

Integrated Research on Acute Malnutrition (IRAM)

Study of the impact of a package of integrated and multisectoral services (PASIM) to reduce child wasting in Chad

IFPRI (promoter)

UNICEF (sponsor)

ASRADD (implementation)

Moustagbal (data collection)

DNTA (research partner)

Integrated Research on Acute Malnutrition (IRAM)

SUMMARY SHEET

Country :	Chad
Type of project :	Research Project Randomized, unblinded, community-based, effectiveness study
Project Title :	Integrated Research on Wasting (IRAM): Study of the impact of an integrated and multisectoral service package (PASIM) to reduce early childhood wasting in Chad
Version :	Version 1, dated February 25, 2021
Project Codes :	IRAM-Tchad Clinic test. Gov: registration to be completed after approval from the ethics committee.
Project summary (objective, intervention, participants, results) :	<p>The general objective of the integrated and multisectoral services package (PASIM) is to reduce the incidence and prevalence of wasting through integrated interventions, including, among other things, strengthening the activity of community care groups. The members of the care groups make home visits to children aged 6-23 months (or up to 59 months when the children are under treatment for wasting or have been discharged in the previous 6 months) to deliver messages for behavioral change related to complementary feeding, health and hygiene ; deliver nutritional supplement and water purification inputs; improve screening coverage (training and supervision of families to take the Mid-Upper Arm Circumference measurements, referral of malnourished cases); and verify adherence to treatment of malnourished cases, in the health district of Mongo, Guéra province, Chad, Central Africa.</p> <p>The evaluation of the impact of PASIM will be based on a cluster randomized controlled trial, consisting of 100 villages or clusters of villages. The selected evaluation model will be that of a comparison of control groups (n=50; no implementation of the intervention) and intervention (n=50) through the follow-up of 3 cohorts :</p> <ol style="list-style-type: none"> 1- Longitudinal in-home follow-up of a semi-open cohort of 1,750 children aged 6 months at enrollment (included continuously for 7 months and all followed through to the end of the study, which will last 9 months in total). 2- Longitudinal follow-up of all children aged 6-23 months enrolled for wasting treatment, based on health system records. 3- Longitudinal follow-up at home for 6 months of a closed

	<p>cohort of 700 children aged 6-23 months at inclusion, discharged from a treatment for acute malnutrition.</p> <p>The primary impact results are as follows:</p> <ul style="list-style-type: none"> - The longitudinal prevalence of wasting at the end of the study (Cohort 1). - The recovery rate (Cohort 2). - The incidence of relapse during the 9 months of the intervention (Cohort 3). <p>Secondary impact results include, but are not limited to :</p> <ul style="list-style-type: none"> - The incidence of wasting during the 9 months of the intervention (Cohort 1) ; - The screening coverage (cohorts 1 and 3); - The proportion of wasting cases enrolled in a treatment program (cohorts 1 and 3); - The adherence to treatment (cohort 2) during the 9 months of the intervention.
Study Tools :	Questionnaires, anthropometric measurements, and biological measurements on capillary blood by finger puncture (rapid malaria test, hemoglobin level)
Consent Forms :	See Appendix 1
Instruments :	See Appendix 2
Duration of the project :	9 months (April 2021 - December 2021)
Sponsor :	Foreign, Commonwealth & Development Office (FCDO) via the United Nations Children's Fund (UNICEF)
Agency of setting implementation :	Sahelian Alliance for Applied Research for Sustainable Development (ASRADD)
Partner institution :	Ministry of Public Health (DNTA)
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List of Abbreviations

ARI	Acute respiratory infection
ASRADD	Sahelian Alliance of Applied Research for Sustainable Development
BCC	Behavior Change Communication
CHW	Community Health Workers
CSB ++	Corn-Soy Blend plus plus
CTPNA	Technical Permanent Committee of Nutrition and Food
DMC II	Developmental Milestones Checklist II
DNTA	Directorate of Nutrition and Food Technology
FARNE	Home for learning, nutritional rehabilitation and awakening
FCDO	Foreign, Commonwealth and Development Office
GAM	Globale Acute Malnutrition
HAZ	Height-for-age index in Z-score
IFPRI	International Food Policy Research Institute
IYCF	Infant and Young Child feeding
MAM	Moderate Acute Malnutrition
MUAC	Mid-Upper Arm Circumference
NGO	Non Governmental Organization
PASIM	Integrated and multisectoral services package
PCIMA	Integrated Management of Acute Malnutrition
PCIMA-C	Integrated Management of Acute Malnutrition at the Community Level
PECIME	Integrated Management of Childhood Illnesses
PECMAS	Management of Severe Acute Malnutrition
RUSF	Ready-to-Use Supplement Food
RUTF	Ready-to-Use Therapeutic Food
SAM	Severe Acute Malnutrition
SBCC	Social and Behavior Change Communication
SIAN	Week of Intensified Nutrition Activities
SQ-LNS	(Small Quantities of) Lipid-based Nutritional Supplements
UNA	Ambulatory Nutritional Unit
UNICEF	United Nations Children's Fund
UNS	Supplementary Nutritional Unit
UNT	Therapeutic Nutritional Unit
VGS	Care Group Volunteer
WASH	Water, Sanitation and Hygiene
WAZ	Weight-for-Age Index in Z-score
WFP	World Food Program
WHA	World Health Assembly
WHO	World Health Organization
WHZ	Weight-for-height index in Z-score

1 Problem Statement and Study Rationale

Worldwide, 47 million children under the age of five suffer from wasting¹ (1). Wasting significantly increases the risk of death: it kills 875,000 children under the age of five per year (2). All member states of the World Health Assembly (WHA) have agreed to reduce and maintain the prevalence of wasting to less than 5% by 2025 (3). However, the prevalence of wasting remains persistently high in many West and Central African countries such as Mali (14.8%), Mauritania (13.5%), Chad (12.9%) and Niger (10.1%). Wasting trends suggest that the WHA goal will not be achieved in these countries, despite their commitment to combat wasting as expressed in their nutrition policies (4). Progress in reducing the burden of wasting is hampered by a number of factors. First, programmatic evidence on how to prevent wasting is limited. There is a growing body of evidence on the effectiveness of dietary supplements in preventing wasting, but little is known about the effectiveness of other strategies such as social and behavior change communication (SBCC) (with or without supplements), cash transfers, or water, hygiene, and sanitation (WASH) interventions (5). Second, coverage of community-based management of wasting (CIMCI) treatment remains low in many settings (6). On the supply side, documented constraints include the complexity of current treatment procedures, which disproportionately affects resource-limited settings, and frequent shortages of treatment commodities. On the demand side, low participation in screening and low treatment uptake and adherence are key constraints to effective treatment. The recent PROMIS studies in Mali and Burkina Faso demonstrate that screening uptake can be more than doubled by providing small quantities of lipid-based nutrient supplements (SQ-LNS) combined with social and behavior change communication (SBCC) as incentives for participation (7,8). However, these studies showed that increased screening in these settings did not automatically lead to increased treatment coverage, which remained below 25%.

There is an urgent need to test innovative solutions to prevent wasting and increase screening, treatment initiation and adherence. Options include integrating prevention into screening to increase coverage and prevent wasting; strengthening referral processes for wasted children and supporting and encouraging parents to enroll their children in treatment; establishing outreach screening and treatment units; transferring some responsibility for treatment to community health workers; and/or simplifying treatment procedures for both parents and service providers.

In response to this urgent need, UNICEF and IFPRI started a multi-country partnership to generate evidence on wasting prevention and treatment interventions in four countries: Chad, Mali, Mauritania, and Niger.

In Chad and Mali, impact evaluations will be conducted to generate solid evidence of the effectiveness of integrated interventions to reduce wasting. Impact evaluation in

¹ Defined in children 0-59 months of age as a weight-for-height score of less than -2 z-score according to WHO weight-for-height references (13); depending on the context and the measurement tools used, wasting is also defined by a brachial perimeter of less than 125 mm in a child aged 6-59 months or by the presence of bilateral edema (0-59 months).

these countries will be combined with a cost study and a documentation of the implementation process. In Mauritania and Niger, in-depth implementation research will be conducted to generate the necessary evidence on how integrated nutrition services are implemented in the field. The proposed studies will help fill important knowledge gaps by assessing the operational feasibility, impact and cost-effectiveness of community-based integrated interventions that use simple procedures to integrate all elements of the continuum of care from wasting prevention to treatment, into a single platform at the community level in four West African countries (**Figure 1**). The evidence generated through this partnership will inform national, regional and global policies on wasting and is consistent with the Global Plan of Action on Child² Wasting (9), ³and the WFP-UNICEF regional partnership.

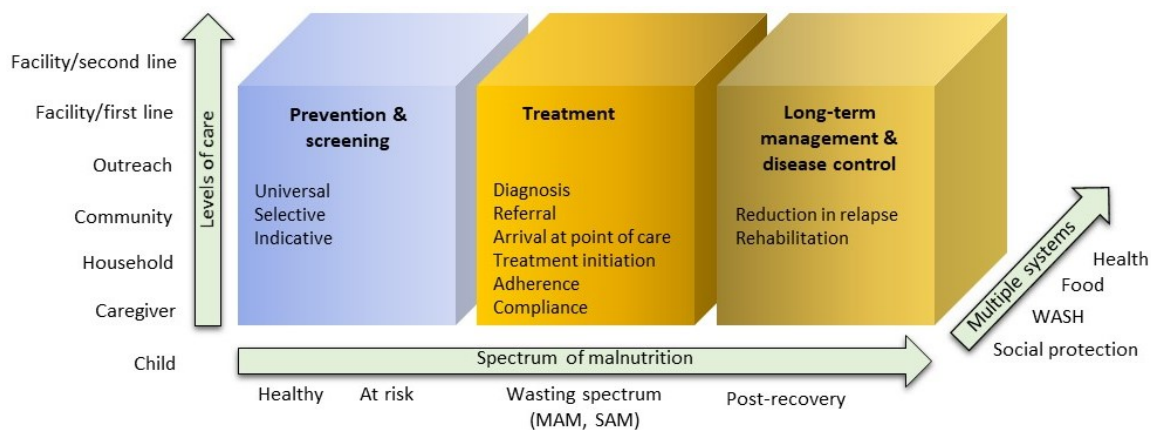


Figure 1: Conceptual Framework of Continuum of Care for wasting

2 General objective

The overall objective of *the intervention* is to reduce the longitudinal prevalence of wasting in children aged 6 to 23 months inclusive (corresponding to a peak prevalence) by integrating several approaches along the continuum of care for wasting into *an integrated, multisectoral package of services (PASIM)*.

The main objective of *the research* is to provide strong evidence of the effectiveness of the integrated interventions of the PASIM to reduce wasting.

The implementation of PASIM will be led by the Sahelian Association for Applied Research and Sustainable Development (ASRADD) in collaboration with the health

² In March 2020, the inter-agency Global Action Plan on child wasting (GAP) was published. UNICEF is partnering with WHO to produce evidence to inform both the GAP and the review of WHO normative guidelines. This project will help fill key knowledge gaps related to this collaboration with WHO.

³ Evidence from this partnership between UNICEF and IFPRI will also include other key stakeholders, including WFP. Within the framework of the regional partnership between UNICEF and WFP, and in particular the associated learning agenda, this project will be conducted to help highlight current gaps in integrated approaches to reduce child wasting, from prevention to treatment.

services of the health district of Mongo, Guéra province, and other implementing partners in the zone. The activities will take place at the health center and community levels, and include i) a prevention component combining the strengthening of community care groups (who will conduct home visits to deliver behavior change messages) and the distribution of a nutritional supplement (CSB++) to [6-11] months old children diagnosed as non-wasted (as a result of the green MUAC) and water purification inputs to all [6-11] months old children unconditionally (regardless of wasting status); ii) a component related to strengthening screening and referral that will involve families (family MUAC approach), with [6-23] months old children, trained and supervised by community care groups (who will also conduct routine screening); children diagnosed as wasted will be referred and will receive treatment (including food supplements) at the FARNE or nutritional units; iii) a treatment component that includes strengthening the protocol for integrated management of acute malnutrition (PECIMA) currently in use in Chad, as well as support from community groups through follow-up home visits to wasting cases for counseling and verification of adherence and compliance to treatment; and iv) a final relapse prevention component combining a 6-month home follow-up by community care groups for [6-23] months old children who recovered from wasting to provide nutritional counseling, a preventive nutritional supplement (CSB++), water purification inputs, and a supervision of testing by families.

3 Research Methods

3.1 Framework of the study

3.1.1 Study area

Chad is a low-income country in Central Africa with a population⁴ of nearly 16 million in 2019. In 2018, 42% of the population lived below the national poverty threshold⁵. The study will be conducted in the health district of Mongo located in the Guéra province, which includes 26 zones of responsibility (ZR) of the health centers (CS). The population statistics of Guéra province show a total of 31,771⁶ children aged 6-59 months in 2019 with 12.9 (12.1-13.7) % of them suffering from a weight-for-height <-2 z-score (10).

When considering data from 2016, and all criteria for defining wasting (defined as WHZ <-2 or MUAC <125 mm or bilateral edema for overall wasting; WHZ <-2 or MUAC <125 mm or bilateral edema for severe wasting), it can be seen that the levels of GAM and SAM in the Guéra are globally slightly above the national average, which is relatively high : between 15 and slightly more than 20% for overall wasting, and around 5% for severe wasting, with no real trend towards improvement since 2016. Even if there is a significant reduction in overall wasting (from 21% to 16%) and severe wasting (from 6.6% to 3.9%) between 2018 and 2019 in the Guera, it cannot be concluded at this stage that this is the result of an overall improving trend.

A contextual analysis of wasting in the Health District of Mongo carried out in 2020 (11) identified the following main factors:

- Suboptimal infant and young child feeding practices (IYCF)
- Seasonal food insecurity
- Insufficient adequate diet knowledge and habits
- Inadequate primary care management
- Cultural factors: use of traditional healers, removal of the uvula, giving the child water from the backwater, early marriages, etc.
- Insufficient autonomy for women
- Poor food hygiene practices
- Suboptimal WASH infrastructures and practices: limited access to clean water, widespread open defecation, waste disposal problems.

⁴ United Nations World Population Prospects, 2019

⁵ Chad Presentation, <https://www.banquemondiale.org/fr/country/chad/overview>; Access on 2020-12-17

⁶ Projections considering the average household size in Chad of 5.2 individuals according to the 2009 census.

In 2015, the SLEAC survey conducted in Chad showed that the coverage of SAM care was 37% and was considered moderate (12). The barriers identified by the survey are a strong lack of knowledge about malnutrition and a poor understanding of treatment and the IMCI programs, the barrier of distance and the availability of means to get to health centers.

Analysis of 2018 and 2019 admission data in the outpatient or therapeutic nutritional units of the Guéra shows a high rate of admission of children already known to PECMAS services, specifically children in relapse (after an episode successfully treated) and children readmitted after dropping out of the program (11). This rate decreased significantly between 2018 and 2019, but still exceeds 10% of children admitted in the age groups above 6 months. In addition, exit data show that successful treatment increased significantly between 2018 and 2019, with a significant decrease in the dropout rate from 7.5% to 2.6%. The death rate is quite low, around 0.5%. On the other hand, the occurrence of shortages of RUSF in UNA as reported in the monitoring files (zero stock at the end of the month) over a 2-year period reveals that all the health centers monitored suffered at least one shortage in 2 years. A third of the 18 facilities had shortages observed 5 times or more over the 24 months observed.

3.1.2 PCIMA National Program

Chad's current national protocol for the management of acute malnutrition has been implemented since 2014. It technically describes the organization of the continuum of care for wasting at the central (national), provincial, district, health center and community levels. It describes all aspects of the implementation of screening and treatment. Routine PCIMA services for the treatment of MAM and SAM are available in health centers throughout the country.

The program for the management of severe or moderate acute malnutrition implemented by the Ministry of Health is currently operating in all health centers in Mongo for the ambulatory management of uncomplicated cases (UNS Supplementary Nutritional Units for MAM, UNA Ambulatory Nutritional Units for SAM). In the district hospital, the pediatric services ensure the management of SAM with medical complications (Therapeutic Nutritional Unit, UNT). In some communities, MAMs are also treated in FARNEs (Homes for learning, nutritional rehabilitation and awakening), which are run by the community and NGO actors in partnership with the health services.

a) Screening platforms

Passive screening is done during preventive child care and curative consultations or immunization sessions by qualified health workers, doctors, and nurses. Passive screening is included in the outreach strategy (health worker going to the village for consultation), but the health center does not organize active screening (in the form of campaigns, for example). Health staff use either tape measures (MUAC) or weight-for-height measurements for diagnosis. However, following the COVID19 pandemic,

precautionary measures have been taken and screening of children has been limited to measuring MUAC, including in health centers. Routine screening is done in the community by CHWs, care groups and mothers using MUAC.

b) Reference and treatment of MAM and SAM

When community workers screen a child for acute malnutrition, the child is: i) either diagnosed as negative (code green, MUAC ≥ 125 mm); ii) or diagnosed as MAM positive ($115\text{mm} \leq \text{MUAC} < 125\text{mm}$, code yellow); iii) or diagnosed as SAM positive (MUAC $< 115\text{mm}$ or bilateral edema, code red). In the case of SAM, the mother-child couple is referred to the health center for confirmation of the diagnosis based on the MUAC and initiation of treatment. If the diagnosis is confirmed, the child is examined to verify the presence or absence of medical complications. Following the COVID19 pandemic, only the MUAC criterion is currently used to screen children.

In the absence of signs of complication, the MAM child is admitted to an outpatient program (UNS or FARNE) with a scheduled follow-up every two weeks. The duration was extended following the COVID19 pandemic; follow-up is currently monthly. The mother receives a ration of food supplements to be given to the child every day (RUSF or CSB++). In the absence of complications, and after a successful appetite test, the SAM child is included in an outpatient treatment program (UNA) with follow-up scheduled every week. The duration was extended following the COVID19 pandemic; follow-up is currently every two weeks. The mother receives a ration of food supplements (RUSF) to be given to the child every day. Complicated cases of SAM or MAM or cases with edema are referred for inpatient treatment at the hospital which has a pediatric ward (UNT ward).

Children are discharged from these treatment programs if they reach a weight-for-height > -2 z-scores and a MUAC $\geq 125\text{mm}$ and the absence of bilateral edema for two consecutive visits.

c) Psycho-cognitive stimulation program at UNA/UNT

During the rehabilitation of children under treatment at UNA/UNT, their psycho-cognitive stimulation should begin, and continue after discharge, to reduce the risk of mental and physical sequels. Psychosocial stimulation should be done by the doctor and nurses. The social worker is in charge of organizing the sessions.

This program includes activities such as :

- Organizing sessions to teach mothers how to make toys themselves with cheap and salvageable materials;
- Organizing training sessions to teach mothers the importance of games and discovery in providing the psycho-cognitive and physical stimulation the child needs (this is an integral part of the treatment);

- Keeping the mother with the child and encourage her to feed, carry, comfort, and play with him/her as much as possible.

3.2 The intervention

3.2.1 Beneficiaries of PASIM

Children receiving PASIM are [6-59] months of age, with various variations in the package depending on the child's age.

3.2.2 Delivery Platform: Community Care Groups

This program is implemented by the NGO ASRADD with technical and financial support from UNICEF and in collaboration with local authorities and technical partners working in the Mongo Health District. It is a multisectoral approach at the community level. Fifteen people from the community, called Care Group Volunteers (VGS), form a community care group (also called care group or *ialafé*), with a coverage radius of 15 to 20 households per VGS. Household eligibility for prevention activities is based on the 1,000-day window: any household with a pregnant woman or a child under the age of two is eligible. Eligibility is extended to children up to 59 months of age for screening, follow-up of children undergoing emaciation treatment, and prevention of relapse within six months of discharge from treatment. The number of groups depends on the size of the village, so that all beneficiaries who wish to be covered can be covered.

The care groups are facilitated and trained by the ASRADD instructor who regularly monitors each group. VGS are trained on key themes and refer women to health centers when needed. All stages of the continuum of care are reinforced by the activities of the care groups, i.e., prevention, screening, monitoring of adherence and compliance to treatment, and referral.

3.2.3 PASIM Services

PASIM's activities are part of the continuum of care for acute malnutrition and aim to fill the gaps identified in the context analysis conducted by IFPRI and UNICEF in 2020 in the health district of Mongo.

The PASIM is delivered by the care groups. Each beneficiary is visited at home at least once a month (up to once a week if possible).

The package of activities includes :

- Prevention over the period of 1000 days (from pregnancy until the child is 2 years old):
 - Behavior change communication (all children in care groups) :
 - Awareness of dietary diversification from 6 months of age and adequate complementary feeding.
 - Raising awareness of good water and hygiene practices.

- Monthly delivery of a nutritional supplement: enriched flour (CSB++), at a rate of 3 kg/month/beneficiary child. The nutritional supplement is limited to [6-11] months old children diagnosed as non-wasted (green MUAC).
- Monthly delivery of a water purification input: bleach or flocculant/decontamination sachets for the potabilization of the water of the whole household. The water treatment input is limited to households with [6-11] months old children.
- Delivery of micronutrient powders to [6-23] months old children (30 sachets per month for 2 months, every 6 months, according to international recommendations).
- Screening for [6-59] months old children:
 - Delivery of a MUAC measuring tape and training of families in its use, and actions to be taken based on the results. This will involve distributing Shakir bands to all households with [6-59] months old children and training mothers/guardians, or any other family members who express an interest, in screening for wasting using the MUAC criteria, and explaining the procedure to follow if the child tests positive in the family.
 - Formative supervision of MUAC measurement in families. The training will be carried out by the members of the care groups and at each home visit, they will be able to ensure that the MUAC measurement technique is well mastered by the mother (or another member) and correct the technique if necessary.
 - Monthly screening by the VGS of the children they follow, using the MUAC.
- Referral to the health center of [6-59] months old children screened as malnourished (result of MUAC orange or red): The VGS refers children who are diagnosed as malnourished to the health center using a referral coupon and makes a note in the care group's follow-up logbook; the ASRADD promoter regularly retrieves this data and follows up with the health center. If the promoter notices that a certain number of children did not follow up on the referral, he returns to the care group, which returns to the families to identify the children who did not go to the health center, understand the reason, and seek solutions with the families.
- Follow-up of [6-59] months old children under treatment and for 6 months after discharge from the national treatment and consolidation program (if eligible): VGS follows children under treatment until they recover (taking treatment until they are cured) and for the whole duration of their consolidation (for children cured of severe emaciation) through home visits.

- They monitor treatment adherence (i.e., families follow the planned schedule of visits and receive inputs for treatment or consolidation) and treatment compliance (i.e., the malnourished or consolidating child receives the planned dose of therapeutic or supplementary food each day).
- They also deliver a water purification input: bleach or flocculant/decontamination sachets for the purification of the water for the entire household.
- Upon recovery or discharge from consolidation program for a child aged [6-23] months, follow-up is extended for 6 months (or until the child is 59 months old) with the delivery of the complete prevention package :
 - Behavior change communication
 - Monthly delivery of a nutritional supplement: enriched flour (CSB++), at a rate of 3 kg/month/child beneficiary
 - Monthly delivery of a water potabilization input: bleach or flocculant/decontamination sachets for the potabilization of the water of the whole household.

Other activities of the care group are carried out upstream of the peak of acute malnutrition (before the child's 6 months of age and during pregnancy) and essentially include activities promoting good practices for the prevention of all forms of malnutrition and illness during the 1,000-day period (which extends from the mother's pregnancy to the child's second birthday), integrating the promotion of good maternal diet and the promotion of exclusive breastfeeding in the first 6 months.

3.3 Target population and study population

Research will be limited to the age group most at risk of wasting. Thus, for this research, the target population is all [6-23] months old children, whether healthy, wasted, or in remission of wasting, living in one of the 100 most populated villages of the Health District of Mongo (representing 8 out of 10 children in the Health District).

The study area includes 100 villages or groups of villages in the health district of Mongo located in the province of Guéra in south-central Chad.

The study populations will be composed of :

- 1- Children recruited at 6 months of age in the 100 most populated villages and followed throughout the study. Children will be enrolled every month during the first 7 months of the study. Including the month of inclusion, children will therefore be followed for 9 months (for children enrolled at the beginning of the study) and for a minimum of 3 months (for children enrolled during the 7th month).

- 2- [6-23] months old children living in the 100 most populated villages, discharged from treatment in the nutritional units and FARNE and followed for a period of 6 months.
- 3- [6-23] months old children living in the 100 most populated villages, enrolled in a wasting treatment program in the nutritional units (UNA, UNS) and the FARNE, and followed up until the end of the program.

3.4 Research Questions

Main Research Question :

- What is the impact of PASIM on the prevalence of wasting in young children?
- What is the impact of PASIM on the recovery rate of wasted children?
- What is the impact of PASIM on the occurrence of relapses after treatment and recovery from wasting?

Secondary Research Questions along the Continuum of Care :

- What is the impact of PASIM on the incidence of wasting in young children?
- What is the impact of PASIM on the wasting screening coverage in young children?
- What is the impact of PASIM on enrollment in a program for treating cases that test positive in young children?
- What is the impact of PASIM on nutritional status at enrollment in treatment in young children?
- What is the impact of PASIM on the duration, coverage, and adherence of/to the treatment of emaciation in young children?
- What is the impact of PASIM on the psycho-cognitive development of young children?
- What is the unit cost of PASIM per beneficiary child?
- If there is an impact of the intervention, how cost-effective is PASIM?
- Is the intervention well implemented, in terms of coverage, effectiveness, uptake, fidelity/rationality of implementation, and potential for sustainability?

3.5 Impact study

A rigorous impact evaluation of the PASIM implemented by ASRADD in collaboration with the health services of Mongo will be conducted by IFPRI in partnership with the national NGO Moustagbal for data collection.

3.5.1 Impact study model

The study design includes a two-group, stratified, randomized, unblinded, community-based efficacy trial. The unit of randomization will be the village or, in some cases, the cluster of small villages (grouped prior to the draw).

The evaluation of the program model in the Mongo district will compare two groups:

- 1) *The control group* receiving the standards of care and the usual activities of the partners without additional support from the IRAM project for the implementation of the PASIM. This includes the usual PCIMA program. This group will also continue to benefit from the BCC and screening services already existing in their areas.
- 2) *The intervention group* will receive the PASIM through the care groups, in addition to the standard of care (the usual PCIMA program) and the BCC and screening services already existing in their areas.

The impact evaluation includes three sub-studies to study the impacts of PASIM along the continuum of care in order to answer the research questions :

1. A longitudinal cohort (**Cohort 1**) to study the impact of the intervention on the prevalence of wasting (impact of prevention and treatment), incidence of wasting (impact of prevention), knowledge and practices of WASH, nutrition and child health. This will be a semi-open cohort in which children who reach 6 months of age will be recruited and followed through to the end of the study.
2. A longitudinal cohort (**cohort 2**) of children aged [6-23] months at enrollment in UNS and UNA (at the health center and at the FARNE site) to study the impact on treatment outcome (drop-out, death, recovery, deterioration), adherence to treatment, and duration of the episode under treatment.
3. A longitudinal cohort (**cohort 3**) of children aged [6-23] months discharged from UNS/UNA/FARNE treatment to study the impact of the intervention on the relapse rate six months after discharge.

3.5.2 Stratification and randomization

For accessibility issues (dispersion of the population in small hamlets) and required number of children for the study (probability of finding the necessary number of children each month), only the 100 most populated villages (or relevant groupings of neighboring villages) in Mongo will be included in the study and randomized between an intervention and a control group, after stratification to balance village size between groups, and area of residence (urban/rural).

A first level of stratification will be based on the criterion of the total population of the village or group of villages to ensure comparability between intervention and control groups. The 50 most populated villages will be randomized separately from the 50 least populated villages.

A second level of stratification will be done in each subgroup according to the type of health center (urban/rural). In fact, a principal component analysis (PCA) showed a profile of villages according to these two criteria (size of village, urban/rural health

center) which summarizes the difference between villages. This *a priori* stratification (before randomization) ensures a more balanced distribution of covariates between the study groups. The balance in the pre-existence of certain relevant PASIM services in certain villages will be verified.

These 100 villages or clusters of villages will be randomly assigned to the intervention and control groups using Stata software by an investigator based in Dakar and outside the study area. Stata's "sample⁷" command was used to perform a simple random draw of half of the villages on the list of 100 villages. The villages randomly selected by the software were assigned to the intervention group and the others to the control group. To ensure the randomness and replicability of this draw, a random seed (the number used to initiate the draw) was obtained from the random number generator on random.org.

PASIM will be implemented by the executing partners in the villages of the intervention group only (50 villages, including 25 large villages and 25 medium villages).

Table 2: Stratification Criteria

Criteria
- Total population of the village
- Urban Health Centre vs. Rural Health Centre

3.5.3 Sample Size, Sampling, Approaches, and Inclusion Criteria

The three cohorts of children needed to longitudinally assess the effects of PASIM along the continuum of care will be as follows:

- Main cohort (#1): includes 1,750 children in the community aged 6 to 6.9 months, included for a period of 7 months and followed up monthly until the end of the study (the total duration of the study is 9 months from April 2021 to December 2021).
- Treatment Cohort (#2): includes all 6-23 months old children living in the 100 study villages, or included in the main or relapse cohort, and registered for treatment, based on health system records.
- Relapse Prevention Cohort (#3): includes 700 children aged 6 to 23 months inclusive who were discharged from treatment and followed up monthly for 6 months.

The main cohort (#1) will include children aged 6-6.9 months. Given the small size of most villages and the sample size needed to detect a significant, plausible and meaningful difference in longitudinal wasting prevalence (primary outcome) between groups, we have calculated that we need to include an average of 3 children per month for 7 months in the 50 largest villages (25 villages in the control group and 25 in the

⁷ Gould, W. W. 2012a. Using Stata's random-number generators, part 2: Drawing without replacement. The Stata Blog: Not Elsewhere Classified. <http://blog.stata.com/2012/08/03/using-statas-random-number-generators-part-2-drawing-without-replacement/>.

intervention group) and an average of 2 children per month for 7 months in the 50 smallest villages in the study area (i.e., the medium-sized villages in the Mongo Health District: equally 25 in the control group and 25 in the intervention group). The children will all leave the cohort in the same month: counting the month of inclusion, the children will be seen for a maximum of 9 months (for children included at the start of the study) and a minimum of 3 months (for children included during the 7th month). This will result in a total sample of 1,750 children (10,500 visits in total of which 1,750 inclusions and 8,750 follow-ups, see Table 1). With 15% dropout, the size of this study would provide sufficient power to detect a relative decrease of about 35% in the longitudinal prevalence of wasting and a relative decrease of about 28% in the incidence of wasting, with a power of 80% and a statistical significance of 5%, taking into account the cluster effect at the village level and the imbalance in cluster size.

In each of the 100 villages, **these children will be randomly selected from a randomly ordered list from a census of children aged 0-6 months (conducted by the survey team in the first month of the survey).** Their parents will be offered the opportunity to participate in the study during a home visit (see **Voluntary and Informed Participation Process and Consent Documentation described in Section 4**). Children whose parents refuse or who are not located will be replaced until a maximum of three new children have been included in a given month, or until the list of eligible children is exhausted. Inclusion will end when 21 children have been included in each of the 50 largest villages and at least 14 children have been included in each of the other 50 villages. Inclusion in the cohort will begin in April and continue until October 31, 2021.

The **criteria for inclusion** of children in the main cohort are:

- 6-6.9 months of age
- Child singleton
- The mother must live in the study area from the time of inclusion.
- The agreement of the mother or guardian

The exclusion criteria are :

- Congenital malformations that make anthropometric measurements impossible.
- Mother intends to leave the study area by December 2021.

The **Relapse Prevention Cohort (#3)** will include [6-23] months old children discharged from the program and living in the 100 villages in the study area. Given the small size of most villages and the required sample size, we have calculated that we need to enroll 8 children in the 50 largest villages and 6 children in the 50 average villages and follow them every month for 6 months each. This will result in a total sample size of 700 children (4,900 visits in total, including 700 inclusions and 4,200 follow-ups). Such a sample size would provide sufficient power to detect a decrease of about 33% in the incidence of relapse.

All available children in each village who are discharged from PCIMA treatment (identified based on nutrition unit registers) will be invited to participate in the study

until the required sample size is reached for each village. **During the discharge visit, parents will be asked if they agree to have their contact (first name, last name, village, and if possible, telephone or location) forwarded to the survey team for an explanatory home visit. If they agree, participation in the study will be offered during a follow-up home visit (see process for voluntary and informed participation and documentation of consent described in Section 4).** In villages with more children than necessary, the study team will select children from a randomly selected list. Inclusion must be completed by June 30, 2021, to allow 6 months of observation before December 31, 2021.

The inclusion criteria for the relapse study are:

- Child has been successfully treated for wasting (moderate or severe) and has been discharged from the national treatment program within the last 30 days.
- The child is between 6 and 23 months of age at inclusion.
- The child is singleton.
- The mother must live in the study area from the time of inclusion.
- The agreement of the mother or guardian

The exclusion criteria are :

- Congenital malformations that make anthropometric measurements impossible.
- Mother intends to leave the study area by December 2021.

Table 1: Chronology of Inclusion in the Main and Relapse Cohorts and the Number of Children Followed Monthly

	April	May	June	July	August	September	October	November	December
Primary Cohort									
Month of inclusion 1 (n = 250)	n = 250								
Month of inclusion 2 (n = 250)		n = 500							
Month of inclusion 3 (n = 250)			n = 750						
Month of inclusion 4 (n = 250)				n = 1 000					
Month of inclusion 5 (n = 250)					n = 1250				
Month of inclusion 6 (n = 250)						n = 1500			
Month of inclusion 7 (n = 250)							n = 1750	n = 1750	n = 1750
Relapse Prevention Cohort									
Month of inclusion 2 (n = 350)		n = 350							
Month of inclusion 3 (n = 350)			n = 7 00	n = 700	n = 700	n = 700	n = 700	n = 700	n = 350
Total number of children in the two cohorts	250	850	1450	1700	1950	2200	2450	2450	2100

The treatment cohort (#2) will include all records of children (aged [6-23] months) living in the 100 villages in the study area and enrolled between April 2021 and December 2021 in a treatment program by the national PCIMA program (UNA, UNS, FARNE, UNT). Treatment data are collected by the health centers as part of their routine.

Each nutritional unit and FARNE will be visited by an enumerator twice a month.

The enumerator will be responsible for monitoring data quality and copying data from the registers to electronic forms.

The copied data will not personally identify the children, except for the children followed in cohorts 1 and 3 whose parents will give their consent as part of the informed consent process to link the treatment data to their cohort data. For other registry data for children outside of cohorts 1 and 3, there is no provision for seeking parental consent as we will treat these data as secondary data. No follow-up visits will be made by the interviewers, so they will not attempt to locate the children. **Thus, the data copied will not include names, phone numbers, or dates of birth.** However, it will include other variables such as anthropometric measures and inputs given and services received, as well as sex, age group, and village code, solely for the purpose of accounting for these primary adjustment factors and the cluster effect when analyzing the data.

The criteria for inclusion in the treatment cohort are :

- The child is included in a national treatment program.
- The child is between 6 and 23 months of age at inclusion
- Child lives in one of the 100 villages in the study area

3.5.4 Study Results

For this study, wasting is defined by $WHZ < -2$ (relative to the WHO reference of 2006) or $MUAC < 125$ mm or bilateral edema. Moderate Acute Malnutrition (MAM) is defined by $-3 \leq WHZ < -2$ (relative to WHO reference of 2006) or $115 \text{ mm} \leq MUAC < 125$ mm. Severe Acute Malnutrition is defined by $WHZ < -3$ (relative to WHO 2006 reference) or $MUAC < 115$ mm or bilateral edema.

The **main results of the** study are:

1. Longitudinal prevalence of wasting among children enrolled at 6 months of age followed monthly until the end of the study (Cohort 1). This indicator is defined for each child as the number of visits during which wasting is observed divided by the total number of monthly visits made (by interviewers).
2. The recovery rate in children enrolled at [6-23] months of age for up to 3 months of treatment in a UNS, UNA or FARNE and followed through to discharge (Cohort 2). This indicator is defined as the number of discharges considered cured according to national program criteria ($WHZ > -2$ and $MUAC \geq 125$ mm and absence of bilateral edema for two consecutive visits, within 12 weeks of enrollment in the program) divided by the total number of discharges recorded.

3. The incidence of wasting in children enrolled at [6-23] months of age at discharge and followed for 6 months (Cohort 3). This indicator is defined as the number of new cases of wasting recorded during monthly visits.

Secondary outcomes of the study include:

For Cohorts 1 and 3 :

- The longitudinal prevalence of :
 - MAM, defined by the number of MAM diagnoses divided by the total number of monthly visits made
 - SAM, defined by the number of SAM diagnoses divided by the total number of monthly visits made
 - The impact of :
 - Wasting, defined by the number of new cases of wasting recorded during monthly visits.
 - MAM, defined by the number of new MAM cases recorded during monthly visits
 - SAM, defined by the number of new SAM cases recorded during monthly visits
 - The prevalence of anemia defined as the proportion of children with a hemoglobin level below 11g/dl at the end of the study.
 - Mean hemoglobin concentration at the end of the study
 - Prevalence of stunting defined as the proportion of children with HAZ <-2 (relative to the 2006 WHO reference) at the end of the study.
 - The average z-scores HAZ at the end of the study
 - Wasting screening coverage defined as the proportion of children screened (using MUAC, weight-for-height or bilateral edema) in the month prior to the monthly visit.
- Two sub-outcomes will also be concerned:
- Screening coverage by care groups.
 - Coverage of the family MUAC component, which is the screening performed by a family member in the past month.
- The referral rate of positive screenings defined as the proportion of children who tested positive during the month (according to the mother) who were referred to the health center or FARNE site.
 - Enrollment of wasting, MAM, and SAM cases defined as the proportion of cases who tested positive in the month prior to the monthly visit who were enrolled in a UNA or UNS treatment program.
 - Children's psycho-cognitive development, as assessed by the DMC-II score at the end of the study
 - Linear growth rate (change in height-for-age index per month)
 - Speed of weight growth (change in weight-for-height index per month)
 - Weight gain (weight change per month)
 - MUAC gain (change in MUAC per month)

- The longitudinal prevalence of childhood morbidity, i.e. acute respiratory infections, fever, diarrhea and malaria, defined by the number of diagnoses of signs of these morbidities divided by the total number of monthly visits made.
- Mother/guardian's knowledge of nutrition, WASH, and health expressed as cumulative total and domain scores in a subsample of children who reached 9 months of age
- Infant and young child feeding practices (IYCF)
 - o Introduction of (semi) solid and soft complementary foods
 - o Minimum dietary diversity in children, defined as the proportion of children who consumed at least 5 of the 8 food groups (including breast milk) the day before the survey.
 - o Minimum meal frequency for children, defined as the proportion of children who had eaten the day before the survey: 2 meals for breastfed children 6-8 months, 3 meals for breastfed children 9-23 months, or 4 meals for non-breastfed children 6-23 months.
 - o Minimum acceptable child feeding, defined as the proportion of children with both minimal dietary diversity and minimal meal frequency on the day before the survey.
 - o Consumption of iron-rich or iron-fortified foods in children.
- Practices related to water, hygiene and sanitation
- Vaccination coverage.

For Cohort 2 :

- Nutritional status (measured by weight-for-height in z-score and MUAC) at enrollment in UNS and UNA in children 6-23 months of age.
- The duration of UNS and UNA treatment defined as the number of days spent on treatment (enrollment and discharge) in children 6-23 months of age at enrollment.
- Treatment adherence defined as the proportion of cases enrolled for treatment who received timely treatment from dedicated services until recovery.
- The treatment outcome (drop-out, death, transfer, non-response rates)
- The longitudinal prevalence of childhood morbidity, i.e. diarrhea, vomiting, fever, respiratory infections and malaria, defined by the number of days for which signs of these morbidities were reported divided by the total number of days in the recall periods.

Finally, the cost-effectiveness of the intervention package will also be evaluated by a sub-study.

3.5.5 Measures and Procedures

For this survey work, interviewers will use Android tablets with specialized software for computer interviews (Survey Solutions software).

In the primary (#1) and relapse (#3) cohorts, children's anthropometric measures will be recorded during monthly home visits, and several modules of questions will be

administered to provide essential insight into relevant parental and household practices. For the treatment cohort, each nutritional unit (26) and each FARNE (about 19) will be visited by an enumerator twice a month. The enumerator will be responsible for monitoring data quality and copying data from the registers to electronic forms.

Questionnaires

- Village/CHW/care group questionnaire: A module of questions will be administered to the village representative at the beginning of the study. Questions about the village's infrastructure and organization and past and current health and nutrition interventions will be asked. In addition, specific questions will be asked to the community health worker and a representative of the existing care group volunteers to understand their roles, activities, motivations and knowledge of nutrition and health at the beginning of the project.
- Health center questionnaire: A module of questions will be administered to a manager of each health center (26) to draw up a profile of the organization of care and available inputs.
- At the household level: Questions on household composition, socio-economic status, household expenditures, household food security, livestock/land/asset holdings, and concession construction materials will be administered. There will be a module of questions on food hygiene, hygiene and sanitation practices. Household participation in social or NGO/government-related programs will also be assessed.
- At the level of mothers/caregivers and children: Questions on the level of education of the mother and father, primary occupation, decision-making power, stress, postpartum depression, and health and nutrition of the eligible child will be administered. Specific questions on nutritional, water, sanitation, hygiene knowledge and practices, and uvula removal practice will be asked to the mother/guardian in charge of the child's care. Other modules will include the use of health care services and contact times with different platforms involved in the prevention, screening, or treatment of wasting. The child's age will be obtained from a birth certificate or using a local events calendar in the event that objective proof of the date of birth cannot be presented.

Anthropometry

Anthropometric measurements will be taken during the initial and final surveys and during the monthly longitudinal follow-up visits. The child's weight will be taken using an electronic scale to the nearest 100g. The length will be measured with a measuring rod to the nearest 1 mm. The Mid-Upper Arm Circumference (MUAC) will be measured using a non-stretch tape with 0.1 cm accuracy. All measurements will be taken in

duplicate by an anthropometer and an assistant. All measurements will be standardized prior to the study. Standardization exercises using repeated measurements on 10 children aged 6-15 months will be repeated every two months. From these standardization sessions, inter- and intra-measurement variations will be documented. The weight-for-height and height-for-age z-scores will be calculated using the WHO 2006 growth standards.

The MUAC, weight and height of the mother will also be measured using a non-stretch tape, a scale, and a tape measure, respectively.

Morbidity and Mortality

During longitudinal follow-up, the assessment team investigators will conduct monthly home visits to provide a daily reminder of child morbidity (acute respiratory infections, diarrhea, fever, and malaria) over the previous 3 days. A diarrheal episode is defined as at least three loose stools in the last 24 hours, or stools with blood. Fever will be measured by a thermometer and the history of fever in the previous days will also be asked. The presence of an acute respiratory infection (ARI) in the previous week will be assessed by recalling the specific symptoms associated with ARI (cough, difficulty breathing, rapid breathing, runny nose). The presence of malaria parasites will be checked for the presence of malaria parasites with a rapid diagnostic test for malaria by capillary finger or heel swab, if body temperature is above 37.5 °C or if the mother reports a fever episode in the child within the last 72 hours.

Hemoglobin measurement on capillary blood

The hemoglobin concentration will be measured at the beginning and end of the program. For this purpose, a drop of capillary blood will be taken from the child's finger. The hemoglobin concentration will be measured by spectrophotometry using a HemoCue 301 (HemoCue Ltd, Dronfield, UK).

Anemia in children and severe anemia are defined by hemoglobin concentrations of less than 11 g.dL⁻¹ and less than 7 g.dL⁻¹ respectively.

3.5.6 Data Analysis

A detailed statistical analysis plan will be developed and made available online before the data analysis begins.

3.6 Cost and cost-effectiveness study

Costs will be estimated from a societal perspective, including all costs incurred by institutions and communities ¹⁰. Costs will be calculated using a combination of accounting records and "ingredient" estimates using unit costs and input quantities ¹¹. An Activity-Based Costing (ABC) methodology will be used, allowing for the categorization and allocation of all program costs to their core activities. Financial costs as well as economic costs (in-kind donations, household expenditures, etc.) will be collected.

To obtain these data, program documentation and expenditure information will be reviewed, and key informant interviews and focus groups will be conducted with staff involved in program implementation. Another outcome of these interviews and focus groups will be an estimate of time allocation; staff time allocation will be used using the ABC method to allocate staff costs among activities. Focus groups will be conducted with households to gain an understanding of the direct and indirect costs they incur in participating in the program. The effect of plausible variation in household cost estimates from the focus groups will be assessed through sensitivity analysis.

The analysis will include both the total costs of the program and the incremental costs of additional activities in the intervention area. Cost-effectiveness ratios will be calculated based on program costs and outcomes. Incremental cost-effectiveness ratios will be calculated by dividing the incremental costs in the intervention area by the number of cases of acute malnutrition prevented in the intervention area compared to the control area. This ratio represents the incremental cost of achieving an additional positive outcome in the intervention zone compared to the control zone. Comparison with other similar published work will be considered where appropriate.

3.7 Data Management

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

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

IFPRI will have exclusive use of the data for primary impact analysis. In accordance with IFPRI's policy on research data management and open access, at the time of publication of scientific articles presenting primary results, the **fully anonymized databases will become a public good** and will be made available to the scientific community, government, and partners.

3.8 Dissemination strategy

The results will be **widely disseminated through restitution workshops (including at least one restitution workshop in Mongo)**, seminars, conferences and/or webinars. Scientific results will be transcribed into non-technical blogs, briefing notes, and social network products that will be **accessible to program planners, implementers, and funders**.

IFPRI will bring its expertise in the dissemination of all research results. This includes free access to the scientific articles published based on this work and the availability of the collected data (which will thus become a public good), after being duly de-identified and anonymized to ensure full protection of the participants' private data.

UNICEF will also provide technical expertise in disseminating findings and conclusions to national and international decision-makers to inform relevant policies and programs for the reduction of wasting.

4 Ethical considerations

The study protocol will be submitted for review to the Institutional Review Board (IRB) of IFPRI (Washington DC, USA) and the National Bioethics Committee of Chad (N'Djamena, Chad). The intervention study will be registered with clinicaltrials.gov or a similar public repository. The data analysis plan will also be recorded.

In accordance with IFPRI requirements, all IFPRI staff participating in the study will have completed the Collaborative Institutional Training Initiative (CITI Program) basic training "Social and Behavioral Research", which addresses research ethics issues in data collection, analysis, and management.

The entire data collection team will be trained in, and bound by, the basic ethical principles outlined below.

4.1 Community Information

The data collection team will inform local and regional health authorities and community representatives. In each village in the study area, representatives of the data collection team will present the objectives and procedures of the study to the village authorities.

4.2 Voluntary and informed participation

The purpose and procedures of the study will be explained to all mothers and heads of households of eligible children in their local language through an information sheet. All respondents reserve the right to refuse to participate in the study. Each interviewer will

be asked to read the consent statement in its entirety, slowly and in the participant's local language so that they can understand it. They will then ask if the consent statement has been understood and if there are any questions.

Consent for children will be given by a parent or legal guardian. An informed consent form will be signed by the child's primary caregiver and, if present, by the head of the household.

4.3 Risks and serious adverse effects

There are no known risks related to the evaluation methods (questionnaires, anthropometry). Good clinical practice will be respected by taking capillary blood samples to determine the hemoglobin level and performing the malaria test during longitudinal follow-up. Conducting field studies during the COVID-19 pandemic requires the implementation of strong mitigation strategies to prevent transmission of the virus. Special precautions will therefore be taken and clearly explained to participants when consent is sought. These precautions are detailed in section 5 below (Specific precautions related to COVID-19).

4.4 Emergencies

In the event of a medical emergency that occurs or is identified during the assessment visits, all study participants in both the control and intervention groups will receive medical care. Medical emergencies will be defined by any severe anemia (hemoglobin level <7g/dL), or danger signs (lack of response to voice and/or pain; unconsciousness; inability to eat or drink; vomiting everything; seizure). **These emergencies will be referred by the data collection team to the health center and the program will bear any medical costs related to these emergencies** (consultation, prescription, hospitalization, and medical evacuation decided by the medical corps within the framework of the national protocol, if they are not already covered by the national free healthcare program), until the medical emergency is lifted (e.g., discharge from hospital). If a chronic disease has caused these emergencies, the care related to the emergency will be covered, but not the chronic pathology. **Drugs prescribed following a referral for a positive malaria test will also be covered.** We do not plan to cover medical care for children identified with emaciation as treatment is currently free of charge for parents. As the indicators related to acute malnutrition are the primary and secondary outcomes of the study, any additional treatment would risk influencing the results and their generalizability. Nevertheless, severe wasting is a medical emergency. Therefore, **all cases of severe wasting according to current national criteria (currently brachial perimeter <115 mm or bilateral edema) that will be identified by the data collection teams and that have not yet been included in a treatment program will also be referred to the nutritional units.**

4.5 Anonymity

Every precaution will be taken to ensure the anonymity of participants during data collection, data management, data analysis and dissemination of results. As described above, completed questionnaires will be automatically deleted from the interviewer's tablet after synchronization on the secure server. The server is accessible only to IFPRI investigators. All databases will be made anonymous using identification codes. Personal data will be used only by the investigation team for the purposes of longitudinal follow-up, in order to trace the children followed in the cohorts on a monthly basis. No personal data will be shared outside the survey team or kept in the de-identified databases.

5 Specific precautions related to COVID-19

Conducting field studies during the COVID-19 pandemic requires the implementation of strong mitigation strategies to prevent transmission of the virus. The following measures will be introduced to reduce the risk of transmission.

5.1 Training of Interviewers

1. Prior to each day of training, all interviewers and support staff will be examined by research staff for possible symptoms (e.g., cough, difficult breathing, fever, fatigue). Suspected cases will be required to stay at home and remain in quarantine for at least 7 days or as per national recommendations if longer. Fever will be measured with a flash thermometer.
2. Interviewer training will be organized in 1 or 2 large auditoriums allowing an interpersonal distance of 2 meters at all times. The auditoriums will be ventilated at each break. During breaks, interviewers will be asked to leave the auditorium in small groups to avoid contact. Meals, coffee breaks and practical exercises will be organized outside.
3. The training and standardization exercises in anthropometry will take place outdoors.
4. During training, all personnel will wear a face mask without exception.
5. After each day of training, the benches, tables and shelves will be disinfected with an alcoholic solution (>70% v/v alcohol).
6. Before transferring the interviewer teams to the Mongo health district, each interviewer will perform a COVID-19 PCR test. Positive cases will be quarantined according to national recommendations.
7. We are training 10% more interviewers than the number needed for the study in order to maintain the possibility of replacing interviewers who present symptoms of COVID-19 and who will have to be quarantined.

5.2 Field Study

1. The informed consent form contains a paragraph explaining to the head of the family and to the interviewees the risk associated with COVID-19 and how the interviews will be conducted to limit the risk of transmission.
2. All interviews will take place outdoors in the open air.
3. Interviewers and anthropometrists will wear a face mask during the administration of the questionnaire and all measurements.
4. The survey team will provide two reusable masks to each household enrolled. At each monthly visit, respondents will wear a face mask. A new mask will be provided by the survey team if the masks distributed at enrollment are not available.
5. The interviewer will stand at a distance of two meters during the interview.
6. Other members of the household will be asked to respect the two-meter distance at all times.
7. Anthropometric agents will wear a face shield in addition to their face mask. They will record the height and weight of the standing adult positioned behind the participant to avoid face-to-face contact. For measurements of children, the child's mother/guardian will be asked to maintain a distance of two meters from the anthropometrics officers.
8. After each measurement, the MUAC tapes, scales and height rods will be disinfected with a 70% alcoholic solution as recommended by the WHO.
9. Before starting the interview, the interviewer will assess the interviewee's temperature and probe for symptoms related to COVID-19. In case of suspected case of COVID-19, the interview will be cancelled.
10. Prior to each workday, team supervisors will measure each interviewer's body temperature and assess the symptoms of COVID-19 (e.g. cough, difficult breathing, fever, fatigue). When a suspected case is encountered, the interviewer will be asked to observe a quarantine according to national recommendations.

6 Partnership and management

This study is the result of a partnership between UNICEF and IFPRI, commissioned to IFPRI by UNICEF. The principal investigators of the study are Dr. Elodie Becquey and Dr. Lieven Huybregts (IFPRI).

The funder of this study is the United Kingdom Foreign, Commonwealth and Development Office (FCDO). The NGO ASRADD implements the IRAM program under the responsibility of UNICEF Chad in collaboration with the relevant local authorities. IFPRI is in charge of evaluating the study and will be responsible for ensuring compliance with the study protocol. The role of designing, conducting and deciding to disseminate the results of the study is reserved to IFPRI, in order to guarantee the study's impartiality. Table 3 provides an overview of all parties involved.

The Directorate of Nutrition and Food Technology (DNFTA) at the Ministry of Public Health and National Solidarity as well as the multisectoral platform Permanent Technical

Committee of Nutrition and Food (CTPNA) and the Provincial Health Delegation will be privileged partners who will support the project in obtaining administrative documents (ethical approval, research authorization) and also in advising and facilitating field work.

Table 3: Overview of actors and roles

Stakeholder	Name	Role
Research Sponsor	UNICEF West and Central Africa Address Dakar Almadies Senegal Telephone: +221 33 831 02 00 Email : - Dolores Rio drrio@unicef.org UNICEF Chad Address Road to the Airport N'Djaména BP 1146 N'Djamena, Republic of Chad Telephone: +235 2251 89 89 Email: - Djibril Cissé dcisse@unicef.org - Saidou KABORE Ksaidou@unicef.org	<ul style="list-style-type: none"> - Financing of the study - Coordination of program implementation
Promoter	IFPRI Dakar Title 3396, Lot #2 BP 24063 Dakar Almadies Senegal Phone: +221.33.869.9800 Email: - Elodie Becquey (PI) E.Becquey@cgiar.org - Mariama Touré M.toure@cgiar.org IFPRI 2033 K St, NW Washington, DC 20006-1002 USA Phone: +1 202-862-5600 Fax: +1 202-467-4439 Email: - Lieven Huybregts (PI) L.Huybregts@cgiar.org - Jef Leroy J.leroy@cgiar.org	<ul style="list-style-type: none"> - Principal Investigator - Study design - Quality control of data collection - Dissemination of results - Guarantor of the research protocol
Implementing Agency	ASRADD Youssef Boye Avenue BP 2449, N'Djamena, Republic of Chad Phone: + 235 99 95 60 68 / 00235 66 28 13 77 Email: - Dr. Moussa Abderamane Mellah03@yahoo.fr	<ul style="list-style-type: none"> - Program Implementation - Project Management - Training and formative supervision of health staff and care groups for the implementation of the PASIM

as described in the protocol		
Data collection Agency	Moustagbal BP 10 - Mongo, Guera, Tchad (+235) 66 75 44 00 / 99 29 52 80 Email: - Abdoulaye Baine moustagbal.dg@gmail.com - Seid Ahmat Djarma djarmaseidahmat@yahoo.fr	- Data collection
Research Partner	Ministry of Public Health Directorate of Nutrition and Food Technology (DNTA)	- Support in obtaining administrative documents (ethics approval, research authorization) - Advices - Facilitation of field work

7 Budget

The IRAM project is funded by the CFODF through UNICEF. Table 4 shows the distribution of the main budget lines for data collection.

Table 4: IRAM Data Collection Budget

DESCRIPTION	TOTAL (XAF)
STAFF	97,591,500
LONGITUDINAL STUDY	95,164,033
Preparatory Phase for Data Collection	1,285,000
Data Collection Supplies	1,771,000
Covid-19 Protections	4,588,800
Biomedical consumables	6,907,650
Training of field agents	12,351,250
Pilot Study (Pre-Test)	1,542,000
Data Collection	66,718,333
Administrative management fees (7%)	13,492,887
TOTAL	206,248,421

8 Timeline

Table 5 provides a chronology of the different components of the IRAM program. The implementation of the study will be finalized at the end of 2020.

Data analysis and dissemination of results in scientific journals and as technical reports on partner websites will take place in 2022.

Table 5: Chronology of the IRAM study

Activities	2021										2022					
	Mar	Apr	May	Jul	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jul
Obtaining ethical approval	x															
Interviewers Training	x	x														
Cohort 1		x	x	x	x	x	x	x	x	x						
Cohort 2		x	x	x	x	x	x	x	x	x						
Cohort 3			x	x	x	x	x	x	x	x						
Data Analysis										x	x	x	x			
Report writing													x	x	x	
Dissemination of results															x	x

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10 Appendices

10.1 Appendix 1: Consent Forms

10.2 Appendix 2: Questionnaires

10.3 Appendix 3: Resumes of Investigators