Caregiver screening for relapse using mid-upper arm circumference among children recovered from severe acute malnutrition

Manual of Operations and Procedures

Centre de Recherche en Santé de Nouna

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ABBREVIATIONS

CHW: Community Health Worker
CSPS: Centre de Santé et de Promotion Sociale
DSMC: Data and Safety Monitoring Committee
HAZ: height-for-age z-score
IRB: Institutional Review Board
MUAC: mid-upper arm circumference
SAM: severe acute malnutrition
SD: standard deviation
UCSF: University of California San Francisco
WAZ: weight-for-age z-score
WHO: World Health Organization
WHZ: weight-for-height z-score

1. INTRODUCTION

1.1 Background and Rationale

Severe acute malnutrition (SAM) affects nearly 19 million children under the age of 5 annually.[1] In 2013, the World Health Organization (WHO) revised guidelines for the treatment of SAM to include community-based outpatient management for children with uncomplicated SAM.[2] These community-based management programs typically include screening by community health workers using mid-upper arm circumference (MUAC) tapes, clinic-based screening using both MUAC (< 11.5 cm) and weight-for-height Z-scores (WHZ < -3 SD), and outpatient treatment. Children who are admitted to the outpatient nutritional program are offered a package of ready-to-use therapeutic food (RUTF), antimicrobials, and vaccinations if missing. The major goal of these programs is to induce rapid, acute weight gain in children to improve probability of survival during the acute episode. Children are followed every other week until nutritional recovery, typically for several weeks to months.

"Nutritional recovery" is based on arbitrary thresholds, and there are limited guidelines for following children post-discharge. Recovery is determined based on achievement of WHZ ≥ -2 and/or MUAC ≥ 12.5 cm with no edema for at least two weeks. Children who achieve these thresholds may still have considerable anthropometric deficits or be moderately acutely malnourished (MAM) but no longer have access to the package of interventions to support recovery in children with SAM, which may lead to relapse. Children who have recovered from SAM have high risk of relapse, with up to 40% of children relapsing post-discharge[3], and children with MAM have high risk of progressing to SAM.[4] The WHO recommends that children who have recovered from SAM be "periodically monitored to avoid a relapse"[2], but provides little further guidance.

Despite a high incidence of relapse, most interventions for SAM are focused on the acute phase of recovery. While interventions prioritizing rapid weight gain have led to improved survival for children with SAM[5], prevention of relapse to SAM after recovery is essential to improve long-term outcomes for children beyond survival. Caregivers have been successfully trained to screen for new-onset SAM in community-based settings and perform as well as community health workers for detecting SAM.[6] Here, we propose a pilot randomized controlled trial in which caregivers will be trained to screen their children post-discharge for relapse based on MUAC criteria to facilitate timely identification and referral to care for children who have relapsed.

1.2 Objectives

SPECIFIC AIM 1: Determine the feasibility of training caregivers to screen for relapse among children recovering from SAM compared to standard of care for early detection of relapse and re-entry to care. *We hypothesize that relapse will be detected earlier in children whose caregivers have been trained to screen for relapse compared to standard of care (no caregiver screening).*

- **Specific Aim 1A: Determine the burden of post-discharge relapse among children recovered from an episode of SAM in Boromo, Burkina Faso.** *We hypothesize that >25% of children who have recovered from SAM in the study facilities will relapse within a 6-month period following their discharge.*
- **Specific Aim 1B: Determine the acceptability and feasibility of training caregivers to screen for relapse after discharge among children recovered from SAM.** *We hypothesize that caregivers will find MUAC screening acceptable and that training them will be feasible, as*

demonstrated by time and costs for training, willingness to participate in training, and follow-up in the trial.

SPECIFIC AIM 2: Determine the accuracy of caregiver-based screening for relapse among children recovering from SAM compared to a gold standard anthropometrist. *We hypothesize that caregiver screening will have a sensitivity and specificity of > 80% for the detection of relapsed SAM (MUAC < 11.5 cm) compared to screening by a trained anthropometrist.*

2. STUDY DESIGN

We propose a 1:1 randomized pilot trial in which caregivers will be trained to screen their children who have recovered from an episode of SAM using MUAC tapes. Children aged 6-59 months with a documented recovery from uncomplicated SAM that was managed in a participating outpatient nutritional program and their caregivers will be eligible for inclusion in the trial. Caregivers will be trained to screen their children weekly for 6 months following discharge from the nutritional program and will be counseled to bring their child back to the nutritional program should their MUAC value fall in the red zone of the MUAC tape (< 11.5 cm). All children will receive a home visit 6 months after they are discharged from the program, and will receive anthropometric measurements (weight, height, MUAC) and referred for care if needed.

2.1. Study Area and Enrollment Facilities

Study Area

This study will be in Boromo District, Burkina Faso. Boromo is in central Burkina Faso and experiences a large burden of SAM annually. The study will be conducted in 10 Centre de Santé et de Promotion Sociale (CSPS) in Boromo, 6 of which participated in our previous study of antibiotics for SAM.

Enrollment Facilities

Primary care facilities typically provide outpatient treatment of common childhood illnesses, vaccination clinics, and antenatal and maternity care. Each facility hosts a nutrition clinic 1-2 days/week during which children are screened and receive care for uncomplicated SAM on an outpatient basis. Children with a clinical complication requiring inpatient treatment are referred to the local district hospital for treatment. Children in the outpatient nutritional program receive weekly follow-up care. Children who relapse will be re-enrolled in the outpatient nutritional program and will receive all components of the outpatient SAM package as part of the trial.

2.2. Recruitment and Eligibility Criteria

Recruitment

Each participating enrollment site will be assigned at least one dedicated study team member who will enter data and conduct outcome assessments. The study team member will be either an existing member of enrollment site staff who will be trained for the study or an external study team member who will be placed at the site for the duration of the study.

This study personnel will review the site logbook and/or medical records every day to identify children who are potentially eligible for participation. The study team will approach the parent or guardian of potentially eligible children to confirm eligibility according to the criteria listed below.

Eligibility criteria for enrollment sites

For inclusion in the study, sites must meet the following criteria:

1. Willing to participate in the study.

2. Participation approved by the district.

Eligibility criteria for individuals

Caregiver-child dyads will be eligible for inclusion in the study if they meet the following criteria:

Inclusion criteria (all must be met):

- Caregiver's aged 18 years old or older or a legal guardian or a relative aged 18 or older
- Child aged 6-59 months
- Child has recovered from an episode of SAM per Burkinabè national guidelines (WHZ ≥ -2 and/or MUAC ≥ 12.5 cm in the past month, with the criterion used for admissions corresponding to the original admission criteria)
- Family is planning to stay in the study area for 6 months
- Appropriate consent from the caregiver or guardian.

Exclusion criteria (any excludes):

- Caregiver age under 18 years old, or legal guardian or relatives under 18 years old
- Child age < 6 months or > 59 months
- Twins/multiple births and children with feeding issues
- Did not recover from SAM in the past month
- Family is planning to move out of the study area in the next 6 months
- Caregiver or guardian refuses to provide consent

Eligibility criteria for staff participants

A study team member who will be placed at the site during the study period will approach the clinic staff to confirm eligibility according to the following criteria:

Inclusion criteria:

- Staff work as a staff member in the nutritional program or work as the chief of the CSPS
- staff or chief of the CSPS consents to participate

Exclusion criteria:

- Staff does not work as a staff member in the nutritional program or does not work as the chief of the CSPS
- Staff or chief of the CSPS refuses to provide consent to participate

2.3. Randomization and Masking

Enrolled caregiver-child dyads will be randomized in a 1:1 allocation without stratification or blocking. The randomization sequence will be generated by the UCSF data team and implemented by the Burkinabè study team. Given the nature of the intervention, UCSF and CRSN investigators, participants, and study team members implementing the intervention will not be masked to allocation. Nutritional program personnel who evaluate children returning for relapse after SAM and study personnel conducting the final 6-month home visit will be masked

to the intervention arm. Data analysts conducting the primary outcome analyses will be masked to allocation.

2.4. Standard of Care

The standard of care arm will include usual care provided to children who have recovered from SAM in outpatient primary care clinics in Burkina Faso. Regardless of their anthropometric measurements, children who have recovered from SAM are enrolled in a moderate acute malnutrition program for three months. Caregivers are requested to bring their child once a month for anthropometric measurements and nutritional counseling. In practice, default rates during the nutritional program and after discharge are high; an aim of this pilot study will be to understand how often caregivers of children who have recovered from SAM return to the clinic as part of routine care and to understand opportunities for strengthening post-discharge care for children who have recovered from SAM.

2.5. Intervention

Caregivers randomized to the caregiver screening arm will undergo a brief training with a study staff member at the time of discharge of their child from the outpatient nutritional program. Each caregiver will be given a standard color-coded MUAC tape and will be trained to return to the clinic for further work up if their child has a red (SAM, MUAC < 11.5 cm) measurement. Caregivers will be instructed to measure their child's MUAC weekly for 6 months. Children of caregivers in the caregiver screening arm will also receive all components of the usual care package in the standard of care arm previously described.

2.6. Outcomes

Acceptability Outcomes. Acceptability outcomes will focus on the acceptability of integrating caregiver screening for relapse as part of discharge from the nutritional program from both the caregiver and clinic perspectives. We will use a mixed methods approach including quantitative surveys of caregivers and in-depth interviews with caregivers in the MUAC screening arm and nutritional program staff.

- **Caregiver acceptability.** At the 6-month visits, caregivers will complete a quantitative survey related to their experiences screening their children for relapse. This will include ease of use, frequency with which caregivers screened their children, whether the MUAC tape was lost or stolen, and quantitative measures of the importance caregivers place on screening their children for relapse and whether this is a priority for them in the context of other demands in their lives. At baseline and at the 6-month visits, caregivers will complete a quantitative survey related to their mental well-being. This will include questions about depression and anxiety. A subset of 20 caregivers will be invited to participate in depth qualitative interviews, which will focus on probing more deeply on caregivers' concerns with regards to malnutrition and their child's health, and whether they found training on screening empowering.
- **Clinic acceptability.** To understand acceptability of MUAC-based screening at the clinic level, we will conduct in-depth interviews with key stakeholders, including nutritional program staff and clinic leadership. We will explore themes related to ease of implementation of the intervention and time for training.

Feasibility Outcomes. Feasibility outcomes will be focused on establishing criteria allowing for implementation of a full-scale efficacy trial as well as implementation of the caregiver screening intervention into the existing health system. Outcomes will include:

- **Proportion of recovered children who relapse.** We will assess the proportion of children who relapse over a 6-month period post-discharge from the nutritional program. This endpoint will allow for assessment of enrollment potential in a full-scale trial as well as document the burden of relapse in this population.
- **Time to conduct MUAC training.** To understand burden on clinic staff, we will measure the time training takes in the caregiver screening arm.
- **Adherence to the follow-up protocol.** We will measure adherence to the relapse follow-up protocol in both the standard of care arm and the caregiver screening arm. Rates of default from outpatient nutritional programs are high in Burkina Faso. By measuring how often children who have been discharged in the standard of care arm return for scheduled follow-up visits, we aim to understand gaps in care and identify opportunities for improving linkage to post-discharge care for SAM. Measuring adherence to the caregiver screening protocol will enhance understanding of acceptability and feasibility of the intervention.

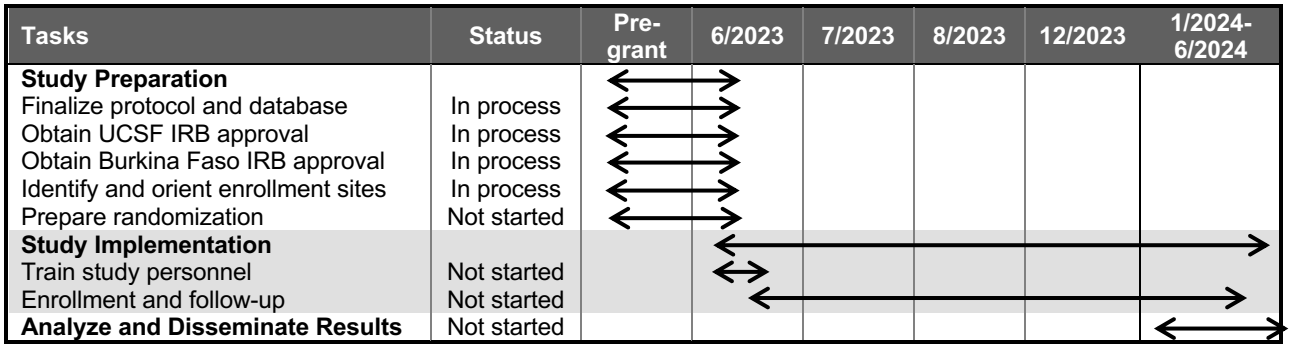
Clinical Outcomes. Assessment of clinical outcomes will inform sample size calculations for a full-scale efficacy trial. Although the trial will be underpowered to detect significant differences in clinical outcomes, we will pre-specify by-arm comparisons to inform design of the full-scale trial

- **Time to detection of relapse.** We will measure time to relapse in both study arms. Children enrolled in the study who return to the clinic, regardless of study arm, will be identified based on the study sticker in their government-issued health card. We have used this method for studies enrolling >50,000 children in Burkina Faso. A study staff member will record the date of relapse and all anthropometric measurements in the study's electronic data capture system.
- **Anthropometric outcomes.** We will measure weight, height, and MUAC at the final 6-month study visit, as well as at each clinic visit that the child makes during the study period. We will use these measurements to calculate WHZ, weight-for-age Z-score (WAZ), and height-for-age Z-score (HAZ) according to 2006 WHO standards. Weight will be measured using a Seca 874 floor scale and height will be measured using a Shorrboard. Anthropometric measurements will be taken in triplicate, with the median used for analysis.
- **Vital status.** Vital status (died, alive, unknown) will be recorded for each child in the study at the time of the 6-month visit, or earlier if the study team learns that an enrolled participate has died. The date of death with be recorded for children who die and a verbal autopsy form will be completed.
- **Hospitalization.** Caregivers will be interviewed at the 6-month visit and asked to report any hospitalizations their children have had during the study period. We will also query hospital records to identify study children who have been hospitalized.

Accuracy Outcomes. Accuracy of caregiver screening will take place as part of the training in the caregiver screening arm. Each caregiver will measure the child's MUAC on their right arm, and the measurement will be recorded in the study's mobile data application by the trainer. Separately and in a masked fashion, the gold standard anthropometrist will measure the MUAC of the child's right arm and record the measurement. The data will be linked by a unique identification number in the child's health card. We will calculate agreement using MUAC as a continuous variable as well as overall accuracy (true positives + true negatives / all positives + all negatives), sensitivity (true positives / true positives + false negatives), specificity (true negatives / true negatives + false positives), positive predictive value (true positives / true positives + false positives), and negative predictive value (true negatives / true negatives + false negatives) for moderate acute malnutrition (MUAC ≥11.5 cm and < 12.5 cm).

2.7. Participant Timeline

Figure 1. Participant Timeline and Flow

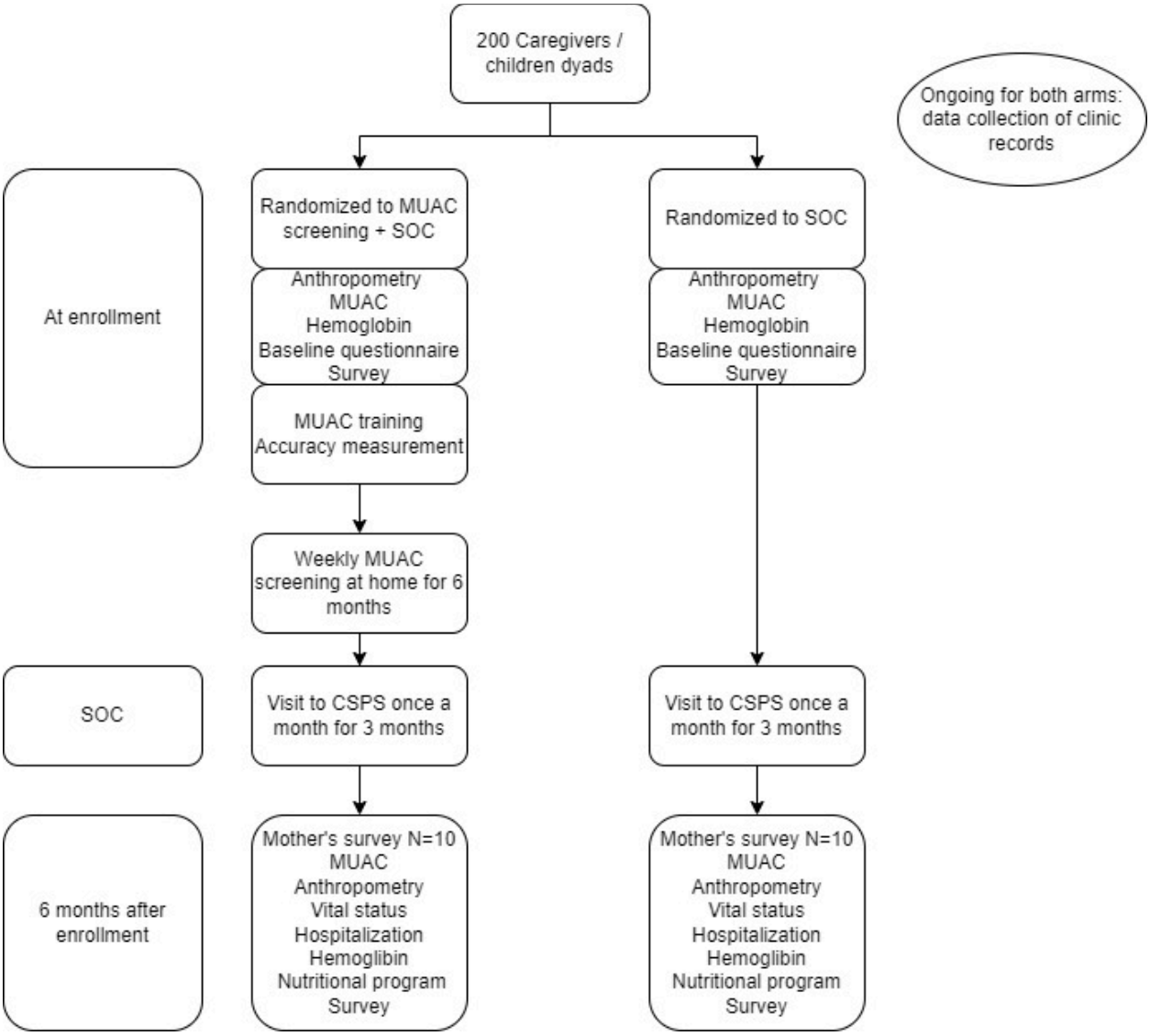


2.8. Study Team, Roles, Responsibilities

- **Investigators (UCSF)**. The investigator will coordinate all study activities, including creating and maintaining all study protocols, obtaining ethical approvals from institutional review boards, designing and implementing trainings for study procedures, and monitoring study progress.
- **Investigators (CRSN).** The CRSN investigator will be responsible for overall study implementation, provide support and monitoring of all study activities for the duration of the study. The Burkina Faso investigator will oversee all local study activities, including training and regular supervision and monitoring of local study staff.
- **Nutritional program staff.** The nutritional program staff will be responsible for evaluating children returning for relapse after SAM.
- **Study personnel (CSPS).** Study personnel at CSPS will be responsible for conducting the final 6-month home. The study personnel will implement all study procedures including recruitment, consent, enrollment and randomization, and collection of all study data, including anthropometric and outcome assessments.
- **Data and Safety Monitoring Committee.** The Data and Safety Monitoring Committee will provide independent oversight of data quality and patient safety during the trial.

3. PROCEDURES

Procedure table



3.1. Training of study personnel

All study personnel participating in study procedures (including enrollment and baseline assessment, randomization, outcome assessments, and data collection) will participate in a 2-day initial training. Participants must achieve a score of >80% on the training quiz to participate in the study and demonstrate agreement with a gold standard grader for all anthropometric assessments.

3.2. Caregiver's training

All caregivers enrolled in the study and randomized to “caregiver screening” will be briefly trained on how to do MUAC measurement.

Trainers
The personnel training the caregivers will be study personnel trained previously on how to train / educate caregivers.

Timing for training
Training will need to be brief and shouldn’t exceed 10 minutes. Time to complete training will be measured.
Caregivers will be trained individually at enrollment.

Training
Supports for training will be used to make sure training is the same for all caregivers.

Training will include:
- Introduction to MUAC: Caregivers will be introduced to what MUAC is, why it is important, and how it is measured. This will be done through simple and easy-to-understand language and demonstrations.
- Training on Measuring MUAC: Caregivers will be trained on how to measure MUAC accurately using a MUAC tape. The training will emphasize the importance of proper technique, measurement accuracy, and what to do regarding colors on the tape.
- Practice Sessions: Caregivers will have the opportunity to practice measuring MUAC under the guidance of trained study personnel. This will help them gain confidence in their skills and ensure that they are measuring correctly.

When to measure MUAC:

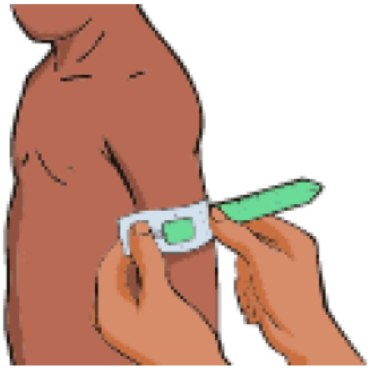
We will ask caregivers to measure MUAC once a week. The day of the measurement will be decided individually with the caregivers of the children enrolled.

Supports for training.

MUAC measurements:

Mesurer le périmétre brachiales
toutes les semaines

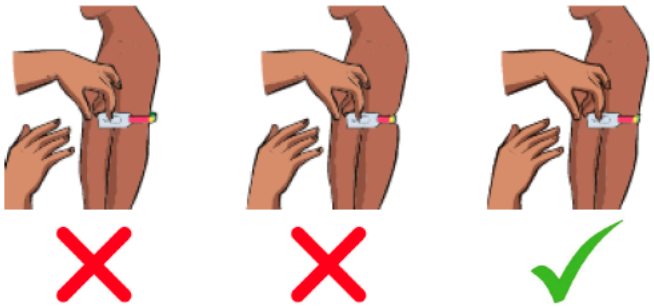
1- Faire glisser la bandelette autour du bras de l'enfant jusqu'au milieu



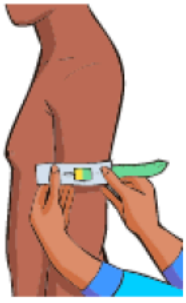
2- Le bras pend le long du corps relaché, serrez la bandelette contre la peau

Attention: pas trop lache, il faut que la bandelette touche la peau

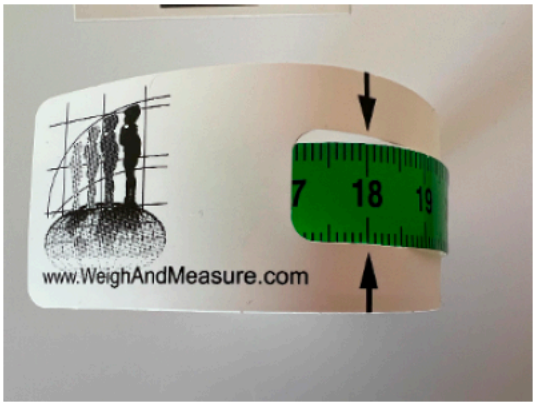
Pas trop serré, il ne faut pas que la bandelette pince la peau

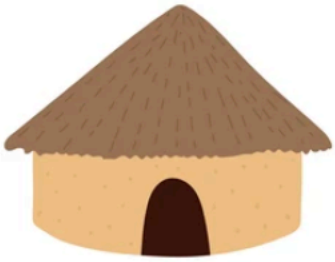


3- Regardez la couleur dans la fenêtre entre les 2 flêches
pour identifier le statut nutritionnel de l'enfant



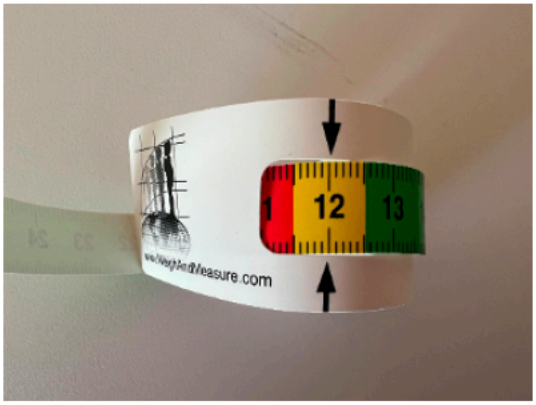
What to do regarding MUAC





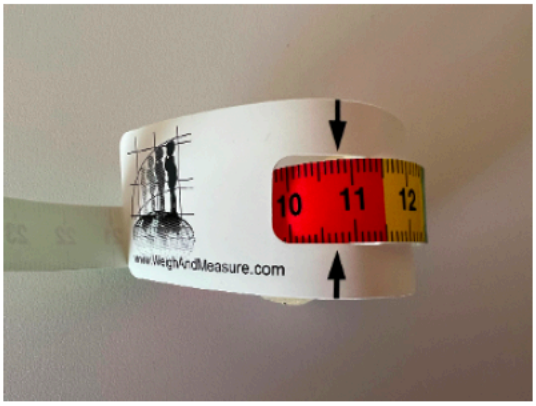
Restez à la maison

Mesurez dans 1 semaine





Allez à la clinique





Allez à la clinique

Accuracy measurement

After training, an accuracy measurement will be performed:

- Caregivers trained will be asked to measure MUAC on a different child than the one they practiced on.
- 1 CSPS personnel will be designated to measure MUAC on the same child

- The study personnel responsible of training the caregivers will record electronically measurements made by the caregiver and the CSPS personnel.

Questionnaires

A series of questions will be asked at Baseline, at each clinic visits during the study period and at the 6 month follow up visits.

Baseline
Information from caregivers and from clinic record will be collected. The information collected will include:
- Clinic records: admission criteria in the nutritional program
- Clinical examination information, anthropometric measurements, and hemoglobin
- Demographic of caregivers
- Child's prior medical history regarding SAM prior admission
- Feeding practice and food insecurity
- Caregiver mental status

Clinic visits
Each time a child will visit the clinic during the 6-month study period, anthropometric measurements and nutritional status of the child will be extracted from the clinic records.

6-month visit

The 6-month visit will be the last one. Information collected during this visit will include:
- Clinical examination: anthropometric measurements, hemoglobin
- Child medical history in the last month and during the study period
- Feeding practices and food insecurity
- Caregiver's mental status
- Caregiver's impression on MUAC measurement to assess for feasibility.

Interviews

Caregivers in the screening group

At the 6-month visit, a study team staff will interview the caregiver focusing on probing more deeply on the caregiver's concerns with regards to malnutrition and their child's health, and whether they found training on screening empowering. The interview will be audio recorded.

Clinic staff

At the 6-month visit, a study team staff will interview the clinic staff to explore themes related to ease the implementation of the intervention and time for training. The interview will be audio recorded.

3.3. Anthropometry

Anthropometric assessments (height or length, weight, and MUAC) will be recorded by study personnel at baseline, at each clinic visit during the study period, and at the final 6-month study visit.

Materials

- Mobile data collection device & accessories
- ShorrBoard
- Seca scale
- MUAC strips
- Chucks and alcohol swabs
- Pens and sharpie markers
- Trash bags
- Extra set of AA batteries (6)

Anthropometry Team

Two study team members will conduct anthropometry: 1) examiner and 2) recorder. The examiner will conduct the anthropometric assessments, and the recorder will enter data into the mobile application.

Measuring Length and Height

A lightweight measuring board will be used to measure the participant's height to the nearest 0.1 cm. Height and length will be assessed with a ShorrBoard. Depending on a child's age and ability to stand, measure the child's length or height.

- **Length:** If a child is less than 2 years old, or cannot stand alone, measure recumbent length. The recorder will select **Length** in the application to indicate that length was measured. A child's length is measured lying down (recumbent).
- **Height:** If a child is able to stand, measure standing height. The recorder will select **Height** in the application to indicate that height was measured. Height is measured standing upright.

If the child has braids or hair ornaments that will interfere with length/height measurements, remove them if possible. Check that any sandals, shoes, or socks have also been removed. Whether measuring length or height, the caregiver/guardian is needed to help with measurements and to soothe and comfort the child. Explain to the caregiver the reasons for the measurements and describe the steps in the procedure. Answer any questions she might have. Show her and tell her how she can help you. Explain that it is important to keep the child still and calm to obtain the best measurement.

ShorrBoard Set-Up

1) Remove ShorrBoard from bag.
2) Stand the ShorrBoard upright. You can step on the base of the board to keep it stable.
3) As you face the board, turn the non-removable bolt counterclockwise to release the extension piece. Note: the bolt remains attached to the back of the extension piece – do NOT remove it.
4) Slide the extension piece into the top end of the main board and fasten the clasp on the back of the board. Make sure the clasp is fastened properly.
5) The auto-lock sliding head/footpiece is stored in the base of the main board and can be moved up and down the length of the measuring board. It should stay in place on its own wherever you position it.
6) The measuring board must be placed against a firm surface for standing height (e.g. wall, table, tree, against a vehicle, etc.). Make sure the board is stable. If necessary, place items such as small rocks underneath the height board to stabilize it during the measurement.
7) Clean the equipment with alcohol swabs at the beginning of each day, and clean with alcohol swabs between each participant.

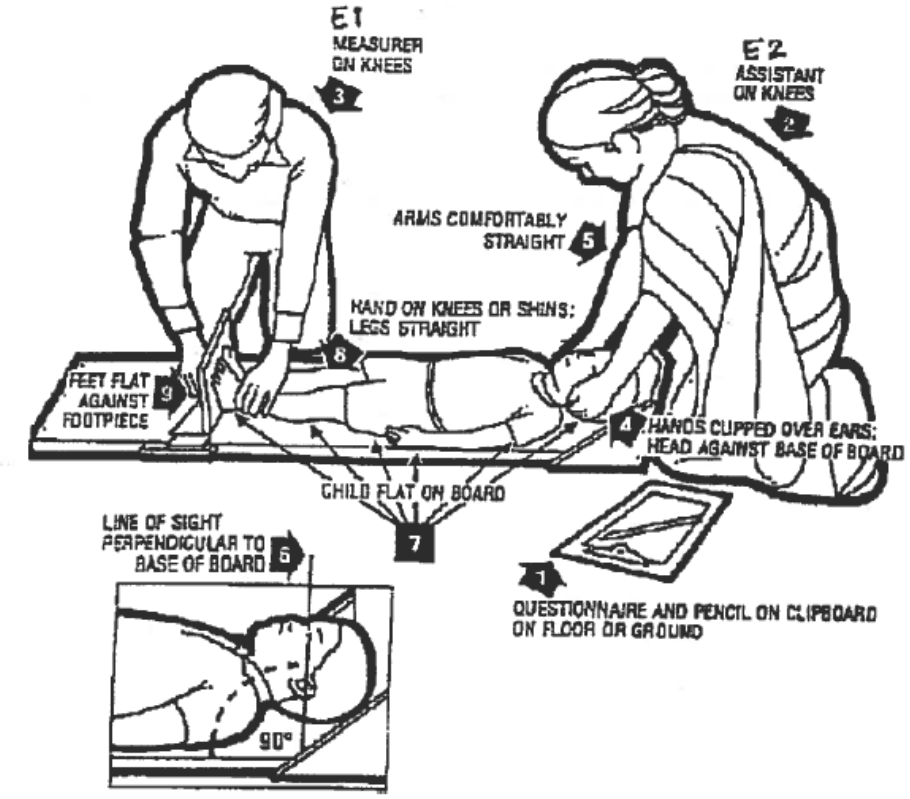
Note: when you set up the board each day, examine each of the pieces to check for damage.

Measure Length

1. Cover the length board with a chuck for hygiene and for the baby's comfort.
2. We usually have the assistant anthropometrist hold the baby's head and the lead anthropometrist manage the legs and feet. The caregiver stands to the side and focuses primarily on soothing the baby. The lead anthropometrist calls out the measurement and the assistant repeats it and then records it on the tablet.
3. Ask the caregiver to stand nearby and focus on soothing the baby.
4. The assistant anthropometrist will place the baby on the length board on his/her back with his/her head fixed against the headboard, compressing the hair and will hold the baby's head in place while the measurement is taken. The assistant should move quickly and surely without distressing the baby.
5. The assistant anthropometrist will quickly position the head so that an imaginary vertical line from the ear canal to the lower border of the eye socket is perpendicular to the board. (The child's eyes should be looking straight up.)
6. **Speed is important.** The lead anthropometrist will manage the baby's legs and feet. Standing on the side of the length board where you can see the measuring tape and move the footboard:
    a. Check that the child lies straight along the board and does not change position.
    b. Shoulders should touch the board, and the spine should not be arched. Ask the caregiver to inform you if the child arches the back or moves out of position.
    c. Hold down the child's legs with the one hand and move the footboard with the other. Apply gentle pressure to the knees to straighten the legs as far as they can go without causing injury or distress. **Note: it is not possible to straighten the knees of newborns to the same degree as older children. Their knees are fragile and could be easily injured, so apply only gentle pressure.**
    d. If a child is extremely agitated and both legs cannot be held in position, measure with one leg in position.

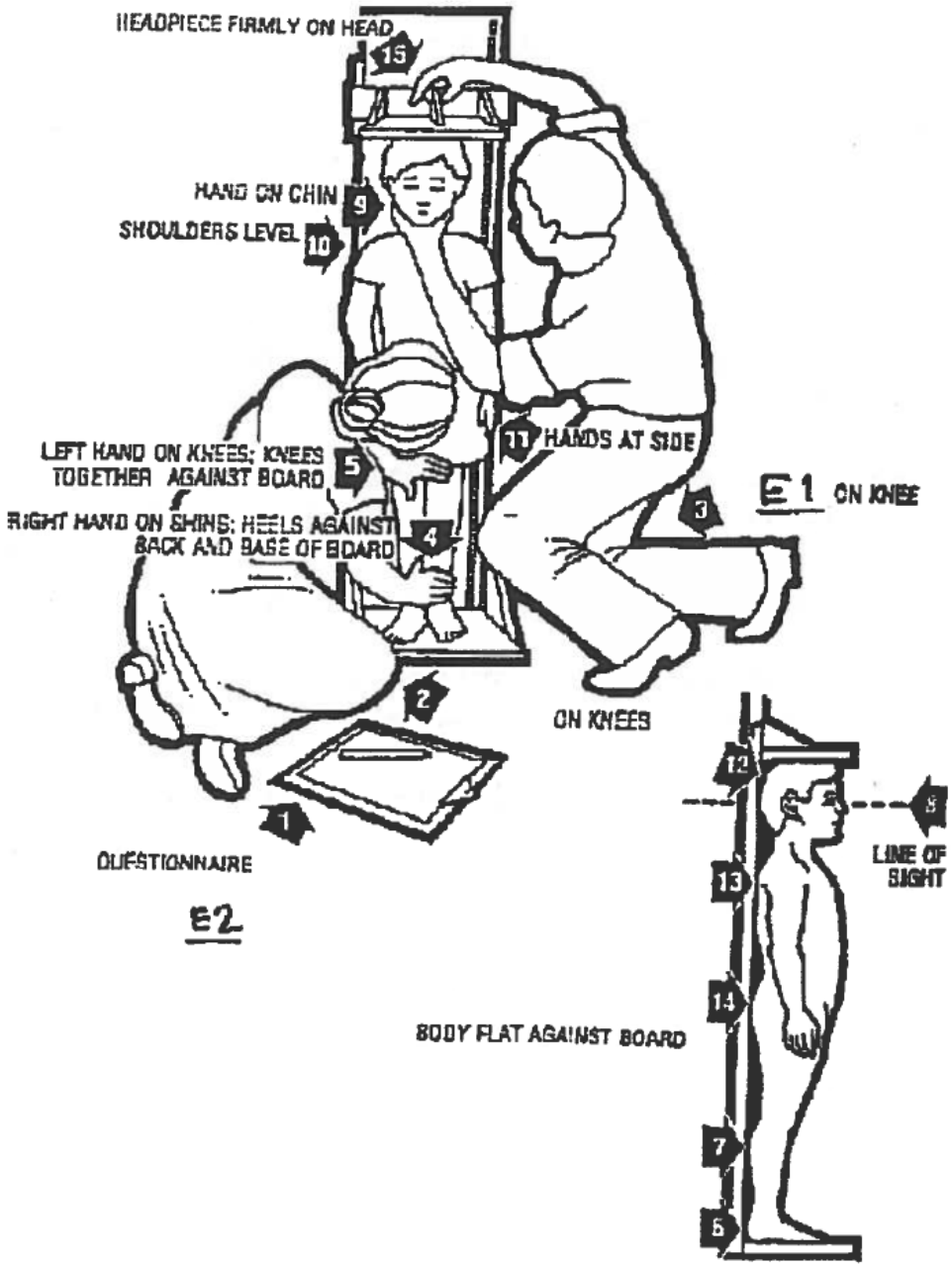
e. While holding the knees, pull the footboard against the child's feet. Many babies will point their toes, but the lead anthropometrist should ensure the feet are perpendicular to the back of the board as much as possible.

7. **Upon reading the measurement, the examiner will clearly call out the number to the recorder.** Record the child's length in centimeters to the last completed 0.1 cm. (1.0 mm).
8. Keeping the child in place, release the sliding footboard, and prepare to repeat the measurement. Re-position the child for a second and third measurement.



Measure Standing Height

1. Ensure that the height board is on level ground.
2. Working with the caregiver, and kneeling in order to be at the level of the child:
    a. Help the child stand on the baseboard with the weight of the child evenly distributed on both feet. The heels of the feet are placed together with both heels touching the base of the vertical board. Place the feet pointed slightly outward at a 60 degree angle.
    b. The back of the head, shoulder blades, buttocks, calves, and heels should all touch the vertical board. Arms should hang freely by the sides of the body with the palms facing the thighs. **Note: Standing with all body parts touching the board may be difficult for some children, in which case, help the child to stand on the board with one or more contact points touching the board.**
    c. Ask the caregiver to hold the child's knees and ankles to help keep the legs straight and feet flat, with heels and calves touching the vertical board. Ask her to focus the child's attention, soothe the child as needed, and inform you if the child moves out of position.
    d. Position the child's head so that a horizontal line from the ear canal to the lower border of the eye socket runs parallel to the baseboard.
    e. Ask the child to inhale deeply and to stand fully erect without altering the position of the heels. If necessary, push gently on the belly to help the child stand to full height.
    f. Still keeping the head in position, use your other hand to pull down the headboard to rest firmly on top of the head and compress the hair.
3. **Upon reading the measurement, the examiner will clearly call out the number to the recorder.** Record the child's height in centimeters to the last completed 0.1 cm (1.0 mm).
4. Keeping the child in place, release the sliding headboard, and prepare to repeat the measurement. Re-position the child for a second and third measurement.


HEADPIECE FIRMLY ON HEAD
15
HAND ON CHIN
9
SHOULDERS LEVEL
10
LEFT HAND ON KNEES; KNEES TOGETHER AGAINST BOARD
5
RIGHT HAND ON SHINS; HEELS AGAINST BACK AND BASE OF BOARD
4
11 HANDS AT SIDE
E1
3
ON KNEE
2
ON KNEES
1
QUESTIONNAIRE
E2
12
8
LINE OF SIGHT
13
14
BODY FLAT AGAINST BOARD
7
6

Dismantling the ShorrBoard

1) Stand the board upright: face the board and step on the base with one foot to keep it stable.
2) Slide the head/footpiece into the base of the main board.
3) Release the clasp on the back of the extension piece and remove it. Push the clasp FLAT against the extension piece.
4) To attach the extension piece to the main board, turn the front of the extension piece inward and place it against the front of the main board. Make sure that all sides of the extension piece are straight and in line with the main board.
5) Push on the bolt that is on the back of the extension piece and screw it into the main board.
6) Put the board back inside of the carrying case for storage until your next use.

Measuring Weight

The SECA 874 scale will be used to weigh infants and children to the nearest 0.1 kg. Infants and young children can also be weighed simultaneously with their parent or guardian by the unique "caregiver-baby" function (parent or guardian is weighed and then the infant or child is weighed while held by the parent).

Explain to the caregiver that we want to weigh her child to see how he or she is growing. If she has a baby or a child who is unable to stand, she will hold the child on the scale. If the child is 2 years or older/can stand alone, the child will be weighed alone.
Children should be wearing only light clothing, no shoes or sandals, no hair ornaments, and no jewelry. Explain that the child needs to remove outer clothing and shoes/sandals in order to obtain an accurate weight. If the baby is wearing a diaper, the diaper should be removed. If any heavy clothes remain on the child, make a note in the *Notes* section.

Seca 874 Scale

1) Remove scale from bag.
2) Be sure that the scale is placed on a flat, hard, even surface. All 4 legs of the scale should make contact with the ground surface, without wobbling. It may be helpful to place a piece of plywood on the ground underneath the scale.
3) When **batt** appears in the display, you should change the batteries. Remove the old batteries and insert 6 new batteries.

Turn the power on the scale when you are ready to begin weighing.

1. **If the child is unable to stand on the scale**, you will use the 2 in 1 weighing function (called *tared* weighing). The **2 in 1** function enables the weight of babies and small children to be determined while an adult holds them.
    a. Identify a suitable area that is flat for horizontal placement of the scale.
    b. Press the start key with no load on the scale. The scale is ready for use when it sets to 0.00.
        i. If necessary, switch the weight display to KG: hold down the 2 in 1 key for about 3 seconds. Press the start key with no load on the scale. Wait until the display shows 0.00.

c. Ask the adult to remove his/her shoes and stand in the middle of the scale without the child. S/he should remove any long garments, as these can cover the display and also lead to variable measurements.
d. After the adult's weight appears on the display, tell him/her to remain standing on the scale. Press the **2 in 1** key to activate the function.
e. The scale stores the weight of the adult and the display returns to zero. When 0.00 and NET appear in the display, hand the child to the adult. The scale will determine the weight of the child. Once the value is stable for about 3 seconds, the weight is measured.
    i. Note: If an adult is very heavy (e.g. more than 100 kg) and the baby's weight is relatively low (e.g. less than 2.5 kg), the baby's weight may not register on the scale. In such cases, have a lighter person hold the baby on the scale.
f. **The positioner will clearly call out the child's weight to the recorder.**
g. Record the child's weight to the nearest 0.01 kg.
h. Repeat the measurement 2 more times. Note that only the baby needs to be removed from the scale; the adult should remain on the scale the entire time.
i. To turn off the **2 in 1** function, press the **2 in 1** key. The **2 in 1** function remains on until you press the **2 in 1** key again, or until the scale switches off automatically.

2. **If the child is able to stand on the scale**, you will weigh the child alone. Talk with the child about the need to stand still. Communicate with the child in a sensitive, non-frightening way.
    a. Press the start key with no load on the scale. The scale is ready for use when it sets to 0.00.
    b. Ask the child to stand in the middle of the scale. Once on the scale, the child must stand still. The HOLD function is automatically activated for weights over 1.5 kg/3.3 lbs. The display flashes until a stable weight has been measured. The display is then frozen until the next weighing operation.
        i. Note: If the child jumps on the scale or won't stand still, you will need to use the tared weighing procedure instead.
    c. **The positioner will clearly call out the child's weight to the recorder.** Record the child's weight to the nearest 0.01 kg.
    d. Repeat the measurement 2 more times. Have the child move completely off the scale and then stand again on the scale.

If no further weighing operations are performed, the scale switches off automatically after 2-3 minutes.

Scale Calibration

In order to monitor the calibration of the scales over time, each team will weigh a 5 kg test weight at the beginning and end of the day.

Measuring Mid-Upper Arm Circumference (MUAC)

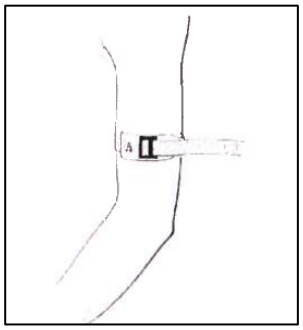
The child's MUAC will be measured **three times**. MUAC measurements will be taken at the midpoint of the **left** arm between the tip of the shoulder and the tip of the elbow using non-stretch MUAC tapes.

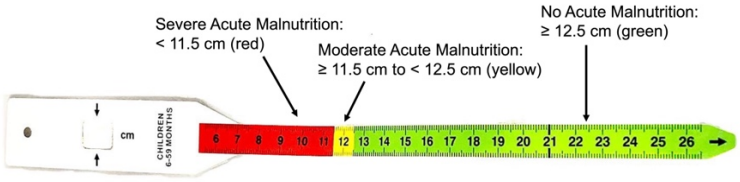


1. First, **find the approximate midpoint of the upper arm**. Have the child stand up straight with feet together, and the right arm bent 90

degrees at the elbow, palm facing up. The examiner is positioned behind the child. If it is helpful, mark the midpoint with a permanent marker.

2. To **measure mid-upper arm circumference**, have the child stand up straight with the arms relaxed at the sides. The examiner will stand facing the child's right side. The measuring tape is placed around the upper arm at the marked point.
3. Wrap the tape around the arm, pulling it to lie flat against the surface of the skin. Be careful not to pull the tape too tightly (to compress the skin).
4. The line for reading measurements is clearly labeled on the MUAC tape (READ (cm)). Read the number aligned with the measurement line on the tape. **Upon measuring, the examiner will clearly call out the number to the recorder.** Record to the nearest 0.1 cm (0.1 cm = 1 mm).
5. Keeping the child in place, release the MUAC strip.





3.4. Follow-up Visits

Unplanned Visit to Clinics and scheduled bi weekly Follow-up Visit

The study personnel in the clinics will record all visits that will take place after the caregivers' enrollment, which will include planned visits for nutritional programs or other clinical visits, and unplanned visits in the instance that the child is sick.

If the visit is unplanned, the study personnel will record the reason for the visit and all the treatment that the child received. The study personnel will obtain the information about the child treatment from the child medical record.

If it's a planned visit, the study personnel will perform anthropometric and will record the measurements. The study personnel will also record how often the caregiver measure the child's MUAC and will keep a record of it.

If an enrolled child dies during the study period, the study personnel will record the date of death for children who die and will complete a verbal autopsy form.

Six Month Follow-up Visit

Outcomes assessments will be conducted at the six months visit. Visits will be a home visit or clinic visit. We will measure acceptability, feasibility, clinical, and accuracy outcomes.

To measure acceptability, the study personnel will collect data through qualitative and quantitative surveys. Caregivers in the MUAC screening arm will take a quantitative survey related to their experiences screening their children for relapse, and twenty caregivers will be interviewed to know caregivers' concerns with regards to malnutrition and their child's health,

and whether they found training on screening empowering. Nutritional program staffs will also be interviewed to understand acceptability of MUAC-based screening at the clinic level.

To measure feasibility, we will assess the proportion of children who relapse over a 6-month period post-discharge from the nutritional program and will document the number of relapses. The study personnel will measure the time it takes to conduct MUAC training in the caregiver screening arm to understand the burden on clinic staff. We will also measure adherence to the relapse follow-up protocol in both the standard of care arm and the caregiver screening arm to enhance understanding of acceptability and feasibility of the intervention.

To assess clinical outcomes, we will measure the time to relapse in both the standard of care arm and the caregiver screening arm. The study personnel will record the date of relapse and all anthropometric measurements in the study's electronic data capture system.

The study personnel will measure weight, height, and MUAC. He/she will use these measurements to calculate WHZ, weight-for-age Z-score (WAZ), and height-for-age Z-score (HAZ) according to 2006 WHO standards. Weight will be measured using a Seca 874 floor scale and height will be measured using a Shorrboard.

The study personnel will record the vital status (died, alive, unknown) w for each child in the study at the time of the 6-month visit, The study team member will record the date of death for children who die and will complete a verbal autopsy form.

The study team will measure hospitalization by interviewing caregivers at the 6-month visit. The caregivers will be asked to report any hospitalizations their children have had during the study period. The study team will also look into hospital records to identify study children who have been hospitalized.

To assess accuracy, each caregiver in the caregiver screening arm will measure the child's MUAC on their right arm during the training, and the study team will record measurement in the study's mobile data application by the trainer.

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4. DATA COLLECTION, MANAGEMENT, AND SECURITY

4.1. Data Collection

Data will be collected on enrolled children every other week or at an unplanned clinic visit, and at 6 month follow-up visits. Written informed consent will be collected on paper and the study team will record measurements and assessments on paper. All other data will be collected electronically on mobile devices.

4.2. Data Management and Security

Electronic data will be uploaded daily to a secure, password-protected, cloud-based server. All devices used for data collection will be password-protected, as will the mobile application itself. Paper forms will be stored in locked cabinets accessible only by specific study personnel at each enrollment site.

Study data will only be accessible by study team members and investigators to protect confidentiality.

4.3. Data Quality and Monitoring

All study team members collecting data will undergo an initial training to learn how to use the mobile devices as well as best practices for data collection. Data collection will be monitored on a weekly basis by the study team. Concerns over data quality and completeness will be relayed to the local study team, and/or additional supervision of data collection by local investigators will be planned as needed. The study team will send quarterly progress reports to the DSMC, including aggregate data on enrollment and follow-up status, weight gain, nutritional recovery, and adverse events.

5. PROTECTION OF HUMAN SUBJECTS

Before any study procedures are implemented, the study team will obtain Institutional Review Board (IRB) approval from committees at UCSF and CRSN. In addition, local study team members will approach each potential enrollment site to describe the study and obtain their consent to participate as a study site. At the individual level, study personnel will obtain written informed consent from the caregiver for all study activities. If, at any time, a caregiver elects to withdraw a child from the study, they will be free to do so

5.1. Institutional Review Board Approval

University of California, San Francisco (UCSF) Committee on Human Research
UCSF's Committee on Human Research will annually review the study protocol for ethical approval.

Comité d'Ethique du Burkina Faso
The study protocol will be reviewed and granted ethical approval by the Comité d'Ethique du Burkina Faso in Nouna before any study activities begin.

5.2. Informed Consent

Study personnel fluent in relevant local languages will approach caregiver of eligible children at the enrollment site. In a private setting, the study personnel will explain the objectives, risks, and benefits of the study as well as detailed information about what study participation entails for the child and the caregiver. The study staff will clarify that participation in the study is voluntary, that participation may be stopped at any time, and that all collected data will be kept confidential and securely stored. The study staff will ensure comprehension by inviting the caregiver to ask questions and will provide time for the caregiver to consider participation. When providing consent, both the study staff and the caregiver will sign two copies of the consent document. One copy will be given to the parent or guardian and the other will be kept for study reference.

6. Sample Size and Statistical Methods

We anticipate enrolling 200 children who have been recovered from an episode of SAM. Although the primary goal of this project is to establish the acceptability, feasibility, and accuracy of the caregiver screening intervention, assuming a probability of relapse of 25% in the standard of care arm, inclusion of 200 cases of SAM (N=100 per arm, 25 events/arm) would yield at least 80% power to detect a hazards ratio for recovery of 0.33. For clinical outcomes, we will compare time to relapse using a log-rank test with a term for randomized treatment assignment. Anthropometric outcomes will be compared by arm with a term for randomized treatment arm and the baseline anthropometric measure, with the exception of growth outcomes (weight gain in g/kg/day and height change in mm/day). Quantitative acceptability and feasibility outcomes will be analyzed descriptively.

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APPENDIX

Appendix 1. Informed Consent Documents
Appendix 2. Qualitative Survey
Appendix 3. Accuracy survey
Appendix 4. Feasibility survey
Appendix 5. Standard medical protocol for children recovered from severe malnutrition

MOP Change Log

Date	Version	Changes
November 30, 2023	1.2	Changed the number of follow-up visits in the SOC for the SOC arm and the screening arm from twice monthly to once monthly
December 4, 2023	1.3	Expanded the eligibility criteria to include children who recovered from SAM in the past month
December 18, 2023	1.4	Added questionnaire about maternal depression and anxiety at baseline and at the 6-month visit.