



BODY COMPOSITION SUB-STUDY SUMMARY

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BACKGROUND

Greater lean body mass is believed to have an impact on health outcomes in children recovering from moderate acute malnutrition (MAM). Different supplementary foods have different macronutrient compositions, and it is hypothesized that lipid-rich foods may result in different amounts of lean body mass accretion than protein or carbohydrate rich foods. The study foods, prepared as recommended, differ in percent of calories from fat, amount of protein, presence of an animal source (dairy) food. These differences might potentially affect lean vs. fat mass accretion during recovery.

1. Super Cereal Plus (SC+) with amylase
2. Corn Soy Blend Plus (CSB+) and Fortified Vegetable Oil (FVO)
3. Corn Soy Wheat Blend (CSWB) and FVO
4. Ready-to-Use Supplementary Food (RUSF)

BODY COMPOSITION

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STUDY DESIGN

Eligible subjects will be children with MAM ages 6-59 months enrolled in the four foods study. For each food, 200 children will be enrolled during specific study time periods: a total sample size of n=800. Informed consent will be sought from the caretakers of all eligible children by a research assistant familiar

with the study and fluent in the caretaker's native language. Duration of the study and participation requirements will be explained. Informed consent will be given verbally and in writing.

AIM I

To compare the effect of four supplementary foods on changes in body composition of 6-59 month-old children with MAM after four weeks of treatment.

HYPOTHESIS IA

The four foods have differential effects on change in percentage of lean mass to fat mass of 6-59 month-old children with MAM after four weeks of treatment.

HYPOTHESIS IB

The change in percentage of lean mass to fat mass of 6-59 month-old children with MAM will correlate with change in MUAC after four weeks of treatment.

HYPOTHESIS IC

The change in percentage of lean mass to fat mass of 6-59 month-old children with MAM will correlate with change in WHZ after four weeks of treatment.

HYPOTHESIS ID

The change in percentage of lean mass to fat mass of 6-59 month-old children with MAM is associated with recovery from MAM after 4 weeks of treatment.

MEASUREMENTS

The outcome measures will be change in percentage of lean mass (which is the reciprocal to change in percentage of fat mass), mid-upper arm circumference (MUAC), and weight-for-height z-score (WHZ) after four weeks of treatment with supplementary foods. Change in percentage lean mass to fat mass will be assessed using deuterium dilution technique analyzed with mass spectrometry. MUAC will be assessed using an insertion tape. Weight will be measured using a weighing scale, height will be measured using a height board, and WHZ will be determined by comparing weight-for-height to the WHO growth standard.

TECHNIQUE

To assess body composition, deuterium dilution technique will be used to estimate total body water. To determine lean mass, total body water will be divided by age and sex-specific hydration factors. To calculate fat mass, fat free mass will be subtracted from total body water. One gram per kg body weight of deuterium oxide diluted in drinking water will be given to the study children. Urine specimen will be collected at two time points: pre-dose and post-dose or 4 hours later. The urine specimen will be ali-

quoted into 2mL cryovials and placed in a cold box with ice packs and transferred to a -20oC freezer until shipped to a laboratory for analysis.^{1,2}

IMPLICATIONS

The results from this study will contribute to the understanding of product effectiveness in terms of total body mass vs. lean body mass accretion. The study will also contribute to building evidence on the 'quality' of growth during recovery and its potential relationship to preventing relapse. This study is operationally important because program implementers typically rely on weight, height, and MUAC as indicators for recovery, but there may be added value in assessing the quality of body mass gain.

1 IAEA. Introduction to Body Composition Assessment Using the Deuterium Dilution Technique with Analysis of Urine Samples by Isotope Ratio Mass Spectrometry. International Atomic Energy Agency, Vienna, Austria (2010).

2 This will be increased to 2 grams per kg body weight at 4 weeks.