# Statistical analysis plan for: R-SWITCH– Research to Improve the Screening for Wasting and the Identification and Treatment of Wasted Children

## 1 Background

Child wasting is the 3rd ranked risk factor of Disability-adjusted life years (DALYs) and death among children under five years of age globally (after low birth weight and short gestation) and is the leading risk factor among children 28 days and older. An estimated 47 million children under five years of age (7% globally) suffer from wasting, and approximately one-third (14.5 million) suffer from severe wasting at any given time (1).

Despite the burden and impact of child wasting on morbidity and mortality, only a small proportion of severely wasted children are presently identified and admitted into treatment programs. In 2020, an estimated 4.9 million severely wasted children received treatment, approximately a third of the total burden globally (3).

Over the past decade operational research has been conducted to explore ways to improve access and coverage and make treatment simpler, more accessible, and more cost-effective. These programmatic innovations and modifications are commonly called “simplified approaches” (4). Most of these simplifications have to-date been tested in small scale, mostly NGO-supported pilot projects or efficacy trials, which showed these approaches were likely feasible, effective and safe, but should be further researched at larger scale (5–8). Making these simplified or alternative approaches part of global and national health policies, and a more mainstreamed component of routine health services, requires evidence of their feasibility and impact when delivered on a scale through national systems.

The Research to improve the screening for wasting and the identification and treatment of wasted children (R-SWITCH) project, born from a collaboration between the United Nations International Children's Emergency Fund (UNICEF) and the International Food Policy Research Institute (IFPRI, the global research lead) with funding from the Bill and Melinda Gates Foundation, aims to tackle this lack of rigorous evidence. The project conducted in Ethiopia, Kenya and Nigeria identifies and tests innovative approaches to detect and treat wasting at different levels of the system (household, community, facility), thereby increasing the proportion of children wasted who receive timely and appropriate treatment. This Statistical Analysis Plan (SAP) documents all the analyses planned for the R-SWITCH study in Ethiopia. This includes the definition of the population of study, statistical methods to assess impact, subgroup and sensitivity analysis of the impact assessment. The protocol was registered on clinicaltrials.gov (NCT06380504).

## 2 Study objectives

The overall objective of the study is to assess the impact on wasting treatment coverage, implementation and cost, of the R-SWITCH package of interventions delivered by Alliance for development groups (AFD) and village health leaders (VHL), which includes scale-up of active screening, family-led MUAC, weight-for-age Z-score based passive screening and admission to treatment services, and follow-up of children enrolled or recently discharged from SAM outpatient therapeutic programs (OTP).

**Primary research question:**

Can an integrated intervention designed to strengthen community-based continuum of care services for children with SAM increase SAM treatment coverage in Kersa and Jeldessa woredas?

**Secondary research questions:**

- What is the impact of the intervention on the screening coverage of children 6-59 months of age with SAM or enrolled in SAM OTP?
- What is the impact of the intervention on the net contribution of screening by family-led MUAC, GMP, IMNCI, EPI to children in 6-59-month-old SAM and enrolled in SAM OTP?
- What is the impact of the intervention on GMP attendance of caregivers of 6-59-month-old SAM and enrolled in SAM OTP children?
- What is the impact of the intervention on the attendance at monthly AFD organized group meetings of caregivers of 6-59-month-old SAM and enrolled in SAM OTP children?
- What is the impact on the rate of home visits conducted by AFD leaders to households with 6-59-month-old SAM and enrolled in SAM OTP children?
- What is the impact of the intervention on the SAM prevalence in 6-59-month-old children?
- What is the impact of the intervention on the MAM prevalence in 6-59-month-old children?
- What is the impact of the intervention on the wasting prevalence in 6-59-month-old children?
- What is the impact of the intervention on the underweight and severe underweight prevalence in 6-59-month-old children?
- What is the impact of the intervention on the stunting and severe stunting prevalence in 6-59-month-old children?
- What is the impact of the intervention on mean WLZ, LAZ, WAZ-scores and MUAC in 6-59-month-old children?
- What is the impact of the intervention on IYCF, health, WASH and SAM-related knowledge among caregivers of SAM and recovering children with SAM 6-59 months of age?
- What is the impact of the intervention on IYCF, health and WASH practices among caregivers of SAM and recovering children with SAM 6-59 months of age?

# 3 Study methods

## 3.1 Study area and population

In Ethiopia, the 2011 and 2016 DHS reports that the prevalence of child wasting is the same at 10%, with a decrease between 2016 and 2019 from 10% to 7% (EPHI and ICF, 2019), however, wasting prevalence in these reports is defined as a weight-for-length Z-score <-2 (WLZ) or the presence of edema. We recently analyzed all available Ethiopian SMART survey data (UNICEF 2019-2022), which shows a child wasting prevalence of 17% and a SAM prevalence of 3.7% using both the WLZ and Mid-Upper Arm Circumference (MUAC) criteria. The study is conducted in Kersa and Jeldessa woreda situated in the Jimma Zone and Dire Dawa zones respectively. While Kersa woreda is more agrarian, Jeldessa is predominantly pastoralist.

## 3.2 Study design

We designed a two-arm, cluster-randomized, unblinded, community-based effectiveness trial to study the impact of the R-SWITCH community package of interventions on SAM treatment coverage. The evaluation

will use a repeated cross-sectional study design (at baseline and after 24 months) to assess the impact of the intervention. The activities of the control and intervention group are summarized in Table .

*Table 2: Intervention package in intervention and comparison groups*

| | | |
|---|---|---|
| Prevention, screening and referral | Key actors: Alliance for Development women groups (AFD, former WDA), self-help groups to monitor and support their members. Supported by Health Extension Workers (HEW).<br>• Monthly group meetings of AFD and their members (caregivers of children 0-59 months of age):<br>• Introduction and refresher of Family-led MUAC<br>• Active screening of wasting by AFD leaders using MUAC and checking on presence of edema<br>• Group SBCC on IYCF, health and WaSH with a focus on wasting and food-based approaches (Home Recipes) for MAM<br>• Promotion of health services (GMP, IMNCI, EPI)<br>• Village health leaders (VHL) program introduced by Ethiopian MOH: conducting home visits and cooking demonstrations for child nutrition. During these contacts children are screened for SAM<br>• Screening criteria for SAM:<br>o Active and passive screening with MUAC<115mm and presence of edema (contacts with AFD, VHL, HEW, health center)<br>o Passive screening with WAZ<-3 at GMP, IMNCI, EPI<br>o Additional passive screening WLZ<-3 at health center<br>• Promotion of Family-led MUAC and SAM awareness to fathers during male support groups and agricultural/pastoralist extension activities and by community and religious leaders (creating social support)<br>• Follow-up by home visits of referred cases of wasting by AFD leaders, cases enrolled in SAM OTP and post-treatment discharged cases<br>• Strengthening communication between HEW and AFDs (introduction of caregiver SAM treatment card) | Operational Standard care:<br>• Existing AFD activities:<br>o Pre-existing family-led MUAC or nothing<br>o Active screening of wasting by AFD leaders using MUAC and checking on presence of edema<br>• Active and passive screening with MUAC<115mm and presence of edema (contacts with AFD, HEW, health center)<br>• Additional passive screening using WLZ<-3 at health center<br>• Existing usual GMP, IMNCI, EPI<br>• Existing follow-up by home visits by HEW of referred cases, cases enrolled in SAM OTP and post-treatment discharged cases.<br>• Village health leaders (VHL) program introduced by Ethiopian MOH: conducting home visits and cooking demonstrations for child nutrition. During these contacts children are screened for SAM |

| | RSWITCH Intervention Group | Control Group |
|---|---|---|
| Treatment | • Admission based on MUAC<115mm or WLZ<-3 (health centers only) or WAZ<-3 (health posts only) or edema.<br>• RUTF dosage based on the weight of children for SAM with 1) MUAC<115mm or 2) WAZ<-3 and MUAC<125mm. One RUTF sachet for children with WAZ<-3 but MUAC≥125mm<br>• AFD leaders conduct home visits (every week/2 week) of Children with SAM under treatment, supporting compliance and adherence.<br>• Involving Religious leaders and Fathers through community-level platforms to promote compliance to the treatment | • Admission based on MUAC<115mm or WLZ<-3 (health centers only) or WAZ<-3 or edema.<br>• RUTF dosage based on the weight of children for SAM with 1) MUAC<115mm or 2) WAZ<-3 and MUAC<125mm. One RUTF sachet for children with WAZ<-3 but MUAC≥125mm |
| Post-treatment | • Schedule 1-2 weekly home visits by AFD leaders up to three months after discharge to early detect possible relapse<br>• Group SBCC on IYCF, health and WaSH with a focus on wasting and food-based approaches (Home Recipes) for MAM to prevent relapse | |

The **primary study population**, in which the primary outcome will be measured, is the population of children aged 6 to 59 months old living in the catchment area of a health post and suffering from SAM defined by WLZ <-3 (relative to the WHO reference of 2006) or MUAC <115 mm or bilateral oedema or currently enrolled in SAM OTP (**"Enrolled in SAM treatment"**). However, children 0- 5 months of age will also be considered for the SBCC intervention connection with GMP programs in both the intervention and control groups. Because the study sample of SAM and enrolled in SAM OTP is likely to be very small (2.5-3.5% based on Ethiopian SMART surveys 2019-2022), we aim at including all SAM and recovering children with SAM in the household-child survey (total anticipated sample n=1,080). Anthropometric outcomes, however, weight, length and MUAC are measured in the census of approximately 31,000 children 6-59 months of age in 40 health post catchment areas (corresponding to *kebeles*) that are part of the study.

The group **'enrolled in SAM treatment' (see also box 1)** is defined by children that are enrolled and actively participating in the existing SAM OTP or under SAM inpatient treatment. 'Enrolled in SAM treatment' is defined as:

- Caregiver confirms enrollment in SAM treatment AND
- Caregiver confirms that her/his child was consuming RUTF during the last 3 days AND
- Caregiver can show at least one full RUTF sachet or at least 2 empty RUTF sachets during the screening survey.

*Inclusion and Exclusion criteria of household-child survey*

The eligibility criteria for the children's inclusion in household-child survey are:

- MUAC < 115mm OR
- Presence of bilateral pitting edema (+/++) OR

- WLZ-score <-3 OR
- Currently enrolled in SAM OTP or inpatient facility ("enrolled in SAM treatment")

The exclusion criterion will be:

- anthropometric malformation or being handicapped which hampers anthropometric measurements.

**Box 1: Clarification on how severe underweight (WAZ<-3) relates to SAM, MAM, and non-MAM/SAM and consequences of the cross-sectional design measuring SAM treatment coverage**

In both study arms, children are eligible for enrollment in SAM OTP if they have a MUAC<115mm or suffer from severe underweight (defined as WAZ<-3) or bilateral pitting edema (+/++). The group of children with severe underweight consists of children with SAM, MAM and even a small proportion that does not suffer from SAM/MAM. Children with MUAC<115mm or bilateral pitting edema (+/++) or with severe underweight and MUAC<125mm will receive the body weight-based dosage of RUTF (as per WHO/Ethiopian protocol). Children with severe underweight but with a MUAC≥125mm will receive a ration corresponding to one sachet of RUTF per day. For this study all forms of RUTF supplementation are referred to as SAM treatment.

This treatment schedule makes it impossible to differentiate children that were originally SAM, MAM or non-MAM/SAM within the group children that are "enrolled in SAM treatment" at the time of the cross-sectional survey assessing treatment coverage. The difficulty is that the health post does not measure child length, and, as such, cannot compile the WLZ-score to assess if a child with severe underweight is SAM, MAM or non-MAM/SAM. Such distinction can only be made using MUAC. Children admitted to SAM OTP with severe underweight and 115mm≤MUAC<125 mm may therefore be either MAM or SAM.

The cross-sectional evaluation of SAM treatment coverage includes both children that are SAM at the time of the survey (defined as MUAC<115mm or WLZ<-3 or presence of bilateral pitting edema) and children currently enrolled in SAM OTP. Such design does not allow us to determine if a child under treatment at the time of the survey was originally enrolled in SAM OTP as a SAM, MAM or non-MAM/SAM child.

**The secondary study population** comprises all children 6 to 59 months old living in the 40 kebeles in both woredas, which is the target population for the R-SWITCH intervention. To identify the population of children suffering from SAM (currently and recovering), and because this population is likely to be very small, we will need to conduct a census of all kebeles of the study to identify eligible children. This includes the measurement of anthropometric outcomes which can be used to assess SAM, MAM and wasting prevalence in the secondary study population of children 6 to 59 months old living in the study kebeles.

## 3.3 Study outcomes

### 3.3.1 Primary study outcomes

For this study, the definition of SAM, MAM and wasting are defined as follows:

- SAM is defined by WHZ/WLZ <-3 (relative to WHO 2006 reference) or MUAC <115 mm or by the presence of bilateral edema.
- MAM is defined by -3≤ WHZ /WLZ<-2 (relative to WHO reference of 2006) or 115mm≤ MUAC <125 mm without bilateral edema
- Wasting is defined by WHZ/WLZ <-2 (relative to the WHO reference of 2006) or MUAC <125 mm or the presence of bilateral pitting edema.

The **primary outcome** of the study is **SAM treatment coverage** (period coverage) defined as the number of children suffering from SAM (currently or on their way to recovery from SAM through treatment for an initial SAM condition) who currently receive treatment, over the total number of children suffering from SAM (see box below).

$$Period\ coverage = \frac{C_{in} + R_{in}}{C_{out} + C_{in} + R_{in}} \times 100$$

$C_{in}$= SAM cases under treatment[1]

$C_{out}$= SAM cases not under treatment

$R_{in}$= recovering SAM cases under treatment defined as cases with MUAC≥115mm and WHZ/WLZ≥-3 and no oedema but still under SAM treatment, or under MAM treatment on their way from SAM status to full recovery. SAM treatment includes both OTP and inpatient treatment.

### 3.3.2 Secondary study outcomes

**Secondary outcomes** of the study include:

- **Point coverage of SAM treatment** defined as the proportion of children with SAM at the time of the survey that are under treatment (see definition under primary outcome) over the total number of children with SAM identified at the time of the survey;
- **Period coverage of SAM treatment of program-eligible children** defined as the proportion of children from the primary population or children with severe underweight (WAZ<-3) at the time of the survey that are under treatment at the time of the survey;
- **SAM screening coverage** defined as the proportion of children from the primary population that were screened in the last month (as reported by the caregiver);
- **Severe underweight screening coverage** defined as the proportion of children with WAZ<-3 that were screened in the last month (as reported by the caregiver);
- **Platform-specific SAM screening coverage** defined as the proportion of children from the primary population that were screened in the last month (as reported by the caregiver):
    - by Family-led MUAC
    - during GMP/EPI
    - during IMNCI
- **GMP attendance** defined as the proportion of caregivers of children from the primary population that attended GMP in the last month;
- **AFD group meeting attendance** defined as the proportion of caregivers of children from the primary population that attended AFD group activities in the last month;

- **AFD home visit coverage** the defined as the proportion of caregivers of children from the primary population that received a home visit by an AFD leader in the last month;
- **VHL home visit coverage** the defined as the proportion of children from the primary population that received a home visit by a VHL in the last month;
- **Knowledge of nutrition, hygiene (WaSH) and health** of caregivers of children of the primary study population at the end of the study expressed as a cumulative total score and by domain;
- **IYCF practices**:
    - Introduction of (semi) solid and soft complementary foods, defined in this study as the proportion of children of the primary study population that were introduced to (semi) solid and soft complementary foods between 6-8 months of age recalled at the time of the survey for the subgroup of children 6-8 months of age;
    - Minimum dietary diversity, defined as the proportion children aged 6-23 months of the primary study population who consumed at least 5 of the 8 IYCF food groups (including breast milk) the day before the survey;
    - Minimum meal frequency, defined as the proportion of children aged 6-23 months of the primary study population who had eaten at least 2 meals for breastfed children aged 6-8 months, at least 3 meals for breastfed children aged 9-23 months, or at least 4 meals for non-breastfed children aged 6-23 during the day before the survey;
    - Minimum acceptable diet defined as the proportion of children aged 6-23 months of the primary study population with both minimal dietary diversity and minimal meal frequency during the previous day
    - Number of food groups consumed by children aged 6-59 months of the primary study population the day before the survey;
    - Consumption of flesh foods or eggs, defined as the proportion of children aged 6-23 months of the primary study population that consumed flesh foods or eggs the day before the survey.
    - Continuous breastfeeding, defined as the proportion of children aged 12-23 months of the primary study population that are still being breastfed.
    - Sweet beverage consumption by children aged 6-59 months of the primary study population the day before the survey;
    - Zero vegetable or fruit consumption by children aged 6-59 months of the primary study population the day before the survey;
    - Minimum milk feeding frequency for non-breastfed children aged 6-23 months of the primary study population the day before the survey;
- **Adoption of practices recommended by AFD/HEW** related to WaSH, vaccination and preventive health care by caregivers of children of the primary study population
- **Prevalence of SAM** defined as the number of children of the secondary study population with WHZ < -3 or MUAC < 115 mm or the presence of bilateral pitting edema over the total number of children of the secondary study population
- **Prevalence of MAM** defined as the number of children of the secondary study population with -3≤ WHZ <-2 or 115mm ≤ MUAC <125 mm over the total number of children of the secondary study population
- **Prevalence of wasting** defined as the number of children of the secondary study population with WHZ < -2 or MUAC < 125 mm or the presence of bilateral pitting edema over the total number of children of the secondary study population

- **Prevalence of stunting** defined as the number of children of the secondary study population with HAZ/LAZ< -2 over the total number of children of the secondary study population
- **Prevalence of underweight** defined as the number of children of the secondary study population with WAZ < -2 over the total number of children of the secondary study population
- **Prevalence of severe underweight** defined as the number of children of the secondary study population with WAZ < -3 over the total number of children of the secondary study population
- **Mean WHZ/WLZ, HAZ/LAZ and MUAC** in the secondary study population
- Unit cost of the community package per child of the secondary study population
- Cost-effectiveness of the community package per DALY averted.

## 3.4 Randomization, sample size and sampling

### 3.4.1 Randomization

The unit of randomization is a health post catchment area with the corresponding catchment population served. Health posts with functional OTP sites, a minimum of two children monthly admission will be eligible for selection as clusters. Lists of health posts will be obtained from each woreda and used as a sampling frame for random allocation to the intervention and control study arms. A statistician not belonging to the study team will randomly allocate the clusters to the intervention and control group. Cluster randomization will be stratified by woreda. As this trial involves the implementation of different services in the intervention and control groups, we cannot blind the study participants. However, study group allocation will be blinded to data collectors and the data monitoring supervisors.

### 3.4.2 Sample Size

Based on the baseline data that found 12% of SAM treatment coverage, a cluster size of 15, and an intraclass correlation coefficient of 0.12 (design effect=2.68), we calculate that 40 clusters (health posts) are required to detect a 18 percent point (from 12% to 30%, the latter being UNICEF's global estimate of SAM treatment coverage) impact on SAM treatment coverage with a power of 90% and a type I error of 5%. The total sample of children would constitute at least 600 children with SAM or enrolled in SAM OTP. The baseline survey found a 2.6% prevalence of children with SAM or enrolled in SAM OTP, so to reach a sample of 600 children with SAM or enrolled in SAM OTP, 23,500 children should be screened for SAM. Minimally detectable differences for various key indicators using this sample size are shown in table3. For unspecified binary outcomes, a sample of 600 children across 40 study clusters provides 90% statistical power to detect an endline difference between study arms of 14 or 18 percentage points, assuming intraclass correlation coefficients between 0.1 and 0.2, respectively, and a control-arm prevalence of 50% (the most conservative scenario).

Table 3. Sample size calculation parameters and assumptions

| *Outcome* | *Control group (based on baseline estimates)* | *Intervention group* | *DE* | *Power* | *Cluster size* | *Minimum nr of clusters for two arms* | *Minimum sample size* |
|---|---|---|---|---|---|---|---|
| ***Main Study outcome*** | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *Treatment coverage* | 12% | 30% | 2.68 | 90% | 15 | 40 | 600 |
| ***Additional study outcomes*** | | | | | | | |
| *Screening coverage (Primary child population)* | 17% | 65% | 2.14 | 90% | 15 | 40 | 600 |
| *SAM prevalence (secondary child population)* | 2.4% | 1.2% | 4.22 | 90% | 587 | 40 | 23,500 |
| *Wasting prevalence (secondary child population)* | 8.7% | 6.2%% | 4.88 | 90% | 587 | 40 | 23,500 |

This study will not involve sampling of subjects *senso stricto*. We will conduct a screening campaign entailing a complete enumeration of the entire secondary study population of two woredas to determine study eligibility. Door-to-door visits to households will be conducted by study teams to screen all children aged 6-59 months of age for wasting through the measurement of MUAC, length (below 24 months of age) or height (above 24 months of age) and weight, and assessment of the presence of bilateral pitting edema. SAM treatment status will be assessed through the caregiver (SAM treatment consultation in the past 15 days and consumption of RUTF).

# 4 Measurements and indicator compilation

Age will be calculated in days counting the number of days between the date of birth and the date of data collection. Date of birth will be collected from birth certificate, mother-child booklet, vaccination card or other official document (birth notification, etc.). When no written record is available, date of birth will be estimated by the enumerator using a detailed calendar of local events.

All weight, length and MUAC measurements will be taken in duplicate by a trained enumerator and a trained assistant, and a third measurement will be taken if the difference between the two repeated measurements is >5mm for length and MUAC and >300g for weight. The average of the two closest repeated measurements will be used for the calculation of nutritional status indicators.

The child weight-for-height and height-for-age z-scores will be calculated using the *zscore06* command in Stata (9), which uses the World Health Organization's growth standard ((10).

Service and screening coverage will be assessed by caregiver recall 1-3 months preceding the time of the survey interview.

Principal component analysis will be used to generate a household wealth status score (11). We will include household-level data on livestock owned, dwelling occupation status, household' characteristics (floor material, number of rooms, etc.), the main source of electricity, and assets owned by 5 to 95% of the study sample. Tertiles of loadings on the principal component with the highest eigenvalue will be used.

More information on study indicators and their definition is presented in section 6.4.1

# 5 Data management

For survey work, interviewers will use Android tablets with specialized software for computer interviewing (Survey Solutions software). Immediately after validation of the questionnaire by the interviewer, each questionnaire will be synchronized via an internet connection on a secure server, and the questionnaire will be automatically deleted from the interviewer's tablet. The server will be accessible only to IFPRI and EPHA investigators. After checking the quality of the data collected, the questionnaire can be returned to the interviewer's tablet for field corrections. Once these corrections have been made, the same synchronization process will allow the data to be stored on the secure server.

Management of all research data will follow IFPRI's institutional protocol for research data management, overseen by the IFPRI Data Governance Committee, as well as UNICEF data governance standards. Data will be stored on a secure server accessible only to principal investigators. All data will then be carefully anonymized and de-identified so that the privacy of participants and research subjects is fully protected. Databases will be anonymized using identification codes. No names, GPS coordinates, dates of birth or other identifying data will be stored in the database.

At the time of publication of scientific articles presenting primary results, the fully anonymized databases (quantitative data) will become a public good and will be made available to the scientific community, government, and partners.

# 6 Statistical analysis

## 6.1 Data sources

The baseline data collected between June and August 2024 will be used to assess the quality of the randomization (balance in sample characteristics), and for possible adjustment for the baseline cluster-level mean of the outcome and strong prognostic factors that are unbalanced at baseline (see robustness analyses). Endline data collected from July and September 2026 will be used to assess the impact of the intervention.

## 6.2 Treatment of missing data for primary study outcomes

Missing data patterns for all indicators at baseline and endline will be reported. If missing primary outcome data (e.g. treatment status) represents less than 5% of the sample, only complete-case analysis will be conducted. If the missing primary outcome data represent more than 5% of the sample data, a sensitivity analysis will be performed to calculate treatment coverage in the best-case scenario (all missing data are receiving treatment in the intervention group and not receiving treatment in the control group)

and worst-case scenario (all missing data are not receiving treatment in the intervention group and receiving treatment in the control group). Missing covariates will be imputed using the cluster mean (12).

## 6.3 Statistical analysis

Data will be analyzed on intent-to-treat basis. Data management, data cleaning, and statistical analyses will be done using Stata 19.0 (Statacorp, USA). The statistical significance will be set at 5%. All statistical tests will be two-sided.

**Primary analysis regression models**. The repeated cross-sectional study design will be used to estimate program impact after 2 years of program implementation. Linear and linear probability mixed-effect regression models will be used for continuous and binary outcomes respectively, with *kebele* as a random intercept and *woreda* as fixed effect to reflect the study design. In case of linear probability models, we will use a robust estimation of standard errors. The impact will be assessed by analyzing differences at endline. For impact models on child anthropometric outcomes, models will include child age, child sex and primiparity measured at individual level at endline, since these variables are known to be prognostic factors for child nutritional status. Adjusting the models for small imbalances in these three covariates will lead to small gains in precision. These models are the principal impact evaluation models.

**Adjusted analysis model.** A second set of estimates will be generated from regression models additionally adjusted for factors associated with SAM treatment coverage in this study's baseline data. These factors were identified by a published baseline study and included household socioeconomic status, household water treatment practices, caregiver possession of a vaccination card, community screening of the child for SAM within the previous three months, and the availability of SAM OTP services at nearby health posts[1]. Baseline cluster means will be calculated for these prognostic factors and included as fixed effects to the regression models.

## 6.4 Considerations for analysis

### 6.4.1 Baseline characteristics

The baseline characteristics of the subjects will be presented by study group. Following the CONSORT guidelines, we will not statistically test for differences between study groups at baseline (15). Imbalance will be considered for absolute differences >10 pp (binary outcomes) or >10 % (continuous outcomes).

The presentation of baseline characteristics will be done as follows:

- Categorical variables: frequencies and percentages, as appropriate. Percentages will be calculated based on the number of participants for whom data is available.
- Continuous variables: mean and SD or median and interquartile range, as appropriate.

For characteristics that may lie on the causal pathway between the intervention and the outcome, we will present only baseline measurements. For characteristics determined before intervention exposure or

[1] B. Biru *et al.*, "Barriers and Factors Associated With Treatment Coverage of Severe Acute Malnutrition Among Children 6–59 Months in Agrarian and Pastoralist Areas of Ethiopia," *Maternal & Child Nutrition*, vol. 22, no. 3, p. e70219, 2026, doi: 10.1111/mcn.70219.

unlikely to be affected by the intervention, we will also assess balance between study arms in the endline sample. These characteristics were prespecified before analysis and are listed in the next section.

| Characteristics | Comments/References | Round presented |
|---|---|---|
| **Village level** | | |
| Distance to the health facility | | Baseline |
| **Household level** | | |
| HH size (mean/SD) | | Baseline and Endline |
| Number of under 5 children in the household (mean/SD) | | Baseline and Endline |
| Dependency ratio (%) | Number of individuals aged 0–14 years and 65 years and above divided by the number of individuals aged 15–64 years, expressed per 100 working-age individuals, following standard definitions from the United Nations and World Bank. | Baseline and Endline |
| Polygamous HH (%) | | Baseline and Endline |
| HH food insecurity (mean and proportion of food secure HH) | Coates J, Swindale A, Bilinsky P. Household Food Insecurity Access Scale (HFIAS) for measurement of food access: indicator guide. Washington, DC: FANTA; 2007. https://doi.org/10.1007/s13398-014-0173-7.2 | Baseline |
| SES status classification (tertiles, %) | Principal component analysis will be used to construct a proxy household Socio-Economic Score (SES) using ownership of various assets (an asset is excluded if ownership is below 5% or above 95% on HH level), housing materials, primary source of lighting, primary energy source, home ownership and livestock ownership. Tertiles of the first principal component (i.e., the one with the highest eigenvalue) will be used. | Baseline |
| Improved water treatment technologies used (%) | USAID (2021) Water and development- Indicator handbook. Washington DC | Baseline |
| Improved sanitation facility (%) | USAID (2021) Water and development- Indicator handbook. Washington DC | Baseline |
| Handwashing station with soap available (%) | USAID (2021) Water and development- Indicator handbook. Washington DC | Baseline |
| Improved primary water source (%) | USAID (2021) Water and development- Indicator handbook. Washington DC | Baseline |
| Male head of household (%) | | Baseline and Endline |
| **Paternal level** | | |

| Characteristics | Comments/References | Round presented |
|---|---|---|
| Father is member of the HH (%) | | Baseline and Endline |
| **Maternal level** | | |
| Biological mother (%) | | Baseline and Endline |
| Age (mean/SD) | | Baseline and Endline |
| Marital status (%) | | Baseline and Endline |
| Main language (%) | | Baseline and Endline |
| Main religion (%) | | Baseline and Endline |
| Mother school attendance (%) | | Baseline and Endline |
| Has an income generating activity (%) | | Baseline |
| Knowledge score in 4 domains (breastfeeding, hygiene, health, supplements) | Self-developed questionnaire of 23 questions based on training curricula of CHPs. Mean scores are presented by domain. | Baseline |
| Possible depression (EPDS≥10)(%) | Cox JL, Chapman G, Murray D, Jones P. Validation of the Edinburgh postnatal depression scale (EPDS) in non-postnatal women. J Affect Disord; 1996;39:185–9. | Baseline |
| Maternal MUAC (mm) (mean/SD) | | Baseline |
| Maternal weight (kg) (mean/SD) | | Baseline |
| Maternal height (kg) (mean/SD) | | Baseline |
| Maternal BMI ($kg.m^{-2}$) (mean/SD) | | Baseline |
| Maternal underweight (%) | Defined as a BMI<18.5 | Baseline |
| Status of women in decision making, community, mobility | Self-developed questionnaire inspired by Pro-WEAI questionnaire to measure women power over decision making about household diet, health decision for the child, community involvement and mobility (women has to inform or ask for permission). No scores is calculated. | Baseline |
| Mother perceived lack of time | A set of 5 questions to measure mother's self-appreciation of time for leisure and workload. | Baseline |
| Assisted delivery of last pregnancy (%) | | Baseline |
| **Child** | | |

| Characteristics | Comments/References | Round presented |
|---|---|---|
| Age (mean/SD) | | Baseline and Endline |
| Male (%) | | Baseline and Endline |
| Primiparity (%) | | Baseline and Endline |
| Weight-for-length Z-score (mean/SD) | Relative to WHO 2006 growth reference | Baseline |
| MUAC (mean/SD) | | Baseline |
| Wasting (WLZ<-2 or MUAC<125mm or edema) (%) | | Baseline |
| Severe Acute malnutrition (WLZ<-3 or MUAC<115mm or edema) (%) | | Baseline |
| Length-for-age Z-score (mean/SD) | Relative to WHO 2006 growth reference | Baseline |
| Stunting (LAZ<-2) (%) | | Baseline |
| Weight-for-age Z-score (mean/SD) | Relative to WHO 2006 growth reference | Baseline |
| Underweight (WAZ<-2) (%) | | Baseline |
| Severe underweight (WAZ<-3) (%) | | Baseline |
| Treatment status (%) | Based on the definition of being under treatment developed in our protocol (section primary study outcomes). | Baseline |
| Screening status (%) | Percentages of children screened by MUAC, weight, length in the last 30 days, 60 days and 90 days according to mother's recall. | Baseline |
| Immunization status (%) | Vaccines received since birth according to observation of the vaccination card/booklet | Baseline |
| Introduction of (semi-)solid or soft foods in children 6-8 months of age | WHO. Indicators for assessing infant and young child feeding practices. WHO: Geneva (2021) | Baseline |
| Continued breastfeeding (%) | WHO. Indicators for assessing infant and young child feeding practices. WHO: Geneva (2021) | Baseline |
| Minimum dietary diversity (%) | WHO. Indicators for assessing infant and young child feeding practices. WHO: Geneva (2021) | Baseline |
| Minimum meal frequency (%) | WHO. Indicators for assessing infant and young child feeding practices. WHO: Geneva (2021) | Baseline |
| Flesh food/eggs consumption (%) | WHO. Indicators for assessing infant and young child feeding practices. WHO: Geneva (2021) | Baseline |

### 6.4.2 Sensitivity analyses

1. We will assess whether impacts on the primary outcome are sensitive to the definition of wasting, by assessing impact on SAM treatment coverage when SAM is defined with 2 alternative definitions: 1) MUAC < 115 mm or oedema, and 2) WLZ < -3 Z-scores or oedema.
2. We will assess the sensitivity of the estimated intervention effects on the primary outcome to the definition of treatment receipt. In the primary analysis, a child reported to have consumed treatment within the previous 3 days will be considered to have verified treatment receipt only if the caregiver can provide supporting evidence to the enumerator by showing at least one full RUTF sachet or two empty sachets. As a sensitivity analysis, we will use a broader definition of verified treatment receipt, whereby evidence recorded on an available treatment card (handed out at SAM OTP services in both study arms) that the child attended a SAM treatment consultation within the previous 7 days will be considered equivalent to showing at least one full RUTF sachet or two empty sachets. This definition was not included in the study protocol and is therefore limited to an assessment of the robustness of the findings.
3. The baseline and endline surveys represent independent groups from the target population: children with SAM or receiving treatment at baseline are generally no longer eligible two years later at endline. In addition, project activities directly modify some determinants of SAM treatment coverage, including the availability of SAM OTP services in both control and intervention areas. We will therefore retain the primary impact analysis without additional adjustment for baseline covariates that appear imbalanced and rather conduct a sensitivity analysis including such characteristics when imbalances are >5 pp for binary outcomes or >10 % for continuous outcomes. For this purpose, baseline cluster means will be calculated and included as fixed effects to the regression models.

### 6.4.3 Secondary analyses of effect modification

Studying effect modification of an intervention offers important insights into the mechanism of a possible impact. Effect modification analyses are exploratory and are intended to assess whether intervention effectiveness differs across contextual, household, caregiver, child, and health-system characteristics that may influence exposure to intervention activities, care-seeking behavior, or access to SAM treatment services. Potential effect modifiers include measures of health service accessibility, community health worker capacity, caregiver resources and autonomy, household vulnerability, and child characteristics.

Given that these tests are exploratory, we will assess interaction terms of pre-determined potential modifiers with study group allocation at a statistical significance set at 10%. Statistical models will be the primary analysis regression models as described in earlier sections, adding the main effect of the potential modifier and its interaction term with the study group. If there are indications of effect modification by one or more covariates (P-value<0.10), we will present impact results stratified by covariate level.

For subgroup analyses involving a small number of clusters (<15 clusters), where feasible, small-sample corrections to the degrees of freedom (Kenward–Roger) will be used rather than robust estimation of standard error to improve the accuracy of confidence intervals and hypothesis tests. Results will be interpreted cautiously because standard error and confidence interval estimation may be less reliable in small samples.

As recommended, potential modifiers are pre-specified below, and the hypothesized effect modification is justified (16).

| Potential modifier (measured at endline) | Hypothesized effect modification |
|---|---|
| Woreda | The intervention effect may vary across the two study woredas, with one woreda being semi-pastoralist and one woreda being agrarian. |
| Distance to health facility (village) | The intervention effect may be attenuated among households located farther from health facilities because transportation and travel burdens may limit treatment uptake following referral. |
| Household wealth status (tertiles) | The intervention may have greater impact among wealthier households, which face fewer financial barriers to accessing care. |
| Household food insecurity* | The intervention may have greater impact among households with stronger livelihoods not facing food insecurity challenges. |
| Father is member of the HH | The intervention may be more effective when fathers are present if this increases financial, logistical, or decision-making support for seeking treatment. |
| Main caregiver is the biological mother | The intervention may be more effective when the biological mother is the primary caregiver because she may be more consistently exposed to intervention activities and more involved in health-related decisions. |
| Maternal literacy | The intervention may have greater impact among literate mothers who can better understand reminders messages and referral instructions. |
| Maternal underweight* | The intervention may have greater impact among mothers that are not underweight and therefore less likely to face a negative energy balance |
| Maternal possible depression (EPDS≥10)* | The intervention may be less effective among mothers experiencing depressive symptoms, which may reduce care-seeking, adherence to referrals, or engagement with health services. |
| Maternal Decision making power* | The intervention may have greater impact among women with higher decision-making autonomy because they may be better able to act on referrals and seek treatment for their child. |
| Mother connected with community* | The intervention may be more effective among mothers with stronger community connectedness due to greater exposure to information, peer support, and community health activities. |
| Maternal mobility* | The intervention may have greater impact among women with higher mobility, as they may be better able to independently seek care, attend health facilities, follow referrals, and engage with community health activities without requiring permission from others. |

| Potential modifier (measured at endline) | Hypothesized effect modification |
|---|---|
| Maternal perceived lack of time* | The intervention may have smaller effects among mothers reporting time constraints, as competing responsibilities may limit their ability to seek treatment or attend follow-up visits. |
| Perception of stigma* | The intervention may have reduced effectiveness among caregivers who perceive greater stigma related to malnutrition or treatment services, potentially discouraging care-seeking. |
| Absence of mother in past month* | The intervention may be less effective among children whose mothers were recently absent because reduced caregiver availability may hinder screening, referral uptake, and treatment seeking. |
| Primiparity | The intervention may be more effective among first-time mothers if they are more receptive to health information, or less effective if they have less caregiving experience. |
| Child age | The intervention effect may differ by child age because younger children may have more frequent contact with health services and caregivers may be more responsive to health advice during this period. |
| Child sex | The intervention effect may differ by child sex due to gender-related differences in caregiving practices or caregiver perceptions of illness and vulnerability. |

* *Assessing effect modification by these covariates and conducting subsequent subgroup analyses may introduce selection bias, as we cannot fully exclude the possibility that the intervention affected these variables, even in the absence of a clear hypothesized causal pathway. These exploratory analyses will be conducted only to help interpret demonstrated intervention effects on primary and secondary outcomes along the hypothesized impact pathways.*

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