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Randomized Controlled Trial of the Impact of Offering a Nutrition and Health Intervention to Children Recovered from Moderate Malnutrition: Final Report

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Abbreviations and Acronyms

ANOVA	analysis of variance
CDC	U.S. Centers for Disease Control and Prevention
CHW	community health worker
CI	confidence interval
CMAM	Community-Based Management of Acute Malnutrition
cm	centimeter(s)
DHS	Demographic and Health Survey
dL	deciliter(s)
EED	environmental enteric dysfunction
g	gram(s)
HAZ	height-for-age z-score
HFIAS	Household Food Insecurity Access Scale
HH	household
HIV	human immunodeficiency virus
ICC	intracluster correlation coefficient
IYCF	infant and young child feeding
kcal	kilocalorie(s)
kg	kilogram(s)
LNS	lipid-based nutrient supplement(s)
LTFU	lost to follow-up
MAM	moderate acute malnutrition
mcg	microgram(s)
mg	milligram(s)
mL	milliliter(s)
MUAC	mid-upper arm circumference
OR	odds ratio
OTP	outpatient therapeutic program
RDA	recommended daily allowance
RUSF	ready-to-use supplementary food
RUTF	ready-to-use therapeutic food
SAM	severe acute malnutrition
SES	socioeconomic status
SFP	supplementary feeding program
TB	tuberculosis
U.S.	United States
USAID	U.S. Agency for International Development
WASH	water, sanitation, and hygiene
WHO	World Health Organization
WHZ	weight-for-height z-score
WLZ	weight-for-length z-score
WUSTL	Washington University in St. Louis

Abstract

Very little is known about what happens to children after initial recovery from moderate acute malnutrition (MAM) and how well that recovery is sustained. Only a few studies have systematically followed children after recovery, and those that have been done found that relapse (defined as reverting to being acutely malnourished) and other poor outcomes are very common. In this study, we conducted a cluster randomized, controlled clinical effectiveness trial to assess the impact of a package of health and nutrition interventions on improving the proportion of children who remained well nourished for one year following recovery from MAM.

We followed 1,487 children who recovered from MAM at 21 health clinics in rural Malawi. Children at 11 clinics received a package of interventions that included a lipid-based nutrient supplement (LNS), zinc supplementation, deworming medication, a bed net, and malaria prophylaxis following discharge from a supplementary feeding program (SFP). The remaining 10 sites served as controls; children at those clinics received the standard of care with no additional interventions. Children returned to the clinics for reassessment at 1, 3, 6, and 12 months following initial recovery from MAM.

The proportion of children that remained well nourished was higher in the intervention group at all follow-up visits, with 53% of children remaining well nourished in the intervention group and 48% in the control group after 12 months ($P = 0.076$). Higher anthropometric measurements upon admission and discharge from the SFP and improved linear growth following recovery, as well as better household (HH) water, sanitation, and hygiene (WASH) factors, were found to be associated with children who remained well nourished during the entire 12-month period following recovery from MAM.

An additional package of basic health and nutrition services provided to children upon discharge from the SFP improves the likelihood that recovery from MAM will be sustained. Still, additional research is needed to identify treatment protocols and other interventions that further increase the likelihood that a child will remain well nourished following MAM treatment.

1 Introduction

Moderate acute malnutrition (MAM) affects 11% of children under 5 years old worldwide, putting them at increased risk of death, illness, and other long-term consequences [1]. While standard recommendations for the treatment of severe acute malnutrition (SAM) have been well established and accepted by the international community, no such standard guidelines exist for the treatment of MAM. There are ongoing investigations regarding the effectiveness of different treatments for MAM [2], yet a large gap in knowledge exists around the sustainability of recovery with the current treatment practices.

Few studies have systematically followed children after recovery from MAM, and those that have been done found that relapse (defined as reverting to being acutely malnourished) and other poor outcomes are very common. A study in Niger followed children who were successfully discharged from supplementary feeding programs (SFPs) for 6 months and found that 20% of children relapsed [3]. Another recent study done by our research team in Malawi found that only 63% of children successfully treated for MAM remained well nourished 12 months [4]. Other studies show a similar trend of high relapse rates among children following SAM treatment [5]. Further observations include the risk of death being highest during and immediately after treatment, then lessening over time [6]. Children with SAM who are admitted to feeding programs are more likely to die after discharge than children with MAM [7]. Children are less likely to relapse with home-based care using ready-to-use therapeutic food (RUTF) than with inpatient care [8].

In addition to high relapse rates, almost all studies report that common childhood illnesses are prevalent among those who relapse or die after initial recovery [4, 5, 7, 9]. Illnesses, such a fever, cough, malaria, and diarrhea, are frequently present during the initial 3 months after discharge, decreasing sharply thereafter [5]. This suggests that the same common infectious diseases that afflict well-nourished children may be responsible for the relapses in children recovering from acute malnutrition [10].

These studies have begun to shed light on issues of child health and nutrition status following discharge from acute malnutrition treatment, yet much remains unknown about what causes relapse and what are the potential solutions for improving sustained recovery. In this study, we conducted a cluster randomized, controlled clinical effectiveness trial to assess the impact of a package of health and nutrition interventions on improving the proportion of children who remained well nourished for 1 year following recovery from MAM.

2. Subjects and Methods

2.1 Subjects and Setting

The study took place in rural, southern Malawi where the population consists mainly of poor, subsistence farmers living in mud and thatch homes. Maize is the staple crop in the region; it is gathered once a year during a single main harvest during April through August. Study sites consisted of 21 health clinics in five different districts: Makhwira, Mitondo, Ndakwera, and Nkhate in Chikwawa District; Chiradzulu and Mauwa in Chiradzulu District; Chamba, Chikweo, Chipalonga, Mlomba, and Nsanama in Machinga District; Chikonde, Mbiza, Milonda, Muloza, Namasalima, and Naphimba in Mulanje District; and Chingale, Matiya, Mayaka, and Namasalima in Zomba District.

Participants enrolled in the study consisted of children ages 6–62 months who had recovered from MAM and been discharged from an SFP. Discharge criteria consisted of mid-upper arm circumference (MUAC) reaching 12.5 cm with no bilateral edema. A child was excluded if he or she was simultaneously involved in another research trial or SFP; had a chronic debilitating illness (other than HIV or tuberculosis [TB]); or had a history of peanut, milk, or soy allergy. A child was also excluded if he or she had received therapy for acute malnutrition within 1 month prior to admission into the SFP so as to focus the study primarily on the sustained recovery of initial MAM. Those whose MUAC dropped below 11.5 cm or who developed edema during the initial treatment for MAM were also excluded from the study.

2.2 Study Design

The study consisted of a cluster randomized, controlled clinical effectiveness trial assessing the impact of a package of health and nutrition interventions on improving the proportion of children who remained well nourished for 1 year following recovery from MAM. The intervention package was randomly allocated across clinic sites rather than at the individual level. Individual random assignment was avoided due to the likelihood of participants at the same site observing the additional intervention services being provided to some children while others received standard of care. By randomly allocating across clinics, the risk of sharing and cross contamination was therefore minimized. Of 21 total sites, 11 were randomly allocated to be intervention sites; children at those sites received the package of interventions in addition to the standard of care. The other 10 sites served as control groups at which children received only the standard of care.

Before enrolling in the study, all children had been diagnosed with MAM, defined as having MUAC < 12.5 cm and > 11.4 cm without bipedal edema, and had enrolled and recovered from MAM in an SFP program. During the SFP treatment, children consistently received one type of the following foods: a whey-based ready-to-use supplementary food (RUSF), a soy-based RUSF, or RUTF, all dosed at approximately 75 kcal/kg of body weight/day.[1] Caregivers were instructed to feed the food only to the malnourished child, to provide him or her with additional complementary foods, and to ration the food until the next fortnightly distribution. Children were scheduled for follow-up appointments on a fortnightly basis, where anthropometric measurements were taken and children were reassessed for clinical symptoms of illness. If a child remained moderately malnourished, an additional ration of food was provided. Children who became severely malnourished were transferred to an outpatient therapeutic program (OTP) or inpatient nutritional rehabilitation center, where they were treated according to Malawian national guidelines. If a child remained moderately malnourished after 12 weeks of SFP treatment, the child was referred to an OTP or hospital for further assessment and treatment as necessary.

[1] The type of food provided was based on availability of ingredients for local RUSF or RUTF production in Malawi. Type of food received during initial SFP treatment was accounted for during analysis when it was found to have statistical significance.

Children were defined as "recovered" from MAM when their MUAC was at least 12.5 cm and they had no bipedal edema. Upon discharge from the SFP (which was also the same time as enrollment in this follow-up study), all caregivers received nutrition counseling. These SFP treatment protocols were the same across all clinics, regardless of whether or not children at the site were chosen to receive the package of interventions.

There was no opportunity to blind participants or field investigators during the course of the study, as it was clear whether or not children received the intervention package. However, each child's data were entered into a computer database and analyzed by individuals blinded to the intervention group. Groups were not revealed until after the end of the trial and all statistical analysis had been completed.

Sample size was calculated based on the hypothesis that the intervention group would experience lower rates of relapse for 12 months following recovery from MAM. Due to the fact that provision of the package of interventions was randomized across clinics, a correction factor was used to adjust for any implementation or population differences between sites. An intracluster correlation coefficient (ICC) of 0.007 (calculated from a previous unpublished study conducted by the same research group that measured relapse across similar clinic sites) and a coefficient of variation of cluster size of 0.65 (calculated from pilot data), power of 80%, and alpha of 0.05 were used to detect a 10% difference in relapse rates between the control and intervention groups. Assuming the control group has 63% of children remaining well nourished [4], in order to detect an improvement of 10 percentage points (to 73%), an average of 58 participants per cluster was needed across the 21 clusters. Sample size was calculated using Stata Version 13.0 (StataCorp LP, College Station, TX). Given the long follow-up period with large gaps between visits, additional children were enrolled to account for the possibility of a high default rate. The final sample size was 1,487 children.

A subsample of 145 children was randomly selected to provide blood samples (0.5 mL) to assess immune function during the time of discharge and the first couple of months thereafter. The blood was used to measure serum C3, a proxy indicator for how well the immune system is able to fight off infection. A low serum C3 may indicate increased susceptibility to infection [12]. Malnourished children have been shown to have low serum C3 levels [11–13], while serum C3 level increases following treatment of malnutrition [11, 14]. After samples were collected, blood was centrifuged to separate the serum from the red blood cells and aliquots were frozen in liquid nitrogen until analysis. Serum C3 was quantified using standard immunochemical techniques [11] at Washington University in St. Louis (WUSTL). A pilot laboratory study was conducted to demonstrate that serum C3 was unchanged when allowed to sit for up to 8 hours before centrifugation, separation, and freezing.

An in-depth household (HH) survey was conducted on a subsample of 315 caregivers upon enrollment in the study. This survey was administered at the home of the caregiver by a trained data collector (either a senior pediatric nurse or a community health worker [CHW]). Information related to common indicators that have been shown to be associated with malnutrition and common childhood illnesses was collected. This included data on a wide variety of socio-demographic characteristics, child dietary diversity, infant and young child feeding (IYCF) practices, and water, sanitation, and hygiene (WASH) factors. This survey was administered to caregivers of children at control sites only.

2.3 Intervention

The control group received nutrition counseling at the point of discharge from an SFP. This consisted of health education messages regarding proper complementary feeding and recognition of common childhood illnesses, with the encouragement to seek medical care if signs or symptoms of illness were noted. A caregiver was informed to bring her child to the health clinic whenever she felt that the child might benefit from assessment. The intervention group received the same nutrition counseling as the control group, plus four additional components in a package of health and nutrition service interventions:

1. **Food:** 40 g/day of a lipid-based nutrient supplement (LNS providing almost 200 kcal and one recommended daily allowance (RDA) of almost all 23 micronutrients included in the supplement for 2 months after discharge from the SFP (**Table 1** and **Table 2**). LNS is a high-lipid, highly fortified supplement. It is used in addition to the diet as a lipid and micronutrient boost, often with the goal of preventing or treating malnutrition in vulnerable populations. The LNS used in this study was produced locally by Project Peanut Butter in Blantyre, Malawi, and contained peanut paste, nonfat dry milk, palm oil, sugar, a micronutrient mix containing concentrated minerals and vitamins, and an emulsifier. The product underwent quality assurance and safety testing for aflatoxin and microbial contamination at the Malawi Bureau of Standards and at Eurofins Scientific Inc. (Des Moines, IA).
2. **Malaria prevention:** A single insecticide-treated bed net upon enrollment and sulfadoxine-pyrimethamine for malaria prophylaxis at a monthly dose of approximately 25 mg/kg (sulfadoxine component) for 3 months during the rainy season (December–February). Previous research shows that the most adverse outcomes in children who have recovered from MAM occur during the rainy season in Malawi following recovery [4]. Thus, the provision of a bed net, as well as malaria prophylaxis during the rainy season, was thought to potentially reduce the risk of poor outcomes, including relapsing to malnutrition. Sulfadoxine-pyrimethamine was chosen as the malaria prophylaxis due to its proven effectiveness [15], low cost, and local availability in Malawi. During the rainy season, each participant was asked to visit the clinic monthly, at which time staff administered the malaria prophylaxis.
3. **Deworming:** A single dose of albendazole (200 mg for children under 2 years and 400 mg for children at least 2 years old) upon enrollment in the study. Administration of albendazole is common practice for deworming in developing countries and is part of many Community-Based Management of Acute Malnutrition (CMAM) protocols.
4. **Zinc:** A 14-day course of 20 mg zinc sulfate starting at the time of discharge from the SFP. This dose has also been shown to decrease the progression of environmental enteric dysfunction [16].

This package of interventions was chosen to increase the likelihood of children remaining well nourished after recovery from MAM at relatively low cost.

2.4 Study Participation

After confirming enrollment criteria were met, informed consent was obtained from all caregivers. Information on demographic characteristics, health history, and HH food insecurity was collected. Health history included questions about past illnesses, immunizations, supplements, malaria prophylaxis, deworming, and use of a bed net. HH food security was assessed using the nine-item Household Food Insecurity Access Scale (HFIAS) [17]. Trained nutrition researchers and senior pediatric nurses then evaluated children for acute malnutrition by taking anthropometric measurements and assessing for edema. Standard methodologies for anthropometric measurements were used, including weight, measured with an electronic scale to the nearest 5 g; length, measured with a rigid length board to the nearest 0.2 cm[2]; and MUAC, measured with a standard insertion tape to the nearest 0.1 cm. Field nutrition nurses

[2] Recumbent length was measured on all children regardless of age. This measurement was later adjusted by the WHO Anthro software by adding 0.5 cm to all children over 87 cm who were measured lying down. This is common practice to produce appropriate length/height measurements if the measures are taken recumbent without regard to the child's age. Using these measures produces appropriate weight-for-height z-scores (WHZ) and weight-for-length z-scores (WLZ) for children 2 years and older and children under 2 years, respectively; and appropriate height-for-age z-scores (HAZ) and length-for-age z-scores (LAZ) for children 2 years and older and children under 2 years, respectively. Throughout the report, the term WHZ is used to encompass both WHZ for children 2 years and older and WLZ for children under 2 years; and the term HAZ is used to encompass both HAZ for children 2 years and older and LAZ for children under 2 years.

and researchers evaluated participants for edematous malnutrition (kwashiorkor) by examining for bilateral pitting edema.

Upon enrollment, all caregivers received the standard of care provided to all children upon discharge from an SFP, including counseling regarding proper complementary feeding practices, identification of common childhood illnesses, and proper care-seeking practices. At intervention sites, in addition to receiving the standard of care, participants were provided with zinc, albendazole, LNS, and a bed net. Children who were randomly selected to provide a blood sample were led to a calm area separate from the rest of the SFP activities. Standard venipuncture was performed using sterile techniques by a senior pediatric nurse to obtain a sample of whole blood.

For those randomly selected to participate in the in-depth HH survey, caregivers scheduled an appointment for a data collector to visit her home at a time convenient for her. Data collectors then traveled to the caregiver's home where s/he administered the survey. Information was collected about socio-demographic characteristics, child dietary diversity, IYCF practices, hygiene and sanitation practices, and water access. Data collectors also observed the presence and location of bed nets, the condition of water storage containers, handwashing demonstrations, and general cleanliness of the child and caregiver. Lastly, caregivers were asked about their knowledge and perceptions of the SFP, MAM, and relapse. Each survey took approximately 1 hour to complete.

All caregivers were asked to return to the clinic for follow-up visits at 1, 3, 6, and 12 months after enrollment. During each follow-up visit, anthropometrics and other clinical observations (such as pallor, rash, or fever) were assessed. Caregivers were interviewed regarding their child's appetite, infectious symptoms, HH food security, and any medicine use during the prior 2 weeks. During the rainy season (December–February), each participant was asked to visit the clinic monthly, when all children were reassessed and the intervention group received malaria prophylaxis. At each visit, a small gift of appreciation, such as a bucket or a piece of cloth, was given to the caregivers to compensate for the time spent bringing her child to the study site.

Each child was classified as having "remained well nourished," defined as having MUAC $\geq$ 12.5 cm at every follow-up visit for 12 months; "relapsed to MAM," defined as MUAC < 12.5 cm and $\geq$ 11.5 cm at any point during the follow-up period; "developed SAM," defined as MUAC < 11.5 cm and/or bipedal edema (kwashiorkor) at any point during the follow-up period; "died"; or ‘‘lost to follow-up" (LTFU), defined as defaulting on a scheduled visit and never returning for the remainder of the follow-up period. Poor outcomes were considered to be relapsing to MAM, developing SAM, or dying. If a child experienced two poor outcomes over the course of the follow-up period, the more severe category was assigned as the final outcome. For example, if a child relapsed to MAM but later developed SAM, the final outcome was "developed SAM." Furthermore, if a child experienced a poor outcome, but was later LTFU, the poor outcome was used as the final outcome.

If a child relapsed to MAM or developed SAM during the follow-up period, s/he was treated following standard treatment protocols using RUSF or RUTF. This child remained in the study to further observe any other poor outcomes for the duration of the follow-up period. If a child presented ill at the clinic site and needed medical treatment, the study team transported the child and caregiver to the nearest health center.

Due to long periods of time (up to 6 months) between scheduled follow-up visits in which participants were expected to return to the clinic for reassessment and data collection, a large proportion of children LTFU was a concern. To address this issue, a caregiver who missed a scheduled follow-up appointment was visited by a CHW at her home to encourage her to return to the clinic the next time that the research team was present there. If the child failed to return during the following week, a second CHW was sent to the home. If the child missed three consecutive visits, the research team then traveled to the home in an effort to find the child and collect the necessary data. If the team was still not successful in locating the child, it was determined that the child was not reachable and considered to be defaulted from that scheduled follow-up appointment.

2.5 Ethical Oversight

The study was approved by the University of Malawi's College of Medicine Research and Ethics Committee, as well as WUSTL's Human Research Protection Office. Permission to conduct the study was also obtained from each site's District Health Officer and/or District Nutritionist.

2.6 Data Analysis

All data were double-entered into two identical Access (Microsoft Corp., Redmond, WA) databases within 24 hours of the data being collected. Discrepancies between the two databases were identified and the values were corrected upon verification with original forms. Databases were synched to Google Drive at the end of every day to ensure no data were lost.

Anthropometric indices were based on the World Health Organization's (WHO) 2006 Child Growth Standards [18] and calculated using the WHO Anthro software (WHO, Geneva). Exploratory analysis was conducted using Box plots and scatter plots to detect outliers. Implausible values were verified and corrected or else removed from the data set. Rates of MUAC and length gain were calculated in mm/day and weight gain was calculated in g/kg/day over the duration of each participant's time in the study. Dichotomous outcomes were compared with either Fisher's exact test or chi-squared tests, while student's t-tests or analysis of variance (ANOVA) were used for comparing continuous variables. Correction factors were included to account for clustering at the health clinic level. P-values less than 0.05 were considered to be statistically significant. All statistical analysis was conducted using Stata Version 13.0 (StataCorp LP, College Station, TX).

Logistic regression with cluster-adjusted robust standard errors was used to determine if the intervention had a statistically significant influence on whether or not a child remained well nourished and to identify factors at the time of admission to and discharge from the SFP for a child remaining well nourished. Models were constructed using backward elimination, whereby all anticipated covariates were initially included and dropped if they were not statistically significant at $P < 0.05$. Covariates used in the initial model included: whether the child received the intervention, age upon admission to initial treatment, sex, type of food received during initial treatment, admission MUAC, admission WHZ, admission HAZ, whether the child had fever during 2 weeks prior to admission, whether the child had diarrhea during 2 weeks prior to admission, admission to treatment during the harvest season (April–August), HFIAS score (0–27), discharge MUAC, discharge WHZ, MUAC increase during treatment, weight change during treatment, number of days to recovery during treatment, whether the mother was known to be HIV-positive, whether the mother was alive, whether the child slept under a bed net at the time of enrollment, whether the child took malaria prophylaxis during the rainy season (December–February) prior to enrollment, whether the child received deworming medication during the month prior to enrollment, and whether the child took any supplements during the year prior to SFP treatment. Further analysis was done to compare the different experiences of those who relapsed, such as children who relapsed once versus children who relapsed multiple times, using chi-squared and Fisher's exact tests to compare dichotomous variables and student's t test for continuous variables.

Data collected from the subsample of HH surveys was also used to create indices later included in logistic regression to identify HH factors across different programmatic sectors that may be associated with whether or not a child remained well nourished after recovery from MAM. Indicators were grouped according to similarity into the following sectoral indices: socioeconomic status (SES), IYCF practices, food security, and WASH. To collect information that is harmonious with other scientific studies and program evaluations, the majority of indicators included in the HH survey were chosen from frequently used, validated assessment tools. Indices were also created following previous research methods and adapted for the local context and available data. Scores from individual indicators were summed together into a final index that was normalized to range from 0 to 10, with 0 being the worst practices or conditions and 10 being the best practices or conditions.

SES Index. Indicators used to measure SES were based on four measures—access to improved water and sanitation; eight selected assets, including specific HH assets; maternal education; and HH income—in the recently validated WAMI index developed by Psaki et al. [19] in an eight-country study. WAMI was chosen due to its simplified nature and associations with child HAZ [19]. In this study, modifications were made to the index. First, we wanted to include water and sanitation indicators separately in a different covariate (the WASH index) in the final regression model. Therefore, to avoid collinearity between the SES and WASH covariates, water and sanitation indicators were not included in the SES index. Second, monthly HH income was not collected due to challenges in gathering accurate information, as many of the families in this context have informal avenues of income and fluctuating income from month to month [20]. Despite the elimination of the income and WASH components from the full WAMI, analysis by Psaki et al. [19] showed that an expanded SES index is an improvement over measuring either maternal education or assets alone. Therefore, we included the same indicators as the original WAMI, while excluding the WASH and income components and including additional indicators regarding assets owned. Each additional asset was chosen based on interviews with local research nurses and CHWs who reflected on various HH items that would likely distinguish wealth in the local context. Following Paski et al. [19], maternal education and the wealth components in the index were equally weighted. **Table 3** contains information on the definition and scoring of indicators used in the final SES index.

IYCF Index. Indicators incorporated in the construction of the IYCF index were based on the WHO's guidance on measurement of Infant and Young Child Feeding Practices Part 1 [21] and Part 2 [22]. Topics included breastfeeding practices, complementary feeding practices, meal frequency, and dietary diversity. Development of the IYCF index followed methods proposed by Ruel and Menon [23] and others [24–26] with adaptations for the local context and available data. In this study, the IYCF index was defined for four different age groups: 6–8 months, 9–11 months, 12–35 months, and 36–59 months. Because feeding practices vary according to age [21–23], this ensured that the indicators were age appropriate. For example, it is important for a child who is 7 months old to continue being breastfed; yet, for a child who is 4 years old, breastfeeding is less important while frequent meals and snacks as part of the normal family diet is important [23]. The following six indicators were included in the IYCF index: if the child was breastfed, if the child is currently breastfeeding, continued breastfeeding beyond 12 months of age, appropriate introduction of semi-solid and solid foods, dietary diversity, and meal frequency. **Table 4** contains information on the definition and scoring of each indicator used in the final IYCF index.

Food Security Index. HH food security was assessed using the validated, nine-item HFIAS [17]. Respondents were asked a series of nine questions regarding the food security situation at the HH level. Topics included worrying about food, being unable to eat preferred foods, eating only a few kinds of foods, eating foods that they did not want to eat, eating smaller meals, eating fewer meals, lack of food in the house, going to sleep hungry, and going a day without eating. For each question to which a respondent answered "no," she was given a score of 0. If a respondent answered "yes," she was then asked to clarify how frequently this occurred in the last month. Respondents were given a score of 1 for "rarely," 2 for "sometimes," and 3 for "often." Scores were summed and ranged from 0 to 27. This HFIAS was administered to the caregiver at the time of admission into the SFP as well as 1, 3, 6, and 12 months following SFP discharge. Scores across all time points were averaged. **Table 5** contains more information on the scoring on the construction of the final food security index.

WASH Index. The WASH index was formed using a variety of indicators selected from commonly used surveys and program evaluations developed by international agencies [27–29] as well as the 2011 Demographic and Health Survey (DHS) [30]. The caregiver's hands and the child's hands were visually inspected for cleanliness. A number of studies have used visual inspection of respondents' hands to characterize their degree of cleanliness. Pickering et al. [31] found that visible dirt on palms or finger pads or under nails is associated with increased microbiological contamination of hands. Another study in Bangladesh found that a child observed to have visibly clean finger pads was associated with reduced diarrhea prevalence [32]. Our study used the same methodology for inspecting hands, which included a three-point scale denoting "clean," "no visible dirt but unclean appearance," and "visible dirt" regarding the palms, finger pads, and finger nails [27]. During data collection training, data collectors underwent examples of proper scoring, with several tests of inter-rater reliability (i.e., where different enumerators coded the same level of cleanliness for a pair of hands).

Use of improved water source and sanitation facilities was based on the WHO definitions [29, 30]. Access to water was also assessed using the number of trips taken each day to fetch water. Although the number of trips to fetch water in a day is not often included in national surveys, such as the DHS, it has been shown that more trips per day fetching water corresponds with worse child health outcomes [33]. Also, interviews with senior research nurses and CHWs confirmed that the number of trips to fetch water would be well understood by respondents as opposed to a more commonly used indicator of "time it takes to fetch water," as most of the local population would not understand formal time keeping (i.e., minutes and hours). Respondents were asked if they take action to treat water, following DHS format [30]. Water storage containers were assessed for having fitted lids [34]. The U.S. Centers for Disease Control and Prevention (CDC) suggests that drinking water storage containers should have fitted lids to avoid contamination [35]. Hygiene was assessed by direct observation of a handwashing demonstration [27, 28], knowledge regarding five critical times for hand washing [28, 30, 34], and the frequency with which the child is bathed. Although the frequency of bathing a child is not commonly used in WASH assessments, this was included as a proxy indicator for hygiene practices in child care. A recent study in Nepal by Khatri et al. [36] found that children were less likely to be underweight if they were bathed on a daily basis. Equal weighting was given to all indicators given the fact that the majority of indicators were binary and recent studies have shown equal weighting produces similar results as other means for index construction [37]. **Table 6** contains information on the definition and scoring of each indicator used in the final WASH index.

The indices were included in a logistic regression model with cluster-adjusted robust standard errors using backward elimination whereby all covariates remained in the model with a p-value < 0.1, with the exception of the indices, which remained in the model regardless of p-value as they were the primary variables of interest in the model. Initial variables used in the full model included sex, age at the time of admission to the SFP, admission MUAC, admission WHZ, whether the child had fever during the 2 weeks prior to admission into the SFP, whether the child had diarrhea during the 2 weeks prior to admission into the SFP, discharge MUAC, discharge WHZ, whether the mother was known to be HIV-positive, SES index score, food security index score, IYCF index score, and WASH index score.

3. Results

3.1 Cluster Randomized Control Trial

Between April 2014 and June 2016, 1,487 children recovered from MAM at 21 health clinics across rural Malawi and were enrolled in the study, with 718 children at 10 control sites and 769 children at 11 intervention sites (**Figure 1**). Characteristics of the two groups of children were mostly similar, with the exception that a higher percentage of children in the control group received RUTF during initial treatment and a higher percentage of children in the intervention groups received a whey-based RUSF (**Table 7**). The control group had slightly more mothers who were known to be HIV-positive, more caregivers who had died, more children admitted for initial MAM treatment during the harvest season (April-August), and a slightly higher percentage of HH food insecurity at the time of admission to initial treatment. Lastly, there were higher proportions of children who slept under a bed net, took supplements, and received deworming medication in the control group. None listed zinc or LNS. These differences between the groups were later controlled for in regression models.

Of the total 1,487 enrolled children, 754 (51%) remained well nourished, 541 (36%) relapsed to MAM, 73 (5%) developed SAM, 15 (1%) died, and 104 (7%) were LTFU at the end of the 12-month follow-up period (**Table 8**). Many children experienced multiple relapses, with some relapsing to up to five times. Of those who relapsed to MAM only, 324 (60%) relapsed once, while 26%, 10%, and 5% relapsed twice, three times, and four or more times, respectively. Additionally, of those who developed SAM, 50 (69%) also relapsed to MAM at least once (data not shown).

The proportion of children that remained well nourished was higher in the intervention group at all follow-up visits, including 604 (78%) vs. 531 (74%) ($P < 0.05$) at 1 month, 530 (69%) vs. 455 (63%) ($P < 0.05$) at 3 months, 491 (64%) v. 421 (59%) ($P < 0.05$) at 6 months, and 407 (53%) vs. 347 (48%) ($P < 0.1$) at 12 months for the intervention and control groups, respectively (**Table 8**). No significant difference was observed in the proportion of children who relapsed to MAM in the control vs. intervention groups. Those who developed SAM was also similar across groups at 1 ($P = 0.077$), 3 ($P = 0.161$), and 6 months ($P = 0.244$). However, by the final 12-month visit, slightly more children in the control group had developed SAM (46, 6%) than the intervention group (27, 4%) ($P = 0.01$). The control and intervention groups experienced similar proportions of death at 1, 3, and 6 months. Those who died by 12-months was higher (13, 2%) in the intervention group than in the control group (2, 0.3%) ($P = 0.007$) (**Table 8**).

The number of LTFU was greater in the control group at all follow-up visits, including 12 (2%) vs. 5 (1%) ($P < 0.1$) at 1 month, 25 (3%) vs. 12 (2%) ($P < 0.05$) at 3 months, 37 (5%) vs. 23 (3%) ($P < 0.05$) at 6 months, and 63 (9%) vs. 41 (5%) ($P < 0.01$) at 12 months, for the control and intervention groups, respectively (**Table 8**). Half of those who were LTFU had moved; 25% were LTFU for unknown reasons; and 25% lived in Mozambique. (Several health clinics located near the Malawi/Mozambique border serve Mozambicans and several of them were enrolled in the study. However, Malawian CHWs are not permitted to travel to Mozambique and were therefore unable to reach caregivers to remind them to return for the next follow-up visit. Muloza, a control site and the second largest clinic site, is located near the Mozambican border and accounted for almost 30% of all the LTFU in the study [**Table 9**]). Those who were LTFU had fewer mothers as the primary caretakers and fewer children taking supplements (**Table 10**).

Given the different proportions of LTFU between control and intervention sites, primary outcomes were also analyzed without those who were LTFU. The statistical significance regarding the impact of the intervention on the proportion of children who remained well nourished is similar when analyzing the data with and without those who were LTFU.

Secondary outcomes, including growth and the proportion of children reporting to have illness during the 12-month follow-up period were similar across both intervention and control groups, with the exception of the control group experiencing less diarrhea at the 1-month follow-up (**Table 11** and **Table 12**). Although the intervention group experienced more children who remained well nourished over the entire duration of the follow-up period, no difference was observed specifically during the rainy season. The intervention's provision of a bed net and malaria prophylaxis throughout the rainy season did not result in a reduction of poor outcomes during the rainy season (**Table 13**).

A clear pattern of relapse exists throughout the calendar year, with the majority of relapses occurring during the rainy season (December–February), which is also the beginning of the "lean season" when food security is lowest before the harvest. Relapse steadily decreases throughout the year to the lowest number occurring during late harvest (September–November), with no difference between the control and intervention groups (**Figure 2**). In addition to patterns of relapse seen across the calendar year, clear trends also appear across the number of months after discharge from the SFP, with approximately half of all relapses occurring within the first 3 months of initial recovery from MAM (**Figure 3**).

Children who relapsed to MAM and/or developed SAM received treatment ranging from 2 to 48 weeks, with an average of 7.4 weeks over the 12-month follow-up period **(Table 14)**. No difference was observed in the length of treatment received between intervention and control groups, with the exception that more children in the control group required 4 weeks of treatment ($P < 0.05$) (**Table 14**). Those who relapsed to MAM multiple times required longer treatment ($P < 0.001$) and had MUAC drop significantly lower than those who relapsed only once ($P < 0.001$) (**Figure 4** and **Figure 5**). Furthermore, 75% of those who relapsed to MAM once maintained a MUAC above 12.0 cm, yet MUAC dropped to at least 12.2 cm or lower for 75% of those relapsing to MAM multiple times (**Figure 5**). Children who relapsed to MAM once were more likely to experience fever during the 2 weeks prior to initial admission to SFP ($P < 0.05$), weighed more upon admission to SFP ($P < 0.05$), and experienced slightly less length gain during SFP treatment than those who relapsed multiple times ($P < 0.05$). All children who relapsed to MAM experienced a decreased HAZ during the follow-up period. Furthermore, HAZ change was worse among those who relapsed to MAM multiple times compared to those who relapsed only once ($P < 0.05$). Also, the percent of children who experienced fever during the 2 weeks prior to the 12-month visit was higher among those who relapsed to MAM multiple times ($P < 0.05$) (**Table 15**).

3.2 Factors Associated with Remaining Well Nourished

3.2.1 Factors during the Initial Treatment for MAM

In bivariate analysis, children who remained well nourished for the entire 12 months following initial recovery from MAM were on average larger upon admission to initial SFP treatment (including MUAC, weight, and length), showed signs of illness prior to admission to SFP treatment, had more siblings, received RUTF as opposed to a RUSF during treatment, were larger upon discharge from initial treatment (including discharge MUAC, MUAC gain, and weight gain), recovered from MAM in less time during initial SFP treatment, and had received supplements prior to SFP[3] (**Table 16**). Almost all characteristics specific to relapsing to MAM versus developing SAM were similar, with the exception of those who relapsed to MAM required longer treatment in an SFP. Also, those who developed SAM had slightly higher discharge MUAC and MUAC gain during SFP treatment than those who relapsed to MAM, although the differences were extremely small (**Table 17**). Also, characteristics of those who died during the follow-up period do not appear to be distinctly different than those who survived, with the exception

[3] Caregivers were asked an open-ended question as to whether or not the child had received any supplements during the year prior to enrolling in the study. If caregivers responded that the child had received supplements, they were asked to specify what supplements.

that those who died had fewer mothers as the primary caregiver and more moderate food insecurity (**Table 18**).

When controlling for other variables in logistic regression, those who received the intervention were more likely to remain well nourished for 12 months following recovery from MAM than those who did not (odds ratio [OR] = 1.40, 95% confidence interval [CI]: 1.06–1.85, P < 0.05) (**Table 19**). The strongest predictors of remaining well nourished consisted of anthropometric measurements during initial treatment. This included larger MUAC upon admission (OR = 1.19, 95% CI: 1.15–1.24, P < 0.001), having larger MUAC change during initial treatment (OR = 5.80, 95% CI: 3.05–11.03, P < 0.001), and higher discharge WHZ (OR = 2.70, 95% CI: 1.87–3.91, P < 0.001) (**Table 19**). Having larger discharge MUAC is considered to be predictive of remaining well nourished for 3 months (OR = 1.14, 95% CI: 1.06–1.23, P = 0.001) and 6 months (OR = 1.10, 95% CI: 1.05–1.15, P < 0.001), but not statistically significant for the entire 12-month follow-up period. Additional predictive factors with strong statistical significance for remaining well nourished for 12 months include being older upon admission to initial SFP treatment, having fever during the 2 weeks prior to admission to initial SFP treatment, previously sleeping under a bed net, having a mother who is known to be HIV-positive, and food insecurity at the time of admission to initial SFP treatment. However, the type of food received during treatment, number of siblings, length of time needed for recovery during initial treatment, and use of supplements were no longer significantly associated at P < 0.05, with remaining well nourished after controlling for other factors (**Table 19**).

3.2.2 Factors during the Follow-Up Period

Overall, 58% of children experienced catch-up growth (as defined by gain in HAZ) throughout the 12 months following initial recovery from MAM. On average, children who remained well nourished experienced a positive change in HAZ between the time of SFP discharge and the 12-month follow-up visit, while those who did not remain well nourished experienced on average a negative change in HAZ (P < 0.05) (**Table 16**). Linear growth rate was also worse for those who relapsed to MAM multiple times versus those that relapsed to MAM only once (P < 0.05) (**Table 15**). Still worse was the linear growth rate for those that developed SAM (P < 0.01) (**Table 17**). Linear growth rate during the follow-up period was worse for those who experienced poor outcomes during the year following recovery from MAM (**Figure 6**). This significant trend of poor linear growth rate is also seen when comparing the proportion of children who experienced catch-up growth across all outcomes—the more severe the outcome, the fewer children who experienced catch-up growth (**Figure 7**).

3.2.3 Household Factors

A total of 315 caregivers of children enrolled in the study participated in an in-depth HH survey at the time of enrollment. Three surveys were excluded due to data entry error, leaving a total of 312 for final analysis. The percentage of children who remained well nourished for the duration of the 12-month follow-up period after initial recovery from MAM was slightly higher, at 58% in this subsample (**Table 20**), than the 51% in the total sample used in the larger study (**Table 8**). Few differences were observed between those HHs whose children remained well nourished and those that did not. On average, caregivers' hands were observed to be cleaner among those whose children remained well nourished than those who did not (P < 0.05) (**Table 20**). A larger percentage (44%) of HHs in the well-nourished group had lids on all water storage containers (as opposed to storage containers *without* lids) than of HHs whose children did not remain well nourished (32%) (P < 0.05). Also, children who remained well nourished lived in more crowded homes (with a higher number of people per room) than those HHs with children who did not remain well nourished (P < 0.05). The percentage of HHs that used an improved sanitation facility [29] was nearly double among the well-nourished group than the group of HHs whose child did not remain well nourished (P = 0.082) (**Table 20**).

When combining the individual indicators into indices based on sectoral relevance (including SES, food security, IYCF, and WASH indices) in bivariate analysis, the indices did not significantly differ between those who remained well nourished and those who did not (**Table 21**). Yet when controlling for other factors in logistic regression, children who scored better on the WASH index were more likely to remain well nourished than those who scored lower (OR = 1.17, 95% CI: 1.03–1.33, $P < 0.05$) (**Table 22**). Other factors associated with remaining well nourished include being female, being older, having higher MUAC upon admission to SFP, and having a lower SES index score (**Table 22**).

3.2.4 Immune Function

Blood samples were collected from a total of 145 children to assess serum C3 levels as an indicator for immune function during initial recovery from MAM and in the immediate months thereafter. Out of the 145 children, 103 provided one sample at discharge from the SFP, 2 children provided one sample at 1 month following discharge, and 40 children provided two samples—one at discharge and one at either 1 or 2 months later—bringing the total number of blood samples to 185. Serum C3 levels ranged from 59 to 190 mg/dL with a mean of 113.23 mg/dL (**Table 23**). Almost all (96%) samples were considered to be within the normal range (80–160 mg/dL).

4. Discussion

4.1 An Intervention to Reduce Relapse Following Recovery from MAM

In this cluster randomized, controlled clinical effectiveness trial, we demonstrate that children provided with an additional package of health and nutrition interventions following treatment for MAM were more likely to remain well nourished during the subsequent 12 months than children who did not receive the intervention. Previous research shows that children who recover from MAM remain at high risk for relapse and other poor outcomes, with only a fraction remaining well nourished [4]. This study is the first scientific evidence to show that providing additional services to traditional SFP treatment can improve the long-term nutritional status of children who recovery from MAM.

The intervention—consisting of LNS, zinc supplementation, deworming, a bed net, and malaria prophylaxis—increased the proportion of children who remained healthy by 4–6 percentage points at all follow-up points during the subsequent year after initial recovery. No impact was observed on reducing other poor outcomes, such as the proportion of those who relapsed to MAM, the proportion of those who developed SAM, linear growth, or the prevalence of illness. A larger proportion of children were LTFU in the control group, in part because one of the control sites was located near the Malawi/Mozambique border, some Mozambican children were enrolled there, and Malawian CHWs were not able to travel into Mozambique to encourage caregivers to return for scheduled follow-up visits. Also, the items provided to caregivers as part of the intervention may have led to an increased incentive for caregivers to return for follow-up visits, leading to less LTFU in the intervention group.

Part of the intervention was designed specifically to address high relapse rates during the rainy season as observed in a prior study [4]. However, despite the provision of bed nets and malaria prophylaxis, no difference was observed in the proportion of children who remained healthy during the rainy season between control and intervention groups. This may indicate that the aspects of the intervention package that resulted in the greatest impact consisted of the LNS, zinc supplement, and deworming medication. However, further research would be needed to identify any effectiveness of each individual component on the long-term nutritional status of children following recovery from MAM.

Despite the positive impact the intervention had on increasing the proportion of children who remained well nourished, only 53% of children remained well nourished. This is lower than a previous study conducted in the same area that observed 63% of children remaining well nourished [4]. The differences could be attributed to several reasons, one of which may be the different admission and discharge criteria into the SFP, as well as the definition of a relapse. The previous study with a higher percent of children that remained well nourished defined relapse to MAM as having both MUAC < 12.5 cm *and* WHZ < −2 [4]. The current study used only the MUAC criterion as the operational definition for relapse. Also, the previous study's participants were enrolled following an SFP that used WHZ as the sole criterion for admission and discharge, while this current study enrolled participants after an SFP that used MUAC as the sole criterion for admission and discharge. Given the increasing use of MUAC as the sole admission and discharge criterion for the treatment of acute malnutrition, the current study's operational definition and subsequent results may be more reflective of long-term outcomes expected from children who recover from MAM.

4.2 Wide Range of Outcomes among Relapsers

Our analysis revealed a wide range of experiences among those who did not remain well nourished following treatment for MAM. One distinction that emerged is the difference between those who relapsed once versus those who relapsed repeatedly. On average, children who relapse to MAM multiple times required longer treatment and experienced a more severe drop in MUAC than those who relapsed only once. Therefore, seemingly two different relapsers are seen. The first are those who experience one short and mild episode of moderate malnutrition with the ability to quickly bounce back and remain well nourished from then on. Despite the one-time relapse, on average these children do quite well, including better linear growth than those who relapsed multiple times. The second type are children who repeatedly relapse with more severe malnutrition requiring longer treatment (up to 48 weeks) without any truly sustained recovery. Clearly, vastly different health trajectories are seen between those who remain well nourished versus those who do not, as well as differences within the relapse group. These varying follow-up experiences highlight that, even though children in SFPs are all classified with the same type and severity of malnutrition (i.e., MAM), not all children with MAM are at the same risk for poor short- and long-term outcomes. This suggests that a uniform approach for treating all children suffering from MAM may not be appropriate for ensuring that all children reach sustained recovery. Perhaps a more comprehensive assessment of children presenting for MAM treatment could help tailor treatment protocols according to the various risk factors that children exhibit that are associated with poor outcomes.

For this to be possible, further research is needed to identify the biological and/or sociological differences between children who remain well nourished and those who experience varying degrees of poor outcomes following MAM treatment. Our study shows that approximately half of all relapses occurred within the first 3 months of initial discharge from SFP. This may suggest that, although children reach a desired anthropometric recovery threshold, underlying physiological or immunological factors may not have fully recovered, leaving the child susceptible to relapse. Although previous research demonstrates that a deteriorated immune function during acute malnutrition [11–13] may take longer to recover than anthropometric measurements [38], our results found normal serum C3 levels at the time of recovery, indicating normal immune function. Other markers of immune function may need to be explored to better understand the underlying health issues of children following MAM treatment. Also, other conditions known to be associated with poor nutrition, such as environmental enteric dysfunction (further discussed later in this report), may also play a role in the various poor outcomes observed.

4.3 Factors and Programmatic Implications for Remaining Well Nourished after Recovery from MAM

Our study identifies several factors associated with sustained recovery from MAM that may provide insight for future interventions that aim to reduce relapse. The strongest predictors of remaining well nourished consisted of having superior anthropometric measurements during SFP, such as a larger MUAC upon admission. For every 1 mm increase in MUAC upon admission to the SFP, a child has 19% higher odds for remaining well nourished for the 12 months following treatment. These results support previous research that indicates the severity of malnutrition at admission to feeding programs is linked to risk for mortality and other long-term outcomes among children following SAM [6] and MAM treatment [4, 39]. While most SFP protocols provide the same treatment to children with MAM regardless of MUAC, these results suggest that treatment and follow-up procedures should differ for children with lower MUAC, given their higher risk for poor long-term outcomes.

In addition to severity of malnutrition upon admission to treatment, our results show that improved discharge MUAC and WHZ were associated with remaining well nourished for 6–12 months following recovery. These results support findings from another recent study that found higher discharge anthropometric measurements to be the most important predictor of sustained nutritional recovery, regardless of the duration of therapy provided [39]. Without international standard protocols regarding SFP discharge criteria, a wide range of anthropometric indicators, cutoffs, minimum lengths of stay, and other factors are used to determine discharge. Our findings may suggest the potential to reduce relapse rates by treating children with MAM with a higher anthropometric target in mind, although this would likely increase the cost for treatment as children would remain in SFPs longer to attain the higher MUAC or WHZ [39].

Interestingly, children with reported clinical signs of illness (fever and/or diarrhea) at the time of SFP admission were more likely to experience sustained recovery than those without illness. It may be possible that children who become malnourished as a result of an acute illness respond well to treatment, recover, and return back to an otherwise normal nutritional status once the illness (and associated malnutrition) is reversed. However, those without clinical signs of illness may be malnourished due to longer-term, underlying health or nutrition issues that leave the child susceptible to repeated episodes of malnutrition. For these children, the temporary gain in weight during SFP appears to result in malnutrition recovery, but not long after the initial gain the deficient underlying issues result in a return to acute malnutrition.

4.4 Link between Poor Linear Growth and Severity or Relapse Following MAM

A consistently strong relationship exists between poor linear growth and relapsing to acute malnutrition following the recovery from MAM. A trend of poor linear growth is seen across all poor outcomes, with the worst linear growth rates associated with multiple relapses and more severe relapses, while the best linear growth rate is associated with remaining well nourished. Results from this study contribute to a growing body of evidence that closely links linear growth and acute malnutrition [40, 41]. Acute malnutrition, or "wasting," and poor linear growth, or "stunting," were traditionally viewed as two distinct manifestations of undernutrition with separate causes and solutions. However, more recent research points to evidence that wasting and stunting share similar causes and effects. In particular, a child who is both stunted and wasted has a higher risk of death than a child who has either of the conditions alone [42].

Some research suggests that wasting or the recovery from wasting has a direct impact on the trajectory of linear growth [40]. Previous studies have shown children who recovered from SAM began linear growth only after reaching a certain weight-for-height threshold [43], while other research demonstrates linear growth and weight gain increase simultaneously [44]. Still, a more recent study contrasts these results by showing improved linear catch-up growth occurring during neither SAM recovery nor long-term follow-up [6]. Our current study found that 58% of children experienced catch-up growth (defined as a positive change in HAZ from the time of discharge to the 12-month follow-up visit) over the course of 12 months following initial recovery from MAM.

The exact physiological links between wasting and stunted are still unclear, but recent evidence suggests that linear growth may be interrupted by wasting due to the role that fat stores play in regulating linear bone growth through a hormone called leptin [45]. In other studies among children recovering from MAM, catch-up growth has been shown to occur only with an increase in leptin concentration [46]. Further longitudinal studies are needed to better understand this relationship between wasting and stunting, particularly among those children who experience repeated relapses to wasting in addition to stunted growth.

4.5 Improved WASH Practices May Reduce Relapse Rates

Nutrition experts and policy makers have recently advocated for more multisectoral programming to address the many causes of acute malnutrition. To better understand which sectoral programming may be associated with preventing relapse after recovery from MAM, we analyzed a subsample of in-depth HH surveys consisting of a variety of cross-sectoral indicators. Our results show that an improved score on an index of WASH indicators was significantly associated with a child remaining well nourished after recovery from MAM. Interestingly, associations between IYCF and food security indices were not significantly associated with whether a child remained well nourished. Our findings may point to links between unsanitary living conditions and practices and repeated bouts of acute malnutrition. These results support other research findings regarding links between poor WASH conditions and malnutrition, such as the hypothesized link between WASH, environmental enteric dysfunction (EED), and linear growth condition [47]. EED is a disorder characterized by poor intestinal absorption and chronic mucosal inflammation that often occurs in children living in unsanitary settings. EED has been well documented to be associated with malnutrition and is lessened with nutritional therapy [48, 49]. Some researchers suggest that EED may play a significant role in causing so many children to be stunted [48] and advocate for more interventions to improve the WASH conditions around young children to prevent EED and its potentially negative impacts on linear growth [50]. Our results suggest that improvements in WASH conditions may also reduce the high number of children who experience repeated spells of acute malnutrition. Further prospective clinical trials are needed to confirm whether a WASH intervention in combination with SFP treatment would reduce relapse. Studies that examine the relationship of EED and relapse are also warranted.

4.6 Conclusion

A package of basic health and nutrition services provided to children upon discharge from an SFP improves the likelihood that recovery from MAM will be sustained. This is the first report to document the impact of an innovative intervention aimed to sustain recovery from MAM. While the intervention was successful in improving the percentage of children who remained well nourished following recovery from MAM, only 53% of children remained well nourished. Our findings suggest that treatment and follow-up protocols should be adapted to children who present to an SFP with more risk factors for long-term poor outcomes. Further studies are needed that examine the underlying physiological and immunological deficiencies that potentially cause such a high proportion of children to experience poor outcomes following MAM treatment. Findings from this study suggest one such area exists around the link between unsanitary HH environment, stunted linear growth, and multiple episodes of acute malnutrition. Given the global burden of MAM, generating such evidence is key to identifying the most-effective treatment protocols to improve both the short- and long-term outcomes of children who recover from MAM.

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Tables and Figures

Table 1. Nutritional content of LNS provided as part of the intervention package to participants in the intervention group

	LNS	IOM RDA[a] (1–3 years)	IOM UL[a]
Mass, g	40.0		
Energy, kcal	216.5		
Protein, g	5.3		
Fat, g	15.2		
Fatty acids, saturated, g	5.6		
Fatty acids, monounsaturated, g	6.3		
Fatty acids, polyunsaturated, g	2.7		
Omega 3, g	0.0		
Omega 6, g	1.9		
Micronutrients			
Biotin, mg	11.1	8.0	
Calcium, mg	310.1	500.0[b]	2500.0
Copper, mg	0.4	0.3	1.0
Folic acid, mcg	213.0	150.0	300.0
Iodine, mcg	98.4	90.0	200.0
Iron, mg	8.2	1.3	40.0
Magnesium, mg	27.6	80.0	65.0
Manganese, mg	1.7	1.2[b]	2.0
Niacin, mg	8.2	6.0	10.0
Pantothenic acid, mg	2.7	2.0[b]	
Phosphorus, mg	541.1	460.0	3000.0
Potassium, mg	368.2	3000.0[b]	
Riboflavin, mg	0.7	0.5	
Selenium, mcg	24.4	20.0	90.0
Thiamine, mg	0.6	0.5	
Vitamin A, mcg	452.1	300.0	600.0
Vitamin B6, mg	0.6	0.5	30.0
Vitamin B12, mcg	1.2	0.9	
Vitamin C, mg	36.0	15.0	400.0
Vitamin D, mcg	11.9	5.0[b]	50.0
Vitamin E, mg	9.2	6.0	200.0
Vitamin K, mcg	34.1	30.0[b]	
Zinc, mg	3.5	0.9	7.0

[a] IOM = Institute of Medicine; RDA = recommended dietary allowance; UL = upper limit
[b] Adequate intake.

Table 2. Composition of LNS

Ingredients	% by weight
Peanut paste	28
Nonfat dry milk	18
Palm oil	24
Sugar	21.2
Micronutrient mix	6.8
Emulsifier	2

Table 3. SES index construction from the HH survey[a]

Indicator	Definition and scoring	Range
Maternal education	Number of years of completed education. Each respondent's score was equivalent to the number of years up to "Form 4"—the completion of primary and secondary education in Malawi. This equals 12 years of education. No respondents completed any higher education.	0–12
Wealth: Ownership of assets	Assets owned by anyone in the home. These include a mattress, bicycle, chair or bench, radio, mobile phone, flashlight, cabinets, shoes, candle, lantern, bank account, and agricultural land.[b]	0–12
Wealth: Crowdedness and size of house	Number of people per room living in the house. Respondents received a score equal to the average number of people per room living in the house, with the exception that they received a 0 if the average number of people per room was less than 1 and a 6 if the number of people per room was greater than 6. Because all the scoring is designed to consistently follow a pattern of higher scores reflecting "better practices" or "more favorable conditions" and lower scores reflecting the opposite, this score was then reversed. Therefore, a respondent with fewer people per room received a higher score than a respondent with more people per room.	0–6
	Number of separate rooms in a house. The score equaled the number of rooms in the house. The term "separate" was defined as a physical wall, which did not include sheets or curtains, dividing a space. The minimum and maximum number of rooms reported was 1 and 6, respectively. To keep equal weighting of each indicator, this scoring was switched from a range of 1 to 6 to a range of 0 to 5, such that one room received a score of 0 and six rooms received a score of 5.	0–5
	A kitchen was deemed a separate room in the house, as was a separate building/hut specifically designed for cooking. A kitchen was defined as a dedicated place where the majority of cooking takes place. Therefore, a response of "yes" to having a separate room as a kitchen meant that the cooking was normally conducted in a space that was divided by a wall from other normal activities (including sitting, resting, sleeping, and socializing). Those with a separate room as a kitchen received a score of 1 and those who did not received a score of 0.	0,1

[a] This index is adapted from the validated SES WAMI index created by Paski et al. [19]. All scores were summed and normalized such that the final SES index ranged from 0 (worst) to 10 (best).
[b] We had originally hoped to include an aspect of how much land was owned to increase variability in the overall SES score. However, due to inconsistent translations of the question, we were unable to include this in the analysis.

Table 4. IYCF index construction from the HH survey[a]

Indicator	Definition	Scoring for each age group				Range
		6–8 months	9–11 months	12–35 months	36–59 months	
Breastfed	If the child was ever breastfed	No = 0 Yes = 1	No = 0 Yes = 1	No = 0 Yes = 1	No = 0 Yes = 1	0,1
Currently breastfeeding	If the child was breastfed in the past 24 hours	No = 0 Yes = 2	No = 0 Yes = 2	No = 0 Yes = 1	N/A	0,2 or 0,1 or N/A
Continued breastfeeding	If the child was breastfed for 12 months or more	N/A	N/A	N/A	< 12 months = 0 ≥ 12 months = 1	N/A or 0,1
Introduction of solid and semi-solid foods	If solid and semi-solid foods were introduced to the child between 6 and 8 months	No = 0 Yes = 1	No = 0 Yes = 1	No = 0 Yes = 1	No = 0 Yes = 1	0,1
Dietary diversity	Dietary diversity was based on 24-hour recall based on seven food groups. Scores were assigned based on number of food groups consumed; food groups included grains, legumes, meats, eggs, vitamin A-rich foods, other fruits and vegetables, and dairy	0 groups = 0 1–3 groups = 1 4+ groups = 2	0 groups = 0 1–3 groups = 1 4+ groups = 2	0 groups = 0 1–3 groups = 1 4+ groups = 2	0 groups = 0 1–3 groups = 1 4+ groups = 2	0–2
Meal frequency	Meal frequency was based on the previous 24 hours, including meals and snacks, other than liquids	0 meals/day = 0 1 meal/day = 1 2+ meals/day = 2	0 meals/day = 0 1–2 meals/day = 1 3+ meals/day = 2	0–1 meals/day = 0 2 meals/day = 1 3 meals/day = 2 4+ meals/day = 3	0–1 meals/day = 0 2 meals/day = 1 3 meals/day = 2 4+ meals/day = 3	0–2 or 0–3
Total		0–8	0–8	0–8	0–8	

[a] The final IYCF index was normalized and ranged from 0 (worst) to 10 (best).

Table 5. Food security index construction from the HH survey

Indicator	Definition and scoring	Range
HFIAS	Average HFIAS score at time of enrollment into the SFP as well as at 1, 3, 6, and 12 months following discharge. The normal HFIAS scores are designed such that a higher score reflects poorer food security while lower scores reflect better food security. However, in our final analysis, we aimed to have all indices created such that higher scores represented better or more favorable conditions. Therefore, the original HFIAS scores were reversed by subtracting 27 minus the average.[a]	0–27

[a] The final food security index was normalized and ranged from 0 (worst) to 10 (best).

Table 6. WASH index construction from the HH survey

Indicator	Definition and scoring	Range
Cleanliness of caregiver's hands	Observed cleanliness of caregiver's hands. Respondents received a score of 1 if the caregiver's hands were observed to be clean and a score of 0 if the hands were observed to be unclean [27, 31].	0,1
Cleanliness of child's hands	Observed cleanliness of child's hands. Respondents received a score of 1 if the child's hands were observed to be clean and a score of 0 if the hands were observed to be unclean [27, 31].	0,1
Improved water source	If drinking water comes from improved water sources. Respondents received a score of 1 if all water sources were improved sources of drinking water and a score of 0 if any water sources were unimproved. Improved water sources included: piped water into dwelling, piped water into yard/plot, public tap or standpipe, tube well or borehole, protected dug well, protected spring, and rainwater. Unimproved water sources included: unprotected spring, unprotected dug well, cart with small tank/drum, tanker-truck, and surface water [29].	0,1
Lids on water storage containers	If water storage containers have lids. Respondents received a score of 1 if all water storage containers were observed to have lids and a score of 0 if any did not have lids [35].	0,1
Number of trips to fetch water	Number times water is fetched in a day. Respondents received a score of 0 for three or more trips and a score of 1 for fewer than three trips per day. This cutoff of three trips per day was used as it has been shown to be an average number of trips per day in southern Africa, with the higher the number of trips associated with poorer child health outcomes [33].	0,1
Treat drinking water	If action is taken to treat or make the drinking water safe. Respondents were assigned a score of 1 if action was taken to make the drinking water safe for human consumption and a score of 0 if no action was taken. Actions for making drinking water safe included: boiling, bleaching, adding chlorine, straining through a cloth, use of water filer, solar disinfection, and letting it stand and settle [30].	0,1
Handwashing	Used soap or ash during a handwashing demonstration. Respondents were observed during a handwashing demonstration. If soap or ash was used during the demonstration, respondents were assigned a score of 1; if neither soap nor ash was used, respondents were assigned a score of 0 [27, 30].	0,1
Knowledge of critical times for caregiver handwashing	Knowledge of critical times for handwashing. The five critical times for washing hands are: after defecation, after cleaning a child, before preparing food, before feeding a child, and before eating [30, 34]. Respondents were assigned a 1 for listing all critical times points and a 0 for not listing all critical time points for washing hands.	0,1
Frequency of bathing child	Number of times child was bathed last week. Respondents were assigned a 0 if the child was bathed less than once per day and a 1 if the child was bathed at least once per day during the previous week [36].	0,1
Improved sanitation facility	If HH uses improved sanitation facility. Respondents received a score of 1 if HH members used an improved sanitation facility and a score of 0 if HH members used an unimproved sanitation facility. Improved sanitation facilities included: flush toilet, piped sewer system, septic tank, flush/pour flush to pit latrine, ventilated improved pit latrine, and pit latrine with slab. Unimproved sanitation facilities included: pit latrine without slab, bucket, hanging toilet or hanging latrine, and no facilities/bush/field [29].	0,1

Figure 1. Flow of participants throughout the study

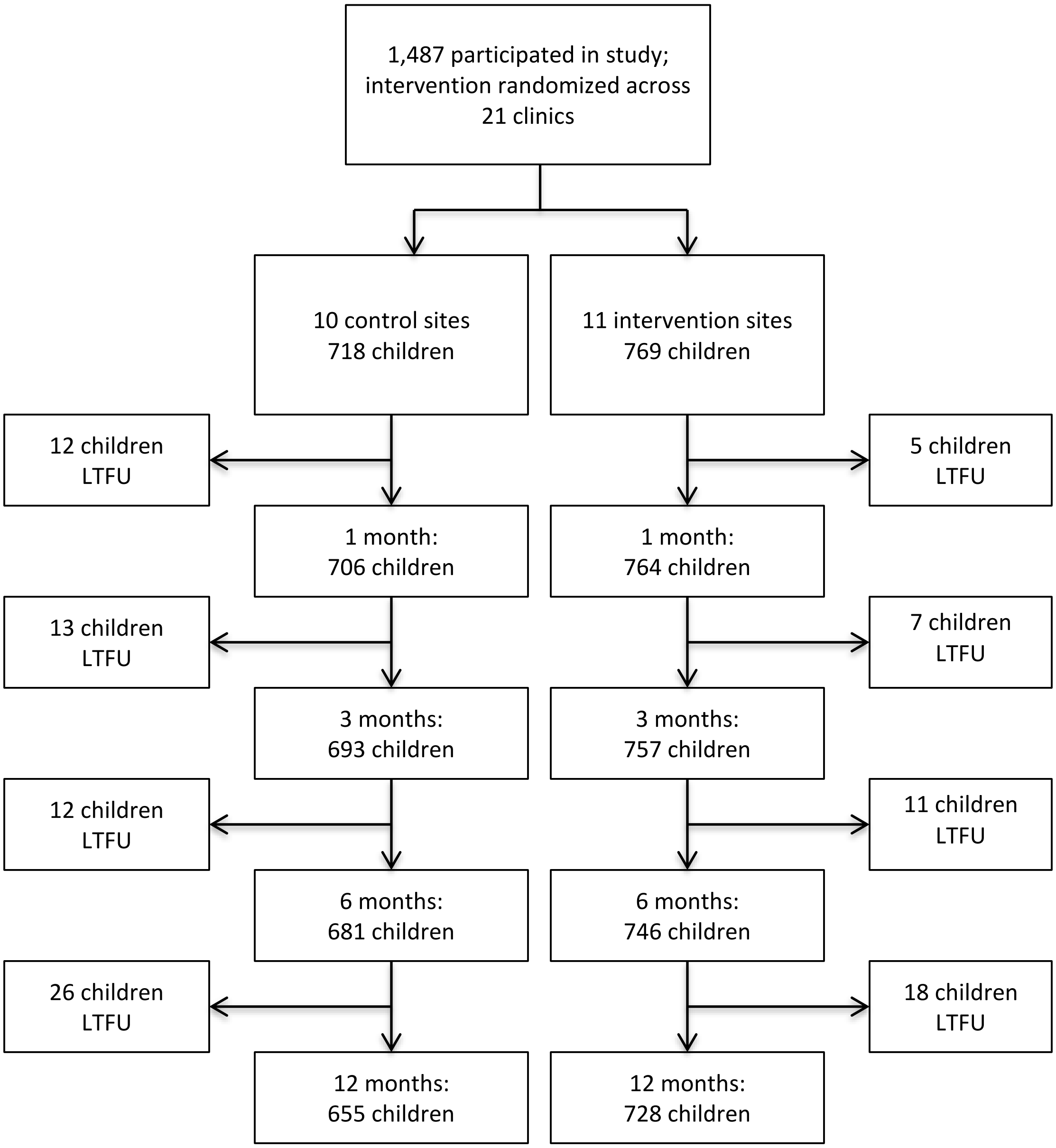


Table 7. Enrollment characteristics for control and intervention groups[a]

	Control[b] (n = 718)	Intervention[b] (n = 769)
Total clusters (clinic sites)	10	11
Female	435 (61)	472 (61)
Age, mo	16.43 ± 9.083	17.01 ± 9.33
Upon Admission to Initial Treatment in SFP		
Type of treatment food received		
Received Whey-Based RUSF**	105 (15)	153 (20)
Received Soy-Based RUSF	128 (18)	155 (20)
Received RUTF**	485 (68)	460 (60)
MUAC, cm	12.10 ± 0.26	12.08 ± 0.27
Weight, kg	7.29 ± 1.19	7.32 ± 1.25
Length, cm	71.21 ± 6.91	71.51 ± 7.27
WHZ	−1.76 ± 0.73	−1.77 ± 0.66
HAZ	−2.62 ± 1.37	−2.73 ± 1.24
WAZ	−2.73 ± 0.83	−2.80 ± 0.76
Primary caregiver is mother	682 (97)	736 (97)
Mother alive*	696 (98)	756 (99)
Father alive	679 (96)	735 (97)
Number of siblings	0.66 ± 1.09	0.57 ± 1.01
Mother known to be HIV-positive*	138 (22)	114 (18)
Fever during 2 weeks prior to admission	479 (71)	486 (67)
Diarrhea during 2 weeks prior to admission	459 (66)	468 (63)
Admission during harvest (Apr–Aug)**	241 (34)	207 (27)
HFIAS score	10.02 ± 5.93	8.03 ± 5.80
Food secure***	43 (6)	116 (15)
Mild food insecurity	23 (3)	27 (4)
Moderate food insecurity***	81 (12)	140 (19)
Severe food insecurity***	552 (79)	465 (62)
Upon Discharge from Initial Treatment from SFP		
MUAC, cm	12.79 ± 0.27	12.78 ± 0.27
MUAC gain, $mm \cdot d^{-1}$	0.30 ± 0.21	0.29 ± 0.21
WHZ	−0.88 ± 0.74	−0.94 ± 0.73
WHZ change	0.88 ± 0.60	0.83 ± 0.51
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	2.98 ± 2.37	2.77 ± 1.90
Length gain, $mm \cdot d^{-1}$	0.27 ± 0.22	0.30 ± 0.22
Time to recovery, d	31.92 ± 20.64	31.50 ± 20.60
Child sleeps under bed net***	584 (81)	463 (60)
Child takes malaria prophylaxis	51 (7)	46 (6)
Child takes any supplements***	459 (64)	390 (51)
Child received deworming medication last month**	159 (24)	122 (17)

[a] P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.
* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.
[b] Values are means ± SD or n (%).

Table 8. Comparison of primary outcomes from SFP discharge to 1, 3, 6, and 12 months follow-up between control and intervention groups

	At 1-month follow-up[a]			At 3-month follow-up[a]			At 6-month follow-up[a]			At 12-month follow-up[a]		
	Control (n = 718)	Intervention (n = 769)	P	Control (n = 718)	Intervention (n = 769)	P	Control (n = 718)	Intervention (n = 769)	P	Control (n = 718)	Intervention (n = 769)	P
Remained well nourished	531 (74)	604 (78)	0.038	455 (63)	530 (69)	0.024	421 (59)	491 (64)	0.039	347 (48)	407 (53)	0.076
Relapsed to MAM	161 (22)	153 (20)	0.233	215 (30)	209 (27)	0.238	234 (33)	230 (30)	0.265	260 (36)	281 (37)	0.895
Once	156 (22)	147 (19)	0.212	183 (25)	176 (23)	0.242	167 (23)	163 (21)	0.339	149 (21)	175 (23)	0.349
Twice	5 (1)	6 (1)	0.851	32 (4)	30 (4)	0.592	55 (8)	51 (7)	0.441	76 (11)	63 (8)	0.113
Three times	0 (0)	0 (0)	n/a	0 (0)	3 (0.4)	0.094	12 (2)	14 (2)	0.826	24 (3)	29 (4)	0.656
Four times or more	0 (0)	0 (0)	n/a	0 (0)	0 (0)	n/a	0 (0)	2 (0.3)	0.172	11 (2)	14 (2)	0.665
Developed SAM	13 (2)	6 (1)	0.077	21 (3)	14 (2)	0.161	24 (3)	18 (2)	0.244	46 (6)	27 (4)	0.010
Died	1 (0.1)	1 (0.1)	0.961	2 (0.3)	4 (0.5)	0.463	2 (0.3)	7 (1)	0.117	2 (0.3)	13 (2)	0.007
Death only	1 (0.1)	0 (0)	0.301	2 (0.3)	2 (0.3)	0.945	2 (0.3)	4 (1)	0.463	2 (0.3)	7 (1)	0.117
Relapse then death	0 (0)	1 (0.1)	0.334	0 (0)	2 (0.3)	0.172	0 (0)	3 (0.4)	0.094	0 (0)	6 (1)	0.018
LTFU	12 (2)	5 (1)	0.064	25 (3)	12 (2)	0.018	37 (5)	23 (3)	0.034	63 (9)	41 (5)	0.009

[a] Values are n (%). P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.

Table 9. Distribution of total children and children who were LTFU, by clinic site

	Total[a] (n = 1487)	LTFU[a] (n = 104)
Control Sites		
Chikonde[b]	90 (6)	10 (1)
Chingale	28 (2)	2 (2)
Milonde[b]	45 (3)	2 (2)
Mlomba	61 (4)	2 (2)
Muloza[b]	165 (11)	30 (29)
Ndakwera	69 (5)	4 (4)
Nkalo	52 (3)	1 (1)
Nkhate	129 (9)	8 (8)
Nsanama	66 (4)	4 (4)
Zombasalima	13 (1)	0 (0)
Intervention Sites		
Chamba	21 (1)	0 (0)
Chikweo	29 (2)	1 (1)
Chipalonga	77 (5)	2 (2)
Makhwira	124 (8)	4 (4)
Matiya	44 (3)	3 (3)
Mauwa	37 (2)	2 (2)
Mayaka	26 (2)	0 (0)
Mbiza[b]	111 (7)	10 (10)
Mitondo	188 (13)	13 (13)
Namasalima[b]	65 (4)	6 (6)
Naphimba	47 (3)	0 (0)

[a] Values are n (%).
[b] Located near the Malawi/Mozambique border.

Table 10. Differences in characteristics between children who were lost to follow-up and all other children[a]

	LTFU[b] (n = 104)	All others[b] (n = 1383)
Female	60 (58)	847 (61)
Age, mo	19.24 ± 9.95	16.54 ± 9.13
Upon Admission to Initial Treatment in SFP		
Type of treatment food received		
Received Whey-Based RUSF	24 (23)	234 (17)
Received Soy-Based RUSF	13 (13)	270 (20)
Received RUTF	67 (64)	878 (64)
MUAC, cm	12.02 ± 0.27	12.09 ± 0.27
Weight, kg	7.71 ± 1.28	7.27 ± 1.21
Length, cm	73.58 ± 7.26	71.20 ± 7.06
WHZ	−1.80 ± 0.70	−1.77 ± 0.69
HAZ	−2.63 ± 1.53	−2.68 ± 1.29
WAZ	−2.74 ± 0.85	−2.77 ± 0.79
Primary caregiver is mother**	92 (92)	1326 (97)
Mother alive	103 (99)	1340 (99)
Father alive	102 (99)	1312 (96)
Number of siblings	0.43 ± 0.83	0.62 ± 1.06
Mother known to be HIV-positive	14 (18)	238 (20)
Fever during 2 weeks prior to admission	71 (76)	894 (68)
Diarrhea during 2 weeks prior to admission	73 (72)	854 (64)
Admission during harvest (Apr–Aug)	40 (38)	408 (30)
HFIAS score	8.44 ± 5.40	9.03 ± 5.98
Food secure	10 (10)	149 (11)
Mild food insecurity	3 (3)	47 (3)
Moderate food insecurity	12 (12)	209 (16)
Severe food insecurity	77 (75)	940 (70)
Upon Discharge from Initial Treatment from SFP		
MUAC, cm	12.83 ± 0.29	12.78 ± 0.21
MUAC gain, $mm \cdot d^{-1}$	0.35 ± 0.24	0.29 ± 0.21
WHZ	−0.88 ± 0.65	−0.91 ± 0.74
WHZ change	0.92 ± 0.65	0.85 ± 0.55
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	3.05 ± 2.25	2.86 ± 2.13
Length gain, $mm \cdot d^{-1}$	0.29 ± 0.23	0.28 ± 0.22
Time to recovery, d	29.41 ± 17.35	31.88 ± 20.83
Child sleeps under bed net	68 (65)	979 (71)
Child takes malaria prophylaxis	8 (8)	89 (6)
Child takes any supplements*	47 (45)	802 (58)
Child received deworming medication last month	15 (16)	266 (21)

[a] P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering. *P < 0.05; ** P < 0.01.
[b] Values are means ± SD or n (%).

Table 11. Percentage of children reported to have illness during the prior 2 weeks at 1-, 3-, 6-, and 12-month follow-up visits in control and intervention groups

	At 1-month follow-up[a]			At 3-month follow-up[a]			At 6-month follow-up[a]			At 12-month follow-up[a]		
	Control (n = 700)	Intervention (n = 728)	P	Control (n = 682)	Intervention (n = 745)	P	Control (n = 649)	Intervention (n = 719)	P	Control (n = 627)	Intervention (n = 695)	P
Fever	254 (36)	306 (40)	0.105	249 (37)	265 (36)	0.709	222 (34)	268 (37)	0.230	212 (34)	244 (36)	0.503
Diarrhea	183 (26)	246 (32)	0.008	175 (26)	194 (26)	0.872	141 (22)	178 (25)	0.181	127 (20)	153 (22)	0.342

[a] Values are n (%). P-values derived using chi-squared tests with adjustment for clustering.

Table 12. Growth outcomes from discharge to 12 month follow-up for control and intervention groups

	Control[a]	Intervention[a]	P[b]
All Children	n = 718	n = 769	
MUAC, $mm \cdot d^{-1}$	0.02 ± 0.03	0.02 ± 0.02	0.824
Weight, $g \cdot kg^{-1} \cdot d^{-1}$	0.71 ± 0.33	0.69 ± 0.29	0.339
Length, $mm \cdot d^{-1}$	0.27 ± 0.07	0.26 ± 0.07	0.609
WHZ change	0.07 ± 0.82	0.06 ± 0.77	0.892
HAZ change	0.02 ± 0.65	0.03 ± 0.67	0.800
WAZ change	0.09 ± 0.67	0.08 ± 0.62	0.871
Children who remained well nourished	n = 347	n = 407	
MUAC, $mm \cdot d^{-1}$	0.03 ± 0.03	0.03 ± 0.02	0.751
Weight, $g \cdot kg^{-1} \cdot d^{-1}$	0.78 ± 0.30	0.74 ± 0.30	0.142
Length, $mm \cdot d^{-1}$	0.28 ± 0.07	0.27 ± 0.07	0.370
WHZ change	0.24 ± 0.74	0.23 ± 0.75	0.841
HAZ change	0.16 ± 0.63	0.16 ± 0.62	0.919
WAZ change	0.28 ± 0.59	0.25 ± 0.60	0.567
Children who relapsed to MAM	n = 260	n = 281	
MUAC, $mm \cdot d^{-1}$	0.01 ± 0.02	0.01 ± 0.02	0.997
Weight, $g \cdot kg^{-1} \cdot d^{-1}$	0.66 ± 0.31	0.64 ± 0.26	0.547
Length, $mm \cdot d^{-1}$	0.27 ± 0.06	0.26 ± 0.07	0.484
WHZ change	−0.11 ± 0.83	−0.14 ± 0.70	0.812
HAZ change	−0.09 ± 0.56	−0.09 ± 0.64	0.600
WAZ change	−0.09 ± 0.63	−0.11 ± 0.53	0.643
Children who developed SAM	n = 46	n = 27	
MUAC, $mm \cdot d^{-1}$	−0.01 ± 0.04	−0.01 ± 0.03	0.920
Weight, $g \cdot kg^{-1} \cdot d^{-1}$	0.51 ± 0.42	0.51 ± 0.33	0.957
Length, $mm \cdot d^{-1}$	0.22 ± 0.10	0.22 ± 0.08	0.771
WHZ change	−0.28 ± 1.02	−0.35 ± 1.04	0.773
HAZ change	−0.48 ± 0.85	−0.64 ± 1.07	0.508
WAZ change	−0.43 ± 0.91	−0.51 ± 0.88	0.766

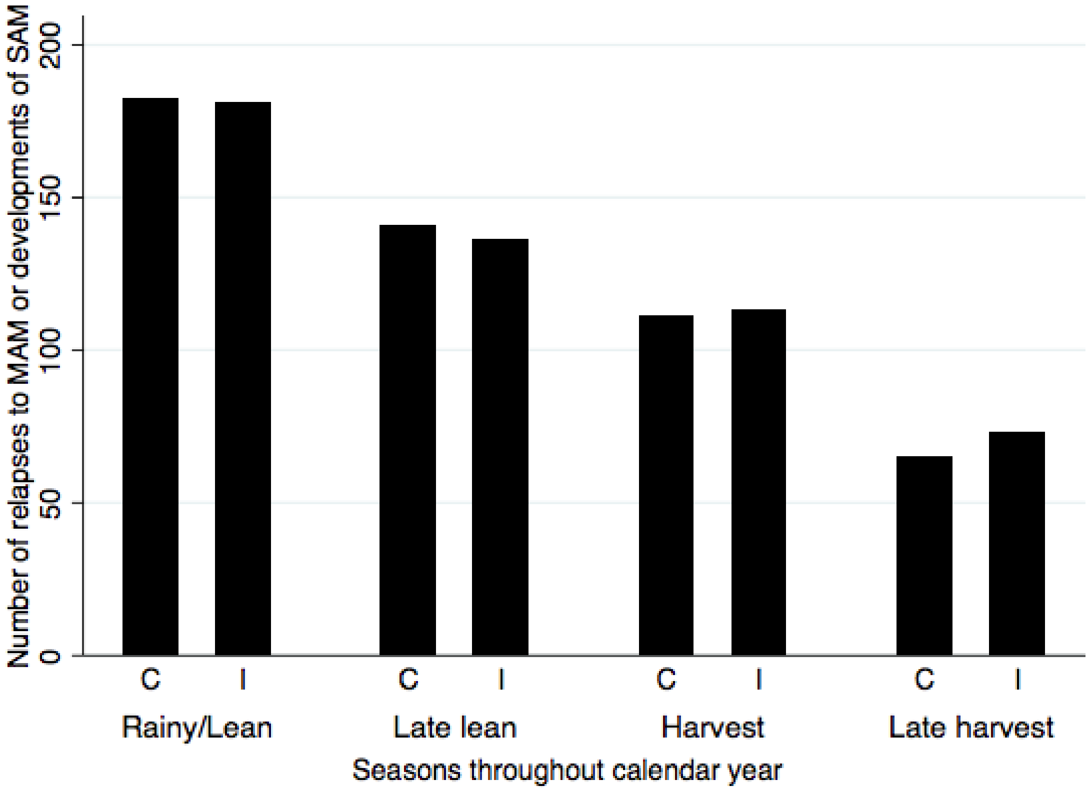
[a] Values are means ± SD.
[b] P-values were derived using student’s t-tests with adjustment for clustering.

Table 13. Primary outcomes during the rainy season (December–February) between control and intervention groups

	Control[a] (n = 718)	Intervention[a] (n = 769)	P[b]
Remained well nourished	487 (68)	547 (71)	0.167
Relapsed to MAM	148 (21)	156 (20)	0.876
Developed SAM	13 (2)	7 (1)	0.132
Received treatment for a previous relapse	9 (1)	10 (1)	0.936
Died	0 (0)	2 (0.3)	0.172
Data not collected during malaria season	61 (9)	47 (6)	0.077

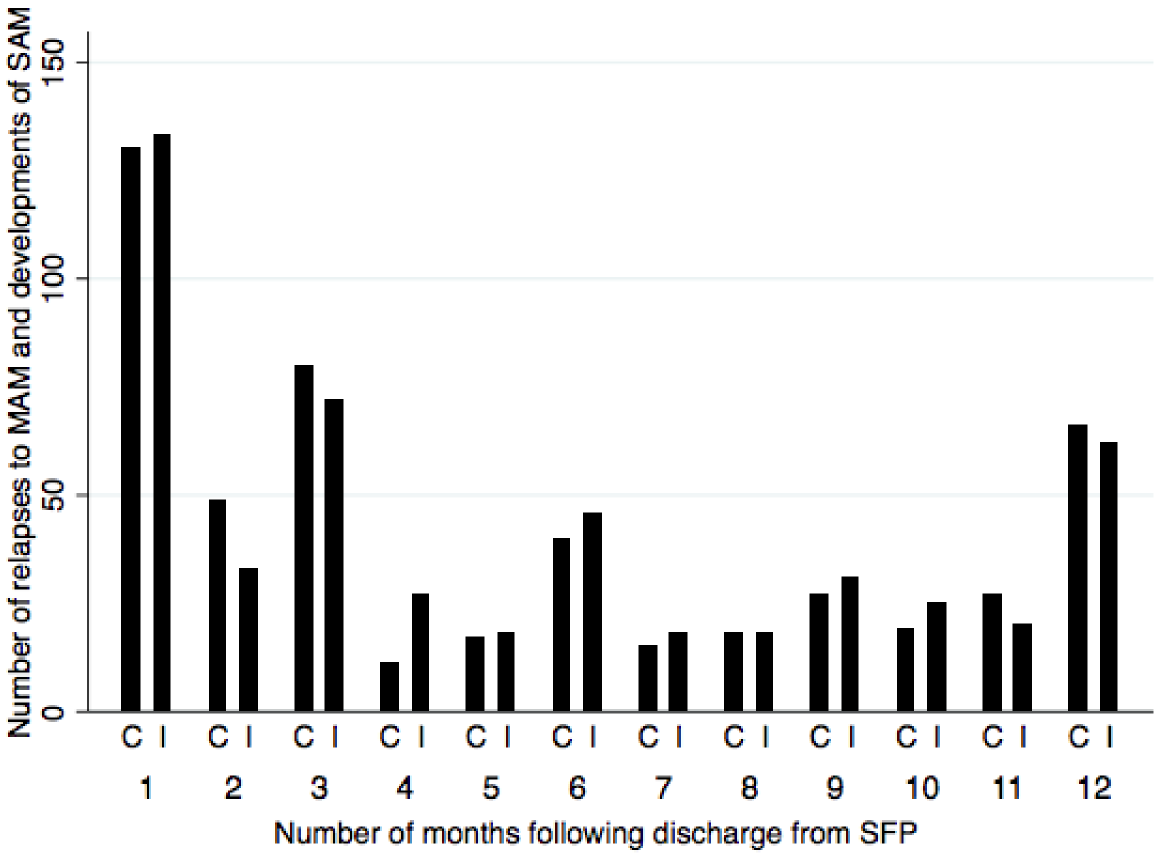
[a] Values are n (%).
[b] P-values were derived using chi-squared tests with adjustment for clustering.

Figure 2. Number of relapses to MAM and developments of SAM for control and intervention groups across the calendar year[a]



[a] C = control group; I = intervention group. Rainy/lean season is December–February; late lean season is March–May, harvest season is June–August, and late harvest season is September–November.

Figure 3. Number of relapses to MAM and developments of SAM for control and intervention groups by number of months from initial SFP discharge[a]



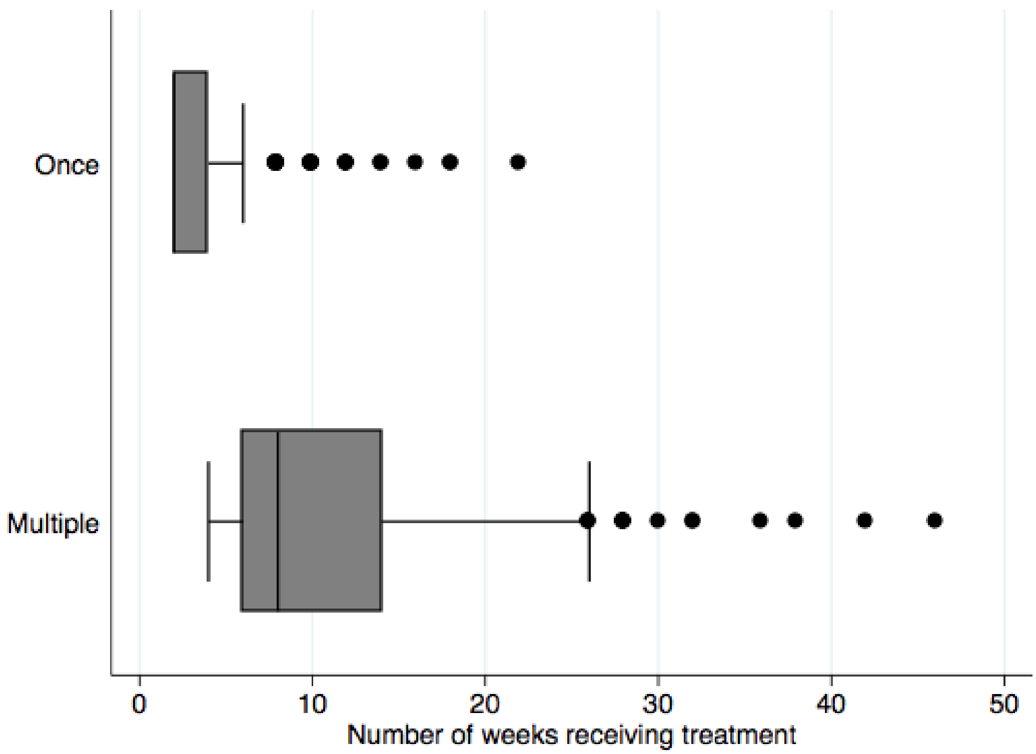
[a] C = control group; I = intervention group.

Table 14. Length of treatment needed for relapse to MAM and/or development of SAM during the follow-up period after initial SFP discharge

	Control[a] (n = 306)	Intervention[a] (n = 314)	P[b]
Average Weeks of Treatment	7.63 ± 7.43	7.16 ± 7.03	0.430
2 weeks	98 (32)	112 (36)	0.613
4 weeks	68 (22)	51 (16)	0.044
5–10 weeks	70 (22)	82 (26)	0.561
11–14 weeks	24 (8)	34 (11)	0.283
15–30 weeks	40 (13)	29 (9)	0.099
30–48 weeks	6 (2)	6 (2)	0.905

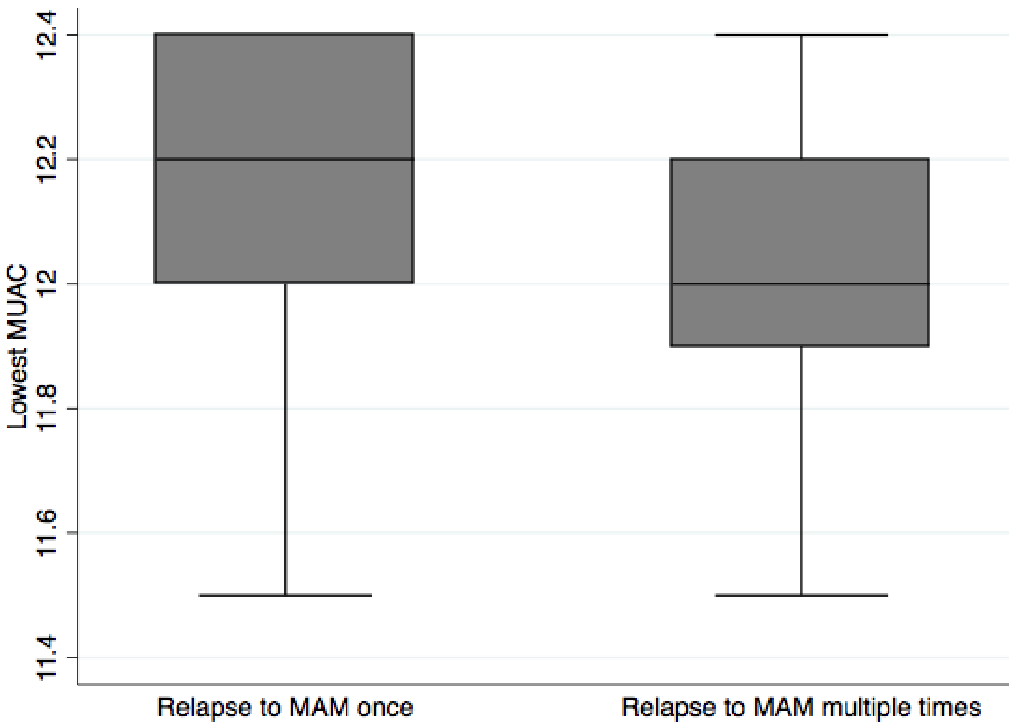
[a] Values are n (%) or means ± SD.
[b] P-values were derived using student's t tests and chi-squared tests with adjustment for clustering.

Figure 4. Number of weeks receiving treatment for those who relapsed to MAM once vs. those who relapsed to MAM multiple times[a]



[a] Mean (SD) number of weeks was 3.63 ± 2.92 for those who relapsed once and 11.12 ± 7.63 for those who relapsed multiple times (P = 0.001). P-values were derived using student's t tests with adjustment for clustering.

Figure 5. Lowest MUAC during the follow-up period for those who relapsed to MAM once vs. those who relapsed to MAM multiple times[a]



[a] Mean (SD) lowest MUAC was 12.18 ± 0.22 for those who relapsed once vs. 12.03 ± 0.23 for those who relapsed multiple times ($P < 0.001$). P-values were derived using student's t-tests with adjustment for clustering.

Table 15. Characteristics of those who relapsed to MAM once vs. those who relapsed to MAM multiple times

	Relapsed to MAM Once[a] (n = 324)	Relapsed to MAM Multiple Times[a] (n = 217)	P[b]
Female	198 (61)	136 (63)	0.694
Age, mo	15.45 ± 7.92	14.57 ± 8.25	0.354
Upon Admission to Initial Treatment in SFP			
Type of treatment food received			
Received Whey-Based RUSF	55 (17)	42 (19)	0.490
Received Soy-Based RUSF	67 (21)	54 (25)	0.258
Received RUTF	202 (62)	121 (56)	0.133
MUAC, cm	12.07 ± 0.27	12.03 ± 0.26	0.396
Weight, kg	7.18 ± 1.12	6.91 ± 1.03	0.035
Length, cm	70.62 ± 6.60	69.43 ± 6.37	0.160
WHZ	−1.74 ± 0.67	−1.81 ± 0.69	0.478
HAZ	−2.61 ± 1.24	−2.69 ± 1.23	0.504
WAZ	−2.71 ± 0.74	−2.83 ± 0.76	0.126
Primary caregiver is mother	313 (98)	209 (98)	0.904
Mother alive	316 (100)	215 (100)	0.235
Father alive	309 (96)	207 (96)	0.986
Number of siblings	0.58 ± 1.01	0.52 ± 1.00	0.639
Mother known to be HIV-positive	50 (17)	34 (18)	0.860
Fever during 2 weeks prior to admission	216 (69)	120 (59)	0.017
Diarrhea during 2 weeks prior to admission	197 (63)	123 (57)	0.254
Admission during harvest (Apr–Aug)	85 (26)	60 (28)	0.672
HFIAS score	8.72 ± 5.61	8.38 ± 6.43	0.777
Food secure	37 (12)	30 (14)	0.393
Mild food insecurity	8 (3)	10 (1)	0.170
Moderate food insecurity	42 (13)	29 (14)	0.876
Severe food insecurity	229 (72)	141 (67)	0.198
Upon Discharge from Initial Treatment from SFP			
MUAC, cm	12.70 ± 0.19	12.70 ± 0.23	0.967
MUAC gain, $mm \cdot d^{-1}$	0.23 ± 0.15	0.24 ± 0.18	0.720
WHZ	−0.92 ± 0.73	−1.03 ± 0.78	0.301
WHZ change	0.82 ± 0.52	0.78 ± 0.51	0.386
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	2.43 ± 1.70	2.08 ± 1.45	0.142
Length gain, $mm \cdot d^{-1}$	0.26 ± 0.20	0.33 ± 0.21	0.011
Time to recovery, d	34.59 ± 21.34	37.96 ± 23.54	0.131
Upon 12 months follow-up			
Length gain, cm	8.99 ± 2.16	8.67 ± 2.04	0.247
Length gain, $mm \cdot d^{-1}$	0.27 ± 0.06	0.26 ± 0.06	0.265
HAZ change	−0.03 ± 0.63	−0.17 ± 0.56	0.019
Fever during 2 weeks prior to follow-up visit	106 (37)	98 (47)	0.014
Diarrhea during 2 weeks prior to follow-up visit	68 (24)	63 (30)	0.096

[a] Values are means ± SD or n (%).
[b] P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.

Table 16. Characteristics of those who remained well nourished for the 12 months following initial recovery from MAM vs. all other children

	Well nourished[a] (n = 754)	All others[a] (n = 733)	P[b]
Female	460 (61)	447 (61)	0.991
Age, mo	17.72 ± 9.78	15.72 ± 8.48	0.050
Upon Admission to Initial Treatment in SFP			
Type of treatment food received			
Received Whey-Based RUSF	120 (16)	138 (19)	0.135
Received Soy-Based RUSF	129 (17)	154 (21)	0.054
Received RUTF	505 (67)	440 (60)	0.006
MUAC, cm	12.12 ± 0.26	12.05 ± 0.27	0.018
Weight, kg	7.44 ± 1.28	7.16 ± 1.14	0.034
Length, cm	72.11 ± 7.35	70.60 ± 6.74	0.034
WHZ	−1.77 ± 0.70	−1.77 ± 0.68	0.954
HAZ	−2.69 ± 1.33	−2.67 ± 1.28	0.832
WAZ	−2.77 ± 0.82	−2.77 ± 0.77	0.992
Primary caregiver is mother	727 (98)	691 (96)	0.176
Mother alive	736 (98)	716 (99)	0.557
Father alive	718 (97)	696 (96)	0.602
Number of siblings	0.70 ± 1.12	0.52 ± 0.96	0.022
Mother known to be HIV-positive	142 (22)	110 (18)	0.052
Fever during 2 weeks prior to admission	513 (72)	452 (66)	0.027
Diarrhea during 2 weeks prior to admission	490 (67)	437 (61)	0.025
Admission during harvest (Apr–Aug)	236 (31)	212 (29)	0.318
HFIAS score	9.22 ± 5.96	8.75 ± 5.92	0.695
Food secure	78 (11)	81 (11)	0.656
Mild food insecurity	25 (3)	25 (4)	0.921
Moderate food insecurity	123 (17)	98 (14)	0.111
Severe food insecurity	508 (69)	509 (71)	0.365
Upon Discharge from Initial Treatment from SFP			
MUAC, cm	12.83 ± 0.30	12.73 ± 0.23	0.002
MUAC gain, $mm \cdot d^{-1}$	0.33 ± 0.23	0.26 ± 0.18	0.008
WHZ	−0.88 ± 0.73	−0.95 ± 0.74	0.472
WHZ change	0.89 ± 0.56	0.83 ± 0.55	0.237
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	3.26 ± 2.32	2.46 ± 1.85	0.015
Length gain, $mm \cdot d^{-1}$	0.27 ± 0.23	0.29 ± 0.21	0.272
Time to recovery, d	29.04 ± 19.29	34.45 ± 21.56	0.017
Child sleeps under bed net	541 (72)	506 (69)	0.250
Child takes malaria prophylaxis	55 (7)	42 (6)	0.217
Child takes any supplements	461 (61)	388 (53)	0.002
Child received deworming medication last month	154 (22)	127 (81)	0.116
Upon 12 months follow-up			
Length gain, cm	9.15 ± 2.34	8.67 ± 2.31	0.045
Length gain, $mm \cdot d^{-1}$	0.27 ± 0.07	0.26 ± 0.07	0.061
HAZ change	0.16 ± 0.62	−0.14 ± 0.67	0.002
Fever during 2 weeks prior to follow-up visit	`225 (30)	232 (41)	0.000
Diarrhea during 2 weeks prior to follow-up visit	120 (16)	160 (28)	0.000

[a] Values are means ± SD or n (%).
[b] P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.

Table 17. Characteristics of those who developed SAM vs. those who relapsed to MAM

	Developed SAM[a] (n = 73)	Relapsed to MAM[a] (n = 541)	P[b]
Female	45 (62)	334 (62)	0.987
Age, mo	15.31 ± 8.51	15.10 ± 8.05	0.878
Upon Admission to Initial Treatment in SFP			
Type of treatment food received			
Received Whey-Based RUSF	13 (18)	97 (18)	0.979
Received Soy-Based RUSF	16 (22)	121 (22)	0.978
Received RUTF	43 (60)	323 (60)	0.998
MUAC, cm	12.09 ± 0.28	12.05 ± 0.26	0.516
Weight, kg	7.04 ± 1.16	7.07 ± 1.09	0.852
Length, cm	69.69 ± 6.70	70.14 ± 6.52	0.714
WHZ	−1.75 ± 0.72	−1.77 ± 0.68	0.912
HAZ	−2.85 ± 1.33	−2.64 ± 1.23	0.217
WAZ	−2.87 ± 0.78	−2.76 ± 0.75	0.255
Primary caregiver is mother	64 (96)	522 (98)	0.326
Mother alive	67 (97)	531 (99)	0.222
Father alive	63 (91)	516 (96)	0.056
Number of siblings	0.41 ± 0.87	0.56 ± 1.00	0.405
Mother known to be HIV-positive	9 (16)	84 (18)	0.779
Fever during 2 weeks prior to admission	38 (60)	336 (65)	0.428
Diarrhea during 2 weeks prior to admission	38 (57)	320 (60)	0.552
Admission during harvest	25 (34)	145 (27)	0.182
HFIAS score	10.63 ± 6.36	8.58 ± 5.95	0.289
Food secure	4 (6)	67 (13)	0.083
Mild food insecurity	3 (4)	18 (3)	0.730
Moderate food insecurity	9 (13)	71 (14)	0.849
Severe food insecurity	55 (77)	370 (70)	0.214
Upon Discharge from Initial Treatment from SFP			
MUAC, cm	12.77 ± 0.26	12.70 ± 0.21	0.027
MUAC gain, $mm \cdot d^{-1}$	0.30 ± 0.18	0.24 ± 0.16	0.048
WHZ	−0.91 ± 0.73	−0.96 ± 0.75	0.711
WHZ change	0.84 ± 0.62	0.80 ± 0.52	0.646
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	2.92 ± 2.40	2.29 ± 1.61	0.094
Length gain, $mm \cdot d^{-1}$	0.31 ± 0.23	0.29 ± 0.21	0.498
Time to recovery, d	29.16 ± 18.22	35.94 ± 22.29	0.018
Child sleeps under bed net	49 (67)	380 (71)	0.554
Child takes malaria prophylaxis	4 (6)	30 (6)	0.973
Child takes any supplements	37 (50)	297 (55)	0.457
Child received deworming medication last month	11 (16)	98 (19)	0.500
Upon 12 months follow-up			
Length gain, cm	7.31 ± 3.06	8.85 ± 2.14	0.005
Length gain, $mm \cdot d^{-1}$	0.22 ± 0.09	0.26 ± 0.06	0.033
HAZ change	−0.53 ± 0.93	−0.09 ± 0.61	0.007
Fever during 2 weeks prior to admission	26 (37)	204 (41)	0.534
Diarrhea during 2 weeks prior to admission	28 (40)	131 (26)	0.017

[a] Values are means ± SD or n (%).
[b] P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.

Table 18. Characteristics of those who died vs. those who survived by 12 months follow-up

	Died (n = 15)	Survived (n = 1472)	P
Female	8 (53)	899 (61)	0.541
Age, mo	15.64 ± 7.23	16.74 ± 9.23	0.790
Upon Admission to Initial Treatment in SFP			
Type of treatment food received			
Received Whey-Based RUSF	4 (27)	254 (17)	0.339
Received Soy-Based RUSF	4 (27)	279 (19)	0.524
Received RUTF	7 (47)	938 (64)	0.171
MUAC, cm	12.12 ± 0.31	12.09 ± 0.27	0.696
Weight, kg	7.15 ± 1.00	7.31 ± 1.22	0.760
Length, cm	70.38 ± 6.32	71.37 ± 7.11	0.748
WHZ	−1.76 ± 0.67	−1.77 ± 0.69	0.987
HAZ	−3.01 ± 0.86	−2.67 ± 1.31	0.521
WAZ	−2.91 ± 0.70	−2.77 ± 0.79	0.517
Primary caregiver is mother	12 (87)	1405 (97)	0.019
Mother alive	15 (100)	1437 (99)	0.640
Father alive	15 (100)	1399 (96)	0.460
Number of siblings	0.27 ± 0.59	0.61 ± 1.05	0.263
Mother known to be HIV-positive	3 (33)	249 (20)	0.313
Fever during 2 weeks prior to admission	7 (50)	958 (69)	0.125
Diarrhea during 2 weeks prior to admission	6 (43)	921 (65)	0.092
Admission during harvest	2 (13)	446 (30)	0.154
HFIAS score	7.72 ± 5.27	9.00 ± 5.95	0.838
Food secure	0 (0)	159 (11)	0.187
Mild food insecurity	1 (7)	49 (3)	0.448
Moderate food insecurity	6 (43)	215 (15)	0.004
Severe food insecurity	7 (50)	1010 (70)	0.096
Upon Discharge from Initial Treatment from SFP			
MUAC, cm	12.87 ± 0.35	12.78 ± 0.27	0.602
MUAC gain, $mm \cdot d^{-1}$	0.29 ± 0.31	0.29 ± 0.21	0.931
WHZ	−0.87 ± 0.83	−0.91 ± 0.73	0.928
WHZ change	0.89 ± 0.58	0.86 ± 0.55	0.896
Weight gain, $g \cdot kg^{-1} \cdot d^{-1}$	2.73 ± 2.75	2.87 ± 2.14	0.876
Length gain, $mm \cdot d^{-1}$	0.31 ± 0.18	0.28 ± 0.22	0.719
Time to recovery, d	41.07 ± 26.56	31.61 ± 20.52	0.481
Child sleeps under bed net	9 (60)	1038 (70)	0.365
Child takes malaria prophylaxis	0 (0)	97 (7)	0.302
Child takes any supplements	7 (47)	842 (57)	0.401
Child received deworming medication last month	3 (23)	278 (20)	0.802

[a] Values are means ± SD or n (%). P-values were derived using student's t-tests and chi-squared tests with adjustment for clustering.

Table 19. Factors associated with children who remained well nourished for 3, 6, and 12 months[a]

	Model for remaining well nourished for 3 months[b]		Model for remaining well nourished for 6 months[c]		Model for remaining well nourished for 12 months[d]	
	Odds ratio (95% CI)	P	Odds ratio (95% CI)	P	Odds ratio (95% CI)	P
Received intervention	1.52 (1.22–1.90)	< 0.001	1.53 (1.17–2.00)	0.002	1.40 (1.06–1.85)	0.020
Age upon admission to SFP, m	1.12 (1.01–1.03)	0.002	1.03 (1.02–1.04)	< 0.001	1.02 (1.01–1.03)	0.004
Admission MUAC, mm	1.17 (1.12–1.21)	< 0.001	1.15 (1.12–1.20)	< 0.001	1.19 (1.15–1.24)	< 0.001
Admission WHZ	0.47 (0.37–0.60)	< 0.001	0.57 (0.45–0.73)	< 0.001	0.51 (0.37–0.72)	< 0.001
Fever during 2 weeks prior to admission	1.42 (1.04–1.93)	0.026	*not significant*		1.31 (1.05–1.62)	0.018
Diarrhea during 2 weeks prior to admission	*not significant*		1.52 (1.12–2.05)	0.007	*not significant*	
Admission HFIAS Score	1.03 (1.02–1.04)	< 0.001	1.02 (1.00–1.04)	0.023	1.02 (1.01–1.03)	0.006
Discharge MUAC, mm	1.14 (1.06–1.23)	0.001	1.10 (1.05–1.15)	< 0.001	*not significant*	
MUAC change during treatment, $mm \cdot d^{-1}$	*not significant*		3.11 (1.47–6.56)	0.003	5.80 (3.05–11.03)	< 0.001
Discharge WHZ	2.61 (1.97–3.48)	< 0.001	2.35 (1.72–3.22)	< 0.001	2.70 (1.87–3.91)	< 0.001
Mother known to be HIV-positive	1.38 (1.07–1.79)	0.013	*not significant*		1.26 (1.03–1.54)	0.029
Child previously slept under bed net	1.35 (1.03–1.77)	0.028	1.33 (1.06–1.68)	0.013	1.38 (1.10–1.73)	0.006

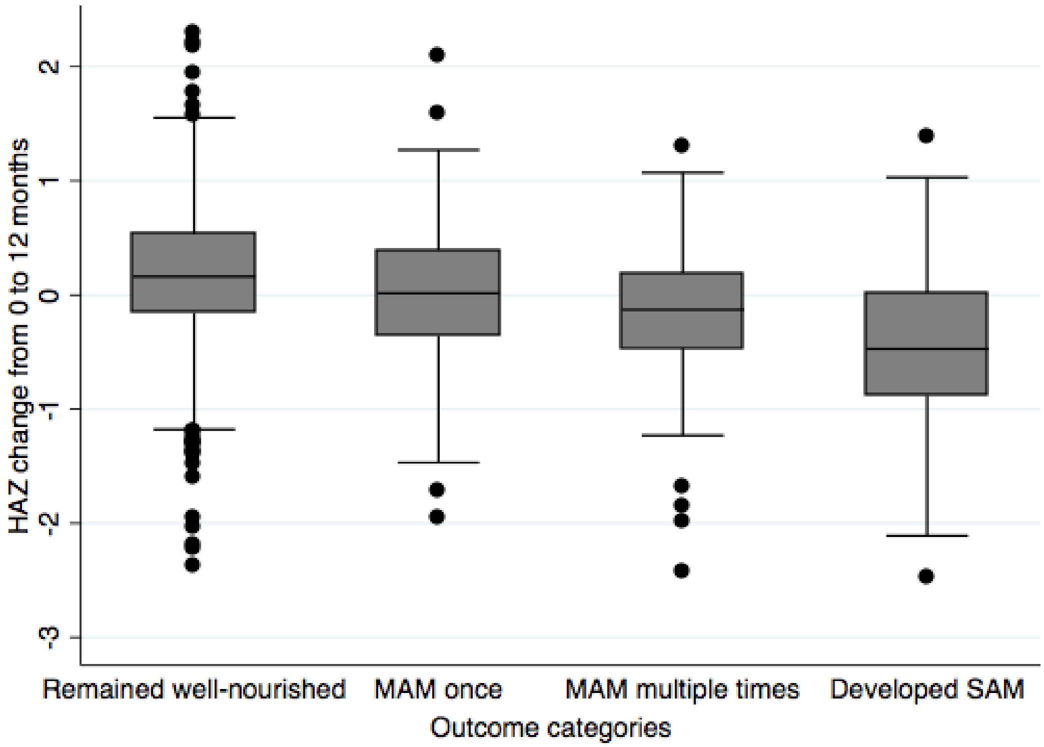
[a] Logistic regression models constructed with robust standard errors to account for clustering and using a backward elimination method, retaining only those factors with P < 0.05.

[b] Logistic regression: Model R2 = 0.094; R2 = 0.113 by Cox and Snell.

[c] Logistic regression: Model R2 = 0.098; R2 = 0.123 by Cox and Snell.

[d] Logistic regression: Model R2 = 0.085; R2 = 0.111 by Cox and Snell; Likelihood ratio test (P=0.572) and Wald test (P=0.222) confirm the final model has stronger predictive power without the variable "Discharge MUAC" included

Figure 6. Change in HAZ from 0 to 12 months following initial recovery from MAM[a]



[a] Statistically significant differences in mean HAZ change between "remained well nourished" and "relapsed to MAM once" at P < 0.01; "relapsed to MAM once" and "relapsed to MAM multiple times" at P < 0.05; and "relapsed to MAM multiple times" and "developed SAM" at P < 0.01. P-values were derived using student's t-test with adjustment for clustering.

Figure 7. Percent of children who experienced catch-up growth during the year following discharge from SFP by outcome

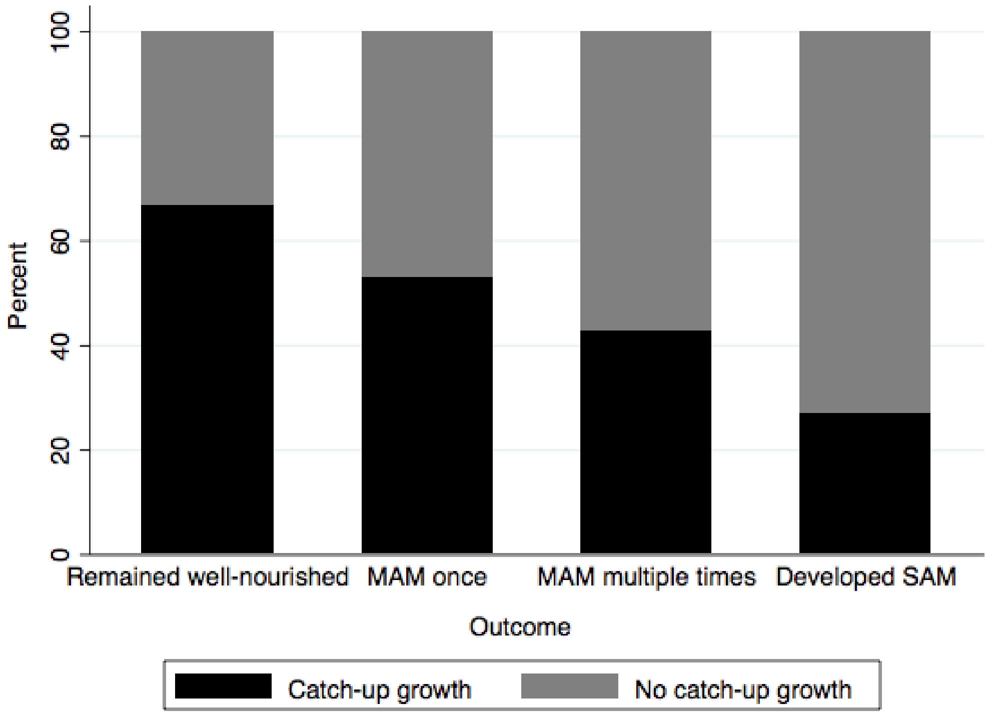


Table 20. Comparison of indicators regarding household characteristics, SES, IYCF practices, food security, and WASH between children who remained well nourished and all other children

	Remained well nourished[a] (n = 180)	All others[a] (n = 132)	P[b]
Characteristics and SES			
Religion			0.340
Christian	133 (74)	108 (82)	
Muslim	44 (25)	23 (17)	
Other	2 (1)	1 (1)	
Other children in home diagnosed with AM	51 (29)	32 (25)	0.438
Years of completed education by caregiver	3.89 ± 2.75	4.17 ± 2.69	0.383
Number of people per room in house	3.18 ± 1.73	2.81 ± 1.38	0.043
House has a separate kitchen	36 (20)	30 (23)	0.577
Average number of assets (out of 12 total)	4.37 ± 1.77	4.34 ± 1.79	0.922
Infant and Young Child Feeding			
Child ever breastfed	176 (99)	131 (99)	1.000
Currently breastfeeding	117 (65)	93 (71)	0.326
Appropriate timing for introduction of solid food	145 (81)	96 (74)	0.208
Minimum meal frequency	65 (51)	61 (60)	0.231
Child dietary diversity score (0–7 food groups)	3.73 ± 1.16	3.58 ± 1.22	0.722
Food Security			
Average HFIAS score throughout 1 year	12.55 ± 3.44	12.88 ± 3.54	0.826
Water, Sanitation, and Hygiene			
Observed cleanliness of caregiver's hands (Average score from 0 [visible dirt] to 2 [clean])	0.93 ± 0.59	0.75 ± 0.56	0.036
Observed cleanliness of child's hands (Average score from 0 [visible dirt] to 2 [clean])	1.00 ± 0.53	0.91 ± 0.55	0.530
Uses improved source for drinking water	134 (74)	90 (68)	0.252
Number of times water is fetched in a day	2.73 ± 1.09	2.92 ± 1.42	0.638
All water storage containers have lids	78 (44)	40 (32)	0.029
Takes action to make drinking water safer	93 (52)	73 (55)	0.567
Uses soap or ash during hand washing	46 (26)	30 (24)	0.788
Knowledge of all five critical times for hand washing	5.29 ± 1.73	5.24 ± 1.85	0.801
Number of times child was bathed during previous week	8.01 ± 3.8	7.82 ± 4.15	0.882
Uses improved sanitation facility	27 (15)	11 (8)	0.082

[a] Values are means ± SD or n (%).
[b] P-values were derived using student's t-tests or chi-squared tests with adjustment for clustering.

Table 21. Comparison of HH SES, food security, IYCF, and WASH indicies between those who remained well nourished and all other children

	Remained well nourished[a]	All others[a]	P[b]
SES	4.08 ± 1.83	4.38 ± 1.81	0.481
Food Security	5.33 ± 1.97	5.34 ± 2.03	0.821
IYCF	6.72 ± 2.20	6.49 ± 2.36	0.600
WASH	5.04 ± 1.64	4.62 ± 1.77	0.280

[a] Values are n ± SD. All indices range from 0 (worst) to 10 (best).
[b] P-values were derived using student's t-tests with adjustment for clustering.

Table 22. Factors in the form of sectoral indices that are associated with children who remained well nourished for 12 months following recovery from MAM

	Odds ratio (95% CI)	P
Child is female	1.51 (1.10–2.13)	0.012
Age upon SFP admission, m	1.03 (1.01–1.05)	0.010
SFP Admission MUAC, cm	2.61 (1.33–5.09)	0.005
SFP Discharge MUAC, cm	2.87 (1.02–8.02)	0.044
SES Index	0.87 (0.77–0.97)	0.016
Food Security Index	1.08 (0.92–1.27)	0.351
IYCF Index	1.11 (0.98–1.25)	0.092
WASH Index	1.17 (1.03–1.33)	0.015

[a] Logistic regression model with robust standard errors to account for clustering and constructed using a backward elimination method, retaining only those factors with P < 0.1, with the exception of the indices, as these were primary variables of interest. All indices range from 0 (worst) to 10 (best). Model R^2 = 0.066; R^2 = 0.085 by Cox and Snell.

Table 23. Serum C3 levels for a subsample of 145 children at SFP discharge and during the follow-up period

	n	Mean[a]	Min	Max	No. below normal range (80–160 mg/dL)
All samples	185	113.23 ± 21.94	59	190	7 (4)
Discharge	143	114.87 ± 22.46	68	190	5 (4)
1 month	35	106.40 ± 19.41	59	152	2 (6)
2 months	7	114.00 ± 18.72	99	147	0 (0)

[a] Values are means ± SD or n (%).