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Original Research Article

# The impact of a continuum of care intervention from prevention to treatment on child wasting compared with usual community group activities: a cluster-randomized controlled trial in Mali

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ABSTRACT

**Background:** Child wasting is associated with a high mortality risk and remains a persistent public health challenge.

**Objectives:** This study aimed to evaluate the impact of an intervention strengthening the continuum of care of child wasting from prevention, screening, and referral to treatment in Mali.

**Methods:** A 2-arm cluster-randomized controlled trial was conducted using 2 study designs to evaluate impact and pathways: *1*) a longitudinal study of children enrolled at 6 mo ($n = 2324$) with monthly follow-up for 3–6 mo to assess wasting prevalence (primary outcome); *2*) a longitudinal study of all children 6–23 mo admitted to outpatient therapeutic programs (OTP; $n = 7104$) assessing recovery and adherence. Additional OTP coverage surveys were conducted at the end of the study. In both study arms, nutrition activity support groups (NASG) screened children for wasting and provided caregiver behavior change communication (BCC). The intervention arm additionally received small-quantity lipid-based nutrient supplements (SQ-LNS), child-centered BCC, family-led screening, and follow-up on referred wasting cases to support OTP admission and adherence.

**Results:** The intervention did not impact wasting prevalence but reduced the incidence of wasting [relative risk (RR): 0.80, 95% confidence interval (CI): 0.64, 0.99] and severe acute malnutrition (SAM) (RR: 0.71, 95% CI: 0.57, 0.89). The intervention significantly increased wasting screening coverage by 37 percentage points (pp) (95% CI: 31, 44) and SAM treatment coverage by 15 pp (95% CI: 0.35, 30). No impacts of the intervention on OTP recovery or adherence were found. NASGs often replaced the monthly home visits with community gatherings to deliver the intervention. NASGs also often distributed SQ-LNS to children they identified with wasting instead of referring them to the OTP.

**Conclusions:** Strengthening the continuum of care of wasting through community groups reduced the incidence of wasting and SAM and improved screening coverage, which translated into a modest gain in SAM treatment coverage.

This trial was registered at clinicaltrials.gov as NCT04872088.

*Keywords*: wasting, children, resource-limited setting, food supplements, prevention, treatment, integrated interventions, screening

## Introduction

Worldwide, 42.8 million children under 5 y of age suffer from wasting at any given time [1]. Wasting significantly increases children's risk of death leading ≤875,000 child deaths, or roughly 1 of 5 deaths in under 5 children globally [2]. Member states of the World Health Assembly (WHA) have agreed to reduce and maintain the prevalence of wasting to <3% by 2030 [3]. However, wasting

*Abbreviations:* BCC, behavior change communication; CHW, community health worker; CI, confidence interval; CMAM, community-based management of acute malnutrition; DHS, Demographic Health Survey; Hb, hemoglobin; HCA, health center catchment area; IRAM, Integrated Research on Acute Malnutrition; ITT, intent-to-treat; IYCF, infant and young child feeding; LAZ, length-for-age z-score; MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference; NASG, nutrition activity support group; OTP, outpatient therapeutic program; pp, percentage points; PROMIS, preventive package for child malnutrition through integrated strategies; RR, relative risk; RUSF, ready-to-use supplementary food; RUTF, ready-to-use therapeutic food; SAM, severe acute malnutrition; SQ-LNS, small-quantity lipid-based nutrient supplement; WASH, water; sanitation, and hygiene; WAZ, weight-for-age z-score; WHA, World Health Assembly; WLZ, weight-for-length z-score.

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prevalence remains persistently high in many West African countries, including Mali (11.9%) [4]. Wasting trends suggest that the WHA goal will not be achieved in most West African countries, despite their commitment to addressing wasting as expressed in their nutrition policies [5].

Progress in reducing the burden of wasting is impeded by several factors. First, programmatic evidence on how to prevent wasting is scant. This observation was highlighted in the recent WHO guideline on the prevention and management of wasting and nutritional edema that formulated for the first-time recommendations on the prevention of wasting [6]. Evidence is particularly sparse for prevention interventions other than nutrition supplements [7], such as behavior change communication (BCC), cash transfers, or water, sanitation, and hygiene (WASH) interventions [8]. Second, coverage of Community-based Management of Acute Malnutrition (CMAM) remains low in many settings [9] due to supply- and demand-side factors. On the supply side, constraints include the complex treatment procedures, and frequent shortages of treatment commodities [10]. On the demand side, low participation in screening, lack of awareness of the existing treatment programs, and high opportunity costs are key constraints to enrolling in treatment [11]. Previous studies in Mali and Burkina Faso showed that providing small-quantity lipid-based nutrient supplements (SQ-LNS) together with BCC on infant and young child feeding (IYCF), child health, and WASH practices can more than double the coverage of child wasting screening by serving as effective incentives for participation [12,13]. However, these studies showed that increased screening in these settings did not result in increased treatment coverage, which remained below 15% in both settings. Additional community support may be needed to facilitate the referral and admission of wasting cases to treatment services.

The objective of the study was to evaluate the impact of the Integrated Research on Acute Malnutrition (IRAM) intervention on the longitudinal prevalence of child wasting. The intervention consisted of an integrated approach aimed at preventing wasting but also strengthening the screening, referral, and treatment of wasting by leveraging existing community groups in Mali. We further examined the effects of the intervention on child anthropometry, morbidity, anemia, and intermediate outcomes along the prevention and treatment impact pathways to strengthen the inference of our findings and to understand the mechanisms of impact. Study outcomes along the prevention impact pathway included the incidence of child wasting, caregiver knowledge and practices related to IYCF, child health, and WASH. Along the treatment impact pathway, we assessed the intervention's effects on screening and treatment coverage for wasting, as well as adherence to and recovery rates within existing outpatient therapeutic program (OTP) services.

# Methods

## Study setting

Mali is a low-income country in West Africa with a population of ~20 million people in 2020 at the inception of this study [14]. In 2021, 20% of the population earned <$2.15 USD per day, whereas 42% lived below the national poverty threshold in 2019 [15]. This study was conducted in the Koutiala health district in the Sikasso region of Mali, with 45 community health centers and 1 district hospital.

According to Demographic Health Survey (DHS) data, wasting prevalence in children under 5 has decreased from 13% to 5.4% between 2012 and 2023 [16,17] with the highest prevalence (10%) observed between 6 and 12 mo of age in 2023. In addition, these wasting prevalence estimates provided by DHS did not include wasting defined as mid-upper arm circumference (MUAC) below 125 mm as proposed by the WHO's definition of wasting [6]. As such, the true wasting prevalence for Mali could be ≤35% higher [18]. In 2017, a cross-sectional survey in the Bla and San health districts adjacent to the study area found 14% of children 6–23 mo of age suffering from wasting [12].

## Intervention and procedures

### *IRAM activities in the intervention and comparison arms*

Since the introduction of Mali's national IYCF strategy in 2012 [19], community care groups called Nutrition Action Support Groups (NASGs; Groupes de soutien aux activités de nutrition in French) have been tasked to raise nutrition awareness during the first 1000 d of life and to deliver preventive BCC on maternal nutrition and IYCF practices. In 2019, UNICEF supported the creation of NASG groups in all villages in the Koutiala health district. The intervention and activities organized in both study arms were implemented by local health workers and NASGs supported by nongovernmental organization World Vision Mali in collaboration with the UNICEF Mali and the district health authorities.

In all 45 health center catchment areas (HCAs) of Koutiala, local health center staff, supported by World Vision Mali project workers, trained NASG members to deliver BCC on prenatal and postnatal care, IYCF practices, childcare at specific ages, hygiene, and health (Supplementary Table 1). The BCC was to be delivered to child caregivers, pregnant, and lactating persons during monthly group sessions. NASG members received tricolored tapes to measure MUAC and were tasked to screen children >6 mo of age for wasting at every contact. Monthly culinary demonstrations were scheduled to show caregivers how to prepare diverse nutrient-rich complementary foods for the young child.

### *Additional activities in the IRAM intervention arm*

In 23 of the 45 HCAs, the IRAM intervention package was implemented to strengthen the prevention, screening, referral, and treatment adherence of children with wasting. An overview of the intervention components is provided in Supplementary Table 2. Monthly home visits by NASG members to households with pregnant or lactating persons and young children (0–17 mo) served as the main delivery platform for the intervention. To facilitate these monthly home visits, the number of NASGs in the larger intervention villages was increased proportional to the size of the village, as each pair of NASG members was assigned to ~30 households. During these home visits, NASG members provided individual counseling, screen children between 6 and 59 mo of age for wasting using MUAC, introduce and monitor the family-led MUAC screening approach (see below), and deliver a monthly ration of thirty 20-g SQ-LNS sachets (Nutriset) for each child 6–17 mo of age. SQ-LNS is a micronutrient fortified peanut-based spread with vegetable oil rich in omega-3 fatty acids, sugar, and milk powder [18]. Caregivers were instructed that the SQ-LNS should not replace or reduce complementary feeding or breastmilk intake and were encouraged to mix the SQ-LNS with the child's complementary foods. Direct consumption from the package was offered as a second option. Children identified with wasting were not to receive SQ-LNS but were instead referred to the nearest severe acute malnutrition (SAM) or moderate acute malnutrition (MAM) treatment site.

During their first contact with child caregivers, NASG members would deliver a tricolored MUAC tape and train the child's caregiver, and any other family member expressing an interest, on how to screen their children using the MUAC tape (referred to as Family-led MUAC approach) and the procedure to be followed if the child was diagnosed as wasted by a family member.

If an NASG member detected a case of wasting during any contact, they referred the caregiver and child to the nearest health center or community health worker (CHW) for treatment. For any case referred by the NASG or admitted to SAM or MAM OTPs managed by the health center or CHW, NASG members from the intervention study arm were tasked to conduct ≤2 home visits per month to confirm successful referral or to ensure adherence to the treatment schedule of the SAM or MAM OTP.

## Theory of change

The IRAM intervention was designed to strengthen the continuum of care from prevention to screening, referral, and treatment of wasting. The main objective of IRAM was to reduce the burden of child wasting, estimated by the longitudinal prevalence of wasting through a prevention impact pathway and a treatment impact pathway (Figure 1).

Along the prevention pathway, the IRAM intervention intended to leverage NASGs to organize monthly gatherings with caregivers and their children and to conduct regular home visits to deliver SQ-LNS and provide BCC with the aim to improve caregiver knowledge of IYCF practices, child health, and WASH. Improved caregiver knowledge would enhance related practices which, when combined with SQ-LNS, could lead to better child nutritional status and a reduced incidence of wasting. A lower incidence of wasting also directly translates to a lower longitudinal prevalence of wasting (Prevention impact pathway). The frequent consumption of SQ-LNS and improved IYCF, health, and WASH practices may also result in fewer child morbidity episodes—often associated with the onset of child wasting—better linear growth and fewer cases of anemia.

Along the treatment impact pathway, the NASGs would ensure high wasting screening coverage by screening children during every contact and introducing family-led MUAC. A high screening coverage with dedicated follow-up of previously referred cases by NASG would lead to higher treatment coverage. In addition, the follow-up home visits by NASG members of children enrolled into MAM or SAM OTP would increase OTP adherence rates leading to more and faster recovery from wasting. Consequently, episodes of wasting incurred would become shorter, which leads to a lower longitudinal prevalence of wasting.

## Study design

The IRAM impact evaluation was designed as a 2-arm, cluster-randomized, nonblinded effectiveness study. A cluster-randomized design was used because individual randomization of the NASG intervention was not feasible. A cluster was defined as the catchment area of a health center. All HCAs from the Koutiala health district were eligible. We used 2 longitudinal studies complemented with 2 cross-sectional coverage surveys.

A population-representative longitudinal study design (referred to as "Prevention cohort") was used enrolling every month a random sample of children aged 6–6.9 mo from May 2021 until November 2021 in both the intervention and comparison HCAs. A second cohort (referred to as "Treatment cohort") included all children 6–23 mo of age admitted to MAM or SAM OTP provided by health centers and CHWs from 7 May 2021, until 28 February 2022, in both the intervention and comparison HCAs. Because of delays, the intervention did

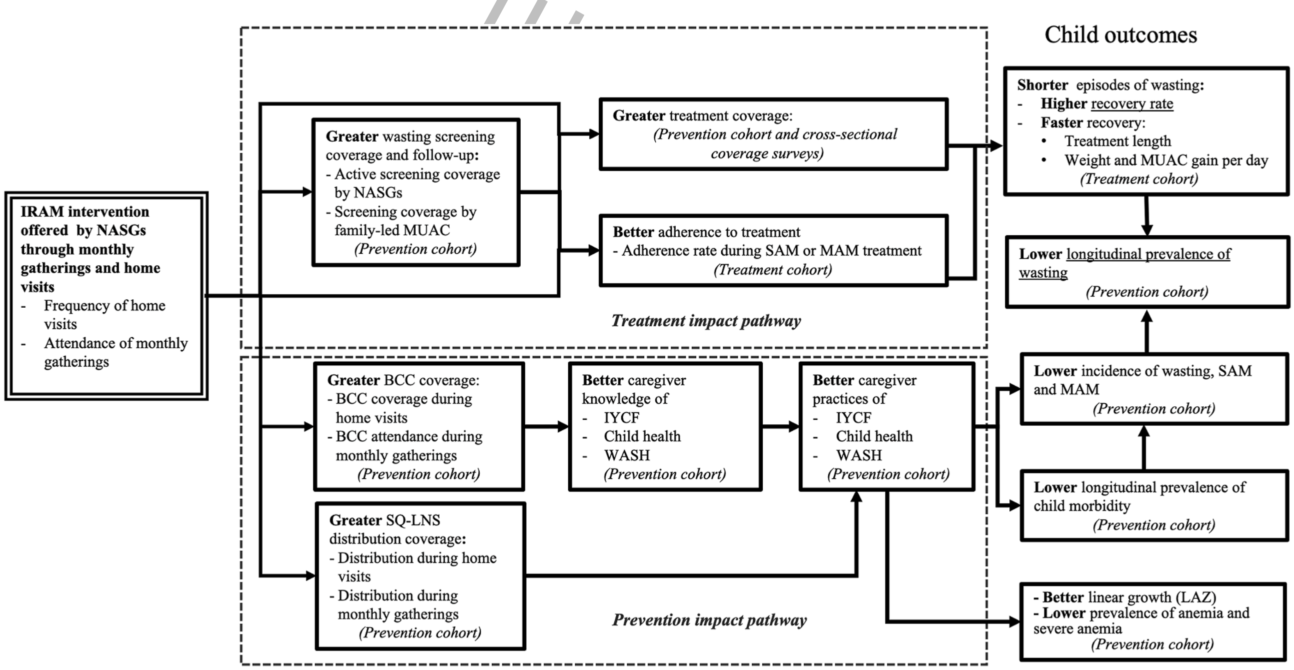


**FIGURE 1.** Program impact pathways, data source, and indicators for evaluation. The intervention's theory of change shows how engaging both prevention and treatment impact pathways can lead to a reduction in the prevalence of child wasting. The diagram presents the evaluation indicators and corresponding data sources (in parentheses and italicized)—derived from the prevention cohort, treatment cohort, or coverage surveys. BCC, behavior change communication; IYCF, infant and young child feeding; LAZ, length-for-age Z-score; MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference; NASG, nutrition activity support group; SAM, severe acute malnutrition; SQ-LNS, small-quantity lipid-based nutrient supplement; WASH, water, sanitation and hygiene.

not begin until 16 July 2021, so the time period from 7 May to 15 July 2021 was considered the baseline period for both cohorts. Starting 16 July 2021, BCC was also delivered to lactating mothers and caregivers of children under 6 mo. As a result, any behavior-related outcomes or anthropometric measures taken at the time of enrollment into the Prevention cohort after that date could no longer be considered true baseline values.

Finally, 2 cross-sectional coverage surveys were conducted toward the end of the study, one in December 2021 and one in February 2022. These surveys were conducted by health center and World Vision Mali staff with support from the research team to estimate wasting and SAM treatment coverage in both the intervention and the control HCA.

## Randomization, sampling, and eligibility

The study area included 45 HCA in the Koutiala health district in the Sikasso region. Because of differences between the health areas in terms of population, urbanity/rurality, and remoteness from the nearest health center, the HCAs in the Koutiala district were first stratified by creating mutually exclusive strata using a list of criteria that were: *1*) recent child nutrition programs conducted by World Vision Mali related to young children nutrition (8/45); *2*) urbanity of the HCA (4/45); *3*) over 10% of the population residing >15 km away from the health center (5/45). Random allocation into comparison and intervention arms was done separately for each stratum. This a priori stratification before randomization was meant to ensure a more balanced distribution of cluster-level characteristics among the study arms.

For the randomization of HCAs, the principal investigator based in the United States (LH), first generated a list of random and unique 2-letter codes (Stata 16.0 software) that were allocated to the study arms (22 for control and 23 for intervention) by stratum. The 2-letter code lists (without study arm allocation information) were sent to Mali, where, per stratum, the World Vision Mali prepared a corresponding number of opaque envelopes each containing 1 of the 2-letter codes from this list. Next, 45 uniformly shaped pieces of paper, each inscribed with the name of 1 of the 45 HCAs and folded in the same way, were distributed across 4 bags, with each bag corresponding to a different sampling stratum. A drawing ceremony was conducted in the presence of the World Vision Mali and district health team, in which a health center senior leader drew a piece of paper from the bag and 1 of the sealed envelopes containing the unique 2-letter code. As he unfolded the piece of paper, he read aloud the name of the HCA and showed the name written on the piece of paper to all participants and wrote that name on the front of the envelope. This process continued until all 45 envelopes were linked to an HCA. The principal investigator then projected the randomization key, and the envelopes were opened 1 by 1. The name of the HCA and the 2-letter code were read aloud so that the result could be recorded and made visible to all participants.

Before the impact evaluation, a census was organized in 4–5 villages per HCA selected at a probability proportionate to their population size to be included in the Prevention cohort. Villages with <1000 inhabitants were excluded from the study for logistical and budgetary reasons. The census listed all children 0–5 mo of age and third trimester pregnant persons. These data were used in the subsequent mo to draw a monthly random sample of children reaching the 6–6.9 mo age bracket to be enrolled in the Prevention Cohort. Children were eligible to participate in the study if they were between 6 and 6.9 mo of age, singleton, with a main caregiver residing in 1 of the 45 HCA at the time of inclusion. Study exclusion criteria were congenital malformations making child anthropometric measurements impossible, and the main child caregiver intending to leave the study area before January 2022.

For the Treatment cohort, all children 6–23 mo of age residing in the villages sampled for inclusion of the in the Prevention cohort and admitted to SAM or MAM OTP managed by the health center or CHW were eligible.

The 2 cross-sectional coverage surveys were conducted in all villages sampled for inclusion of the Prevention cohort. A door-to-door strategy was used to collect anthropometric measures of all children between 6 and 23 mo of age and to assess whether children were currently enrolled in existing SAM or MAM OTP.



## Study outcomes

Wasting was defined as weight-for-length Z-score $<-2$ (WLZ; relative to the median of WHO 2006 growth reference [21]) or MUAC $<125$ mm or the presence of bilateral pitting edema. MAM was defined as $-3 \leq$ WLZ $< -2$ or 115 mm $\leq$ MUAC $<125$ mm. SAM was defined as WLZ $< -3$ or MUAC $<115$ mm or the presence of bilateral pitting edema.

The primary outcome for the Prevention cohort was the longitudinal prevalence (also referred to as the proportion of time diseased) of wasting in children enrolled at the age of 6 mo followed monthly until they reached the age of 12 mo or until the end of the study. Longitudinal prevalence was defined as the number of visits during which wasting is observed divided by the total number of monthly measurements for each child. The primary outcome for the Treatment cohort was the recovery rate in children 6–23 mo of age enrolled in SAM or MAM OTP, defined as the number of children who recovered from SAM or MAM according to the criteria of the national protocol [22] (WLZ $\geq$–1.5 and MUAC $\geq$125 mm and absence of bilateral pitting edema during 2 consecutive visits, within 12 wk after admission to OTP) divided by the total number of admissions.

Other study outcomes assessed monthly by study enumerators in the Prevention cohort were the longitudinal prevalence for SAM and MAM; the incidence of wasting, SAM and MAM; wasting screening coverage (defined as the proportion of children screened using MUAC, WLZ, or bilateral pitting edema in the month before the monthly visit); coverage of active screening performed by NASGs; coverage of screening by caregivers or family members; SQ-LNS distribution coverage (defined as the proportion of caregivers with eligible children who received a monthly dose of SQ-LNS in the month before the monthly visit); BCC attendance or receipt of counseling (defined as the proportion caregivers attending a BCC session or who received counseling in the month before the monthly visit); longitudinal prevalence of acute respiratory infections, fever (axillary temperature $\geq$37.5°C), diarrhea, or malaria; IYCF practices [23]; change in length-for-age z-score (LAZ), weight-for-age z-score (WAZ), WLZ, and MUAC. Additional outcomes assessed when a child was discharged from the Prevention cohort at 12 mo of age or at the end of the study were caregiver knowledge on IYCF and WASH, screening of wasting, MAM, and SAM OTP; WASH practices [24]; immunization coverage as indicated on vaccination cards; hemoglobin (Hb) concentration; the prevalence of anemia and severe anemia defined as Hb concentration <10.5 and 7 g/dL, respectively, as per the latest WHO guideline [25]. Treatment single coverage was assessed among children who had MAM, SAM, or were recovering from either condition at the time of the home visit. Single coverage was calculated using monthly reported OTP attendance and anthropometric data [26] using Equation 1.

$$\text{single coverage } (\%) = \frac{C_{in} + R_{in}}{C_{in} + R_{in} + C_{out} + R_{out}} \times 100 \qquad (1)$$

with $C_{in}$ defined as the number of wasting or SAM cases identified at the time of the survey who were enrolled in OTP, $C_{out}$, the number of wasting or SAM not enrolled in OTP, $R_{in}$, the number of cases that were not wasted or SAM, but that were enrolled in OTP at the time of the home visit and thus recovering from previous wasting or SAM, and $R_{out}$, the number of recovering cases of wasting or SAM that were not wasted or SAM at the time of the survey and not enrolled in OTP. $R_{out}$ cases were estimated by assessing whether the child had wasting or SAM during the 2 monthly home visits preceding the visit when the determination was made.

Other outcomes assessed in the Treatment cohort in children 6–23 mo of age were the treatment outcome defined by the Mali national treatment protocol [recovery (defined above), default (defined as absence in 2 consecutive consultations), death, transfer (defined as transfer to an inpatient care facility because of a lack of recovery in 12 wk, lack of weight gain, or development if clinical complications), or erroneous discharge (defined as recovery declared by health staff despite child not considered recovered by MUAC or WLZ criteria)], WLZ and MUAC at admission, treatment duration, adherence to the treatment schedule defined as the ratio of attended consultations over the number of scheduled consultations, weight and MUAC gain in grams per day per kg of body weight and mm per day, respectively, calculated by subtracting the values at the end of treatment from those at admission divided by treatment duration in days.

Finally, we estimated wasting and SAM treatment coverage using 2 screening and coverage surveys organized by World Vision Mali in all study clusters toward the end of the study. Because data from these cross-sectional surveys do not allow us to estimate the $R_{out}$ from Equation *1*, we estimated the period prevalence of wasting and SAM treatment coverage instead as shown in Equation *2*.

$$\text{Period prevalence of coverage } (\%) = \frac{C_{in} + R_{in}}{C_{in} + R_{in} + C_{out}} \times 100 \qquad (2)$$

Similar to the prevention cohort, OTP enrollment was assessed based on caregiver reports and verification of the appropriate ready-to-use therapeutic food (RUTF) or ready-to-use supplementary food (RUSF) supplement.

## Data collection and measurements

Data collection for both the Prevention and Treatment cohorts took place from 7 May 2021 to 28 February 2022.

### *Prevention cohort*

Enrollment in the Prevention cohort occurred between May and November 2021, targeting children aged 6–6.9 mo. Each child participated in the cohort for a duration of 3–6 mo and was discharged upon reaching 12 mo of age or at the end of the study. Independent study field teams, unaffiliated with the intervention's operations, conducted monthly home visits to administer a household and child questionnaire and to measure the child's anthropometry. All data were collected using Survey Solutions v20.6 (World Bank) software installed on tablets. Data were synchronized weekly to a dedicated protected server.

Child age was calculated using the date of birth estimated at study enrollment from, in order of priority, birth certificates, vaccination cards, or by using a local events calendar. Child anthropometry was measured at enrollment and at each monthly visit of the longitudinal follow-up. Child weight was measured to the nearest 100 g using an electronic scale (SECA 876). Child's length was measured to the nearest 1 mm using length boards/stadiometers (Weigh and Measure LCC). MUAC was measured using a nonstretch tape with 0.1 cm accuracy (SECA 201). All measurements were taken in duplicate by a trained anthropometrist and the study enumerator as assistant. All measurements were standardized before the study. Standardization exercises using repeated measurements on 10 children aged 6–23 mo were repeated every 2 mo throughout the study. The MUAC, weight, and height of the mother were also measured using the same equipment. The child WLZ and LAZ were calculated using the zscore06 command in Stata [27], which uses the WHO's growth standard [21]. A wasting episode was defined as beginning when a child was identified as wasted during the study team's monthly measurement and ended once the child was no longer wasted at any subsequent monthly check. MAM and SAM episodes were defined in a similar manner.

Hb concentration in children was assessed at both enrollment and the end of study follow-up. This involved collecting capillary blood, with the Hb concentration in the second drop of blood measured using a HemoCue 301 device (HemoCue Ltd). Control solutions (Eurotrol) were used weekly to assess the accuracy of the measurements.

At every home visit, enumerator asked the caregiver to recall any child morbidity symptoms (acute respiratory infections, cough, vomiting, breathing difficulties, diarrhea, and fever) over the 3 d preceding the monthly visit. A diarrheal episode was defined as $\geq$3 loose stools in the last 24 h or stools with blood. Fever was measured with a standard thermometer. The presence of malaria parasites was assessed using CareStart Malaria Pf/Pv Combo rapid diagnostic test in capillary Q3 finger blood if the child's body temperature was >37.5°C or if the mother reported a fever episode in the child within the past 48 h.

At study enrollment, we collected descriptive data at various levels. At the household level, we collected data on household composition, food security using the household food insecurity access scale [28], WASH standard indicators [24], housing material, primary light and energy sources, home ownership, and household assets. The latter 4 (only retained if present in 5%–95% of households) were used to construct a proxy score for household socioeconomic status using principal component analysis. Households were grouped into tertiles based on the first principal component values being the one with the highest eigenvalue [29]. We also collected data on maternal and paternal schooling, engagement in any income-generating activities, and parental confidence in caring for their young child, assessed using the Karitane Parenting Confidence Scale [30]. Maternal depression was evaluated using the Edinburgh Postnatal Depression Scale, which has been shown to be valid beyond the postpartum period as well [31]. Maternal weight (SECA 876) and height (Weigh and Measure LCC) were measured in duplicate, and BMI was calculated as weight divided by height squared. Minimum dietary diversity for women—defined as consumption of $\geq$5 of 10 food groups during the previous 24 h—was derived from an open 24-h dietary recall [32].

Child attendance to SAM or MAM OTP was assessed by asking caregivers who reported their child was currently enrolled in OTP to show a sachet of RUTF supplement for SAM or RUSF supplement for MAM as proof.

### *Coverage surveys*

During this door-to-door survey, health center staff and CHWs measured child weight, length, and MUAC and assessed the presence of edema using the same equipment as the study teams. Caregivers were asked if the child was currently attending MAM or SAM OTP and if ≥1 RUSF or RUTF sachet could be shown as proof of recent attendance. Before the surveys, health center staff and CHWs were trained and their measurements of child weight, length, MUAC, and edema assessment standardized by the research team.

### *Treatment cohort*

The Treatment cohort used child data from each OTP consultation recorded by health center staff or CHW in routine treatment registers. Each health center was visited by a study enumerator every 1–2 wk during the day of the OTP consultation. Each CHW providing OTP was visited monthly by a study enumerator. Study teams were responsible for monitoring data quality and copying data from the registers and treatment cards to electronic forms on their tablet.

## Data analysis

### *Sample size*

For the Prevention cohort, we calculated that 42 clusters allowed for the detection of a minimum difference of 4.55 percentage points (pp) or a relative risk (RR) of 0.65 in the longitudinal prevalence of wasting assuming a baseline longitudinal prevalence of 13.2%, a SD of 0.24 pp for the comparison arm, an SD of 0.19 pp for the intervention arm, a mean cluster size of 55 (anticipating a loss of follow-up of 15%), a statistical power of 80%, a type I error of 5% and an intracluster coefficient of 0.04. These estimates were obtained from a previous longitudinal study conducted in the adjacent Segou region [12].

For the Treatment cohort, we aimed to include OTP treatment records for all children aged 6–23 mo with SAM or MAM. On the basis of 2019 health district statistics, we anticipated enrolling 750 cases of SAM and 1000 cases of MAM over 8 mo of follow-up. With 42 clusters averaging 50 SAM/MAM cases each over this period, and assuming a recovery rate of 79% for SAM/MAM OTP (as per 2019 health district statistics), statistical power of 80%, a type I error rate of 5%, and an intracluster coefficient of 0.05, this allowed for the detection of a minimum difference of ~9.0 pp in recovery rate between study arms.

### *Statistical analysis*

Data were analyzed separately for each cohort on an intent-to-treat (ITT) basis. To allow for an ITT analysis in the presence of missing data in the prevention cohort, we used multiple data imputation under the missing at random assumption to impute missing weight, length, and MUAC data for the calculation of longitudinal prevalence of wasting (primary study outcome for the Prevention cohort), SAM, and MAM. A total of 50 imputed datasets were created for this purpose. Outcomes were not imputed for the Treatment cohort.

For the analysis of the impact of the intervention on the longitudinal prevalence of wasting, SAM, MAM, and morbidity, and the incidence of wasting, MAM and SAM, and morbidity signs in the Prevention cohort, we used mixed-effects Poisson regression models with sampling stratum as fixed effect and HCA as a random intercept to obtain adjusted risk estimates. Robust estimation of SEs was used for the models assessing the intervention effect on longitudinal prevalences.

Continuous outcomes (such as WLZ, WAZ, MUAC, and LAZ) measured monthly in the Prevention cohort were analyzed using linear mixed-effects models with continuous variable follow-up time (in months) and sampling stratum as fixed effects, HCA, and child as random intercepts and follow-up time (in months) as a random slope. For each model, we assessed if the addition of a quadratic term of time improved the model fit using a likelihood ratio test comparing the model with and without the quadratic term. To assess the impact of the intervention, we assessed the interaction between intervention allocation and follow-up time using regression models adjusted for cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study to account for cohort effects, child sex, and primiparity.

The impacts of the intervention on dichotomous outcomes such as recovery rate (Treatment cohort), treatment coverage (Prevention and Treatment cohorts and coverage surveys), and service coverage (Prevention cohort) were estimated using linear probability mixed-effects models with robust estimation of the SEs, with sampling stratum as fixed effect and HCA as random effect.

For each regression analysis, we also present impact estimates adjusted for the cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study to account for cohort effects (May–November), child sex (male/female), and primiparity (yes/no). Data management, cleaning, and analyses were done using Stata 17.0 (StataCorp). The statistical significance was set at 5%. All statistical tests were 2-sided.

## Study registration and ethics

The study protocol and its amendment have received approval from the Institutional Review Board of International Food Policy Research Institute (PHND-21-0309) and the Ethics Committee of the Faculty of Medicine, Pharmacy and Onto-Stomatology (2021/97/CE/USTTB) of Mali (Bamako, Mali). The intervention study was registered with clinicaltrials.gov (NCT04872088) before the start of data collection. The statistical analysis plan was uploaded to the same registry on 22 September 2021, before data analysis was started. The purpose and procedures of the study were explained to caregivers of eligible children in their local language and through an information sheet. An informed consent form was signed by the child's primary caregiver and, if present, by the head of the household. Informed consent was obtained after the randomization of clusters to intervention and comparison study arms.

During enumerator home visits, if a child was identified as suffering from wasting, severe anemia, or malaria or exhibited any general danger sign—such as altered consciousness, repeated vomiting, refusal to eat or drink, or convulsions—requiring immediate medical attention, the enumerator notified their supervisor who issued referral to the nearest health center. Treatment of wasting and malaria was provided free of charge at health centers, whereas other treatment costs were reimbursed by the study. World Vision Mali ensured that all health centers had sufficient RUTF and RUSF stocks to guarantee MAM and SAM OTP.

# Results

## Characteristics of participants enrolled in the Prevention cohort

After the initial census and cluster randomization, 3 [comparison (C): $n = 3$; intervention (I): $n = 0$] of the 45 clusters were omitted from the study because of the presence of armed groups operating in the area (Figure 2). The Prevention cohort study enrolled 2324 children belonging to 2324 households between 7 May and 30 November 2021. The last follow-up visits were conducted in February 2022. Less than

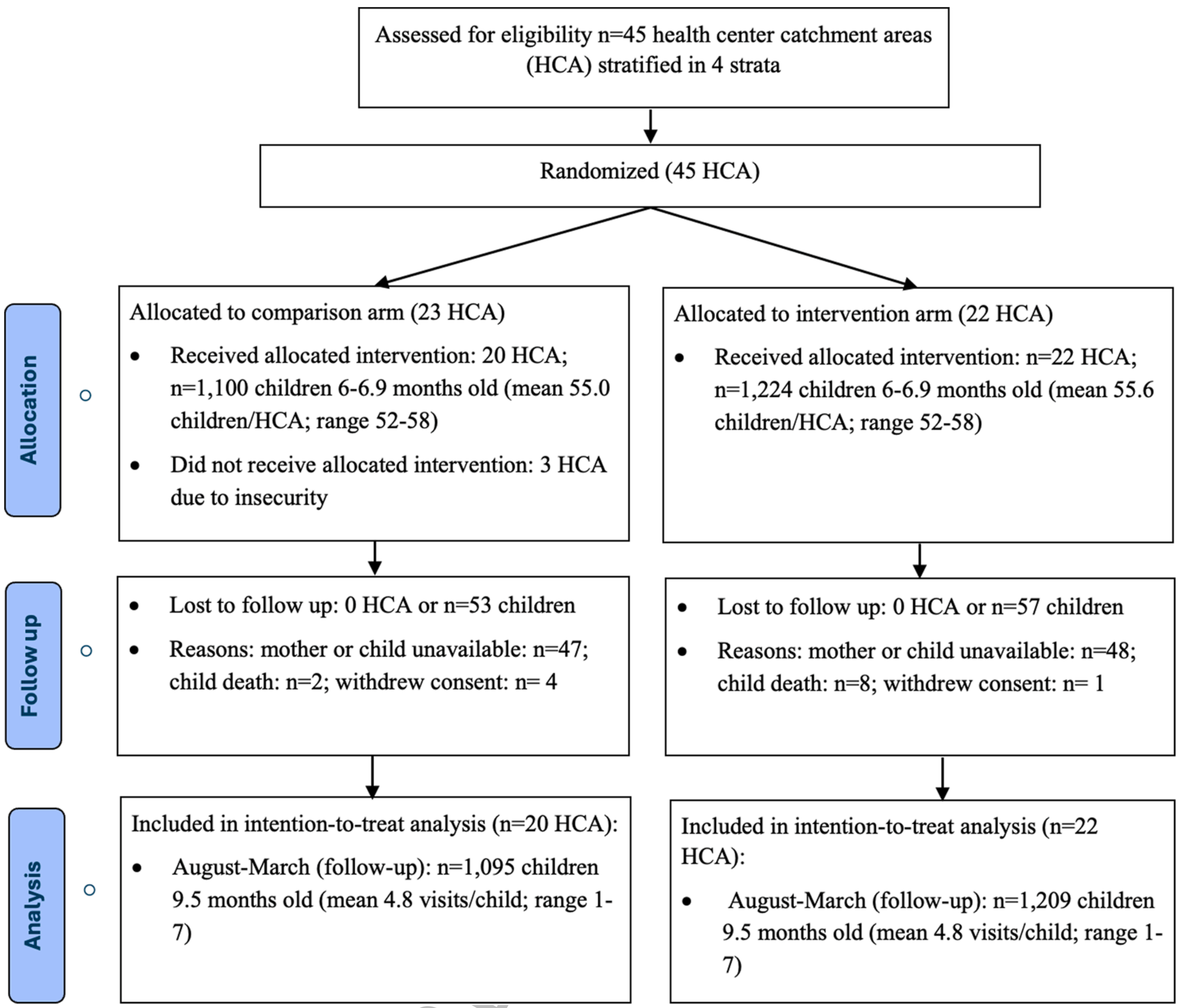


**FIGURE 2.** Trial profile of the Prevention cohort.

5% of children (C: $n = 53$; I: $n = 57$) were lost to follow-up, mainly due to travel or relocation out of the study area (C: $n = 47$; I: $n = 48$). Data from 1008 children, enrolled during the baseline period, were used in baseline estimates before the implementation of the intervention, and follow-up data from 2304 children (C: $n = 1095$; I: $n = 1209$) were used to assess the impact of the intervention.

Household and caregiver characteristics were balanced between study arms during the baseline period (May–July 2021) as well as at the enrollment into the cohort for the total study sample. These data reflect poor socioeconomic, health, hygiene, and care conditions (Table 1).

On the child level, we observed that during the baseline period the study enrolled fewer male (50% compared with 57%) and primiparous (13% compared with 18%) infants in the intervention arm than the comparison arm. Also, slightly lower prevalences of wasting and stunting were observed in the intervention arm as compared with the comparison arm (Table 1). Considering the whole sample, however, consisting of both baseline period and follow-up period, these imbalances were smaller for the baseline period. We presented characteristics of the whole sample households, caregivers, and children enrolled in the Prevention cohort (May–November 2021), indicating which variables—such as anthropometry—may have been influenced by BCC delivered to caregivers between July and November, before the child reached 6 mo of age and entered the study (Table 1). As such, the values of these variables cannot be considered unbiased baseline measures.

During the baseline period, anemia was present in 45% of children at 6 mo of age (Table 1). Child undernutrition was highly prevalent with 1 in 4 children suffering from wasting and close to 5% suffering from SAM. In addition, 1 in 4 children were suffering from stunting.

## Characteristics of children enrolled in the Treatment cohort

After the initial census and cluster randomization, 3 [comparison (C): $n = 3$; intervention (I): $n = 0$] of the 45 clusters were omitted from the study because of the presence of armed groups operating in the area (Supplementary Figure 1). During the baseline period, 187 and 167 children with wasting were admitted to OTP per month in the comparison and intervention arm, respectively (Table 2). During the follow-up period, these numbers increased to 393 and 472 per month in the comparison and intervention arm, respectively. During the baseline period, most cases of wasting enrolled in OTP were with SAM, whereas during the follow-up period, the proportion of wasting cases that were SAM and MAM OTP were more similar. Child age and sex were similar over study arms and the baseline and follow-up period.

**TABLE 1**
Household, caregiver, and child characteristics during the baseline period and at enrollment for the whole sample into the Prevention cohort

| | Baseline period[1] | | Total sample[1] | |
|---|---|---|---|---|
| | Comparison | Intervention | Comparison | Intervention |
| Household characteristics | n = 480 | n = 528 | n = 1100 | n = 1224 |
| Household size | 6.7 ± 3.2 | 6.4 ± 2.8 | 6.4 ± 3.0 | 6.2 ± 2.6 |
| Number of children <5 y | 1.8 ± 0.82 | 1.8 ± 0.82 | 1.8 ± 0.77 | 1.8 ± 0.77 |
| Number of adults 15–64.9 y | 2.6 ± 1.1 | 2.5 ± 1.02 | 2.5 ± 0.99 | 2.5 ± 0.93 |
| Polygamous household | 127 (26%) | 141 (27%) | 265 (24%) | 313 (26%) |
| HH food security | | | | |
| HFIAS Score[2] | 2.0 ± 3.5 | 2.0 ± 3.5 | 2.0 ± 3.5[3] | 2.0 ± 3.5[3] |
| Food secure | 259 (54%) | 288 (55%) | 621 (56%)[3] | 719 (59%)[3] |
| Socioeconomic status classification[4] | | | | |
| Low | 178 (37%) | 188 (36%) | 379 (34%) | 396 (32%) |
| Average | 164 (34%) | 186 (35%) | 363 (33%) | 412 (34%) |
| High | 138 (29%) | 154 (29%) | 358 (33%) | 416 (34%) |
| Improved water treatment technologies used[5] | 183 (38%) | 233 (44%) | 430 (39%)[3] | 519 (42%)[3] |
| Improved sanitation facility[5] | 201 (42%) | 193 (37%) | 433 (39%)[3] | 442 (36%)[3] |
| Handwashing station with soap available[5] | 56 (12%) | 53 (10%) | 139 (13%)[3] | 124 (10%)[3] |
| Improved primary water source[5] | 271 (56%) | 325 (62%) | 666 (61%) | 740 (60%) |
| Distance to nearest health center[6] (km) | 4.1 (0.82, 7.5)[7] | 4.1 (0.76, 7.4)[7] | 4.1 (0.74, 7.6)[7] | 4.3 (0.76, 7.5)[7] |
| Paternal characteristics | n = 467 | n = 518 | n = 1041 | n = 1186 |
| Father is household member | 391 (84%) | 442 (85%) | 864 (83%) | 984 (83%) |
| Father is head of household | 335 (72%) | 389 (75%) | 699 (67%) | 798 (67%) |
| Never attended school | 251 (52%) | 302 (57%) | 516 (47%) | 601 (49%) |
| Has an income-generating activity | 271 (56%) | 315 (60%) | 577 (52%) | 636 (52%) |
| Parental confidence scale[8] | | | | |
| Severe clinical range (<31) | 97 (20%) | 136 (26%) | 207 (19%)[3] | 281 (23%)[3] |
| Moderate clinical range (31–35) | 114 (24%) | 137 (26%) | 223 (20%)[3] | 266 (22%)[3] |
| Maternal characteristics | n = 480 | n = 528 | n = 1100 | n = 1224 |
| Biological mother | 479 (100%) | 524 (99%) | 1094 (99%) | 1217 (99%) |
| Age (y) | 28 ± 6.4 | 28 ± 6.7 | 28 ± 6.5 | 28 ± 6.5 |
| Spouse of household head | 460 (96%) | 513 (97%) | 1059 (96%) | 1196 (98%) |
| Never attended school | 354 (74%) | 388 (73%) | 793 (72%) | 932 (76%) |
| Has an income-generating activity | 244 (51%) | 266 (50%) | 560 (51%) | 591 (48%) |
| Probable depression (EPDS ≥13)[9] | 63 (13%) | 58 (11%) | 123 (11%) | 147 (12%) |
| Parental confidence scale[8] | | | | |
| Severe clinical range (<31) | 22 (4.6%) | 26 (4.9%) | 52 (4.7%)[3] | 70 (5.7%)[3] |
| Moderate clinical range (31–35) | 132 (28%) | 154 (29%) | 267 (24%)[3] | 383 (31%)[3] |
| Number of food groups consumed | 4.1 ± 1.3 | 4.0 ± 1.2 | 4.0 ± 1.2[3] | 3.9 ± 1.2[3] |
| Minimum dietary diversity for women[10] | 161 (34%) | 168 (32%) | 343 (31%)[3] | 372 (30%)[3] |
| BMI ($kg/m^2$) | 23 ± 3.9 | 23 ± 5.4 | 22 ± 3.7[3] | 22 ± 4.3[3] |
| BMI <18.5 $kg/m^2$ | 27 (5.7%) | 22 (4.3%) | 74 (6.8%)[3] | 63 (5.3%)[3] |
| Assisted delivery of last newborn[11] | 409 (85%) | 463 (88%) | 926 (85%) | 1071 (88%) |
| Had ≥4 ANCs during last pregnancy | 154 (48%) | 197 (53%) | 349 (47%) | 425 (48%) |
| Child characteristics | n = 480 | n = 528 | n = 1100 | n = 1224 |
| Age (mo) | 6.5 ± 0.28 | 6.5 ± 0.29 | 6.5 ± 0.29 | 6.5 ± 0.30 |
| Male | 275 (57%) | 263 (50%) | 610 (55%) | 641 (52%) |
| Primiparity | 85 (18%) | 69 (13%) | 176 (16%) | 184 (15%) |
| Hemoglobin concentration (g/dL) | 11 ± 1.1 | 11 ± 1.1 | 11 ± 1.1[2] | 11 ± 1.1[2] |
| Anemia (Hb <10.5 g/dL) | 210 (44%) | 244 (47%) | 680 (62%)[2] | 763 (63%)[2] |
| Severe anemia (Hb <7 g/dL) | 1 (0.21%) | 2 (0.38%) | 5 (0.46%)[2] | 4 (0.33%)[2] |
| Child and visit characteristics | n = 937[12] | n = 1008[12] | n = 1100 | n = 1224 |
| Wasting[13] | 238 (25%) | 211 (21%) | 257 (23%)[3] | 241 (20%)[3] |
| Severe acute malnutrition[14] | 41 (4.4%) | 48 (4.8%) | 65 (5.9%)[3] | 60 (4.9%)[3] |
| Stunting (LAZ <−2) | 244 (26%) | 215 (21%) | 218 (20%)[3] | 209 (17%)[3] |
| Weight-for-age Z-score | −1.3 ± 1.1 | −1.2 ± 1.1 | −1.1 ± 1.1[3] | −1.0 ± 1.1[3] |
| Weight-for-length Z-score | −0.57 ± 1.1 | −0.49 ± 1.1 | −0.52 ± 1.1[3] | −0.45 ± 1.1[3] |
| Length-for-age Z-score | −1.3 ± 1.1 | −1.3 ± 1.0 | −1.1 ± 1.1[3] | −1.0 ± 1.1[3] |
| MUAC (mm) | 132 ± 10 | 132 ± 11 | 132 ± 11[3] | 133 ± 13[3] |

Results are mean ± SD or n (%). Q14
Abbreviations: ANC, antenatal consultation; Hb, hemoglobin; LAZ, length-for-age z-score; MUAC, mid-upper arm circumference.

[1] Baseline sample enrolled from 7 May until 15 July 2021; Total sample enrolled from 7 May until 30 November 2021.
[2] HFIAS, Household Food Insecurity Access Scale [28].
[3] These variable values may have been affected by BCC delivered before the child's enrollment in the Prevention cohort.
[4] Socioeconomic status class presented as tertiles from the first principal component using data on asset ownership, housing materials, primary source of lighting, primary energy source, and home ownership.
[5] Water, Hygiene and Sanitation standard indicators [24].
[6] Linear distance between households and the nearest health center or CHW was calculated using Global Position System coordinates collected at household and health center and CHW level.
[7] Median distance (IQR).
[8] Karitane Parenting Confidence Scale [30].
[9] EPDS, Edinburgh Postnatal Depression score [31].
[10] Defined as having consumed ≥5 of 10 food groups in the past 24 h [32].
[11] Assisted by a medical doctor, midwife, or trained traditional midwife.
[12] Based on all repeated measurements collected during the baseline period from 7 May until 15 July 2021.
[13] Defined as weight-for-length Z-score <−2 or MUAC <125 mm or nutritional edema.
[14] Defined as weight-for-length Z-score <−3 or MUAC <115 mm or nutritional edema.

**TABLE 2**
Characteristics of children 6–23 mo of age at admission for outpatient therapeutic programs, during the baseline, and follow-up period, Treatment cohort

| Children with wasting enrolled in SAM or MAM OTP | Baseline[1] | | Follow-up | |
|---|---|---|---|---|
| | C | I | C | I |
| | $n = 562$ | $n = 485$ | $n = 2755$ | $n = 3302$ |
| Male child | 244 (43%) | 212 (44%) | 1152 (42%) | 1322 (40%) |
| Child age at admission (mo) | 12 ± 4.0 | 12 ± 3.8 | 12 ± 3.9 | 12 ± 3.8 |
| Number of children admitted per month to OTP | 187 | 162 | 393 | 472 |
| Children with SAM | 347 (62%) | 351 (72%) | 1436 (52%) | 1592 (48%) |
| Number of children admitted per month to SAM OTP | 116 | 117 | 205 | 227 |
| Children with MAM | 215 (38%) | 134 (28%) | 1319 (48%) | 1710 (52%) |
| Number of children admitted per month to MAM OTP | 72 | 45 | 188 | 244 |

Results are mean ± SD or $n$ (%).
Abbreviations: C, comparison arm; I, intervention arm; MAM, moderate acute malnutrition; SAM, severe acute malnutrition.
[1] Values at admission of OTP during the baseline period between 7 May and 15 July2021. The sample was limited to children 6–23 mo of age treatment outcome data in treatment registers during this baseline period.

## Impact on child-level outcomes

### *Prevention cohort*

Unadjusted regression analysis indicated that the intervention significantly reduced the longitudinal prevalence of wasting [RR: 0.83; 95% confidence interval (CI): 0.69, 0.99] compared with the comparison arm (Table 3). However, adjusting for the prevalence of child wasting at baseline, child age, child sex, primiparity, and month of cohort enrollment, the impact became smaller and was no longer statistically significant at the 5% level. Similar findings were obtained for the MAM and SAM longitudinal prevalences.

The intervention had a significant positive impact on MUAC change over time (+1.2 mm per month; 95% CI: 0.28, 2.0) (Supplementary Figure 2) and on WAZ change over time (+0.14 per month; 95% CI: 0.05, 0.23) (Supplementary Figure 3). We did not observe any significant impacts on changes in WLZ and LAZ over time.

The intervention had no impact on the longitudinal prevalence of child morbidity symptoms and malaria diagnosed by point-of-care tests in the subgroup of children with fever (Supplementary Table 3).

Adjusted regression analyses showed that the intervention led to a 20% (RR: 0.80; 95% CI: 0.64, 0.99) reduction in the incidence of wasting and reduced SAM and MAM incidence by 29% (RR: 0.71; 95% CI: 0.57, 0.89) and 21% (RR: 0.79; 95% CI: 0.63, 1.0), respectively (Table 4).

The intervention led to a significant increase in child Hb concentration (+0.35 g/dL; 95% CI: 0.20, 0.51) and a significant reduction in child anemia (−14 pp; 95% CI: −21, −7.8) relative to the comparison arm at the end of the study (Table 5).

### *Treatment cohort*

The intervention did not impact recovery rate, default, death, or transfer rates (Table 6). Similar results were found for SAM and MAM OTP subgroups (Supplementary Table 4). There was no difference in MUAC, WLZ, and LAZ at admission between study arms and between the baseline and follow-up period. We did not observe any difference between study arms for treatment duration, weight, and MUAC gain in children enrolled in SAM OTP. However, the intervention appeared to have a negative impact on weight gain (−0.86 g/kg/d; 95% CI: −1.4, −0.31) in children enrolled in MAM OTP (Supplementary Table 4).

## Intermediate outcomes on the prevention impact pathway

We did not find evidence for an impact on caregiver knowledge on breastfeeding, complementary feeding, child health, and hygiene and CMAM treatment practices (Supplementary Table 5). One notable exception was knowledge of screening for wasting using MUAC which was 11 pp (95% CI: 5.9, 16) higher in the intervention arm at the end of study follow-up.

We did not observe any impact of the intervention on any of the IYCF and WASH practices at the end of study follow-up (Supplementary Tables 6 and 7). Similarly, we did not observe any difference between study arms in vaccination card possession and cumulative immunization coverage for various vaccines in the subgroup of children with available vaccination cards (Supplementary Table 8).

## Intermediate outcomes on the treatment impact pathway

Along the treatment pathway, we assessed the impact of the intervention on treatment coverage using 2 independent data sources. Using data from the Prevention cohort, we found that the intervention increased SAM treatment coverage by 11 pp (95% CI: 1.3, 21) (Table 7). Using data from 2 stand-alone coverage surveys conducted in all study clusters in children 6–23 mo of age, we observed in the second survey only that the intervention led to a borderline positive effect of 11 pp (95% CI: −0.29, 22) on wasting treatment prevalence and a positive impact of 15 pp (95% CI: 0.35, 30) on SAM treatment coverage.

Using Treatment cohort data, we did not observe any impact of the intervention on adherence rates to treatment of wasting or SAM OTP (Table 7).

**TABLE 3**

Impact of the intervention on the longitudinal prevalence of wasting, SAM, and MAM, Prevention cohort

| | Baseline[1] | | Follow-up | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|---|---|
| | C | I | C | I | RR | 95% CI | RR | 95% CI |
| | *n* = 957 | *n* = 1053 | *n* = 6780 | *n* = 7500 | | | | |
| Wasting[2] | 26% | 21% | 18% | 15% | 0.83 | (0.69, 0.99) | 0.87 | (0.73, 1.1) |
| SAM[3] | 4.5% | 4.6% | 3.6% | 2.6% | 0.76 | (0.55, 1.1) | 0.78 | (0.56, 1.1) |
| MAM[4] | 21% | 16% | 14% | 12% | 0.84 | (0.70, 1.0) | 0.88 | (0.74, 1.0) |

Results are *n* or %. Missing data have been imputed using multiple imputation strategy. The effect of the intervention on the longitudinal prevalence of wasting, SAM, and MAM was analyzed using mixed-effects Poisson regression models using robust estimation of SEs with sampling stratum as fixed effect and health center catchment area as random intercept. Adjusted models had in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, and primiparity as fixed effects.

Abbreviations: C, comparison; CI, confidence interval; I, intervention; RR, risk ratio.

[1] Based on all repeated measures collected during the baseline period from 7 May until 15 July 2021.

[2] Wasting, defined by WLZ $<-2$ or a MUAC $<125$ mm or the presence of bilateral pitting edema.

[3] SAM, severe acute malnutrition, defined by WLZ $<-3$ or a MUAC $<115$ mm or the presence of bilateral pitting edema.

[4] MAM, moderate acute malnutrition, defined by $-3 \leq$ WLZ $< -2$ or a $115 \leq$ MUAC $< 125$ mm.

**TABLE 4**

Impact of the intervention on the incidence of wasting, SAM, and MAM, Prevention cohort

| | Baseline[1] | | Follow-up | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|---|---|
| | C | I | C | I | IRR | 95% CI | IRR | 95% CI |
| Wasting[2] | | | | | | | | |
| Number of children | 480 | 528 | 1100 | 1222 | | | | |
| Number of episodes/time at risk (child-years) | 148/26 | 131/30 | 507/308 | 463/357 | | | | |
| Incidence | 5.8 | 4.4 | 1.6 | 1.3 | 0.77 | (0.62, 0.95) | 0.80 | (0.64, 0.99) |
| SAM[3] | | | | | | | | |
| Number of children | 480 | 528 | 1100 | 1222 | | | | |
| Number of episodes/time at risk (child-years) | 36/34 | 33/37 | 142/377 | 111/422 | | | | |
| Incidence | 1.1 | 0.89 | 0.38 | 0.26 | 0.70 | (0.55, 0.90) | 0.71 | (0.57, 0.89) |
| MAM[4] | | | | | | | | |
| Number of children | 480 | 528 | 1100 | 1222 | | | | |
| Number of episodes/time at risk (child-years) | 120/28 | 107/33 | 435/336 | 400/380 | | | | |
| Incidence | 4.3 | 3.3 | 1.3 | 1.05 | 0.79 | (0.63, 0.98) | 0.79 | (0.63, 1.00) |

Results are *n* or %. Missing data were imputed using multiple imputation strategy. The effect of the intervention on the incidence of wasting, SAM, and MAM was analyzed using mixed-effects effects Poisson regression models with sampling stratum as fixed effect and health center catchment area as random intercept. Adjusted models had in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, and primiparity as fixed effects.

Abbreviations: C, comparison; CI, confidence interval; I, intervention; IRR, incidence risk ratio.

[1] Based on all repeated measurements collected during the baseline period from 7 May until 15 July 2021.

[2] Wasting, defined by WLZ $< -2$ or a MUAC $< 125$ mm or the presence of bilateral pitting edema.

[3] SAM, severe acute malnutrition, defined by WLZ $< -3$ or a MUAC $< 115$ mm or the presence of bilateral pitting edema.

[4] MAM, moderate acute malnutrition, defined by $-3 \leq$ WLZ $< -2$ or a $115 \leq$ MUAC $< 125$ mm.

## Program exposure

Over the 7 mo of implementation, the intervention had a significant impact on the coverage of intervention services offered during contacts with the NASG members: 37 pp higher (95% CI: 31, 44) for wasting screening coverage, 5.6 pp higher (95% CI: 0.23, 11) for BCC coverage, and 50 pp higher (95% CI: 44, 55) for SQ-LNS coverage (Table 8).

The intervention led to positive impacts on the coverage of the 2 main delivery platforms (home visits and monthly group gatherings) through which NASG delivered the intervention activities (Table 8). Home-visit coverage was 8.4 pp higher (95% CI: 4.2, 13) and attendance at NASG group gatherings was 33 pp higher (95% CI: 27, 39) in the intervention arm as compared with the comparison arm. However, home-visit coverage in the intervention arm remained low with an average of 10% of beneficiaries receiving these visits. Conversely, 37% of intervention beneficiaries attended NASG group gatherings on average.

During the home visits, in both study arms, the most frequently delivered service was screening for wasting (91% in both study arms), followed by SQ-LNS distribution (61%; only in the intervention arm) and delivery of BCC/counseling (42% in both study arms). If a group gathering was organized, SQ-LNS was the predominant activity in the intervention arm (89%), followed by screening for wasting (similar in both study arms C: 58%; I: 64%). In both study arms BCC/counseling coverage through group gatherings was found very low (<10%).

In the monthly Prevention cohort data, we observed, in the intervention arm, a continuous increase in coverage of SQ-LNS distribution (Supplementary Figure 4) and screening for wasting (Supplementary Figure 5) during the first 5 mo of implementation, reaching saturation between month 5 and 7 at 65%–70% for both SQ-LNS coverage and screening coverage of wasting. In the comparison arm, screening coverage varied between 10% and 20%. The most common platform through which intervention beneficiary households received the SQ-LNS was the monthly gathering organized by NASG

**TABLE 5**

Impact on child hemoglobin and anemia at the endline of the study, Prevention cohort

| | Baseline[1] | | Endline/study exit | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|---|---|
| | C | I | C | I | Δ | 95% CI | Δ (pp) | 95% CI |
| | $n = 473$ | $n = 524$ | $n = 1070$ | $n = 1237$ | | | | |
| Hb concentration (g/dL) | 11 ± 1.1 | 11 ± 1.1 | 10 ± 1.2 | 11 ± 1.2 | 0.36 | (0.20, 0.52) | 0.35 | (0.20, 0.51) |
| Anemia[2] | 210 (44%) | 244 (47%) | 576 (54%) | 497 (40%) | −14[3] | (−21, −7.9) | −14[3] | (−21, −7.8) |
| Severe anemia[4] | 1 (0.21%) | 2 (0.38%) | 5 (0.47%) | 6 (0.49%) | | | | |

Results are mean ± SD or *n* (%). The effect of the intervention on the prevalence of anemia using mixed-effects linear probability regression models with sampling stratum as fixed effect and health center catchment area as random intercept using robust estimation of SEs. The effect of the intervention on Hb concentration was analyzed using a mixed-effects linear regression model with sampling stratum as fixed effect and health center catchment area as random intercept. Adjusted models had in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, child age, and primiparity as fixed effects.

Abbreviations: C, comparison; CI, confidence interval; I, intervention; Hb, hemoglobin; pp, percentage points.

[1] Hemoglobin concentration and anemia status were assessed at enrollment in the Prevention cohort during the baseline period of May–July 2021. Stunting, wasting SAM and MAM outcomes were assessing using repeated monthly measurements during the baseline period from 7 May until 15 July 2021.

[2] Anemia, defined by an Hb concentration <10.5 g/dL.

[3] Risk difference expressed in percentage points.

[4] Severe anemia, defined by an Hb concentration <7 g/dL; the regression model did not converge to provide model estimates.

**TABLE 6**

Impact of the intervention on treatment recovery of wasting and adherence rates to the treatment schedule, Treatment cohort

| Treatment outcome | Baseline[1] | | Endline | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|---|---|
| | C | I | C | I | Δ[2] | 95% CI | Δ[2] | 95% CI |
| | $n = 562$ | $n = 485$ | $n = 2755$ | $n = 3302$ | | | | |
| Recovery rate[3] | 302 (54%) | 266 (55%) | 1749 (63%) | 2178 (66%) | 0.82 | (−7.6, 9.2) | −0.43 | (−7.6, 6.7) |
| Default[4] | 119 (21%) | 68 (14%) | 407 (15%) | 519 (16%) | 1.4 | (−3.0, 5.8) | 0.98 | (−3.0, 4.9) |
| Death | 2 (0.36%) | 2 (0.41%) | 1 (0.04%) | 6 (0.18%) | 0.14 | (−0.01, 0.29) | 0.14 | (−0.010, 0.28) |
| Transfer[4] | 84 (15%) | 105 (22%) | 305 (11%) | 358 (11%) | 0.23 | (−3.6, 4.1) | 0.46 | (−3.0, 4.0) |
| Erroneous discharge[5] | 55 (9.8%) | 44 (9.1%) | 284 (10%) | 235 (7.1%) | −2.4 | (−6.8, 2.1) | −2.2 | (−6.3, 1.9) |

Descriptive results are shown as *n* (%). The effect of the intervention was analyzed using mixed-effects linear probability regression models with sampling stratum as fixed effect and health center catchment area as random intercept using robust estimation of SEs. Adjusted models had in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, child age, and primiparity as fixed effects.

Abbreviations: C, comparison arm; I, intervention arm.

[6] Erroneous recovery declared by health staff (child is not considered recovered using MUAC or WLZ criteria). Q16

[1] Based on outcome data collected during the baseline period from 7 May until 15 July 2021.

[2] Risk difference expressed in percentage points.

[3] Recovery defined by the national Mali treatment protocol: demonstrating absence of edema and, WHZ ≥−1.5 or MUAC ≥125 mm during consecutive consultations.

[4] Default of treatment as defined by the national CMAM protocol as not attending 2 consecutive consultations.

[5] Child did not recover within 12 wk, did not exhibit weight gain, or developed medical complications and was therefore transferred to an inpatient care facility.

(40%), followed by collecting the SQ-LNS at the NASG's residence (18%) which was not included in the intervention protocol. In fewer occasions, SQ-LNS was obtained from a NASG through a home visit as originally planned (10%), or from CHWs (5%).

Most of the screening for wasting was done by NASG members (39%). The intervention increased screening by caregivers and family members (family-led MUAC approach) over time. The distribution of MUAC tapes to intervention households suffered from a 4-mo lag phase (Supplementary Figure 6). Toward the end of the study 60% of intervention arm households possessed a MUAC tape. However, in the subsample of intervention arm households with a MUAC tape available, only 41% of households reported monthly screening. Contrary to screening and SQ-LNS coverage, the intervention did not increase BCC coverage over time as compared with the comparison arm (Supplementary Figure 7).

Intraclass correlation coefficients for all study outcomes are reported to quantify between-cluster heterogeneity and inform future studies (Supplementary Table 10). Q5

## Discussion

The IRAM-Mali integrated intervention strengthening both wasting prevention and wasting treatment found no impact on the longitudinal prevalence of wasting. Preventive SQ-LNS and BCC reduced the incidence of child wasting by 20%, SAM by 29%, and MAM by 21%. Integrating wasting screening with SQ-LNS distribution boosted screening coverage by 37 pp, which in turn increased SAM OTP coverage by 11–15 pp. NASG follow-up at home of children admitted to OTP did not improve caregiver adherence to treatment schedule or recovery rate.

**TABLE 7**

Impact of the intervention on treatment coverage and adherence rate of wasting treatment and SAM treatment coverage, by cohort (Prevention or Treatment) or by coverage survey

| | Baseline[1] | | Follow-up/Endline | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|---|---|
| | C | I | C | I | Δ[2] | 95% CI | Δ[2] | 95% CI |
| Prevention cohort | $n = 274$ | $n = 238$ | $n = 1352$ | $n = 1230$ | | | | |
| Wasting treatment coverage | 75 (27%) | 78 (33%) | 497 (37%) | 535 (44%) | 5.5 | (−0.81, 12) | 3.6 | (−2.6, 9.7) |
| | $n = 54$ | $n = 62$ | $n = 316$ | $n = 253$ | | | | |
| SAM treatment coverage | 20 (37%) | 32 (52%) | 180 (57%) | 166 (66%) | 8.6 | (1.4, 16) | 11 | (1.3, 21) |
| Coverage surveys[3] | | | | | | | | |
| First survey | | | $n = 856$ | $n = 1082$ | | | | |
| Wasting treatment coverage | | | 158 (22%) | 216 (24%) | 1.9 | (−9.9, 14) | 1.8 | (−9.9, 13) |
| | | | $n = 258$ | $n = 291$ | | | | |
| SAM treatment coverage | | | 32 (20%) | 46 (26%) | 7.1 | (−6.5, 21) | 6.8 | (−7.0, 20) |
| Second survey | | | $n = 625$ | $n = 698$ | | | | |
| Wasting treatment coverage | | | 61 (14%) | 125 (22%) | 11 | (−0.32, 23) | 11 | (−0.29, 22) |
| | | | $n = 163$ | $n = 165$ | | | | |
| SAM treatment coverage | | | 8 (14%) | 24 (26%) | 15 | (−0.09, 30) | 15 | (0.35, 30) |
| Treatment cohort | $n = 554$ | $n = 478$ | $n = 2644$ | $n = 3152$ | | | | |
| Adherence rate to full schedule[4] | 387 (70%) | 360 (75%) | 1771 (67%) | 1948 (62%) | −4.8 | (−13, 3.3) | −4.0 | (−12, 4.0) |

Descriptive results are shown as mean ± SD or $n$ (%). The effect of the intervention on wasting and SAM treatment coverage and adherence estimates was analyzed using mixed-effects linear probability regression models with sampling stratum as fixed effect and health center catchment area as random intercept using robust estimation of SEs. Adjusted models pertaining to the Prevention cohort data using in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, child age, and primiparity as fixed effects. Adjusted models using the cross-sectional survey coverage data were adjusted additionally for child sex and age. Adjusted models pertaining to the Treatment cohort data were adjusted additionally for adherence rates observed during the baseline period (May–July 2021), child sex and age and admission to OTP.

Abbreviations: C, comparison arm; I, intervention arm; SAM, severe acute malnutrition.

1 Based on all repeated measurement data from Prevention cohort and Treatment cohort collected during the baseline period from 7 May until 15 July 2021.

2 Risk difference expressed in percentage points.

3 Data originated from 2 cross-sectional surveys in all study clusters conducted early December 2021 (first survey) and February 2022 (second survey). Data shown are for the subsample of 6–23 mo of age.

4 Attending all scheduled weekly SAM or bi-weekly MAM OTP consultations.



The lack of intervention effect on the longitudinal prevalence of wasting (RR: 0.87; 95% CI: 0.7, 1.1) suggests that complex interventions implemented over a short 7-mo period are inadequate in addressing the persistent challenge of child wasting in high-burden settings. In contrast, the implementation over 24 mo in the neighboring Segou region in Mali of preventive package for child malnutrition through integrated strategies (PROMIS) Mali, an integrated intervention of SQ-LNS, BCC, and community-based wasting screening, achieved a 30% reduction in the longitudinal prevalence of wasting [12].

## Prevention impact pathway

Preventive BCC and SQ-LNS substantially reduced the incidence of child wasting. Although the study design does not allow us to isolate the effects of BCC from those of SQ-LNS distribution, careful assessment of the prevention impact pathway and previously conducted studies suggest that the primary driver of impact may be SQ-LNS. First, the strength and consistency of the evidence base for SQ-LNS far outweigh that for BCC, with a 14% relative reduction in wasting, and 31% in severe wasting, [33–35]. In contrast, the evidence for BCC is mixed with some meta-analyses or systematic reviews reporting little to no effect of BCC on IYCF practices [36,37], whereas others showed modest improvements in WAZ, WHZ, and LAZ in general [37] or in food secure settings only [38]. Second, although SQ-LNS coverage steadily rose to 65%–70% in the intervention arm toward the end of the study, BCC coverage never surpassed 20%. Third, the intervention did not produce measurable gains in intermediate behaviors related to health, WASH, or IYCF practices.

Originally, IRAM aimed to deliver the integrated package of SQ-LNS, BCC, and wasting screening primarily via monthly NASG home visits in addition to standard of care monthly group BCC. However, NASG volunteers were unable to sustain the required caseload of 30 or more visits per month, and home-visit coverage was only 10%. Most NASG shifted intervention delivery through pre-existing monthly gatherings. This diluted the intended personal nature of BCC. Even when home visits were conducted, individual BCC was provided in only 43% of home visits. In addition, the group BCC was often not organized or did not include all caregivers attending these monthly gatherings, resulting in a 6% coverage.

We also observed several challenges with the SQ-LNS distribution as well. SQ-LNS distribution shifted from anticipated home visits to community gatherings and 10%–15% of intervention caregivers reported collecting SQ-LNS from NASG volunteers' homes, an observation also made previously [12]. These deviations likely reflect both logistical gaps (e.g., caregivers not attending the gatherings) and organizational inconsistencies (e.g., gatherings not organized), suggesting that decentralized community models may be more challenging to deliver an integrated package according to study protocol than more centralized health facility-based models.

## Treatment impact pathway

IRAM significantly increased screening coverage by 37 pp, largely due to NASG members screening children during the monthly gatherings where BCC was delivered and SQ-LNS distributed. The family-led MUAC approach was gradually rolled out, but utilization of the MUAC tapes was limited with only 41% of these households reported

**TABLE 8**
Service coverage by study arm, Prevention cohort

| | Follow-up | | Unadjusted model | | Adjusted model | |
|---|---|---|---|---|---|---|
| | C | I | Δ[a] (pp ) | 95% CI | Δ[a] (pp ) | 95% CI |
| Total coverage main services | $n$ = 5253 | $n$ = 5807 | | | | |
| MUAC screening coverage | 914 (17%) | 3262 (56%) | 37 | (31, 44) | 37 | (31, 44) |
| BCC/ counseling coverage | 420 (8.0%) | 784 (14%) | 5.7 | (0.19, 11) | 5.6 | (0.23, 11) |
| SQ-LNS coverage | 47 (0.89%) | 3168 (55%) | 49 | (44, 54) | 50 | (44, 55) |
| Platform: monthly home visits by NASG | $n$ = 5215 | $n$ = 5795 | | | | |
| Received home visit by NASG in past 30 d | 95 (1.8%) | 602 (10%) | 8.4 | (4.2, 13) | 8.4 | (4.2, 13) |
| Services delivered during home visit | $n$ = 95 | $n$ = 602 | | | | |
| MUAC of the child measured by NASG | 86 (91%) | 540 (92%) | 3.8 | (−5.3, 13) | 2.7 | (−6.1, 11) |
| BCC received | 40 (42%) | 250 (43%) | 3.5 | (−14, 21) | 2.6 | (−15, 20) |
| SQ-LNS received | 1 (1.1%) | 369 (61%) | 51 | (35, 67) | 47 | (33, 61) |
| Platform: monthly gathering organized NASG | $n$ = 5253 | $n$ = 5807 | | | | |
| Mother attended gathering in past 30 d | 62 (1.3%) | 1983 (39%) | 36 | (29, 42) | 36 | (29, 42) |
| Services delivered during monthly gathering | $n$ = 62 | $n$ = 1983 | | | | |
| MUAC of the child measured by NASG | 36 (58%) | 1261 (64%) | 0.37 | (−21, 22) | 0.59 | (−20, 21) |
| BCC received | 2 (3.2%) | 123 (6.2%) | 3.0 | (−3.1, 9.0) | 3.3 | (−2.9, 9.4) |
| SQ-LNS received | 12 (19%) | 1767 (89%) | 70 | (55, 85) | 69 | (54, 84) |

Results are $n$ (%). The effect of the intervention on the prevalence of service coverage or attendance was analyzed using mixed-effects linear probability regression models with sampling stratum as fixed effect and health center catchment area as random intercept using robust estimation of SEs. Adjusted models had in addition cluster baseline means (May–July 2021 period) of the outcome under analysis, month of enrollment into the study (cohort effect), child sex, and primiparity as fixed effects.

Abbreviations: BCC, behavior change communication; C, comparison arm; CI, confidence interval; I, intervention arm; MUAC, mid-upper arm circumference; NASG, nutrition activities support group; pp, percentage points; SQ-LNS, small-quantity lipid-based nutrient supplement; Δ, difference in prevalence expressed in percentage points.

[1]Risk difference expressed in percentage points. Q17

screening their child at least monthly. Whereas previous studies have established that caregivers are technically able to measure their child's MUAC accurately [39], it is less clear whether this approach allows for earlier detection of wasting and increases screening coverage compared with other approaches [40–42].

Contrary to the PROMIS Mali study, where an impact of 28 pp on screening coverage did not lead to any impact on treatment coverage [12], the increase in screening coverage because of the IRAM intervention led to a positive, albeit limited, impact on SAM treatment coverage. This finding is robust as it is derived from 2 independent data sources: the Prevention cohort and coverage surveys. However, the prevalence estimates from the coverage surveys during exhaustive screening campaigns point at low SAM treatment coverage, varying between 14% and 26%, well below the SPHERE standard of 50% for Q6 rural areas [43]. In contrast, the higher SAM treatment coverage estimates from the Prevention cohort (57%–66%) were likely the result of study enumerators referring to OTP any child they identified with wasting in the study cohort, in both study arms.

IRAM tasked NASG members with conducting home visits for children previously identified with wasting or enrolled in OTP to support caregiver adherence and improve recovery rates. However, low monthly home-visit coverage—including among households with children enrolled in OTP (data not shown)—likely contributed to the modest gains in SAM treatment coverage and the absence of improvement in OTP adherence.

Another hypothesis for the limited impact of the intervention on treatment coverage could be the confusion between preventive SQ-LNS and RUTF/RUSF used for treatment. An exploratory analysis showed that SQ-LNS was frequently (93%) distributed by NASG to children identified with wasting who were not enrolled in OTP at the time of SQ-LNS distribution (Supplementary Table 9). Moreover, in 85% of these cases, the child consumed SQ-LNS in the 3 d preceding the monthly follow-up visit by study enumerators. In contrast, in the subgroup of children already enrolled into OTP at the time of SQ-LNS distribution, only 20% of children identified with wasting received SQ-LNS. Two possible explanations can be put forward: either NASG volunteers considered SQ-LNS equivalent to the therapeutic treatment supplements (RUTF or RUSF), or they were reluctant to deny the SQ-LNS to caregivers of children they diagnosed with wasting. As such, a substitution effect by SQ-LNS of appropriate wasting treatment cannot be ruled out. Further operational research should assess how such apparent contamination of the treatment impact pathway by the prevention pathway can be minimized, for instance, by delivering preventive supplements exclusively through CHWs or health center staff managing MAM and SAM treatment under OTP.

Another plausible explanation for the intervention's limited effect on treatment coverage is confusion between preventive SQ-LNS and the RUTF/RUSF used for wasting treatment. Exploratory findings indicate that NASG volunteers frequently distributed SQ-LNS—93% of the time—to children identified with wasting who were not enrolled in OTP at the time of distribution (Supplementary Table 9). Moreover, in 85% of these cases, the child had consumed SQ-LNS in the 3 d before the enumerators' follow-up visit. In contrast, among children already enrolled in OTP, only 20% of those identified with wasting received SQ-LNS. Two interpretations for this observation can be put forward: NASG volunteers may have viewed SQ-LNS as interchangeable with therapeutic supplements, or they may have felt uncomfortable withholding SQ-LNS from caregivers of children they themselves identified as wasted. Either way, a substitution of SQ-LNS for appropriate treatment cannot be ruled out. Future operational research should examine how to prevent this type of contamination between prevention and treatment pathways—for example, by restricting distribution of preventive supplements to CHWs or health-facility staff managing MAM and SAM under OTP.

Surprisingly, the intervention negatively affected weight gain during MAM OTP, despite similar anthropometric status at admission across study arms. A possible explanation is that the preventive BCC/SQ-LNS package may have averted wasting in more responsive children, leaving a higher share of treatment-resistant cases—such as those with underlying morbidities—in the intervention arm. These children typically recover more slowly. However, the quasi-experimental design of the Treatment cohort, with overlapping prevention and treatment components, limits firm interpretation.

## Strengths and limitations

The study used a rigorous randomized controlled design and assessed multiple intermediate outcomes along the prevention and treatment impact pathways, drawing on several data sources. We closely tracked the coverage of prevention and treatment services to improve internal validity and to link impacts to actual caregiver–child exposure.

Most indicators—including screening, BCC exposure, SQ-LNS receipt, treatment coverage, and child morbidity—relied on caregiver recall and may be prone to error, although such bias is likely nondifferential across study arms. Although the randomized design supports unbiased impact estimates in the Prevention cohort, results from the Treatment cohort warrant caution. Limited information in OTP registers prevented checking for baseline differences or adjusting for them, and the effectiveness of the preventive intervention may have shifted the profile of children entering OTP. A key operational limitation was the 5-mo delay in reaching adequate service coverage, leaving only a short window for measurable impact within the 7-mo implementation period. Some expected improvements in child health and nutrition may simply not have had time to materialize.

## Programmatic implications

Relying on community volunteers to deliver complex interventions remains challenging. In Mali, NASG volunteers had limited capacity to conduct effective home visits, and shifting activities to group sessions, although more efficient, reduced the ability to tailor BCC to individual needs. Aligning incentives with workload could improve adoption and coverage.

Protocol deviations, such as SQ-LNS being given outside the designated platform or to children with wasting, highlight the need for stronger training and supervision to ensure fidelity. Future programs should also test new approaches for delivering BCC that more effectively improve IYCF, WASH, and health practices, and include messaging on the risks of wasting to strengthen referral and treatment coverage. Where preventive supplements like SQ-LNS are used, closer coordination with treatment services is essential to avoid substitution for therapeutic products. Finally, given the substantial start-up lag observed in this study, future evaluations should allow sufficient time for community-based interventions to reach full coverage before assessing impact.

In conclusion, the 7-mo IRAM intervention delivered a large-scale, integrated intervention implemented by NASG volunteers to strengthen the full continuum of care for child wasting. Although the intervention did not significantly reduce the longitudinal prevalence of wasting, it was effective in lowering the incidence wasting and SAM. In addition, the intervention substantially increased screening coverage, which in turn led to small positive impact on SAM treatment coverage. Future implementation research should examine how to more effectively leverage community groups to improve intervention delivery and achieve greater impact in the prevention and management of child wasting.

## Uncited Reference

[20]

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## Author contributions

The authors' responsibilities were as follows – LH, EB: designed research; LH, EB, LD, TF, MT, MO, AH, RLB: conducted the research; LH, LD, TF: analyzed data; LH: developed the first draft and revised the manuscript; EB, RLB, LD, MT: critically reviewed the manuscript; and all authors: read and approved of the final manuscript.

## Conflict of interest

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## Data availability

Data described in the manuscript and code book will be made publicly and freely available at IFPRI's Dataverse (www.dataverse.harvard.edu/dataverse/IFPRI).

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajcnut.2026.101294.

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