDs and three individual interviews will be conducted to ensure comprehensiveness and representativeness of the qualitative data. In this study, intervention fidelity is defined according to three categories: (1) treatment delivery, (2) treatment receipt, and (3) technology acceptance. Fidelity to treatment delivery will be measured as the proportion of messages that are successfully delivered to a participant's mobile phone (based on automated tracking). Fidelity to treatment receipt will be measured as the proportion of delivered messages that are responded to as well as average monthly changes in responsiveness over time (ie, attenuation). Fidelity to technology acceptance will be measured as the proportion of caregivers who come to health facilities when messaged to do so as well as the proportion of caregivers who report a continued interest in participating in the MAMMS intervention during endline acceptability assessments. All measures of fidelity will be stratified by mobile phone ownership and caregiver literacy. Serious adverse events, defined by death or hospitalisation, will be recorded to help assess feasibility and any unintended negative consequences of study enrollment will be reported. The effect of seasonality will be explored in all analyses that will be conducted. Missing data will be handled by imputation if appropriate.

Patient and public involvement

Prior to study initiation, key stakeholders were informed of the study, including the study sites and surrounding communities, and the Ministry of Health. Community sensitisation builds on the existing nutritional programme in Migori county, and will be undertaken through a community advisory board.

Ethics and dissemination

The study protocol received ethical approval from the University of Washington and the Kenya Medical Research Institute (SERU 3821, V.1.4, 24 January 2020), and will be overseen by an independent data and safety monitoring board comprised of experts in paediatrics, nutrition programme implementation, and trial methodology. Study progress and results will be shared with key stakeholders through local and international meetings throughout the study. The primary manuscripts will be published within 2 years of study completion, alongside the dataset and statistical code required for replication. No patients or public were involved in designing this trial.

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