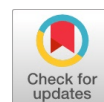




Effect of Community-Based Directly Observed Supplemental Feeding (Home Cooked Meals Vs Improvised Ready-to-Use Therapeutic Food) on Nutritional Status of Children with Acute Moderate or Acute Severe Uncomplicated Malnutrition: A Randomized Controlled Trial



Janine V. Uy, Portia Menelia D. Monreal

Abstract: *Background:* Undernutrition is a widespread phenomenon across the Philippines, which contributes significantly to childhood morbidity and mortality. This study assessed the effect of community-based home-cooked meals versus improvised ready-to-use therapeutic food (RUTF) over three months on the nutritional status of undernourished children, as measured by weight gain plotted against Weight-for-Length/Body Mass Index (WFL/BMI) z-scores.

Method: A community-based non-blinded randomised controlled trial was conducted in twenty-one (21) children with either acute moderate or severe uncomplicated malnutrition. Undernourished children were randomised by lot to either home-cooked meals or improvised RUTF, with two groups receiving both powdered cow milk and multivitamins for 20 days/month for 3 months. Monthly measurements of child weight gain with an increase in WFL/BMI z score 1 SD above their previous score.

Results: Baseline characteristics were comparable between the two groups ($p > 0.05$). There was a significant increase in weight from baseline to the 1st-, 2nd-, and 3rd-month of the intervention for both home-cooked meals ($p = .001$) and improvised RUTF ($p = .000$). When comparing the two interventions, there was no significant difference between the two groups (RR 4.55, 95% CI 0.63-32.56). Improvements in the nutritional status and behaviour of children, such as increased utensil utilisation and decreased sugar-sweetened beverage intake, were also observed through nutritional counselling.

Conclusions: Both home-cooked meals and improvised RUTF provide nutritional rehabilitation for children after 3 months, with average weight gains of 2kg (improvised RUTF) and 1.8kg (home-cooked meal) and a BMI increase of 1.1 in both groups. Improvised RUTF may be given as an adjunct for additional calories. Nutritional counselling is essential for children's nutritional values and behaviour.

Keywords: Acute Moderate Malnutrition, Acute Severe Uncomplicated Malnutrition, Community-Based Supplemental Feeding, Undernourished Children, Nutritional Status

Nomenclature:

RUTF: Ready-to-use Therapeutic Food
DOH: Department of Health
UNICEF: United Nations Children's Fund
MAM: Moderate Acute Malnutrition
MUAC: Mid-Upper Arm Circumference
SAM: Severe Acute Malnutrition
WHO: World Health Organization
DepED: Department of Education
HNC: Health and Nutrition Centre
WFL: Weight-for-Length
BMI: Body Mass Index
CBC: Complete Blood Count
ICH-GCP: International Conference on Harmonization on Good Clinical Practice
GRP: Good Research Practice
PDRI: Philippine Dietary Reference Intake
RENI: Recommended Energy and Nutrient Intake
IPR: Implementing Rules and Regulations

I. INTRODUCTION

Malnutrition is a widespread phenomenon across the Philippines, especially undernutrition, which contributes significantly to childhood morbidity and mortality. Minimal progress has been documented in addressing undernutrition, while overnutrition has already emerged as an alarming public health concern. This growing double burden of malnutrition hinders the country's socioeconomic development [1]. Starvation and nutritional deficiencies contribute to impaired physical and brain development and ultimately, to early deaths of infants and young children. A diet lacking in vitamins and minerals affects immunity and optimum development. Globally, more than one-third of preschool-age children are vitamin A deficient [2]. According to a United Nations Children's Fund (UNICEF) study in 2017, the Philippines ranked 9th in the world with the highest number of stunted children, estimated at 3.4 million children, and more than 300,000 children under 5 years who are severely wasted. This statistic remains a major public

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*Correspondence Author(s)

Dr. Janine Vasquez Uy*, Department of Paediatrics, University of Santo Tomas Hospital, Metro Manila, NCR, Philippines. Email ID: janine_uy23@yahoo.com, janineuy23@gmail.com, ORCID ID: [0009-0006-4848-8289](https://orcid.org/0009-0006-4848-8289)

Dr. Portia Menelia D. Monreal, Department of Paediatrics, University of Santo Tomas Hospital, Metro Manila, NCR, Philippines. Email ID: pdmonreal@ust.edu.ph

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health concern, especially during calamities and disasters, when the burden of malnutrition significantly increases [3]. Thirty-three per cent of children under the age of 5 years are stunted, which hinders their ability to reach their full mental and physical potential. This percentage has not decreased over the past 15 years due to several factors, including poverty, lack of access to nutritious foods, low prioritisation by government and non-government agencies, limited commitment to nutritional interventions, and ongoing infections that undermine nutrition. Studies were likewise conducted to determine the effects of malnutrition on children's ability to learn and perform academically [4]. Interventions such as community-based supplemental feeding are directed towards preventing and treating nutritional deficiencies by optimising children's nutritional well-being. Supplementary feeding is the provision of additional food to children or families beyond the normal home ration. The ration for one child should provide a maximum of 1000 to 1200 kcal/person/day and 10-12% of energy from protein. Local foods such as rice, beans, and vegetables form the basis of supplementary rations; however, fortified foods or micronutrient supplements, blended cereals with oil or sugar, supplementary porridges, and high-energy and protein biscuits can also be used [5]. Provision of Ready-to-use Therapeutic Food (RUTF) has been used to treat acute malnutrition, providing safe food at home and enabling rapid weight gain in undernourished children. It can be consumed directly, providing sufficient nutrients for complete recovery. An improvisation of the Department of Health's (DOH) RUTF was also developed and used to supplement the feeding of malnourished children when the actual RUTF was unavailable [6].

II. RESEARCH QUESTION

"Compared to home-cooked meals, will community-based supplemental feeding with improvised RUTF for three months improve the nutritional status of children with acute moderate or acute severe uncomplicated malnutrition?"

III. OBJECTIVES

A. General

To determine the effect of home-cooked meals vs improvised RUTF given for three months on the nutritional status of undernourished children based on weight gain plotted on WFL/BMI z- scores

B. Specific

- To determine the prevalence of malnutrition among the children in the chosen community.
- To compare the effect of home-cooked meals and improvised RUTF given for three months on the nutritional status of children with acute moderate or acute severe uncomplicated malnutrition.
- To compare the baseline and post-intervention nutritional status of children with acute moderate or acute severe uncomplicated malnutrition given community-based supplemental feeding with either home-cooked meals or improvised RUTF.

- To provide nutritional counselling to create opportunities for sustaining optimum physical growth and development, including lifestyle modification.

IV. SIGNIFICANCE OF THE STUDY

Adequate and proper nutrition is essential for the growth and development of children, including their mental, psychological, and physiological development. Low demand for nutritious food is affecting these developments, which now pose a significant challenge to the country's food supply and nutrition programs. Various government and non-government agencies have undertaken feeding programs to address malnutrition. Developmental challenges also account for major morbidity and disability in childhood and later, poor output in adult life. Counselling is beneficial and integral to any nutrition program, promoting adequate physical and mental nutrition among undernourished children [7].

This study aimed to evaluate the effect of supplemental feeding (home-cooked meals and improvised RUTF) on the nutritional status of undernourished children in the community. The outcome of this study would be beneficial for formulating better plans and valuable recommendations to maximise improvements to the existing feeding program being rendered in a community setting.

V. REVIEW OF RELATED LITERATURE

A. Malnutrition (Undernutrition)

Malnutrition is a complex term that encompasses both overnutrition associated with overweight and obesity and undernutrition, defined as an inadequate intake of energy and protein to meet the body's daily needs for growth, maintenance, and specific functions. The spectrum of malnutrition ranges from being acutely undernourished to being chronically undernourished, as well as having micronutrient deficiencies [8].

Acute malnutrition results from sudden, inadequate food intake, often due to pathological causes. It is usually correlated with protein-energy malnutrition, wasting, kwashiorkor, and marasmus. It can be defined as moderate acute malnutrition (MAM) if the weight-for-height z-score is between -2 and -3 or the mid-upper arm circumference (MUAC) is between 115 millimetres and <125 millimetres. Severe acute malnutrition (SAM), on the other hand, is defined as a weight-for-height z-score of < -3 or MUAC < 115 millimetres, or the presence of bilateral pitting oedema, or both. Chronic malnutrition results from inadequate intake or absorption of essential nutrients over time. It is associated with impairments in development and, later, in quality of life, more pronounced in the first year of life, when rapid growth and development occur. According to UNICEF, undernutrition results from the complex interplay of different significant risk factors which, studies have shown, include inadequate dietary intake, inappropriate feeding, micronutrient deficiencies, fetal growth restriction, inadequate sanitation, lack of parental education,





family size, incomplete vaccination, poverty, or economic, political, and environmental instability and emergencies leading to food insecurity [8].

B. Undernutrition in the Philippines

The Philippines is a middle-income country that had the highest economic growth in Southeast Asia in 2014. Despite substantial economic growth, the country's nutritional indicators are still insufficient, and there is still a lack of progress towards the targets for wasting in children under five years old and anaemia among women of reproductive age by 2025. The prevalence of wasting consistently increased from 2003-2013, with only a slight decrease in recent years. The prevalence rate of 33% is classified as very high by World Health Organization (WHO) based on new 2018 classification. Prevalence of stunting correlates well with poverty, showing 50% of children belonging to the poorest socio-economic strata are stunted compared to 15% in the richest. Stunting is higher in rural (38%) than in urban areas (28%) [9].

According to the National Nutrition Survey, wasting increased from 7.3% in 2011 to 7.9% in 2013, then decreased to 7.1% in 2015. This translates to nearly 1.5 million wasted Filipino children under five years of age, around a third (estimated 500,000) of whom are severely wasted [9]. Poor feeding increased the prevalence of stunting, from 17% in children aged 6–11 months to 36% in children aged 12–23 months, suggesting an improper, inadequate diet during the period when exclusive and frequent breastfeeding should be observed, and complementary feeding should be diverse [1].

The Philippine Plan of Action for Nutrition 2017-2022 sets goals to fight malnutrition, including reducing stunting from 33.4% to 21%, reducing wasting from 7.9% to less than 5%, addressing growing overnutrition across the population, and addressing micronutrient deficiencies. Addressing malnutrition poses a challenge that will require extensive cooperation and commitment from government agencies and both public and private sectors [1].

The DOH and UNICEF provided nutrition supplies such as RUTF to treat up to 50,000 children who were severely malnourished in the provinces in 2017. Providing adequate, high-quality nutrition is the foundation of every child's survival, health, and development. Identifying malnourished children and treating them early are essential for prevention of further complications [3].

C. Complications of Undernutrition

Undernutrition has been one of the most important public health concerns due to its continuing physiologic consequences that predispose a child to diabetes mellitus later in adulthood, hypertension, dyslipidemia, hypoglycemia, heart failure, anaemia, electrolyte imbalance, malabsorption and a reduced quality of life leading to death. Studies have also shown that undernutrition is closely related to poor mental development, school achievement, and behavioural abnormalities. The fetal period and the first 2 years of life are major risk periods for motor, cognitive, and speech delays, proving that nutrition may affect certain developmental domains of the brain. It is a predictor of a child's development in the hearing, language, and social interaction domains. Malnourished children are observed to

be more apathetic and explore less in their environment due to the negative effects of undernutrition on the central nervous system. It affects the child directly by failing to receive and interact effectively with information from the environment, or indirectly by exhibiting actions not appropriate to environmental stimulation [10]. The relationship between poverty, poor home environment, chronic malnutrition and developmental delay is well established [11]. Children exposed to acute malnutrition in early life have poor cognitive function, school achievement and behavioural problems, which may lead to attention deficit and lower socio-economic status later in adulthood [7]. In addition to neurodevelopmental complications, undernutrition also increases susceptibility to numerous infections, which is described as a vicious cycle that usually begins with infections, commonly diarrhoea in children, leading to undernourishment, which, in turn, increases the risk for prolonged illness and susceptibility to further infection [8].

D. Supplemental Feeding

The Department of Education (DepED) has launched multiple feeding programs to address undernutrition and short-term hunger among public school children. A pilot implementation of a feeding program for undernourished Kinder to Grade 3 students in selected schools was conducted, resulting in 73% of the children regaining normal nutritional status by the end of 120 feeding days. Thus, the DepED feeding program has evolved and also retained some of its main features such as the 100-120 feeding day duration; the use of standardized recipes with malunggay and the 20-day cycle menu, with each meal providing the child with at least 300 additional calories; the establishment of a school-based feeding core group; and involvement of volunteer parents in the preparation of meals and the feeding of children. Multiple local and international studies have reported different durations of supplemental feeding, ranging from 1-month interventions to 3-year interventions [12]. Feeding programs that provided a moderate (30-59%) or high (60% or more) percentage of the dietary reference intake energy resulted in greater growth than those provided less than 30%. A systematic review showed that studies providing more than 30% of the recommended daily energy intake were more effective at promoting child growth [13].

i. Home-Cooked Meal

Supplemental feeding with local goods such as rice, beans and vegetables has been used to treat undernutrition. Supplementary porridges, cooked according to a child's recommended energy and nutrient intake, can be made at home. A home-cooked meal offers readily available ingredients, lower cost, and better palatability, thereby promoting greater compliance. However, preparation can be time-consuming and has a short shelf life [5].

ii. Ready to Use Therapeutic Food

RUTFs are specially formulated bars, pastes, or biscuits that provide high-quality protein, energy, and micronutrients for treatment of undernourished children. It is recommended for outpatient treatment and during the rehabilitation



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phase of inpatient treatment. RUTFs are more nutrient dense, have very low moisture content, and are resistant to microbes. It can be easily produced; however, it is limited due to the unavailability of necessary ingredients in some locations. Studies have shown that children with severe acute malnutrition given RUTF for community-based treatment are more likely to achieve nutritional recovery than giving unfortified porridge, with an estimated case fatality rate of 4% and a recovery rate of 80%. Reviews and meta-analyses have shown that RUTF can achieve a 51% nutritional recovery in children compared with the standard care group. It is a cost-effective and life-saving intervention; thus, current research is now focusing on developing equally effective alternatives using cheaper, locally produced ingredients [14].

Local production of RUTF consists of sugar, milk, oil, and vitamin and mineral supplements. It is less time-consuming since no cooking is needed before consumption. It has a longer shelf life and is soft, palatable, and easy for children to eat without any preparation, providing 520-550 kcal/100g. UNICEF presented a RUTF called Plumpy Nut, produced by Nutri-Sève, designed to treat acute malnutrition without complications, with an energy value of 500 kcal/sachet [14].

iii. Cow Milk

Cow milk protein is a key ingredient used to treat acute malnutrition, such as F-100, wherein cow milk is the only protein source, and RUTFs, which contain 50% protein from cow milk. These products have been shown in multiple studies to improve nutritional recovery by stimulating plasma insulin-like growth factor 1, suggesting that milk has a growth-stimulating effect that promotes weight gain in undernourished children [14].

According to the WHO, 25% to 33% of protein intake should come from dairy protein, equivalent to 15 to 20 g of skim milk powder or 200 to 250 mL of milk per 1,000 kcal. The recently published WHO Technical Note "Supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age" proposes a protein content of 20–43 g/1,000 kcal, as this would positively affect weight and linear growth. Powdered polymeric cow milk can provide approximately 149 kcal/240ml or 0.62 kcal/ml [15].

iv. Multivitamins

Multivitamins address micronutrient deficiencies that are associated with acute undernutrition. In most cases, children have low energy intake; therefore, supplements are given to provide additional energy and macronutrients, thereby increasing body weight. Studies show that multi-nutrient supplementation is much more effective than single nutrient therapy. In most cases, correction of micronutrient deficiencies, together with an energy- and protein-dense diet, is routinely included in the nutritional rehabilitation phase to promote weight gain [7].

E. Nutritional Counselling

Nutrition counselling is an integral part of treating malnutrition. It involves a dynamic interaction between parents, guardians or children and a trained counsellor or

health worker to identify children's immediate nutritional needs and goals, and how to achieve them. It aims to help them understand and act on current problems and to explain the benefits of behaviour change. Optimal counselling is the key to successful health and nutrition outcomes. Counselling is needed to educate and motivate parents and guardians to explore available foods for energy- and protein-dense meals. It should be individualized and should provide specific recommendations that are nutritionally adequate and locally adapted. Supporting materials such as flipcharts, counselling cards, brochures, and referral forms can also be used to support effective communication [16].

VI. METHODOLOGY

A. Research Design

This is a randomised controlled trial of community-based research conducted among children with either acute moderate or acute severe uncomplicated malnutrition.

B. Study Population

i. Inclusion Criteria

- Children with moderate acute malnutrition based on WHO Child Growth Charts WFL/BMI z scores of between -2 and -3 (Wasted)
- Children with severe uncomplicated acute malnutrition based on WHO Child Growth Charts WFL/BMI z scores of below -3 (Severely Wasted)
- Children living in and registered residents of a chosen community

ii. Exclusion Criteria

- Children with hemodynamic instability, sepsis, and gastrointestinal symptoms such as diarrhoea and vomiting
- Children with pulmonary conditions such as PTB or pneumonia
- Children with history of hematologic and oncologic conditions
- Children with neurological and developmental disorders such as stroke, Down's syndrome, cerebral palsy, global developmental delay, intellectual disability and those with congenital anomalies wherein good compliance would be difficult
- History of food or milk allergies

C. Data Collection

i. Assessment of Nutritional Status

Initial weight and height were measured and recorded for all children aged 1 to 18 years using standard techniques. For children under 2 years old, weight was measured using an infant weighing scale (Perlong Rgz-20A) without clothing. Supine length was measured with a tape measure on a flat surface, while the infant was placed supine, legs gently extended at the hips and knees. For children above 2 years old, weight was measured using a weighing scale (Detecto RGT-140) with minimal clothing and bare feet. Height was measured





using a tape measure attached to a wall, with a child standing on a flat surface, weight distributed evenly on both feet, heels together, and the head positioned perpendicular to the body. The weight-for-length (WFL) for children < 2 years old and body mass index (BMI) for children > 2 years old were plotted on the WHO Child Growth Standards growth charts using z-scores. Children falling below the -2 S.D. of WFL or BMI were considered wasted, and those falling below the -3 S.D. of WFL or BMI were severely wasted. All identified undernourished children were included in the study. They were measured again using the same Detecto RGT-140 weighing scale and a standardised height chart attached to a wall at the start of the feeding program. A 24-hour dietary recall and a healthy lifestyle assessment were also conducted as part of the nutritional assessment to determine each participant's actual caloric intake and dietary practices. A baseline complete blood count (CBC) and fecalysis were requested to detect infection. Proper collection, handling, and storage of blood and faecal samples were observed. The specimens were processed on the same day in a single accredited laboratory and disposed of after use. All children were screened for PTB infection through a tuberculin skin test in 2018.

ii. Developmental History

Developmental history was conducted on each undernourished child using the modified Denver Developmental Screening Test (DDST). All children developmentally at risk would be referred to a developmental specialist.

iii. Nutritional Intervention

Home-cooked meals and improvised RUTF were provided by the principal investigator and calculated based on the FNRI-Philippine dietary reference intake (PDRI) by a nutritionist. Both meals had the same calorie count, providing 30% of each child's Recommended Energy and Nutrient Intake (RENI). Home-cooked meals like arroz caldo with egg, chicken macaroni soup, bread with egg and butter, arroz caldo with chicken, and champorado with toasted dilis were prepared based on the calories found in the Philippines' food exchange list, providing 30% of each child's RENI based on their age group, prepared by one of the community residents. The improvised RUTF was composed of 1 tbsp of peanut butter, 1 tbsp of powdered milk, 1 tsp of sugar, and 1 tsp of oil. The principal investigator mixed all ingredients to yield 125 kcal per piece, then brought them to the community, where they were packed, sealed, and prepared for consumption. Powdered polymeric cow milk containing 153 kcal/200ml and multivitamins were also provided together with a home-cooked meal and improvised RUTF. Nutritional counselling was conducted by a nutritionist, educating parents, guardians, and children on the importance of proper nutrition for weight gain, strengthening immunity, lifestyle modification, and addressing other identified needs.

D. Procedure and Measures

Detailed instructions on the mechanics of the feeding program were discussed with the parents or guardians of undernourished children. Nutritional screening was conducted for all children using their weight and height,

which were plotted on the WHO growth chart to obtain WFL/BMI z-scores. All children with moderate or severe uncomplicated acute malnutrition, with WFL/BMI between -2 and -3 (wasted) or below -3 (severely wasted), who met the inclusion and exclusion criteria were included in the study. Those children with severe complicated malnutrition were referred to a hospital for admission and consult with a specialist. Once all stable undernourished children were identified, a nutritional assessment was conducted, including a 24h food recall, a healthy lifestyle assessment, WHO growth chart WFL/BMI z-scores, and baseline CBC and fecalysis. A developmental history was also conducted using Modified DDST as part of the program.

All undernourished children underwent nutritional counselling. Those children identified with intestinal parasitism or mild-to-moderate infection were treated accordingly. Those with severe infection were excluded from the study and referred to a paediatrician or infectious disease specialist. All undernourished children were randomized through draw lots into one of the following groups in a 1:1 ratio (see Appendix 4 for recipe and nutrition guide):

Group 1 – Home-cooked meal, Powdered Cow Milk (153 kcal/glass),

Multivitamins

Home-cooked meals: Arroz caldo with egg (244.3 kcal), Chicken macaroni soup (258 kcal), Bread with egg and butter (255.5 kcal), Arroz caldo with chicken (244.3 kcal), and Champorado with toasted dilis (284.3 kcal)

Group 2 – Improvised RUTF (125 kcal/pc), Powdered Cow Milk (153 kcal/glass), Multivitamins

Each child received varying amounts of improvised RUTF, with calories calculated to be 30% of their RENI. Both groups consumed their meals with the supervision of the principal investigator. The feeding program was started on Day 1 and consisted of 1 serving of improvised RUTF or home-cooked meals (see Appendix 5 for complete serving-size information), 1 glass of powdered cow's milk, and multivitamins. The principal investigator observed actual feedings to ensure that all participants had consumed their meals. All supplemental meals were comprised of 30% of the recommended caloric intake for each age group. This program continued for 20 days per month for 3 months. The meals provided were only a supplement, not a substitute, for the daily breakfast, lunch, and dinner the participants consumed at home. During the program, monthly nutritional assessment and counselling were conducted in the community for 3 months by the principal investigator and nutritionist, respectively.

Neither the principal investigator nor the nutritionist was blinded in this study. Blinding of participants, investigators, and nutritionists was difficult in this kind of study for the following reasons: First, blinding participants was not feasible due to the obvious differences in appearance between the two types of supplemental foods. Second, since this was a directly observed feeding, it was difficult for the principal investigator to be blinded in this study. Lastly, nutritional counselling is a two-way interaction between the participants

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and/or legal guardians and the nutritionist. Discussion of their nutritional needs, practices, and goals, including their food intake, was part of the counselling; hence, the nutritionist was not blinded in this study. These conditions were also mentioned in a systematic review conducted by Kristjansson et al (2016), wherein an assessment of the quality of randomized controlled trials using the Cochrane Collaboration “risk of bias” tool was done to identify the degree of bias in every aspect of the supplemental feeding studies, including blinding of participants and/or personnel and blinding of outcome assessment. Mentioned in this study that blinding of participants and personnel is not usually possible in supplementary feeding studies. Blinding of outcome assessment is possible; however, it was not done in most studies and was rarely reported. No studies likewise used allocation concealment or sequencing. The quality of primary studies with these circumstances was rated as having low to moderate bias [13]. Many studies with nutritional counselling were likewise not blinded.

Data were kept confidential and recorded by two different observers. Nutritional status was assessed using the same weighing scale and height chart used at the start of the program, with the WHO Child Growth Standards WFL/BMI z-scores plotted.

E. Ethical Considerations

This research study was done in agreement with the ethical guidelines set by the Declaration of Helsinki 2015, WHO Operational Guidelines in Biomedical Studies 2011, International Conference on Harmonization on Good Clinical Practice (ICH-GCP), Council for International Organizations for Medical Sciences 2016, Good Research Practice (GRP), Philippine National Ethical Guidelines for Health and Health-Related Research of 2017, Philippine Data Privacy Act of 2012 and its Implementing Rules and Regulations (IRR) of 2016. It was submitted to the University of Santo Tomas Research Ethics Committee for approval.

i. Ethical Guidelines

This study strictly adhered to the Philippine National Ethical Guidelines for Health and Health-Related Research of 2017. All materials and methods were submitted to the Research Ethics Committee for approval. Participation was voluntary, and participants may decline at any time. Informed consent was obtained after a thorough explanation of the contents; a copy was given to a parent of the participants. An appropriate referral system was arranged in the event of complications or untoward events.

ii. Conflict of Interest

The principal investigator and the University of Santo Tomas Hospital Department of Paediatrics, Section of Pediatric Gastroenterology, Hepatology & Nutrition shouldered all necessary costs for the program. This was an investigator-initiated study. There was no conflict of interest in writing, presentation, review, and possible publication of this research study. Standard of care was provided to all participants regardless of their economic status, gender, race, or creed.

iii. Privacy and Confidentiality

This research study adhered to the principles set by the Data Privacy Act of 2012 and its implementing rules and regulations in 2016 in the collection, retention, and processing of personal information. Throughout the data collection process and statistical analysis, a Subject Identification Code, instead of the subject's name, was assigned to each participant and placed in a sealed envelope accessible only to the principal investigator. The information was kept private throughout the course of the study and would be shredded after 2 years to protect the participant's identity and ensure complete concealment and confidentiality of their medical records. Only the personal data necessary for the study was collected. The principal investigator respected the participants' right to privacy unless required by law or when there was a likelihood of illegal or harmful behaviour. In any case where confidentiality or anonymity is breached, it should cause only minimal harm to the participants.

iv. Vulnerability

Given that the study participants were undernourished children, recognition of their vulnerability through consent documentation was taken. The mechanics of the feeding program were explained completely and thoroughly to at least one parent or legal guardian. All queries were addressed. No child was subjected to unnecessary harm throughout the study. Participants were informed that they may withdraw from the study at any time. Parental consent and age-appropriate assent were obtained before participation. Care was taken to obtain informed consent, ensuring it was given freely and voluntarily.

v. Recruitment

The nutritional status of all 116 children/adolescents aged 1-18 years was assessed. There were no recruitment materials, such as flyers, posters, or leaflets, involved.

vi. Informed Consent Process/ Voluntary Participation/ Withdrawal Process

The parents or legal guardians of the child or adolescent participant were given a full explanation. Parental consent and verbal assent were obtained before the study. The principal investigator discussed the study and how the child would participate based on the individual's capacity and level of understanding. Informed consent was obtained at the beginning of the study and continued throughout the study through repeated explanations of the research process, answering their questions, and obtaining their agreement with respect for their dignity and autonomy. The possible adverse effects and potential benefits of participating in the study were explained thoroughly. Participants were informed that they may withdraw from the study at any time, as participation was voluntary, and that in case of complications, such as a food or milk allergic reaction, food intolerance (diarrhoea, abdominal pain or vomiting), noncompliance with the prescribed milk and food, and If a participant develops an infection requiring hospitalisation, the





participant will be withdrawn from the study. During the study, the principal investigator was not involved in the participants' medical care. The rotating pediatric resident at the community served as their healthcare provider.

vii. Benefits

The significance of this research study was to identify and improve the nutritional status of undernourished children. Providing home-cooked meals or improvised RUTF would improve children's nutritional status, thereby reducing morbidity and mortality by preventing complications of undernutrition. The community's nutritional practices could also be improved through nutritional counselling, thereby preventing malnutrition.

viii. Risks

This research study required the participants to consume all freshly prepared meals and powdered cow milk provided by the principal investigator. Possible adverse effects were described and discussed with the parents or guardians, including food or milk allergies and intolerances. Immediate care and stabilisation of the participant would be provided by the rotating pediatric resident at the community, and the participant would be further assessed and managed in a hospital care setting if needed. If the participant, parents, or guardians noted any complications at any time during the study, the participant will be withdrawn.

ix. Compensation and Expenses

The feeding program was offered free of charge to the participants. No compensation in the form of money or free items was provided.

VII. STUDY OUTCOMES

Child weight gain, plotted on the WHO Child Growth Standards WFL/BMI z-scores, was the primary outcome of this study, interpreted as an increase in z-score by 1 SD above their previous score. The secondary outcome was to determine the prevalence of intestinal parasitism among undernourished children.

VIII. STATISTICAL CONSIDERATION AND DATA ANALYSIS

Sample size was estimated using OpenEpi v3, software used for sample size and power calculations. Margin of error was computed as 2.8% based on a standard deviation of 15.99. The standard deviation was calculated from the participants' baseline weights, collected at the beginning of the study. Since this was a pilot study, the sample size was determined to assess whether the minimum number of participants was met, based on a 5% types 1 error rate and 80% power. A rule of thumb can also be used to estimate sample size subjectively without using a statistical formula, but using a margin of error, which indicates the extent to which the sample population is reflective of the overall population at a given confidence level, is more objective and hence used in this study. With a population size of 116, a 95% confidence level, and a 20% dropout rate, a minimum of 15 patients were needed to detect a statistically significant

effect with 80% power.

The experimental and control interventions used in the study were improvised RUTF and home-cooked meals, respectively. The primary outcome was child weight gain, based on WHO Child Growth Standards WFL/BMI z-scores. Data were encoded in MS Excel by the principal investigator. Stata MP version 14 software was used for data processing and analysis. Continuous variables were presented as mean (SD) or median (IQR), depending on the data distribution. Categorical variables were presented as frequencies and percentages. Continuous data were analysed using an independent t-test or Mann Whitney U test. Categorical data were analyzed using Fisher's exact test. Statistically significant differences were also computed using repeated-measures one-way ANOVA and Tukey's HSD post-hoc test. P values ≤ 0.05 were considered statistically significant.

IX. RESULTS

A. Demographic and Clinical Characteristics of the Participants

Table-I illustrates the demographic and clinical characteristics of the participants. Results indicated that majority of the participants were males (71%) than females (29%), were wasted and severely wasted by nutritional severity (95% and 5%, respectively), took multivitamins (48%), Vitamin C (24%) and zinc (5%), had less than 2 hours sedentary activity (100%), had more than 2 hours of physical activities (100%), had three meals per day (100%), and did not have any developmental disorders or problems (0%). The mean age of the participants was 10.57 years (SD=3.06), and the median weight and height were 21.40 kilograms (IQR=17–24) and 124.00 centimetres (IQR=113.50–133), respectively. The mean hematocrit, haemoglobin, WBC count, and platelet count were 40.57% (SD=3.70), 13.83 g/dL (SD=1.22), $5.38 \times 10^9/L$ (SD=0.48), and $295.95 \times 10^9/L$ (SD=58.30), respectively. Among participants, 5% had intestinal parasitism, with a prevalence of 4.76% (95% CI: 0.6–30.89%). The mean daily caloric intake was 1,345 calories (SD=117.96), with a percentage deficiency of 28.73 (SD=17.35). Comparative analyses indicated that these characteristics did not differ significantly between the two treatment groups ($p > 0.05$).

Feeding history was also obtained. All participants responded ALWAYS for Group I: rice and bread (100% for both groups), SELDOM for Group II: fat (100% for both groups), Group IX: beef (100% for both groups) and Group XI: beans (100% for both groups). Frequency of feeding varied between the two groups, being ALWAYS for Group X: eggs and Group XII: milk; OFTEN for Group III: green leafy vegetables, Group IV: non-leafy yellow vegetables and Group VI: chicken; SELDOM for Group V: fruits, Group VII: fish and Group VIII: pork; however, results were not significantly different. No significant difference between the two groups in the frequency of water and SSB (sugar-sweetened beverages) intake, with ALWAYS responses for SSB intake in 54% of both groups.



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Table I: Baseline Characteristics of the Participants (N = 21)

CHARACTERISTICS	Total (n=21)	Improved RUTF (n=11)	HC (n=10)	p-value (Two-Tailed)
Age (Years; $\bar{x}$, SD)	10.57 $\pm$ 3.06	10.84 $\pm$ 2.84	10.28 $\pm$ 3.43	0.6845a
Sex				
Male	15 (71%)	7 (64%)	8 (80%)	0.635 ^b
Female	6 (29%)	4 (36%)	2 (20%)	
Weight (Kilogram; Median, IQR)	21.4 [IQR: 17-24]	21.5 [IQR: 17-24]	18.65 [IQR: 16.6-37]	0.8326 ^c
Height (Centimeter; Median, IQR)	124 [IQR: 113.5-133]	125.5 [IQR: 114-133]	117.75 [IQR: 113-158]	0.7782 ^c
Malnutrition severity				
Wasted	20 (95%)	10 (91%)	10 (100%)	1.000 ^b
Severely Wasted	1 (5%)	1 (9%)	0 (0%)	
Hematocrit (%; $\bar{x}$, SD)	40.57 $\pm$ 3.70	41.82 $\pm$ 2.86	39.20 $\pm$ 4.16	0.1063 ^a
Hemoglobin (g/dL; $\bar{x}$, SD)	13.83 $\pm$ 1.22	14.22 $\pm$ 0.98	13.41 $\pm$ 1.37	0.1329 ^a
WBC (10 ⁹ /L; $\bar{x}$, SD)	5.38 $\pm$ 0.48	5.30 $\pm$ 0.32	5.47 $\pm$ 0.62	0.4319 ^a
Platelet (in x 10 ⁹ /L $\bar{x}$, SD)	295.95 $\pm$ 58.30	299.27 $\pm$ 58.01	292.30 $\pm$ 61.53	0.7921 ^a
Intestinal Parasite in Fecalysis (f, %)				
With	1 (5%)	0 (0%)	1 (10%)	0.476 ^b
Without	20 (95%)	11 (100%)	9 (90%)	
Kcal (Per Day; $\bar{x}$, SD)	1345 $\pm$ 117.96	1381.09 $\pm$ 96.31	1305.90 $\pm$ 131.63	0.1490 ^a
% deficiency (Kcal; $\bar{x}$, SD)	28.73 $\pm$ 17.35	28.43 $\pm$ 15.99	29.07 $\pm$ 19.62	0.9350 ^a
Feeding History				
Group I rice and bread				
Always	21 (100%)	11 (100%)	10 (100%)	–
Often	0 (0%)	0 (0%)	0 (0%)	
Seldom	0 (0%)	0 (0%)	0 (0%)	
Group II fat				
Always	0 (0%)	0 (0%)	0 (0%)	–
Often	0 (0%)	0 (0%)	0 (0%)	
Seldom	21 (100%)	11 (100%)	10 (100%)	
Group III vegetable (green leafy)				
Always	5 (28%)	4 (36%)	1 (14%)	0.604 ^b
Often	8 (44%)	5 (45%)	3 (43%)	
Seldom	5 (28%)	2 (18%)	3 (43%)	
Group IV vegetable (nonleafy yellow)				
Always	5 (28%)	4 (36%)	1 (14%)	0.604 ^b
Often	8 (44%)	5 (45%)	3 (43%)	
Seldom	5 (28%)	2 (18%)	3 (43%)	
Group V fruits				
Always	2 (10%)	0 (0%)	2 (20%)	0.412 ^b
Often	4 (19%)	2 (18%)	2 (20%)	
Seldom	15 (71%)	9 (82%)	6 (60%)	
Group VI chicken				
Always	7 (33%)	2 (18%)	5 (50%)	0.404 ^b
Often	9 (43%)	6 (55%)	3 (30%)	
Seldom	5 (24%)	3 (27%)	2 (20%)	
Group VII fish				
Always	5 (24%)	4 (36%)	1 (10%)	0.513 ^b
Often	5 (24%)	2 (18%)	3 (30%)	
Seldom	11 (52%)	5 (45%)	6 (60%)	
Group VIII pork				
Always	3 (18%)	1 (13%)	2 (22%)	1.000 ^b
Often	1 (6%)	0 (0%)	1 (11%)	
Seldom	13 (76%)	7 (88%)	6 (67%)	
Group IX beef				
Always	0 (0%)	0 (0%)	0 (0%)	–
Often	0 (0%)	0 (0%)	0 (0%)	
Seldom	21 (100%)	11 (100%)	10 (100%)	
Group X eggs				
Always	13 (62%)	9 (82%)	4 (40%)	0.070 ^b
Often	3 (14%)	0 (0%)	3 (30%)	
Seldom	5 (24%)	2 (18%)	3 (30%)	



Group XI beans				
Always	0 (0%)	0 (0%)	0 (0%)	—
Often	0 (0%)	0 (0%)	0 (0%)	
Seldom	21 (100%)	11 (100%)	10 (100%)	
Group XII milk				
Always	12 (57%)	6 (55%)	6 (60%)	1.000 ^b
Often	0 (0%)	0 (0%)	0 (0%)	
Seldom	0 (0%)	0 (0%)	0 (0%)	
None	9 (43%)	5 (45%)	4 (40%)	
Group XIII: water, no. of times/wk	7.81 ± 4.21	8 ± 3.79	7.6 ± 4.84	0.8344 ^a
Group XIV: SSB, no. of times/week	2.90 ± 3.14	3.36 ± 3.50	2.40 ± 2.80	0.4973 ^a
Always	7 (54%)	5 (71%)	2 (33%)	0.209 ^b
Often	2 (15%)	0 (0%)	2 (33%)	
Seldom	4 (31%)	2 (29%)	2 (33%)	
Supplements (f, %)				
Iron	0 (0%)	0 (0%)	0 (0%)	—
Multivitamin	10 (48%)	7 (64%)	3 (30%)	0.198 ^b
Zinc	1 (5%)	1 (9%)	0 (0%)	1.000 ^b
Fluoride	0 (0%)	0 (0%)	0 (0%)	—
Calcium	0 (0%)	0 (0%)	0 (0%)	—
Vit A	0 (0%)	0 (0%)	0 (0%)	—
Vit D	0 (0%)	0 (0%)	0 (0%)	—
Vit C	5 (24%)	1 (9%)	4 (40%)	0.149 ^b
Healthy Lifestyle Assessment (f, %)				
Sedentary activity				
>2 hours	0 (0%)	0 (0%)	0 (0%)	—
≤2 hours	21 (100%)	11 (100%)	10 (100%)	
Physical activity				
≤2 hours	0 (0%)	0 (0%)	0 (0%)	—
>2 hours	21 (100%)	11 (100%)	10 (100%)	
3 meals/day	21 (100%)	11 (100%)	10 (100%)	—
No SSB intake	8 (38%)	4 (36%)	4 (40%)	1.000 ^b
Bottle feeding	0 (0%)	0 (0%)	0 (0%)	—
Utensils	11 (52%)	5 (45%)	6 (60%)	0.670 ^b
Alcohol	0 (0%)	0 (0%)	0 (0%)	—
Smoking	0 (0%)	0 (0%)	0 (0%)	—
Drugs	0 (0%)	0 (0%)	0 (0%)	—
Developmental Problem (f, %)	0 (0%)	0 (0%)	0 (0%)	—

^aIndependent t test was used; ^bFisher's exact test was used; ^cMann-Whitney U test was used

B. Tests of Within-Subjects Effects (Home Cooked Meals and Improvised RUTF)

Repeated-measures ANOVA showed significant differences in weight between baseline and the 1st-, 2nd-, and 3rd-month of the intervention for both participants in the improvised RUTF and home-cooked meal groups (Tables II and IV). Post hoc tests also showed a statistically

significant increase in weight at the 1st-, 2nd-, and 3rd-month of feeding compared to baseline values for both the improvised RUTF and home-cooked meal groups. There were significant improvements in weight gain as early as the first month of intervention for both groups. No significant weight changes were observed between the 2nd and 3rd months (Tables III and V).

Table II: Tests of Within-Subjects Effects (Improvised RUTF)

Measure: Weight						
Source		Type III Sum of Squares	Df	Mean Square	F	Sig.
Time	Sphericity Assumed	26.481	3	8.827	34.517	.000
	Greenhouse-Geisser	26.481	1.283	20.645	34.517	.000
	Huynh-Feldt	26.481	1.389	19.063	34.517	.000
	Lower-bound	26.481	1.000	26.481	34.517	.000
Error (time)	Sphericity Assumed	7.672	30	.256		
	Greenhouse-Geisser	7.672	12.827	.598		
	Huynh-Feldt	7.672	13.891	.552		
	Lower-bound	7.672	10.000	.767		



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Table III: Pairwise Comparisons (Improvised RUTF)

Measure: Weight						
(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. ^b	95% Confidence Interval for Difference ^b	
					Lower Bound	Upper Bound
1	2	-.855*	.157	.002	-1.371	-.339
	3	-1.645*	.264	.001	-2.509	-.781
	4	-2.018*	.330	.001	-3.099	-.938
2	1	.855*	.157	.002	.339	1.371
	3	-.791*	.151	.002	-1.286	-.296
	4	-1.164*	.194	.001	-1.798	-.529
3	1	1.645*	.264	.001	.781	2.509
	2	.791*	.151	.002	.296	1.286
	4	-.373	.125	.083	-.783	.037
4	1	2.018*	.330	.001	.938	3.099
	2	1.164*	.194	.001	.529	1.798
	3	.373	.125	.083	-.037	.783

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Table IV: Tests of Within-Subjects Effects (Home-Cooked Meal)

Measure: Weight						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Sphericity Assumed	18.798	3	6.266	18.023	.000
	Greenhouse-Geisser	18.798	1.267	14.833	18.023	.001
	Huynh-Feldt	18.798	1.380	13.619	18.023	.001
	Lower-bound	18.798	1.000	18.798	18.023	.002
Error (time)	Sphericity Assumed	9.387	27	.348		
	Greenhouse-Geisser	9.387	11.406	.823		
	Huynh-Feldt	9.387	12.422	.756		
	Lower-bound	9.387	9.000	1.043		

Table V: Pairwise Comparisons (Home-Cooked Meal)

Measure: Weight						
(I) time	(J) time	Mean Difference (I-J)	Std. Error	Sig. ^b	95% Confidence Interval for Difference ^b	
					Lower Bound	Upper Bound
1	2	-.630*	0.121	0.003	-1.038	-0.222
	3	-1.400*	0.328	0.012	-2.502	-0.298
	4	-1.770*	0.357	0.005	-2.969	-0.571
2	1	.630*	0.121	0.003	0.222	1.038
	3	-0.77	0.242	0.067	-1.583	0.043
	4	-1.140*	0.304	0.027	-2.163	-0.117
3	1	1.400*	0.328	0.012	0.298	2.502
	2	0.77	0.242	0.067	-0.043	1.583
	4	-0.37	0.131	0.119	-0.81	0.07
4	1	1.770*	0.357	0.005	0.571	2.969
	2	1.140*	0.304	0.027	0.117	2.163
	3	0.37	0.131	0.119	-0.07	0.81

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

C. Within-Group Comparison of Malnutrition by Treatment Group

The between-group comparison of malnutrition by treatment group is presented in [Table VI](#). It can be noted that after 1 month, only 6 participants remained, as indicated by nutritional severity. Only 1 participant (10%) in the HC (Home-cooked meal) group had malnutrition, compared with 45% in the improvised RUTF group. Results, however,

were not statistically significant. In months 2 and 3, all participants in the HC group had normal nutritional status, whereas one patient in the improvised RUTF group was wasted. No significant difference was observed in the proportions. There was no statistically significant difference in participant weights between the improvised RUTF group and the home-cooked meal group.





Table VI: Within-Group Comparison of Malnutrition by Treatment Group (N = 21)

	Improvised RUTF (n=11)	HC (n=10)	P value ^a	RR (95% CI)
Month 1	5 (45%)	1 (10%)	0.149	4.55 (0.63-32.56)
Month 2	1 (9%)	0 (0%)	1.000	–
Month 3	1 (9%)	0 (0%)	1.000	–

^aFisher's exact test was used

D. Within-Group Comparison of Healthy Lifestyle Assessment

Table VII presents the within-group comparisons of the healthy lifestyle assessment among participants. It can be noted that sedentary activity remained below 2 hours among all participants, and physical activity consistently exceeded 2 hours from baseline (Table I) throughout the three months. Similarly, the results showed that the number of meals per day remained at 3. At baseline (Table I), only 36% of the improvised RUTF and 40% of the HC (Home-cooked) groups had no SSB (sugar-sweetened beverage) intake.

After 1 month, 82% of the improvised RUTF group and 90% of the HC group had no SSB intake; however, these proportions did not differ significantly. At months 2 and 3, all participants had no SSB intake. It can also be gleaned from the table that all participants used utensils during months 1-3, compared with the baseline (Table I), where only 45% of the improvised RUTF and 60% of the HC groups used utensils. Moreover, none of the participants reported bottle feeding, alcohol intake, smoking, or drug use from baseline to all the follow-up periods.

Table VII: Within-Group Comparison of Healthy Lifestyle Assessment (N = 21)

Healthy Lifestyle Assessment	Month 1			Month 2			Month 3		
	Improvised RUTF (n=11)	HC (n=10)	p-value (Two-Tailed)	Improvised RUTF (n=11)	HC (n=10)	p-value (Two-Tailed)	Improvised RUTF (n=11)	HC (n=10)	p-value (Two-Tailed)
Sedentary activity									
>2 hours	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–
≤2 hours	11 (100%)	10 (100%)		11 (100%)	10 (100%)		11 (100%)	10 (100%)	
Physical activity									
≤2 hours	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–
>2 hours	11 (100%)	10 (100%)		11 (100%)	10 (100%)		11 (100%)	10 (100%)	
3 meals/day	11 (100%)	10 (100%)	–	11 (100%)	10 (100%)	–	11 (100%)	10 (100%)	–
No SSB intake	9 (82%)	9 (90%)	1.000a	11 (100%)	10 (100%)	–	11 (100%)	10 (100%)	–
Bottle feeding	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–
Utensils	11 (100%)	10 (100%)	–	11 (100%)	10 (100%)	–	11 (100%)	10 (100%)	–
Alcohol	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–
Smoking	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–
Drugs	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–

X. DISCUSSION

This study assessed the effect of community-based supplemental feeding with either a home-cooked meal or improvised RUTF on the nutritional status of undernourished children by comparing their BMI z-scores pre- and post-feeding every month for 3 months.

Malnutrition is one of the major contributors to death among the pediatric population due to the lack of access to nutritious foods. Moreover, feeding practices such as inadequate breastfeeding, inappropriate foods, and failure to provide nutritious foods contribute to malnutrition. For years, in feeding programs, home-cooked meals have been the standard for providing adequate nutrition to malnourished children. One of the recently developed home-based treatments for malnutrition is RUTF, which has revolutionised the treatment of severe malnutrition by providing safe foods at home and ensuring rapid weight gain among severely malnourished or wasted children [6]. RUTF is a ready-to-use paste that does not need to be mixed with water, thus minimising potential contamination and bacterial proliferation. It has been developed according to a standard, energy-rich composition defined by the WHO. The ingredients of RUTF include milk powder, sugar, peanut butter, vegetable oil, vitamins, and minerals; however, its composition may vary depending on availability, cost, and acceptability in the local setting. RUTF has a long shelf life without refrigeration and can be stored for 3-4 months even

at tropical temperatures. Moreover, it can be consumed directly by the child without any preparation and provides sufficient nutrients for complete recovery [17]. For this study, the principal investigator used an improvised RUTF rather than the actual RUTF (Plumpy'Nut) supplied by the DOH.

Results of this study showed that, among the 116 children, the prevalence of malnutrition was 18.10% (95% CI: 12.04-26.32%), and 95% of these malnourished children were classified as wasted, and 5% were severely wasted. Two out of ten children have chronic malnutrition, and this proportion is predominant among children who are 3 years of age. This result may be attributed to limited access to high-calorie snacks and foods that are hardly affordable [18]. This finding also denotes that although the prevalence of malnutrition is somewhat low, it remains an important nutritional concern in the communities of the Philippines. Results also showed that although most participants were not infested with intestinal parasites, 5% had intestinal parasitism (prevalence 4.76%; 95% CI: 0.6-30.89%) and were treated accordingly. None of them had developmental problems.

Results also showed significant weight gain from baseline to the 3rd month of feeding with both home-cooked meals and improvised RUTF, as evidenced by BMI z-scores improving to 1 SD above

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their previous values. Nutritional improvement was already significant and evident after the first month of feeding, compared with the 2nd and 3rd months, for both interventions. Thus, this proves that both interventions can provide adequate nutritional rehabilitation as early as 1 month of the feeding program. The improvement in RUTF in this study has also been shown to be nutritionally beneficial and easily replicated.

Although the proportion of malnourished children decreased after the three-month improvised RUTF and home-cooked meal interventions, it did not differ significantly between the two intervention groups at Months 1, 2, and 3. This result is consistent with the pooled summary statistic estimated by Schoonees et al. (2019) [17], which found little to no difference between RUTF and home-cooked meals. Two other findings of this study further support this result. First, the overall percentage caloric deficiency was 28.73% (SD=17.35), with a deficiency of 28.43 calories (SD=15.99) and 29.07 calories (SD=19.62) in the improvised RUTF and home-cooked meals groups, respectively. This caloric deficiency is below the allowable or recommended deficit of approximately 33% to 50% of daily caloric intake and is insufficient to induce significant malnutrition or weight loss [18]. Second, the evaluation of participants' feeding histories showed that children in both groups almost always consumed group I (rice and bread), group X (eggs), and group XII (milk), and often or seldom ate the other food groups. Third, vitamin and mineral intake was also inadequate among participants, contributing to micronutrient deficiencies and potentially leading to insufficient daily caloric intake and overall nutrition.

It is also interesting to note that, although most indicators of a healthy lifestyle did not change significantly over time from baseline in both groups, the proportion of utensil utilisation improved from baseline to Month 1 and remained sustained until Month 3. Improvement was also observed in SSB intake among some children from baseline to Month 1, and eventually in all of them from Months 2 and 3 onward. This result demonstrates the impact of nutritional counselling on further improvements in mothers' health practices, which, in turn, favourably influenced their children's eating and healthy lifestyle behaviours. Nevertheless, cognizant of the fact that the study was only conducted for a 3-month duration, the principal investigator was aware that the long-term effectiveness of the counselling remained uncertain, a notion supported by Black et al. (2017) [19].

Despite the results presented, this study has certain limitations. First, it was conducted in a single rural community in Bulacan, Philippines, wherein the characteristics and nutritional profiles may differ from those of other communities, particularly urban ones; hence, selection bias is highly likely. Second, the intervention – improvised RUTF and home-cooked meals – comprised 30% of participants recommended intake, with 70% of that coming from the children's respective homes. Hence, the current results may be attributable to changes in feeding

patterns and/or meal schedules in the children's homes rather than to the supplemental feedings provided. The effect of participant's daily intake of other meals in addition to their daily activities was beyond the scope of this study. Third, several confounding factors which were difficult to control in this study (e.g., other sources of caloric intake, effect of nutritional counselling, etc.) may have contaminated or biased the current results. Finally, although the study was proposed to be conducted for 6 months (120 feeding days), the current COVID-19 pandemic shortened this duration to 4 months (80 feeding days), with data collected only after 3 months of feeding (60 feeding days). As such, the long-term effect of the improvised RUTF was not assessed and remains uncertain.

XI. CONCLUSION

As shown in the per-group analysis, there were significant improvements among participants at each month and at the end of the study compared with baseline measurements. This significant nutritional improvement was achieved by increasing their BMI z-scores to 1 SD above their previous scores, a change already evident as early as the first month of intervention in both groups. The increase in z-score by 1 SD above their previous scores was associated with average weight gains of 2kg and 1.8kg for improvised RUTF and home-cooked meals, respectively, and a BMI increase of 1.1 for both interventions, crossing the z-score line among participants. Thus, the study concluded that both home-cooked meals and improvised RUTF improve the nutritional status of children, moving them from severely wasted to wasted and from wasted to normal after 3 months. Although there is still no sufficient evidence to conclude that improvised RUTF provides better nutritional support compared to the standard home-cooked meals, due to the ease of preparation, consumption and storage of improvised RUTF together with its nutritional benefits, it may be given as an adjunct to the standard home-cooked meal to maximize additional calories, thereby further improving the child's nutritional status.

The study also showed improvements in children's nutritional status and behaviour through nutritional counselling based on their utensil use and SSB intake. The importance of feeding history and the correction of micronutrient deficiencies associated with malnutrition were likewise emphasised, as this will further strengthen our goal of reducing undernutrition in the Philippines. Prevalence of intestinal parasitism was 4.76% among undernourished children and was treated accordingly.

Furthermore, effective implementation of the community feeding program requires active and full participation by participants and their parents/guardians, as well as strong support from healthcare volunteers to strengthen the feeding system and its implementation.





RECOMMENDATIONS

Future investigators are recommended to lengthen the intervention period. Thus, continuous implementation of the community feeding program is recommended.

Given the focused locality, future investigators may broaden the geographical scope and use cluster sampling to identify locations where malnutrition is most prevalent. Thus, it enables investigators to survey further areas that will benefit most from the intervention and to initiate health promotion by teaching them how to prepare their own improvised RUTF.

Due to the improvements in nutritional values and behaviour observed in this study, the investigators also recommend continuing to inculcate positive attitudes towards health and nutrition among children through school activities and, likewise, motivating them to disseminate information on health and nutrition values and behaviours.

In addition, future investigators could explore other benefits of community feeding programs beyond physical and nutritional development, such as in-school or academic performance and social development.

DECLARATION STATEMENT

After aggregating input from all authors, I must verify the accuracy of the following information as the article's author. The article remains impartial and unbiased:

- **Conflicts of Interest/ Competing Interests:** Based on my understanding, this article has no conflicts of interest.
- **Funding Support:** This article has not been sponsored or funded by any organization or agency. The independence of this research is crucial to affirming its impartiality, as it has been conducted without external influence.
- **Ethical Approval and Consent to Participate:** Yes, securing ethical approval and consent from all participating individuals is essential. The study was done in agreement with the ethical guidelines set by the Declaration of Helsinki 2015, WHO Operational Guidelines in Biomedical Studies 2011, International Conference on Harmonization on Good Clinical Practice (ICH-GCP), Council for International Organizations for Medical Sciences 2016, Good Research Practice (GRP), Philippine National Ethical Guidelines for Health and Health-Related Research of 2017, Philippine Data Privacy Act of 2012 and its Implementing Rules and Regulations (IRR) of 2016. The University of Santo Tomas Research Ethics Committee approved it.
- **Data Access Statement and Material Availability:** The adequate resources of this article are publicly accessible.
- **Author's Contributions:** The authorship of this article is contributed equally to all participating individuals.
- **Informed Consent or Ethical Clearance** Yes, I have. The authors obtained informed consent given the potential risks associated with consuming freshly prepared meals, improvised RUTF, and powdered cow milk. The participants' parents or legal guardians were given a full explanation. The possible

adverse effects and benefits were explained thoroughly, and participants may withdraw from the study at any time if complications arise, such as food or milk allergies, food intolerance, noncompliance with the prescribed milk and food intake, or infection requiring hospitalisation.

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AUTHOR'S PROFILE



Dr. Janine Vasquez Uy is the Head of the Pediatric Intensive Care Unit at Metro Lemery Medical Centre in Batangas. She earned her doctoral degree and completed her pediatric residency at the University of Santo Tomas Hospital. She completed her PICU fellowship training at the Philippine Children's Medical

Centre.



Dr. Portia Menelia Decano Monreal is the Chief of Section of Pediatric Gastroenterology, Hepatology and Nutrition in the Department of Pediatrics of the University of Santo Tomas Hospital. She is also an Associate Professor in the Department of Pediatrics of the UST Faculty of Medicine and Surgery.

SUPPLEMENTARY DATA



UNIVERSITY OF SANTO TOMAS HOSPITAL RESEARCH ETHICS COMMITTEE

6th Floor Clinical Division Building
España Blvd., Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_urb@yahoo.com.ph



19 January 2021

JANINE V. UY, MD
Resident-in-Training/Principal Investigator
Department of Pediatrics
University of Santo Tomas Hospital

Re: Approval Letter to the Review of Final Report Protocol
Protocol Reference No.: REC-2019-06-116-TR-FR
Protocol No./Title: "Effect of Community Based Directly Observed Supplemental Feeding (Home Cooked Meals versus Improvised Ready to Use Therapeutic Food) on Nutritional Status of Children with Acute Moderate or Acute Severe Uncomplicated Malnutrition in Gawad Kalinga Enchanted Farm: A Randomized Controlled Trial"
REC Initial Approval Date: 04 September 2019

Dear Dr. Uy:

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** would like to inform you that your **Final Study Report Version 1** submitted last **04 December 2020** has been assessed and approved through **expedited review**. Please note that the validity of your ethical approval expires effective today and the study protocol will be transferred for archiving as **INACTIVE FILE**. All study related protocol records will be made available for three (3) years in the archive until **19 January 2024**.

Thank you for updating us on the results of your study.

For the USTH – Research Ethics Committee:

JOSEPHINE M. LUMITAO, MD, MHPed, FPOGS
REC Head

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6th Floor Clinical Division Building
España Blvd., Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_urb@yahoo.com.ph



COMMITTEE COMPOSITION FORM

Protocol No./Title: "Effect of Community Based Directly Observed Supplemental Feeding (Home Cooked Meals versus Improvised Ready to Use Therapeutic Food) on Nutritional Status of Children with Acute Moderate or Acute Severe Uncomplicated Malnutrition in Gawad Kalinga Enchanted Farm: A Randomized Controlled Trial" (as amended)

Principal Investigator: Resident-in Training Dr. Janine V. Uy

Department: USTH Dept. of Pediatrics

Name of Institution: UNIVERSITY OF SANTO TOMAS HOSPITAL (USTH)			
Address of Institution: España Blvd., Manila, Philippines, 1015			
No.	Name of Member	REC Designation/ Department/Expertise	Affiliation w/ the institution
1	Josephine M. Lumitao, MD	Head Obstetrics & Gynecology/ Bioethics	Yes
2	Anna Lea L. Enriquez, MD	Vice-Head Anesthesiology/Psychology	Yes
3	Raymund Gabriel A. Naranjilla, MD	Member Secretary Medicine - Adult Cardiology	Yes
4	Wilson L. Tan De Guzman, MD	Regular Member Medicine Interventional Cardiology	Yes
5	Edmund R. Advincula, MD	Regular Member Pediatrics	Yes
6	Joanavin D. Ngo, MD	Regular Member Medicine - Rheumatology	Yes
7	Dennis L. Del Rosario, MD	Regular Member Ophthalmology	Yes
8	John Rey B. Macindo, RN, MPH (c.)	Regular Member Non-Institutional/ Nursing/Public Health	No
9	Sr. Maria Vida C. Cordero	Regular Member Non-Institutional/Layperson	No

Date of Approval: 19 January 2021 (REC-2019-06-116-TR-FR)

Name and Signature:

JOSEPHINE M. LUMITAO, MD, MHPed, FPOGS
REC Head

COMMITTEE COMPOSITION FORM

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