Joint Event
21st World Congress on
Nutrition and Food Chemistry
3rd Euro-Global Summit on
Probiotics & Nutraceuticals

August 24, 2022
WEBINAR

Development of Ready –To- Use Therapeutic Food (RUTF) using locally available foods and determination of its effectiveness in mice

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Acute malnutrition is a global public health issue, affecting millions of people worldwide. Currently, 47 million (6.9%) of children under five years are wasted, of which 14.3 million (2.1%) of them are severely wasted (Bank and Joint, 2020). In Africa, 12.7 million (6.4%) of children under five years are wasted and 3.5 million (1.8%) of them severely wasted; with West Africa accounting for the highest number 4.8 million (7.5%) wasted and 1.1 million (1.8) severely wasted (Bank and Joint, 2020). Children living with chronic infectious diseases like HIV/AIDS and tuberculosis and those living under emergency conditions are the most affected with wasting. Additionally, despite the presence of clear management/treatment protocol for Severe Acute Malnutrition using Ready to Use Therapeutic Foods (RUTFs), coverage of the treatment for SAM is very low due to persistent inadequate availability of RUTF. Also, the imported RUTF is very expensive for the low income Countries to afford making it difficult for SAM children to access the treatments they require. This therefore calls for development of cost-effective local solution for the treatment of SAM, thus the proposed development of RUTF. The therapeutic food product shall be formulated from ten commonly available foods, sugar and vegetable oil, using the creative formulation software; "Concept 4-ED Creative Formula concepts- LLC'. Three recipes with nutrients composition closest to standard RUTF shall be selected from the formulations, each recipe prepared independently and mixed to form three different food products. The nutrients composition of the developed products shall be analyzed, sensory evaluation conducted and the three formulated products shall be tested for their effectiveness in mice using standard RUTF as control.

Background: The importance of coverage in the success of Community Management of Acute Malnutrition (CMAM) programs is well documented (Sebinwa U, 2014 and Rogers E et al, 2015) Achieving high program coverage is reported as one of the forces behind the shift from centralized treatment in the form of Therapeutic Feeding Centers (TFCs) to the current decentralized community-based programming namely Community Based Management of Acute Malnutrition (CMAM). (Rogers E et al, 2015) However, persistent inadequate availability of Ready to use Therapeutic Food (RUTF) remains a stumbling block to achieving the required coverage for the success of Community Management of Acute Malnutrition (CMAM) program. (Sebinwa U, 2014) (ACF report 2011) According to UNICEF which supplies the largest amount of RUTF globally, the RUTF procured by the organization covers only 25% of the global estimated number of children suffering from severe wasting. (UNICEF, 2021) While the one procured by governments, non-governmental organizations NGOs) and other United Nations (UN) agencies covers only an additional 5%-10%. UNICEF, 2022) this leaves the highest percentage (65%- 70%) of children suffering from severe acute malnutrition with no access to the right treatment. In Central and Western Africa, only half of the health facilities offer SAM treatment and supply

of RUTF in these facilities is inadequate to meet the needs (UNICEFb, 2020). In Nigeria, only 20% of the estimated 2 million children affected with SAM are reached for treatment. (UNICEFa, 2020) Furthermore, imported RUTF has been reported with challenges of poor acceptability by the local communities. (Choudhury N et al, 2018 and Nabuuma D et al, 2013) Currently, development partners especially UNICEF and WHO are supporting Countries to establish local production of RUTF for local use; (Wasnik V and Rathi M, 2012) however, most of the current locally formulated and produced RUTFs require high investments in forms of the processing plants and raw material which has resulted into locally produced RUTF being more expensive than the imported (UNICEF, 2022,23) Also the RUTF produced currently is inadequate to meet global demand. As a result, Countries and development partners are struggling to provide enough RUTF to the affected persons. Given that most of the communities affected with SAM are poor, it may not be feasible and sustainable using an expensive product like the commercial RUTF to treat such a condition which is associated greatly with poverty. Thus, the need to formulate a less costly therapeutic food product with nutrients composition similar to F100 and commercial RUTF, using local ingredients and low-cost traditional equipment and technology. The proposed food product can be easily produced by local communities and local institutions which is important in tackling the challenges of insufficient supply.

Justification: The core principles of CMAM program include, ensuring maximum coverage and access, timeliness, appropriate care and care for as long as it is needed. To achieve this, tools, resources and commodities required to deal with the identification, treatment and management of acute malnutrition should be readily available. This study which aims at formulation of a therapeutic food product for treatment of SAM which is less costly and which can be produced easily by local community without requiring highly specialized equipment and technology, will contribute to addressing the challenge of insufficient therapeutic food for treatment of SAM. This will in turn contribute to ongoing efforts by the Country toward the attainment of the national government's declared goal of universal health coverage (UHC). This is because the community level production of RUTF has the potential to facilitate a sustainable community level management of un-complicated SAM in the absence of the commercial RUTF, thereby empowering local communities and Countries to ensure self-reliance and reduce cost burden of importing or purchasing standard commercially produced RUTF.

Objectives of the study

Main objective: To develop RUTF locally using available food commodities and traditional equipment

Specific objectives

1. To develop a RUTF using locally available foodstuff and traditional technology
2. To analyze the developed therapeutic food product for its Nutrients composition.
3. To assess the acceptability of the developed food product
4. To determine the effectiveness of the developed therapeutic foods in mice

Hypothesis: RUTF for the management of SAM can be developed locally at community level using locally available food commodities.

Methodology

Selection of the foods ingredients: Ten commonly available foods in Uganda shall be selected and used in the formulation of the Ready to use therapeutic food, and these shall include: Peanuts (Ground nuts) (Arachis hypogaea), Rice (Oryza sativa), figure millet (Eleusine coracana), brown sorghum (Sorghum bicolor), silver fish, beans, orange fleshed sweet potatoes (Ipomoea batatas), soy beans (Glycine max), sesame seeds (Sesamum indicum) and corn (maize) (Zea mays). Also to be added shall include vegetable oil, sugar and dried fruits and vegetables powder which shall be added to the formulations to increase the energy and nutrients density and palatability.

Formulation and selection of the recipes: By optimizing the nutrient composition of the ingredients and prices, and targeting the nutrient composition of F100, the creative formulation software; "Concept 4-ED Creative Formula concepts- LLC Education version 8.01.01" will be used to generate formulations. (43,44) Three formulations whose predicted compositions shall be closest to that of F100 will be selected. The total ingredient costs of the formulations generated by the software will be compared to the cost of imported RUTF developed by nutriset on a weight basis.

Processing/preparation of ingredients: Food substances that constitute the three selected formulations shall be prepared separately before mixing. Preparation of each food constituent shall follow procedures necessary for enhancing the acceptability and nutrition quality of the final product. Food types with anti-nutritive components like oxalates and phytates shall be processed in a way that reduces the amount of such components to enhance the digestibility and absorption of nutrients contained in such a food.

Analysis on the nutrient composition of the products: After mixing the ingredients to homogeneity, the nutrient composition of the three formulated foods shall be analyzed for their energy, fat, protein, vitamins and mineral, moist, ash, phytates contents and protein digestibility. The moisture and ash content of the product shall be determined using the air oven method of AOAC International (1998). (20,45) The protein content will be determined with reference to the Kjeldhal method, while the Soxhlet method will be used to determine the crude fat content (AOAC International 1998). The crude fiber content of the formulated therapeutic foods shall be determined by adding 100mls of 0.25NH2SO4 into a flask containing 2g of a sample, and the mixture will be heated under reflux for 1 hour with heating mantle. The hot mixture shall be filtered through a fiber sieve cloth, the filtrate obtained shall be thrown off and the residue returned to the fiber flask to which 100ml of (0.31NNaOH) shall be added and heated under reflex for another 1 hour as described by Ashaye (2010). The carbohydrate content shall be calculated by difference as described by FAO (2003). While the gross energy content of the formulated therapeutic foods will be determined using the bomb calorimeter as described

according to the AOAC International (1990) method. The energy content of the product shall also be calculated using the Atwater conversion factors of 17 kJ/g (4 kcal/g) of carbohydrate, 37 kJ/g (9 kcal/g) of fat and 17 kJ/g (4 kcal/g) of protein (FAO 2003).

In vitro protein digestibility of the formulated therapeutic foods shall be determined using the pepsin–pancreatin enzyme system as described by Chavan et al (2001). The amino acid score and protein digestibility corrected amino acid score (PDCAAS) will be calculated using the software predicted amino acid profile, the determined *in vitro* protein digestibility of the Formulated therapeutic foods and the amino acid requirement pattern for 6-month to 1-year-old healthy infants as the reference pattern as described by WHO technical report on protein and amino acid requirements in human nutrition. The phytate content of the formulated therapeutic foods will be determined using the anion-exchange (AOAC International 1998) method. To determine the microbiological quality of the formulated therapeutic food, the total plate count and the yeast and mold count shall be determined on plate count and potato dextrose agar, respectively. All experiments shall be carried out in the Chemistry and Microbiology Laboratories at Bayero University, Kano Nigeria.

Microbial analysis (shelf life): The shelf life of the three developed therapeutic foods shall be determined using a certified laboratory.

Sensory evaluation of the formulated Therapeutic Food to determine acceptability Acceptability of the TF shall be evaluated by mothers of children less than five years, because the mothers are able to both objectively evaluate the sensory characteristics of the formulated therapeutic food and assess whether their children can consume the therapeutic food or not. The characteristics to be evaluated shall include; appearance, taste and overall acceptability of the three TF products using a five-point Likert scale, where 1 shall mean dislike extremely and 5 like extremely. The recruitment criterion shall ensure that only mothers with at least one child aged between 6 months to 59 months of age and have no allergies to the constituents of the products are selected. The acceptability, cost and nutrient quality of the products shall be compared with the standard imported RUTF.

Determination of effectiveness of the developed therapeutic food products: The effectiveness of the three developed therapeutic foods shall be determined in the laboratory using experimental mice, where a total of 30 weanling female mice shall be fed on a restricted diet for a period of 14 days to induce undernutrition. On the 14th day, the mice shall be randomly grouped into 5 groups consisting of 6 mice each. Three of the groups shall be fed exclusively on one of the three developed therapeutic foods while the fourth group shall be fed exclusively on the standard RUTF which will act as the control for three weeks (21 days). The fifth group shall be anesthetized, and their blood will be collected (1ml) by cardiac puncture for hematological and biochemical analyses. The quantity of food fed by each of the four groups shall be evaluated through weighing the food given and the remains of the food after feeding. The mice and their droppings shall be weighed at the interval of three days for 21 days. Also the tail length and the length of the mice (nose to anus length) shall be measured at the interval of 3 days from the beginning of restricted feeding till the end of the experiment. On the 21st

day of feeding, the mice in each group will be anesthetized with ketamine (200 mg/kg) and xylazine (16 mg/kg) in a solution that will be administered intraperitoneally. Blood will be collected (1ml) by cardiac puncture for hematological and biochemical analyses. The blood will be centrifuged at 4000 rpm and the serum separated. Hematological parameters as well as total blood cell counts will be determined. The serum levels of the following biochemical parameters will be evaluated: total protein, albumin, glucose, creatinine, creatinine kinase, urea, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AST), cholesterol, iron, calcium, sodium, and potassium levels. All samples shall be measured by a biochemistry laboratory at Makerere University. After blood collection, the mice will be euthanized in a CO2 chamber and disposed by burying in the soil

Biography

Bumba Erinest is currently a student at Bayero University, Kano Nigeria studying a Master degree in Public Health Nutrition and Policy. He holds a Bachelor's degree in human Nutrition from Makerere University. He currently does voluntary work with Nutrition Society of Uganda and World Public Health Nutrition Association. He is also at intern at UGANDA'S Ministry of Health Kampala. Formally, he worked as a Nutrition officer and Deputy Analyst with Action Against Hunger International. He has extensive experience working in emergency nutrition interventions, Nutrition programing and policy and advocacy for Nutrition.

Received: May 07, 2022; **Accepted**: May 09, 2022; **Published**: August 03, 2022