Project INT 6058

"Contributing to the Evidence Base to Improve Stunting Reduction Programmes"

Sub-projectURT6030:"Using stable isotope technique to evaluate effectiveness of Social Behavioural Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Iringaand Njomberegions, Tanzania

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Abbreviations and Acronymns

BMI	Body Mass Index
D_2O	Deuterium Oxide
EBF	Exclusive Breast-Feeding
EED	Environmental Enteric Dysfunction
FFM	Fat Free Mass
FM	Fat Mass
FQ	Food Frequency
FtF	Feed the Future
FTIR	Fourier Transform Infrared Spectrometry
GHI	Global Health Initiatives
HAZ	Height for Age Z-score
IAEA	International Atomic Energy Agency
LAZ	Length for Age Z-score
MBNP	Mwanzo Bora Nutrition Program Nutrition
NMNAP	National Multisectoral Nutrition Action Plan
NNS	National Nutrition Survey
SBCC	Social and behavior change communication
SUN	Scaling Up Nutrition
TBW	Total Body Water
TDHS	Tanzania Demographic Health Survey
TFNC	Tanzania Food and Nutrition Centre
UNICEF	United Nations Children's Fund
WASH	Water, Sanitation and Hygiene
WAZ	Weight for Age Z-score
WHO	World Health Organization
WLZ	Weight for Length/Height Z-scores

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Abstract

Background: The prevalence of stunting and underweight in Tanzania is considerably high. Several interventions are being implemented countrywide to combat the problem. This include intervention such as promotion of exclusive breastfeeding (EBF) and continued breastfeeding, promotion of healthy, and diverse complementary feeding, with or without provision of food supplements, preventive zinc supplementation, micronutrient supplementation that includes zinc and interventions targeting improvement of WASH (Water, Sanitation and Hygiene). However, evaluating the effectiveness of these programmes is often given marginal importance or is limited to the monitoring of programme implementation.With a greater understanding of the shortand long-term consequences of undernutrition, UNICEF and other international partners have shifted emphasis from efforts to reduce underweight prevalence to prevention of stunting among children. The World Health Assembly Global Nutrition Target 2025 calls for a 40 per cent reduction in the number of children under 5 years of age who are stunted.

The Accelerating Stunting Reduction Programme (ASRP)is among ongoing nutrition intervention initiatives in Tanzania aimed to address stunting by investing in the establishment of community, health and nutrition systems/mechanisms for the promotion of high impact interventions.ASRP's main approach to reduce stunting is throughimplementation of specific social behavior change communication (SBCC) package in which key messages are delivered to the community by Community Health Workers (CHW's) targeting pregnant, lactating women and mothers of children under 5years of age on monthly basis.

Stable isotope techniques will be used in the proposed study to evaluate the impact of SBCC in promoting exclusive breastfeeding (EBF) in areas which are covered by ASRP particularly Iringa region.

Objective: To evaluate effectiveness of SBCC interventions in increasing rates of exclusive breastfeeding

Materials and methods: Cross-sectional study will be conducted in two Regions, Iringa and Njombe. Two districts of Iringa (Iringa DCand Kilolo)and Njombe(Njombe DC andWanging'ombe). Iringaregion is one of regions covered by ASRP SBCC interventions. EBF for children 3-6 months will be investigated through recruiting mother-baby pair from the designated districts. Njombe will serve as a comparison Region since it's a non ASRP region for the similar study to assess the impact of SBCC interventions in promoting EBF. Data on socioeconomic and socio-demographic characteristics, living conditions of children as well as health data will be collected using structured questions. Anthropometric indices will be measured using standard methods and saliva samples will be collected to estimate breast milk intake and

determine EBF using dose to mother deuterium dilution techniques.The study will be carried out from July 2019 to June 2020.

Budget: The project will need an estimated sum of Tzshs **92,313,000.00** for field study. The International Atomic andEnergy Agency will provide laboratory and field consumables.

1.0 Introduction

1.1 Stunting: An Overview

Stunting, defined as having a height-for-age Z-score (HAZ) that is more than two standard deviations below the age-sex median for a well-nourished reference population, remains widespread in low- and middle-income countries. Black et al. (2013) estimated that in 2011, 165 million children in low- and middle-income countries were stunted. Children who are stunted are at an increased risk for repeated infections and are more likely to die from diarrhea, pneumonia, and measles, and may be at an increased risk in adulthood for chronic diseases such as cardiovascular diseases.

Adequate nutrition is critical to a child's optimal development, particularly during the first 1,000 days (conception through the child's second birthday), a period of rapid growth where nutrient deficiencies can have long-term harmful consequences. Studies have found that well-nourished children enroll in school earlier, perform better in school, and miss fewer days of school due to illness, and complete more years in school, resulting in increased learning and higher wages in adulthood (Grantham-McGregor et al., 2007; Hoddinott et al., 2008).

In Tanzania, stunting is one of the most important public health problems.For the past two decades, reduction of stunting has been on high priority in the development agenda of the country. It is addressed by various global and national commitments, as reflected in the targets of Millennium Development Goals, Food and Nutrition Policy, National Nutrition Strategy (NNS), Scaling Up Nutrition (SUN) movement, Tanzania Vision 2025, National Strategy for Growth and Reduction of Poverty (NSGRP), and Primary Health Services Development Program (PHSDP), among others. Despite these commitments and investment, the prevalence of stunting is still high (TDHS, 2015/16).

Several interventions are being implemented countrywide to reduce stunting in early childhood through increased micronutrient intake, promotion of balanced diet, reduction in the underlying factors of stunting through reduction of morbidity and environmental enteric dysfunction (EED). These interventions include; i) promotion of exclusive breastfeeding (EBF) and continued breastfeeding; ii) promotion of healthy, and diverse complementary feeding, with or without provision of food supplements; iii) preventive zinc supplementation; iv) micronutrient supplementation that includes zinc; and v) interventions targeting improvement of hygiene (e.g. Water, Sanitation and Hand washing) and reduction of EED. However, evaluating the effectiveness of these programmes is often given marginal importance or is limited to the monitoring of programme implementation.

UNICEF is supporting Nutrition Interventions in some regions including Iringa and Njombe. The overall goal of the program is to support the Government of Tanzania to improve the

nutritional status of children, pregnant and lactating women in Tanzania, with specific focus on reducing maternal anemia and childhood stunting by at least 20% in Iringa, Njombe, and Mbeya Regions.

The ASRP's main approach to reduce stunting and anemia is through social and behavior change communication (SBCC). SBCC supports the prevention of malnutrition as well as the promotion and maintenance of good nutrition. It helps to build political and society-wide awareness and commitment to nutrition improvement. SBCC also enhances individual behaviors and household practices, promotes collective actions in communities, improves the delivery of nutrition counseling services and the demand for these services, and enhances the overall enabling environment for good nutrition outcomes. The proposed evaluation study seeks to employ stable isotope methods to track progress and effectiveness of SBCC in promoting exclusive breastfeeding in ASRP areas. Also, the influence of SBCC on child feeding practices and the overall nutritional status of children will be investigated., Key behaviours that have been promoted by ASRP include: seek and use reproductive health, family planning, antenatal and postnatal care Services; practice exclusive breastfeeding up to six months; and introduce appropriate, complementary feeding, while continuing breastfeeding up to 24 months; practice hand washing with soap and water at four critical times; clean home compounds, remove stagnant water, and wastage.

1.2 Infant and Young Child Nutrition Situation

Malnutrition, particularly under nutrition, which is reflected by stunting, underweight, wasting, micro-nutrient deficiency disorders continue to be among the major nutritional problems affecting infants and young children in Tanzania. According to TDHS (2015/16) 34 percent of children are stunted, 14 percent are underweight and 5 percent are wasted. Compared to TDHS 2005 and 2010, Tanzania has made progress in reducing child malnutrition. However, the prevalence of stunting is unacceptably high and remains a big challenge. Poor infant and young child feeding practices are among the most serious obstacles in attaining and maintaining their good health. Over 97 percent of mothers in Tanzania do breastfeed, however, the prevalence of exclusive breastfeeding in infants aged 0-6 months is less than 50 percent (TDHS, 2015/16). WHO (2003) recommends breastfeeding infants exclusively for the first six months of life and continued breastfeeding for two years along with complementary foods as one of key strategies for child survival. Exclusive breastfeeding (EBF) is defined as giving only breast milk to the infant, without mixing it with water, other liquids, herbal preparations or food in the first six months of life, with the exception of vitamins, mineral supplements or medicines (WHO, 2003). Current data shows that 59 percent of infants fewer than 6 months are exclusively breastfed, more than half (51%) were breastfed within 1 hour after birth and 14 percent were given prelacteal feed (TDHS-MIS 2015/16). The TDHS-MIS further indicates that 58 percent of children 6-59 months are anemic with haemoglobin less than 11.0g/dl. Twenty seven percent had mild anaemia, while 30 percent had moderate anemia. Only 2 percent were severely anaemic.

Early complementation is also a problem in Tanzania; at the age of 0-3 months about 15.6 percent of infants were given complementary foods. Only 10 percent of children aged 6 -23

months were fed in accordance with minimum acceptable standards with respect to IYCF feeding practices (TDHS-MIS 2015/16).

Normally, malnutrition rates increase between 6 and 18 months, the period of complementary feeding (Patel et al., 2012). In developing countries adequate nutrition is not met as a result of poverty, lack of nutrition knowledge, poor child feeding practices and infections which results in high morbidity and mortality. Inappropriate practices such as early or delayed introduction of complementary foods, low energy and nutrient density of foods offered, feeding thin consistency feeds and in small amounts and food restriction due to cultural beliefs are common (Ijarotimi Steve Oluwole, 2013).

3.0 Literature Review

3.1 Causes of stunting

In the widely-used UNICEF Conceptual framework, for example, early life child under nutrition is directly caused by disease and/ or inadequate dietary intake. In turn, these reflect four underlying causes, household food insecurity, inadequate care, unhealthy conditions and absence of access to health services (UNICEF 1990).Similar observations were made by Black et al (2013) who described causes of stunting into two major categories which are “distal” and “proximal” determinants of under nutrition. The team termed “distal” determinants as those encompasses socioeconomic and political factors, such as wealth status, race, region, and education level while “proximal” determinants are immediate and direct influences on health, including infectious illnesses, inadequate nutrient density and dietary diversity, poor dietary practices, and limited access to food.

According to Frongillo (1999) and Golden (2009) stunting often begins in utero due to poor maternal nutrition and continues during the first 2 years of life due in part to inadequate hygiene and infant and young child feeding practices, and reflects a failure to reach one’s genetic potential for height. Thus, focusing attention on the period before and during pregnancy and the first two years of life is the key to success in reducing or eliminating stunting in child’s life.

3.1.1Complementary Foods and Feeding Practices

Infants and young children are at an increased risk of malnutrition from six months of age onwards. However, children not exclusively breastfed are at high risk of malnutrition earlier. World Health Organization (WHO) and UNICEF recommends exclusive breast feeding for the first six months of life, followed by the introduction of complementary foods at six months with continued breast feeds until at least the age of two years(WHO 2001; WHO 2003). However, in many low and middle income countries, complementary foods are introduced too early or too late and the quality and of the foods is insufficient, leading to a great risk of nutritional deficiencies during the second half of infancy (Pelto et al., 2003). The early introduction of

complementary foods pre-disposes the infants to reduced protective benefits of the breast milk and reduces the benefit of a nutritional complete food. Also, the risks of microbial contamination as a result of poor hygiene that results to gastrointestinal infections are higher with complementary foods (Trowbridge, 2002).

Studies have demonstrated the importance of optimal nutrition in early childhood, particularly during the 'first 1000 days' of life (from conception to two years) (De Onis et al., 2013).Poor diet quality, and inadequate breastfeeding and complementary feeding practices are associated with growth faltering in children. Stewart et al. (2013) describe the period between 6 to 24 months as of particular importance, because children are no longer exclusively breastfed and are introduced to new and often inadequate complementary foods. From six months and beyond, breast milk alone does not provide adequate amounts of energy or nutrients to meet infants growing needs. Complementary foods in Tanzania like many African countries are made from cereal grains, or legumes that contain high amounts of anti-nutrients, such as phytic acid, that can inhibit the absorption of vitamins and minerals, particularly iron and zinc (Gibson et al., 2003). Also these foods are made into porridge that is thin in consistency (too watery) and therefore lack needed energy and many essential nutrients (Gibson et al., 1998) to meet the daily requirements for proper growth and development.

In Tanzania, poor infant and young child feeding practices are among important risk factors in undernutrition. According to TDHS (TDHS, 2015/16) over 97 percent of mothers in Tanzania do breastfeed, however, the prevalence of exclusive breastfeeding in infants aged 0-6 months is less than 60 percent. Similar findings were observed in National Nutrition survey (NNS 2014). These are the factors that contribute to under nutrition in Tanzania. Also from the TDHS 2010 data 81 percent of infants aged less than 2 months were on breast milk only, the proportion declined to 51 percent among infants at 2-3 months and 23 percent among those aged 4-5 months. Early complementation is also a problem of concern in Tanzania. At the age of 0-2 months about 11 percent of infants were given complementary foods, 33 percent at 2-3 months and 64 percent at 4-5 months (TDHS 2010).

3.1.2Water, Sanitation and Hygiene (WASH) and Nutrition

Among the underlying causes of under-nutrition are poor sanitary and hygiene conditions coupled to a lack of access to safe water. Diarrhoea, a consequence of poor WASH, is a leading cause of death in children, resulting in 8% of all under-five deaths globally (UNICEF/WHO/WB, 2015). Repeated episodes of diarrhoea contribute to under nutrition by hindering the absorption of nutrients. Children who are undernourished are also at high risk of suffering more frequent and severe episodes of diarrhoea, creating a vicious cycle (Mara et al., 2010). The World Health Organization estimates that 50% of under nutrition is associated with infections caused by unsafe water, inadequate sanitation or insufficient hygiene (WHO, 2008). Similarly, 25% of cases of chronic malnutrition can be attributed to children suffering five or more episodes of diarrhoea before the age of 2 years (Checkley et al. 2008). Poor sanitation is also a source of frequent infections caused by intestinal parasites (Ziegelbauer et al. 2012). Such infections can lead to anaemia, poor growth and impaired cognitive development.

In Tanzania, data from NNS SMART of 2014 indicated that hand washing practices using soap especially at critical times is a big problem among household's members. Only 11.7% of the interviewed household's members reported having used soap for hand-washing at least at two critical times during past 24 hours including after defecating.

3.2 Methods for assessing EBF

A standard method for assessing exclusive breastfeeding used in the DHS is 24 hours recall, where mothers/ caretakers are asked about breastfeeding practices in the past 24 hours preceding the survey (Agampondi et al., 2009; WHO, 2008).However, the *24-hour recall* method is subject to recall bias and tends to overestimate EBF prevalence compared to *recall since birth* method (Agampondi et al., 2009; Engebretsen et al., 2007; Aart et al., 2000). Also, DHS often report on the preceding 24 hour practice which may not be representative of breastfeeding practice over the first six month period. The introduction of water, teas and other foods early in life is common practice, and often this practice will not always be reported or detected in maternal recall information. International Atomic Energy Agency (IAEA), of which Tanzania is a member, has developed a method where deuterium oxide (which is a stable isotope) is used to accurately monitor the EBF status of the population (IAEA, 2010). This simple non-invasive technique makes it possible to measure the volume of human breast milk intake and to detect the introduction of other fluids, besides human milk in the diet of the infant and thus validating mothers/caretakers reports of EBF. The technique also enables the determination of mother's and child's body composition a variable that can be related to breastfeeding practice and breast-milk intake.

6. 0 Statement of the Problem

Stunting is a problem of public health significance in Tanzania affecting about 34% of children under the age of five. Although there is remarkable reduction in stunting, there is still a huge gap to be filled. Statistics shows that stunting rates continue to drop from 40% in 2005(TDHS 2005) to 34 per cent in2016 (TDHS 2015/16). The continuing decline can be attributed to government commitment to increase use of key health and nutrition interventions, such as high coverage of routine under-five immunizations, Vitamin A supplementation, and the use of insecticide treated bed nets and better drugs to treat malaria. Despite these improvements, children die every day of mainly preventable and treatable conditions.

Infant and young child nutrition is one of the priority areas in the National Multisectoral Nutrition Action Plan (NMNAP) which aims at reducing stunting in the country from the current 34 percent to 28 percent by 2021. The NMNAP is expected to also contribute to the Sustainable Development Goals (SDGs), specifically goal 2 on "zero hunger" aiming at ending all forms of malnutrition by 2030.

Current progress of reducing stunting in Tanzania is insufficient, and further investment and action are needed to reach the target of reducing the number of stunted children by 2025. Exclusive breastfeeding and adequate complementary feeding are key interventions for improving child survival, potentially saving about 20 per cent of children under five. As more

women engage in the practice of breastfeeding after realizing its importance, there are however, a large number of women who are still unaware, or who just ignore the practice.

The overall goal of the UNICEF Nutrition Program (ASRPP) is to support the Government of Tanzania to improve the nutritional status of children, pregnant and lactating women in Tanzania, with specific focus on reducing maternal anemia and childhood stunting by at least 20% in Iringa, Njombe, and Mbeya Regions. Assessing the impact of SBCC on rates of EBF is a challenge because it is based on mothers' self-reported behavior. Studies have shown the tendency of mothers to over-reporting rates of EBF (Haider et al., 2000). Stable-isotope method makes it possible to measure the volume of human breast milk intake and to detect the introduction of other fluids, besides human milk in the diet of the infant.

The aim of the proposed study is to measure breast-milk and non-breast-milk water intakes by using the dose-given-to-the mother (dose-to-mother) deuterium dilution technique and to validate reported exclusive breastfeeding in mother-infant pairs.

6. 1 Research questions

The following research question will be investigated:

- Does a social and behavioral change communication (SBCC) intervention affect the rates of exclusive breastfeeding (EBF) among children less than six months?

6.2 Hypothesis

Social and Behavioural Change Communication (SBCC) will positively affect the rates of exclusive breastfeeding.

7. 0 Main Objective

To monitor and evaluate the effectiveness of Social and Behavioral Change Communication (SBCC) interventions in increasing rates of exclusive breastfeeding

7. 1 Specific objectives

- To assess exclusive breastfeeding in children aged 3 - 6 months using dose to mother deuterium dilution technique.
- To validate mothers reports on exclusive breastfeeding using stable isotope techniques

8. 0 Methodology

8. 1 Study design

Study design

A cross-sectional study among lactating mothers who have been exposed to SBCC interventions and those who have not been exposed will be conducted in areas with and without SBCC nutrition interventions. The study will involve mother–infant pairs. Mothers will be interviewed to assess socio demographic data. Breast-feeding and complementary feeding practices will be assessed by interviewing the mother about current feeding practices and with a 24-hour recall. After the interview, anthropometric measurements from infants and mothers will be taken using standardized procedures and calibrated equipment. The study will then compare results of subjects from the districts with SBCC interventions against districts with no intervention.

Study Area

This study will be carried out in 4 districts from Iringa and Njombe regions respectively. Kilolo and Iringa DC (Iringa region) represent UNICEF project area where SBCC interventions have been carried out while Njombe DC and Wangingombe (Njombe region) represent 2 districts that do not implement the SBCC interventions.

Study Subjects

All mothers with infants aged from 3 to 5.9 months and attending the RCH postnatal clinics in Iringa DC, Kilolo, Njombe DC and Wangingombe districts.

8.2 Recruitment

Records from the RCH will be used to identify mothers who had had a baby in the last 6 months. Mothers of children who are currently aged from 3 to 5.9 months will be recruited to participate in the study

8.3 Sample size calculation

The sample size for this study will use a power calculation to determine the required number of participants in each group. The calculation is based on IAEA Human Health Series No. 7(IAEA, 2010). The sample size, n, in each group will be calculated by the following equation.

$$n = f(\alpha, \beta) . 2 \frac{\sigma^2}{\delta^2}$$

Where:

σ = Standard deviation, for this study, will be taken as 130g/d for human milk intake;

δ = the difference in means for human milk intake between intervention and control groups. This study assumes for 100g;

α = is significance level, here considered as 0.05;

β, Power = the study will use power of 80%;

$f(\alpha,\beta)$ = multiplication factor, for α=0.05 and β = 80%; the factor will be 7.85;

Therefore, the sample size for this study will be:

$$n = 7.85 \times 2 \times \frac{130^2}{100^2} = 27$$

Since this will be a cross-sectional study, we are taking into consideration individual non-response of up to 20% (i.e. that we will not be able to collect adequate saliva samples) due to various reasons. Therefore, this study will require at least 33 mother-baby pairs in each group to obtain statistically significant results.

8.3.1 Sampling procedures

The sample design for this study will involve two stage procedures. The first stage will be random selection of clusters for both intervention and control regions based on probability proportional to size. The second stage will be selection of households based on systematic random sampling where children aged 3 – 18 months meeting all inclusion criteria will be included in the study.

8.4 Inclusion criteria Exclusion criteria

Inclusion criteria

- Children aged 3 -18 months.
- Resident of the study area within health facility proximity
- Informed consent.
- Mothers who report practicing EBF

Exclusion criteria

- Sick children 7 days before the day of assessment
- Chronic diseases
- Ongoing medical treatment likely to affect body composition
- Those living outside the study area.

Recruitment Procedures

Mother infant pair will be enrolled from health facilities in the district. Briefly, a list of health facilities with Reproductive and Child Health (RCH) care clinic will be prepared. Two RCH care clinics one from rural and the other from urban setting will be randomly selected. Mother infant pair attending clinics for monthly growth monitoring will then be approached through the clinic in charge. These mothers will be introduced to the study and the purpose of the study will be explained to them. Mothers who will express interest will be enrolled into the study and they will be required to give informed consent.

8.5 Data collection and Research Instrument

Data collection will be performed at the selected village health facilities. A structured questionnaire designed using REDCap electronic data capture tools will be administered to the child's parents/guardian to collect information on socioeconomic and socio-demographic characteristics, living conditions of their child as well as health data and feeding pattern based on 24-hour recall dietary intake in the household. Questions will be in local language (Kiswahili) to facilitate communication with the mother. Breast-milk intake will be determined by using dose to mother deuterium dilution techniques. Anthropometric measurements will be performed in both the mother and her child following standard procedures. A team comprising investigators and medical personnel from the health facility will administer the questionnaire and conduct all the measurements.

8.6. Assessment of human milk intake by stable isotope technique

8.6.1 Dose preparation and storage

A standardized dose of deuterium oxide will be prepared according to IAEA guidelines (IAEA 2010). All mothers will be given 30g of Deuterium oxide regardless of their body weight. The doses will be packed in screw capped and leak proof, polypropylene bottles to avoid losses during storage and contamination by moisture from the atmosphere. Bottles will be labelled with a dose number and the date the dose was prepared. Doses will be made in batches and stored in a refrigerator until required.

8.6.2 Dose administration

Baseline saliva samples will be obtained from both the mother and her baby before the mother consumes the dose. Saliva collection and dose administration will be in accordance to IAEA guidelines (IAEA, 2010). Immediately after thorough mixing (by inverting) of the dose will be given to the mother through drinking with straw followed by additional 50 mL of drinking water.

8.6.3 Saliva sampling from the mother

Saliva samples will be collected and stored according to IAEA guidelines (IAEA, 2010). The procedure will be clearly explained to the mother before sampling. During saliva sample collection, mothers will not be allowed to eat or drink anything for at least half an hour before

collection. The mother will be given sterile cotton wool ball to soak up saliva. To facilitate soaking she will move it around her mouth for 2 min or until sodden. Cotton wool filled with saliva will be transferred directly into 20ml disposable syringe. Saliva will then be squeezed into 2ml storage cryovials. Sample vials will be stored in zip-lock bags to prevent cross-contamination between participants, and between pre-dose and post-dose specimens. Saliva sampling will be done before giving the dose as baseline. Post-dose saliva samples will be collected on next day 1, 2, 3, 4, 13, and 14 following the schedule in Table 1 below.

8.6.4Saliva sampling from the Baby

Saliva samples will be collected hygienically at least 15 minutes after last breast milk intake. Saliva will be sampled using a cotton wool swab. The swab will be moved around the baby's mouth until the cotton wool is sodden. The cotton wool from the sodden swab will be removed and placed in the barrel of the 20 mL syringe and squeezed with plunger to collect the saliva sample. It may take several attempts to collect the required volume (minimum 2 mL). The vial will be stored as explained in IAEA guidelines (IAEA, 2010). Baseline saliva sampling in infants will be done before dosing the mother with Deuterium oxide. Post-dose saliva samples will be collected on next day 1, 2, 3, 4, 13, and 14 with her/his mother following the schedule in the Table 1 below.

Table 1. Enrolment and Follow-Up Schedule for Exclusive Breast Feeding In Mothers and Their Infants

No of Visit	Week days	Number of enrolment pairs	Number follow-up pairs	Total subject pairs
-	*Monday*	Courtesy call & preparations		
Day 0	*Tuesday*	20	0	20
Day 1	*Wednesday*	6	20	26
Day 2	*Thursday*	6	26	32
Day 3	*Friday*	Enrollment for missed pairs	32	32
Day 4	*Saturday*	0	32	32
Day 5	*Sunday*	0	12	12
Day 6	*Monday*	0	6	6
Day 7	*Tuesday*		Follow-up for missed pairs	
Day 8	*Wednesday*	Courtesy call and logistics for the next district		
Day 9	*Thursday*			
Day 10	*Friday*			
Day 11	*Saturday*	resting		
Day 12	*Sunday*	Preparations for next follow-ups		
Day	*Monday*	0	20	20

13				
Day 14	***Tuesday***	0	26	26
Day 15	***Wednesday***	0	12	12
Day 16	***Thursday***	0	6	6
Day 17	***Friday***	0	Follow-up for missed pairs	

8.6.5 Storage of Saliva Samples in the Field and at the Laboratory

A total of 7 samples from each mother and 7 samples from her baby will be collected. Saliva sample vials from each mother–baby pair will be stored together in zip-lock bags to prevent cross-contamination between participants, and between pre-dose and post-dose specimens. The participant's identification number will be written on both the sample vials and the zip-lock bags. Saliva samples will be stored in a cool box temporarily in the field before long term storage in the freezer at -20^0C until analysis.

8.6.6Laboratory analysis

Laboratory analysis will be done based on method developed by IAEA 2010. Under this method body composition is calculated after estimation of total body water to the mother and her baby by deuterium dilution technique. The instrument used for measurement of deuterium enrichment in the sample is Fourier Transform Infrared Spectrophotometer (FTIR). The instrument should be calibrated using the 1000 mg/kg (ppm) standard. The accuracy of deuterium analysis over the range of enrichments to be measured should be checked using gravimetrically prepared standards.

8.6.6.1 Preparation deuterium oxide standard for FTIR calibration

Larger volume (normally 1 litre) of calibrating standard solution of approximated concentration of 1000 mg/kg (ppm), or 1 g/L will be prepared by weighing 99.8 at% Deuterium Oxide (manufactured by sigma Aldrich and supplied by Sercongroup UK) and diluting it with normal drinking water. The same drinking water will serve as a zero standard. Actual enrichment of calibrating standard will calculated and recorded before storage for further use. Calibration standard will be stored in a tightly closed container that will be placed in a cool dark place out of direct sunlight

8.6.6.2 Preparation ofD_2O enrichment standard curve

Standard curve used for checking accuracy of deuterium analysis will be prepared using volumes (100ml) of enrichment standards ranging from 0 (natural abundance in drinking water) to 2000 mg/kg.The different concentrations of enrichment standards will be prepared following the same procedure for preparation of calibrating standard above. The actual enrichment (mg/kg) for each standard will be calculated from the weights as described above. The measured enrichments against calculated enrichments of the standards will be plotted to make the standard curve. If the

gradient of the calibration curve is not close to 1, the data input will be checked or procedure will be repeated using new standards to rule out problems associated with the weighing, calculations and analysis.

8.6.6.3 Measurement of deuterium enrichments of the samples with FTIR

The instrument that will be used for measuring enrichments of samples and standards is Agilent 4500t FTIR using Micro Lab® operation software. The instrument will be operated according to instrument instructions and software operation manual customized in TFNC laboratory SOP. Ideally, the instrument is provided with a dedicated sample receptacle accessory called the Tumbler for analysis. . The TumblIR makes it much easier to prepare, load, analyze and clean the sample. The alignment of the accessory is pre-set at the factory and so there is no need of adjustments. The instrument will be warmed up (30min) before performance test. After ensuring performance check the instrument is cleaned then background spectrum is collected followed by collection of sample spectrum.

8.6.6.4 Quality control and qualityassurance

The performance test is conducted before sample analysis to ensure the instrument is running properly. The instrument provides both diagnostic values and performance validation tests to demonstrate the system's performance. The diagnostic values provide quick assessment of the instrument's function. This assessment is done daily before sample analysis. If the instrument is not functioning properly, one of the diagnostic values will be out of specification i.e. the instrument is operating outside of the factory-defined parameters. The 'Performance validation' checks the instrument's is done bi-annually to ensure sensitivity (performance), stability and frequency precision (laser calibration).TFNC will participate in IAEA FTIR Interlaboratory test which will provide external quality assurance check for the results.

8.6.6.4. 1Isotopic Fractionation and control measures

Deuterium oxide (^2H_2O) is not chemically identical to water since the bond between ^2H and O is slightly shorter than the bond between ^1H and O. The energy of the bond between ^2H and O is slightly greater than the energy of the bond between ^1H and O. This can lead to isotopic fractionation when water undergoes a chemical or physical change such as evaporation. Isotopic fractionation of water is common when water liquid becomes water vapour.

To minimise fractionation the following measures will be taken:

- vials must have a good seal to prevent loss of sample and ingress of moisture from the atmosphere during storage
- If previously frozen, the dose must be completely thawed before use
- dose bottle should be inverted to mix in any condensation on the lid before removing the lid
- the lid must not be removed until the mother is ready to drink the dose
- Do not leave bottles open to the atmosphere, especially in warm humid climates

8.6.6.5 Calculations for body water

Intake of human milk by the baby is calculated from the disappearance of ^{2}H from the mother and its appearance in the baby.Intake of human milk and water from sources other than human milk will be calculated by fitting the deuterium enrichment data to the formulas derived in two compartment steady state models for water turnover in the mother and in the baby. The models and assumptions were described in detail by Coward, W.A., et al., (1982) and repeated by Haishma et al. (2003).
After drawing the isotope elimination curve (log/linear plot of enrichment of deuterium in body water versus time) water turnovers will be calculated.

Water turnover in the mother will decrease exponentially overtime and is given by a single exponential equation:

$$\frac{E_{m(t)}}{E_{m(0)}} = e^{-k_{mm}t}$$

Where

Em(t) is the deuterium enrichment in the mother's body water at time t, in mg/kg or ppm;

t is the time since the dose was taken, i.e. time post-dose in days;

Em (0) is the deuterium enrichment in the mother's body water at time zero mg/kg (ppm), i.e. the y intercepts of the isotope elimination curve (log/linear plot of enrichment of 2H in body water versus time)

kmm is the fractional water turnover in the mother (kg/d), i.e. the gradient of the isotope elimination curve

Water turnover in the baby will decrease exponentially over time and is fitted to the following multi-exponential model:

$$E_{b(t)} = E_{m(0)}\left(\frac{F_{bm}}{V_b}\right)\left(\frac{e^{-k_{mm}t} - e^{(F_{bb}/V_b)t}}{(F_{bb}/V_b) - k_{mm}}\right)$$

Where

Eb (t) is the deuterium enrichment in the baby's body water at time, t, in mg/kg (ppm);

tis the time since the dose was taken by the mother, i.e. time post-dose in days;

Em(0) is the deuterium enrichment in the mother's body water at time zero mg/kg (ppm), i.e. the y intercept of the mother's isotope elimination curve (log/linear plot of enrichment of 2H in the mother's body water versus time)

Fbm is the transfer of water from the mother to the baby via human milk (kg/d);

Vb is the baby's total 2H distribution space (kg). Vb is assumed to change linearly with initial and final values determined from the baby's weight (W, kg). *Vb* = 0.84 W0.82 [15];

kmm is the fractional water turnover in the mother (kg/d), i.e. the gradient of the mother's isotope elimination curve

Fbb is the total water loss in the baby (kg/d).

Curve fitting and calculation of end points will be performed using the 'Solver' function in Microsoft Excel provided at http://elearning.iaea.org

8.6.6.6 Safety and security measures

Deuterium Oxide used does not emit potentially harmful radiations and is free from microbes. The amount of deuterium consumed in this kind of study is far less to toxicity level of 15%. However, extra measures will be taken to ensure no accidental consumption of above the recommended safety levels. Deuterium oxide waste will be handled and disposed according to material safety data sheets. Deuterium Oxide dose will be prepared hygienically and administered by well trained staffs to minimize any possible health risks due to cross contamination. Samples will be stored -20^{o}C after collection and during analysis while records will be stored in a locked metal cabinet. Records and samples will be maintained at TFNC for five years after completing the study before destruction by incineration.

8.6.7 Measuring weight and height/length

Anthropometric measurements for the mother and her infant will be performed following standard procedures. Mothers will be asked to empty their bladder (and if possible bowels) before being weighed, in minimal clothing. Weight and height/length will measured at the baseline and again on Day 14 to make sure that it has not changed substantially. The mother's weight will be measured to the nearest 0.1 kg using electronic scale while height will be measured to the nearest 0.1 cm using a stadiometer. Weight and height will be recorded on the mother's information sheet.

The baby's weight will be measured using electronic baby scale to the nearest 0.01kg. The baby's length will be measured using a measuring board (sometimes called an infantometer). Weight and length will be measured at the baseline and again on Day 14.

Nutritional parameters of Length/height-for-age (LAZ), weight-for-height (WLZ) and weight-for-age (WAZ) Z-scores will be computed using World Health Organizations' (WHO) Anthro software. Children will be classified as stunted, wasted or underweight. Stunting will be defined as a height-for-age z score < -2 standard deviations (SD) (severe stunting, <-3 SD), under-weight

will be defined as WAZ < - 2 SD (severe under-weight, < - 3 SD), and wasting will be defined as WHZ < - 2 SD (severe wasting, < - 3 SD).

8. 7 Nutritional knowledge, attitudes, and practices

Nutritional knowledge
Questions will be asked to the mothers to assess the nutritional knowledge. These will include: (a) participation in training on nutrition for infants and children and women (b) correct definition of good nutrition, (c) knowledge of dietary recommendations for vulnerable groups and (d) knowledge of the relationships between diet and disease, including the consequences of poor nutrition.

Attitude on nutrition
Mothers will be asked four questions to assess their attitudes towards nutrition recommendations for infants and children. These will include their thoughts about the importance and usefulness of (a) eating various foods, (b) consumption of fruits and vegetables, (c) increasing meal frequency, and (d) consumption of special diets.

Dietary practices
Five aspects of dietary consumption patterns will be used for assessing the dietary practices of the mothers: (a) number of meals consumed in the preceding 24 hours to the survey, and (b) number of food-groups consumed. The foods reportedly consumed in the preceding 24-hour recall will be grouped in 12 food-groups: cereals, roots/tubers, legumes, milk/milk products, fish, poultry, meat, eggs, fruits, vegetables, oils/fats, and sugar/honey), (c) reported consumption of special diets, (d) portioning of meals within the household, and (e) Food taboos.

8. 8. Statistical analysis

Data will be analyzed using STATA version 14.0 (StataCorp. US). Descriptive statistics will be run. Frequencies for nominal variables and means with their standard deviations for continuous variables will be provided. Emergency Nutrition Assessment for Standardized Monitoring and Assessment of Relief and Transition (ENA for SMART) will be used to convert raw anthropometric data (weight, height and age of the children) into anthropometric Z-scores that will be used to classify children into levels of nutritional status (stunting, wasting and underweight/overweight). The classification of the nutritional status will be done according to the WHO cut-off points recommended by the World Health Organization. The z-score data will then be transferred to STATA/SPSS to be analyzed with other variables.

Associations between feeding practices and sociodemographic variables as well as between feeding practices *and nutritional status* will be determined using chi-square test.
Comparisons between infant and maternal characteristics in each feeding pattern category and differences between breast milk and non-breast milk water intakes among groups will be done using Student t test. The validity of a test is defined as its ability to distinguish between those

with a disease and without. In this case, we will be able to identify the ability of dietary instruments to distinguish between infants that are exclusively breast-fed or not. Sensitivity is defined as the ability of the questionnaire to identify correctly those who are exclusively breast-fed, whereas specificity is defined as the ability of the questionnaire/instrument to identify correctly those infants who are not exclusively breast-fed.
To validate reported breastfeeding practices against the classification based on the dose to mother (dose-to-mother) deuterium dilution technique (reference method), we will calculate sensitivity, specificity, and predictive values with their respective 95% confidence intervals. Significance will be considered at p value < 0.05.

8.9Project Administration Plan

This is a collaborative research project that will involve four institutions: Ministry of Health, Social development, Gender, Elderly and Children, Tanzania Food and Nutrition Centre and UNICEF -Accelerating Stunting Reduction Program (ASRP). Ministry of Health will be the lead institution. It will be responsible for administrative aspects covering management of grants and research coordination while Tanzania Food and Nutrition Centre will be responsible for laboratory analysis for EBF, complementary feeding practices and nutritional aspect of the project. Evaluation of the effectiveness of SBCC interventions will be done using stable isotope techniques with the support from the International Atomic Energy Agency (IAEA) Vienna, Austria and the Government of Tanzania.

Elizabeth Proscovia Ndaba is a Nutritionist working in Nutrition Section, Ministry of Health, Community Development, Gender, Elderly and Children, Tanzania. She holds MSc in Human Nutrition from Michigan State University USA. She has experience in designing and implementing nutrition programs at district and national level. In the proposed study she will be Principal Investigator and will be responsible for the study administration in collaboration with Co-PI from TFNC. She will also participate in the scientific aspect of the study.

Justin Ngaileis a Radiation Health Physicist at the Tanzania Atomic Energy Commisson. He holds PhD in Medical Radiation Physcics from University of Dar es Salaam, Tanzania. He has experience in health research. In the proposed study he will be Co-Principal Investigator and will participate in the scientific and administrative aspects of the study.

Elifatio Towo is the acting Director Department of Food Science and Nutrition at TFNC. He holds PhD in food biotechnology from the University of Chalmers, Sweden and MSc in food chemistry from the University of Gothenburg, Sweden. He has expertise in infant feeding and food fortification and experience in assessment of nutritional status, interventions on prevention and control of micronutrients deficiencies, food processing, and food product development. He will be Co-Principal Investigator and will participate in the scientific aspect of the study.

9.0Project team members and their roles

Michael Magangais an experienced technician. He holds an Advanced Diploma in Medical Technology from Muhimbili University of Health and Allied Sciences. He has also attended short courses on the application of isotopic techniques in determining body composition and Breast milk feeding intake. He will be responsible in administering stable isotopes and analysis of saliva samples using FTIR. In addition, he will be responsible in sample storage and monitoring laboratory equipment.

Tedson E. Lukindo is a Biochemist. He holds MSc in Life sciences and Bioengineering. He has experience in health research and he has participated in performing immunodiagnostic tests and determining drug resistance in malaria. He has experience in using stable isotope techniques to assess body composition in children and adults. In the proposed study he will participate in the scientific aspect of the study and in collecting and analyzing saliva samples for deuterium enrichment using FTIR.

Kaunara A. Azizi is a Microbiologist. He holds MSc in Microbiology and Immunology. He has experience in health research and in analyzing microbial contaminants in foods, feeds and in body fluids. He has experience in using stable isotope techniques to assess body composition in children and adults. In the proposed study he will participate in the scientific aspect of the study and in collecting and analyzing saliva samples for deuterium enrichment using FTIR.

Francis K. Milinga is a Biochemist. He holds MSc in Biochemistry. He has experience in health research and in analyzing in body fluids. He has experience in using stable isotope techniques to assess body composition in children and adults. In the proposed study he will participate in the scientific aspect of the study and in collecting and analyzing saliva samples for deuterium enrichment using FTIR.

EpimakSauli is a Nutrition Epidemiologist. He holds MSc in nutritional epidemiology. He has experience in nutritional research, and he has participated in Tanzania Demographic Health Surveys in both data collection and analysis. In the proposed study he will participate in the scientific aspect of the study particularly data analysis

10.0 Ethical Considerations:

A set of ethical principles that have been laid out to guide the execution of scientific research, studies (CIOMS, 2002) will be adhered to. These include individual informed consent, confidentiality of the information collected, protection of vulnerable groups and equitable distribution of burden and benefits of the interventions.

10.1 Information to the subjects

Before conducting the study, investigators will meet with stakeholders in the area designated for the study to explain the purpose of the study, objectives, methods, benefits and risks, right to abstain from participation in the study and right to terminate at any time from the study. Based on this information, parents/guardians will be able to make decisions on whether to allow their children to participate in the study or not.

10.2 Confidentiality

Strict confidentiality will be maintained. Efforts will be made to ensure that participation in this study will only be known to the researchers who will be obliged to abide strictly with the study ethics. In the event of a breach in confidentiality, appropriate disciplinary measures will be undertaken to the responsible person. Participants will not be identified in any reports or publications of this study. However, the overall study results may be shared with members of the scientific community at large and will become a matter of public record.

10. 3 the use of stable isotopic techniques

Stable isotopes are safe to use and do not present radiation hazards. They are naturally present in all biological materials such as foodstuffs that we eat; for example maize, bread, tomato, rice and sugarcane. Also, the application of stable isotopes does not require special environment for use or disposal. Deuterium is the only stable isotope that is going to be used in this study; it does not require invasive method of administration, and it is taken orally.

10. 4 Compensation

There will be no special incentives to the research participants such as allowances or stipends for participating in the study. However, there will be transport reimbursement.

10. 5 Use of Anthropometric methods for nutritional status assessment.

Anthropometric methods are relatively non-invasive methods that assess the size an individual. The measurements do not subject the participant to any danger.

10. 6 Enrolment

Enrollment to the study will be voluntary and each mother will be required to provide informed consent.

10. 8 Beneficiaries of the project

The beneficiaries of the project will include:

- Brest feeding women
- Policy makers on public health programmes.
- The Community
- Research institutions and NGOs working on children programmes.
- Public health stakeholders.

10. 9 Dissemination Plan

Findings of this study will be disseminated in three types of fora, at villages which were involved in the study, District Health Management Team, National and International Conferences and as publications in scientific journals.

11. 0 Budget

The total budget for the proposed study is as shown below for each component and the detailed budget is shown in appendix 6.

Summary of the budget for Implementing project INT 6058

Pre-study activities in Iringa and Njombe	5,118,000
Data collection in Iringa DC and Kilolo in Iringa	35,575,000
Data collection-Njombe DC and Wanging'ombe in Njombe	40,620,000
Data analysis, saliva samples analysis and report writing	11,000,000
Grand Total	**92,313,000**

12. 0 Study Activities and Timeline

No	Activity	2019					2020							
		Feb-April	May-e	July-Sept	Nov	Dec	Jan	Feb	Mar	April	May	Jun	Jul	Aug
1.	Submission of proposal to Research and Ethics Committee (REC – NIMR)													

2.	Iringa and Njombe: Training of Research Assistants and Recruitment of participants													
3.	Data collection in Kilolo													
4.	Data collection in Iringa DC													
5.	Data collection in Njombe DC													
6.	Data collection in Wanging'ombe													
7.	Data Analysis and Report writing													
8.	Dissemination of Results													
9.	Project Closure													

13. 0 References

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ANNEX 1: Questionnaire in English

Project INT6058"Contributing to the evidence base to improve stunting reduction programmes"

Questionnaire for collecting data for the Sub-project titled: "Using stable isotope techniques to evaluate effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Dodoma region, Tanzania".

Questionnaire No._____

CONFIDENTIAL

All information collected in this study is strictly confidential and will be used forProject purposes only

PART 0: IDENTIFICATION INFORMATION

Mother – baby pair ID…….

Name of mother……..

Name of the baby……

Name of the District…….

Name of the Ward…….……..

Name of the Health Facility……. …….

Name of the Interviewer……..

Date of interview……..……

PART A: SOCIO-DEMOGRAPHIC DATA

(Interviewer: The following questions should be asked to the mother)

Q1. How old are you?	Years ☐
Q2. Please tell me the sex of your child	1 = M 2 = F ☐
Q3. Please tell me the name and date of birth of the child involved in this study	Name: _____ ____/____/_____

	(dd/mm/yyyy)
Q4. Please tell me about your marital status(tick the appropriate response)	1. Never married ☐ 2. Married/co-habiting ☐ 3. Separated ☐ 4. Divorced ☐ 5. Widowed ☐
Q 5. Have you ever attended school?	0 = No 1 = Yes ☐
Q 6. If yes, what is the highest level of school you attended(tick the appropriate response)	1. None ☐ 2. Primary (did not complete) ☐ 3. Primary (completed) ☐ 4. Secondary (did not complete ☐ 5. Secondary (completed) ☐ 6. College ☐ 7. University ☐
Q 7. What is your main occupation?(tick the appropriate response)	1. Unemployed ☐ ~~2. Self employed~~ ☐ 3. Casual work ☐ 4. Wage employed ☐ 5. Subsistence farmer ☐ 6. Cash crop farmer ☐ 7. Artisan ☐ ~~8. Housewife~~ ☐

Q 8. Has the father of your child attended school?	0 = No Skip to Q10 1 = Yes ☐
Q 9. If yes, what is the highest level of school he attended(tick the appropriate response) –	1 None ☐ 2 Primary (did not complete) ☐ 3 Primary (completed) ☐ 4 Secondary (did not complete ☐ 5 Secondary (completed) ☐ 6 College ☐ 7 University ☐
Q 10. What is the main occupation of the father of your child? (tick the appropriate response)	1. Unemployed ☐ 2. Self employed ☐ 3. Casual work ☐ 4. Wage employed ☐ 5. Subsistence farmer ☐ 6. Cash crop farmer ☐ 7. Artisan ☐
PART B: INFANT AND YOUNG CHILD FEEDING PRACTICES Next I would like to ask you some questions about the health and feeding of (NAME) including what liquids or foods he/she might have had yesterday.	
Q 11. Did you ever breastfeed (NAME)?	0= No 1 = Yes ☐
Q 12. If yes, how long after birth did you first put (NAME) to the breast?	If Hours, enter code 1. If Days, enter code 2. ☐ Days or Hours or '00' 77 = Don't Know ☐☐
Q 13. During the first three days after delivery, did you give (NAME) the first liquid that came from your breasts (colostrums)?	0 = No 1 = Yes ☐☐ 77 = Don't Know

Q 14. In the first three days after delivery was (NAME) given anything to drink other than breast milk, such as other milk, tea, traditional medicine, sugar water or plain water?	0 = No/ 1 = Yes ☐☐ 77= Don't Know
Q 15. Are you still breastfeeding (NAME)?	0 = No ☐ 1= Yes
Q 16. If no, for how many months did you breastfeed (NAME)?	_____Months
Q 17. Did (NAME) drink anything from a bottle with a nipple yesterday or last night?	0 = No 1 = Yes ☐☐ 77 = Don't Know
Q 18. At any time yesterday or last night has (NAME) received any of the following?(tick appropriate responses)	1. Breast milk?..... ☐ 2. Plain water?…… ☐ 3. Sweetened water, juice or fruit juice, soda (carbonated Drinks/Fanta?..... ☐ 4. Soup broth?..... ☐ 5. Infant formula?..... ☐ 6. Tinned, or powdered milk?..... ☐ 7. Fresh milk?..... ☐ 8. Dilute porridge/beverage made from grains (e.g. sorghum, maize.etc)?..... ☐ 99. Any other liquids e.g. tea, coffee, infusions, fermented drinks? –Specify:_____ ☐
Q19. Has (NAME) started receiving any semisolid or mushy food such as porridge or potage?	0 = No 1 = Yes ☐
Q20. If yes, at what age did (NAME) start receiving semi-solid food such as porridge?	Months 77 = Don't Know ☐☐

Q21. In the last 24 hours, how many meals and snacks did (NAME) eat in additional to breast milk?	Number of non-breast milk meals ☐ Number of non-breast milk snacks ☐ 77 = Don't Know ☐
Q22. Does (NAME) eat from his/her own separate bowl?	0 = No 1 = Yes ☐
Now I am going to ask you about the foods (NAME) consumed yesterday and I want to know whether he/she consumed the food whether eaten on its own or combined with other foods at any time during the day or night.	
Question 23	**Foods consumed yesterday?**
a). Porridge (made from a single or mixed grain)	0= No 1= Yes ☐
b) If yes, what was the thickness?	1 = Thin: e.g. like soup/drink 2 = Medium: Not thick enough to stay on a spoon ☐ 3 = Thick: Thick enough to stay on a spoon
c) Noodles, rice, bread, maize, wheat, sorghum, millet or other staple foods made from grain	0 = No 1= Yes ☐
d) Potatoes, cassava, yams white sweet potatoes or other white root vegetables	0=No 1= Yes ☐
e) Commercial infant or young child cereal (from a box, tinetc)	0= No 1= Yes ☐
f) Green leafy vegetables such as spinach, cassava leaves (kisamvu), or amaranth (mchicha)	0= No 1= Yes ☐
g) Pumpkin (squash), carrots yams, yellow sweet potatoes	0= No 1= Yes ☐
h) Ripe mangos or papayas	0= No 1= Yes ☐
i) Other vegetables or fruits e.g. bananas, tomatoes, tree tomato, passion fruit, pineapple, green mango	0= No 1= Yes ☐
j) Liver, kidney, heart, other organ meats	0=No 1= Yes ☐
k) Meat (beef, pork, lamb, goat), poultry (chicken or other birds)	0=No 1= Yes ☐
l) Fresh or dried fish	0=No 1= Yes ☐
m) Small dried fish or Sardines	0=No 1= Yes ☐

n) Eggs	0=No 1= Yes ☐
o) Beans, peas , soya, groundnuts	0=No 1= Yes ☐
p) Oil or fat or foods made with these	0=No 1= Yes ☐
q) Red Palm oil	0=No 1= Yes ☐
r) Sugar/sweet snacks (e.g., biscuits, mandazi, etc.)	0=No 1= Yes ☐
s) Milk, yogurt, cheese or other foods made from milk	0=No 1= Yes ☐
t) Any other solid or semi-solid /mushy food?	0= No 1= Yes ☐ Specify: _____
Now I would like to ask some questions about the health of (NAME)	
Q24. Has (NAME) had diarrhea, (this means 3 or more times a day of loose stools) in the past 2 weeks?	0 = No 1 = Yes ☐☐ 77 = Don't Know
Q25. Was (NAME) given the same amount to drink as before the diarrhea, or more, or less?	1= Same 2= More ☐☐ 3= Less 77= Don't know
Q26. Was (NAME) given the same amount of food to eat as before the diarrhea, or more or less food?	1= Same 2= More ☐☐ 3= Less 77= Don't know
Q27. Did you seek advice or treatment for the diarrhea?	0 = No 1 = Yes ☐
Q28. If yes, where did you seek advice (or from whom)?	**Health Facility:** a. Public Hospital ☐ b. Private Hospital ☐ c. Health center/health post ☐ d. Private Clinic ☐ e. Outreach/mobile clinic ☐

	f. Other – Specify: _____ ☐
	Community: g. Midwife ☐ h. TBA/traditional healer ☐ i. CHW ☐ j. Mother support group ☐ k. Pharmacist ☐ l. Friend ☐ m. Relative or neighbor ☐ o. Mother or mother-in-law ☐ p. Other – Specify: _____
Q29. Has (NAME) been ill with a fever at any time in the past 2 weeks?	0 = No 1 = Yes ☐☐ 77 = Don't Know
Q30. Has (NAME) been ill with a cough at any time in the past 2 weeks?	0 = No 1 = Yes ☐☐ 77 = Don't Know
Q31. Has (NAME) received a Vitamin A capsule within the past 6 months?	0 = No 1 = Yes ☐☐ 77 = Don't Know
PART E: MOTHER'S KNOWLEDGE AND ATTITUDES	
Q32. Has the Community Health Worker ever talked to you about breastfeeding your child?	0 = No ☐ 1 = Yes
Q33. Can you tell me until what age a baby **should** receive *only* breast milk, that is, no other food, water or teas?	Months ☐☐ 77 = Don't Know
Q34. Has the Community Health Worker ever talked to you about complementary feeding?	0 = No ☐ 1 = Yes

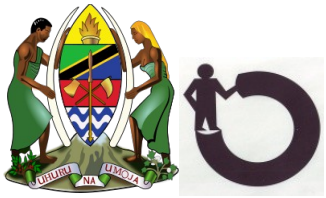
Q35. How many meals and snacks per day should a child eat other than breast milk? PLEASE MAKE SURE TO ASK ABOUT BOTH MEALS AND SNACKS IN EACH AGE GROUP (a, b, c)	Meals: Snacks: a) 6-8 months old? # times ☐ ☐ b) 9-11 months old # times ☐ ☐ c) 12-24 months old # times ☐ ☐
Q36. Have you ever heard of a condition called anaemia?	0 = No 1 = Yes ☐
Q37. Can you identify some signs that a child has anaemia?	0 = No 1 = Yes ☐
Q38. If yes, please tell me some of the signs that a child has anaemia. (prompt for more)	1. White/pale eyes, nails, hands ☐ 2. Feeling faint ☐ 3. Oedema ☐ 4. Weight loss ☐ 5. Hair changes colour (goes blond, red, ect) ☐ 6. Apathy (child doesn't play) ☐ 7. Other – Specify: _____
Q39. Do you know of any foods that are high in iron?	0= No 1 = Yes ☐
Q40. If yes, tell me some of the foods that are high in iron. (prompt for more answers)	1. Liver, kidney, heart, other organ meats ☐ 2. Meat (beef, pork, lamb, goat), poultry (chicken or other birds) ☐ 3. Green leafy vegetables such as spinach, cassava leaves (kisamvu), or amaranth (mchicha) ☐ 4. Fresh fish ☐ 5. Small dried fish ☐ 6. Other vegetables or fruits e.g. bananas, tomatoes, tree tomato, passion fruit, pineapple, green mango ☐ 7. Eggs ☐ 8. Milk ☐ 9. Others – Specify: _____
Q41. Have you heard that you can buy some foods that have vitamins and minerals such as iron already added to them?	0= No 1 = Yes ☐

Q42. If yes, what are some examples of foods with vitamins or minerals such as iron already added? (prompt for more)	1)_____ 2)_____ 3)_____
PART C: HYGIENE AND SANITATION	
Q 43. What is the main source of drinking water for your household in the dry season?	1= Piped water (into dwelling/compound/plot) 2= Public tap 3= Open public well 4= Covered public well 5= Pond/river/streams /lake/spring 6= Rain Water harvesting 7= Water tank 8= Bottle water 99=Other–Specify: _____
Q 44. What is the main source of drinking water for your household in the rainy season?	1= Piped water (into dwelling/compound/plot) 2= Public tap 3= Open public well 4= Covered public well 5= Pond/river/streams /lake/spring 6= Rain Water harvesting 7= Water tank 8= Bottle water 99= Other – Specify: _____
Q 45. Do you treat your water in any way to make it safer to drink?	0 = No 1 = Yes
Q 46. If yes, what do you usually do to the water to make it safer to drink?	1= Boil 2= Add bleach/chlorine (water guard)

	3= Strain it through a cloth ☐☐ 4= Use water filter (ceramic, sand, composite, etc.) 5= Solar disinfection 6= Let it stand and settle 99= Other – Specify: _____ 77= Don't know
Q 47. Do you wash your hands with soap?	0 = No 1 = Yes ☐
Q 48. If yes, when do you wash your hands with soap?	1. Before preparing/handling food ☐ 2. Before feeding children ☐ 3. Before eating ☐ 4. After preparing food 5. After field work/cleaning ☐ 6. After changing babies/cleaning child who has Defecated ☐ 7. After eating ☐ 8. After defecating/using toilet facility ☐ 9. While washing rest of body ☐ Other–Specify: _____
Q 49. Do you wash your children's hands with soap?	0 = No 1 = Yes ☐

Q 50. If yes, when do you wash your children's hands with soap?	1. Before they eat 2. After they eat ☐☐ 3. After they defecate/use toilet facility 4. While washing rest of the body 99. Other – Specify: _____
Q 51. Does your household have any mosquito nets that can be used while sleeping?	0 = No 1 = Yes ☐
Q 52. Did anyone sleep under this mosquito net last night?	1 = Yes ☐☐ 0 = No 77 = Don't know
Q 53. Who slept under this mosquito net last night?	1. Child NAME)?..... ☐ 2. Mother of (NAME)…….. ☐ 3. Husband/father of (NAME)..... ☐ 4. Older siblings..... ☐ 5. Younger siblings?..... ☐ 6. Grandmother?..... ☐ 7. The whole family?..... ☐ 8. Other family members?..... ☐ 99. Other – Specify: ☐

ANNEX 2: Questionnaire in Kiswahili



Project INT6058"Contributing to the evidence base to improve stunting reduction programmes"

Questionnaire for collecting data for the Sub-project titled: "Using stable isotope techniques to evaluate effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Dodoma region, Tanzania".

NambayaDodoso_____

SIRI
Taarifazotezitakazokusanywakwenyeutafitihuunisirinazitatumikakwenyeutafitihuutuu

SEHEMU 0: TAARIFA ZA UTAMBULISHO
Mama na mtoto – Nambaya Utambulisho…….
Jina la mama…….
Jina la mtoto……
Wilaya…….
Kata……..……..
Jina la Kituo cha Huduma ya Afya……. ……..
Jina la Mhojaji …….
TareheyaUsahili……..……

SEHEMU A: DATA YA SOCIO-DEMOGRAPHIC *(Interviewer: The following questions should be asked to the mother)*	
Q1. Je, una umrigani?	Miaka ☐
Q2. Tafadhali niambie, mtoto wako niwa jinsiagani?	1 = Me ☐ 2 = Ke
Q3. Tafadhali niambie jina la mtoto wako na tarehe ya kuzaliwa	Jina: _____ ____/____/_____ (siku/mwezi/mwaka)
Q4. Tafadhali niambie hali ya ndoa yako (Weka alama ya vema kuonyesha jibu)	1.Sijaolewa ☐ 2.Tunaishi kinyumba ☐ 3.Tumetengana ☐ 4.Tumeachana ☐ 5.Mjane ☐
Q 5. Je, umewahikwendashule?	0 = Hapana 1 = Ndiyo ☐
Q 6. Kama jibuniNdiyo, nikiwangogani cha juu cha elimuuliyofikia? (Weka alamayavemakuonyesha jibu)	8. Hakuna ☐ 9. Msingi (Lakinisikumaliza) ☐ 10. Msingi (nilimaliza) ☐ 11. Sekondari (sikumaliza) ☐ 12. Sekondari (nilimaliza) ☐ 13. Chuo ☐ 14. Chuo Kikuu ☐
Q 7. Je, unafanyakazigani? (Weka alamayavemakuonyesha jibu)	9. Sinaajira ☐ 10. Nimejiajiri ☐ 11. Kibarua ☐ 12. Nimeajiriwa ☐ 13. Kilimo cha kujikimu ☐ 14. Mkulimamkubwa ☐ 15. Fundi ☐ 16. Mama wa nyumbani ☐

Q 8. Je, baba wamtotoamekwendashule?	0 = Hapana 1 = Ndiyo ☐
Q 9. Kama jibuniNdiyo, nikiwangogani cha juu cha elimualichofikia? (Weka alamayavemakuonyesha jibu)	8 Hakuna ☐ 9 Msingi(Hakumaliza) ☐ 10 Msingi (Alimaliza) ☐ 11 Sekondari (Hakumaliza) ☐ 12 Sekondari (Alimaliza) ☐ 13 Chuo ☐ 14 Chuo Kikuu ☐
Q 10. Je, baba wa motto anafanyakazigani? (Weka alamayavemakuonyesha jibu)	8. Hajaariwa ☐ 9. Amejiajiri ☐ 10. Kibarua ☐ 11. Ameajiriwa ☐ 12. Kilimo cha kujikimu ☐ 13. KilimoKikubwa ☐ 14. Fundi ☐
PART D: ULISHAJI WA WATOTO WACHANGA NA WATOTO WAKUBWA Next I would like to ask you some questions about the health and feeding of (NAME) including what liquids or foods he/she might have had yesterday.	
Q 11. Je, unamnyonyeshahuyumtoto? (tajajina lake)?	0= No 1 = Yes ☐
Q 12. Kama jibuniNdiyo,ilichukuwamudaganikuanzakumnyonyeshabaadayakuzaliwa? (tajajina la mtoto)	Kama ni masaa weka 1. Kama ni siku weka 2. ☐ 77 = Sijui ☐☐
Q 13. Je, sikutatu za mwanzobaadayakuzaliwaulimpamtotoyalemaziwayamwanzo(tajajina la mtoto)?	0 = Hapana 1 = Ndiyo ☐ 77 = Sijui

Q 14. Je, katikasikutatubaadayakuzaliwa, mtoto(tajajina lake)alipewakinywajichochotembaliyamaziwa ya mama kama vile aina nyingine za maziwa, chai, dawa za kienyeji, maji ya sukari au maji ya kunywa?	0 = Hapana 1 = Ndiyo ☐☐ 77= Sijui
Q 15. Je, badounamnyonyeshamtoto (tajajina la mtoto)	0 = Hapana ☐ 1= Ndiyo
Q 16. Kama jibuniHapana, ulimnyonyeshamtotowakokwamudawamiezimingapi (tajajina la mtoto)?	_____Miezi
Q 17. Je, (tajajina la mtoto) alikunywakinywajichochotekwa kutumia chupa jana au jana usiku?	0 = Hapana 1 = Ndiyo ☐☐ 77 = Sijui
Q 18. Je, muda wowote jana au jana usiku mtoto At any time yesterday or last night has (tajajina lake) alipewa moja wapo ya vinywaji/vyakula vifuatavyo? (Weka alamayavemakuonyesha jibu)	1. Maziwa ya mama?..... ☐ 2. Maji?…… ☐ 3. Maji ya sukari, maji ya matunda au, soda?..... ☐ 4. Mchuzi?..... ☐ 5. Maziwa ya kopo?..... ☐ 6. Maziwa ya unga?..... ☐ 7. Maziwa ya ng'ombe..... ☐ 8. Uji mwepesi (k.m wa mahindi, mtama n.k.)?..... ☐ 99. Kinywaji kingine chochote k.m chai, kahawa n.k.? ☐ Vinginetaja:_____
Q19. Je, mtoto (tajajina lake) amekwishaanzakupewavyakula laini kama vile uji na viazi /ndizi zilizopondwa pondwa?	0 = Hapana 1 = Ndiyo ☐
Q20.Kama jibuniNdiyo,mtoto (tajajina lake)alianzakupewavyakulalainiakiwanaumrigani?	Miezi 77 = Sijui ☐☐

Q21.Katikakipindi cha saa 24 zilizopitamtoto (tajajina lake)	Idadi ya mlo

amepewachakulanavitafunwa mara ngapi?	Idadi ya vitafunwa 77 = Sijui
Q22. Je, mtoto (tajajina lake) anakulakwenyesahani/bakuliyake mwenyewe?	0 = Hapana 1 = Ndiyo

Now I would like to ask some questions about the health of (NAME)	
Q24.Je, mtoto (tajajina lake) ameharisha, (yaanikupata choo lainimaratatu au zaidi)katikakipindi cha wiki mbilizilizopita?	0 = Hapana 1 = Ndiyo ☐☐ 77 = Sijui
Q25. Je, mtoto (tajajina lake) alipewakiasikilekile cha majialichokuwaanapewakabla ya kuharisha au alipewa zaidi au pungufu?	1= Kiasikilekile 2= Zaidi ☐☐ 3= Pungufu 77= Sijui
Q26. Je, mtoto (tajajina lake)alipewakiasikilekile cha chakulaalichokuwaanapewakabla ya kuharisha au alipewa zaidi au pungufu?	1= Kiasikilekile 2= Zaidi ☐☐ 3= Pungufu 77= Sijui
Q27. Je, ulitafuta ushauri au tiba ya kuharisha popote?	0 = Hapana 1 = Ndiyo ☐
Q28. Kama jibu ni Ndiyo, ushauri huo uliupatia wpi?	**Kituo cha Huduma ya Afya:** a. Hospitali ya serkali ☐ b. Hospitali binafsil ☐ c. Kituo cha Afya ☐ d. Kituo binafsi cha Afya ☐ e. Clinic itembeayo ☐ f. Penginetaja _____ ☐
	Community: g. Mkunga ☐ h. Mkunga/Mganga wa Jadi ☐ i. Wahudumu wa Afya ya Jamii ☐ j. Kikundi cha Kinamama ☐ k. Bwana Dawa ☐ l. Rafiki ☐ m. Ndugu/Jirani ☐ o. Mama/Mama mkwe ☐ p. WengineTaja _____

Q29. Je, mtotowako (tajajina lake)amepatahomakatikakipindi cha wiki mbilizilizopita?	0 = Hapana 1 = Ndiyo 77 = Sijui
Q30. Je, mtotowako (tajajina lake) amepatakikohozikatikakipindi cha wiki mbilizilizopita?	0 = Hapana 1 = Ndiyo 77 = Sijui
Q31. Je, mtotowako (tajajina lake) alipatamatoneya Vitamin A miezi sita iliyopita?	0 = Hapana 1 = Ndiyo 77 = Sina
SEHEMU E: UELEWA NA MTAZAMO WA MAMA	
Q32.Je, Wahudumu wa Jamii wa Afyawalisha zungumza na wewe kuhusu kumnyonyesha mtoto wako?	0 = Hapana 1 = Ndiyo
Q33. Je, unawezakuniambiamtotoanatakiwakunyonyeshwamaziwaya mama pekeehadiumrigani?	Miezi 77 = Sijui
Q34. Je, Wahudumu wa Afya walisha kukueleza kuhusu vyakula vya kulikiza?	0 = Hapana 1 = Ndiyo

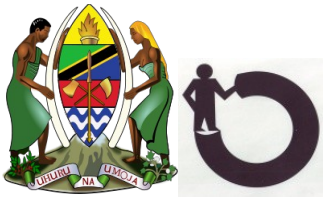
Q35. Mtoto anatakiwa kula milo na vitafunwa mara ngapi mbali na maziwa ya mama?	Mlo: Vitafunwa a) Miezi 6-8 ☐ ☐ b) Miezi 9-11 ☐ ☐ c) Miezi 12-24 ☐ ☐
Q36. Je, umekwisha sikia kuhusu upungufu wa damu?	0 = Hapana 1 = Ndiyo ☐
Q37. Je, unaweza kutambua dalili/ishara za upungufu wa damu?	0 = Hapana 1 = Ndiyo ☐
Q38. Kama jibu ni Ndiyo, tafadhali niambie baadhi ya dalili/ishara hizo katika orodha iliyoonyeshwa hapa	1. Rangi ya macho na kiganja iliyofifia ☐ 2. Kusikia kizungu zungu ☐ 3. Oedema ☐ 4. Kupungua uzito ☐ 5. Kubadilika kwa rangi ya nywele ☐ 6. Kutochangamka ☐ 7. Zinginetaja _____
Q39. Je, unafahamu aina za vyakula vyenye madini ya chuma kwa wingi?	0= Hapana 1 = Ndiyo ☐
Q40. Kama jibu ni Ndiyo, niambie baadhi ya vyakula hivyo kwenye orodha iliyoonyeshwa	1. Maini, figo, moyo n.k. ☐ 2. Nyama (ng'ombe, nguruwe, kondoo, mbuzi) na ndege (kuku, bata nk.) ☐ 3.Mboga za majani kama vile spinach, kisamvu na mchicha ☐ 4. Samaki wabichi ☐ 5. Dagaa ☐ 6. Vingine ni mboga na matunda kama vile ndizi mbivu, nyanya, psesheni nanasi na maemb ☐ 7. Mayai ☐ 8. Maziwa ☐ 9. Vinginetaja _____
Q41. Je, ulikwishasikiakwambaunawezakununuavyakulavilivyoongezewa vitamin namadinikama vile madini ya chuma?	0= Hapana 1 = Ndiyo ☐
Q42. Kama jibuniNdiyo, tafadhalitajabaadhiyavyakulahivyo	1)_____ 2)_____ 3)_____

PART C: AFYA NA USAFI WA MAZINGIRA	
Q 43. Tadhali niambie chanzo kikuu cha maji ya kunywa kwenye kaya yako	1= Bomba la maji nyumbani 2= Bomba la maji kwa ajili ya watu wote 3= Kisima cha wazi cha watu wote ☐☐ 4= Kisima kilichofunikwa cha watu wote 5= Dimbwi/mto/kijito /ziwa/chemchemi 6= Uvunaji wa maji ya mvua 7= Maji ya tangi 8= Maji ya chupa 99=Kinginetaja _____
Q 44. Je, nini chanzo kikuu cha maji kwenye kaya yako wakati wa masika?	1= Bomba la maji nyumbani 2= Bomba la maji kwa ajili ya watu wote 3= Kisima cha wazi cha watu wote 4= Kisima kilichofunikwa cha watu wote 5= Dimbwi/mto/kijito /ziwa/chemchemi 6= Uvunaji wa maji ya mvua ☐☐ 7= Maji ya tangi 8= Maji ya chupa 99= Kinginetaja_____
Q 45. Je, unatibu maji ilikuyafanya kuwa salama kwa kunywa?	0 = Hapana ☐ 1 = Ndiyo
Q 46. Kama jibu ni Ndiyo, unayafanyaje maji ili yaweze kuwa salama kwa kunywa?	1= Chemsha 2= Naweka dawa(chlorine /water guard) 3= Nakamuakwakitambaasafi ☐☐ 4= Nachuja (ceramic, sand, composite, etc.) 5= Naua viini vya maradhi kwa kutumia mwanga wa jua 6= Naacha yatuame

	99= Nyinginetaja _____ 77= Sijui
Q 47. Je, una mazoea ya kunawa mikono yako kwa sabuni?	0 = Hapana 1 = Ndiyo ☐
Q 48.Kama jibuniNdiyo, niwakatiganiunanawamikonokwasabuni?	1. Kabla ya kuandaa /kushika chakula ☐ 2.Kabla ya kumlisha mtoto ☐ 3.Kabla ya kula ☐ 4. Baada ya kuandaa chakula 5. Baada ya kutoka shambani ☐ 6. Baada ya kubadilisha nguo za mtoto/kumtawaza mtoto ☐ 7. Baada ya kula ☐ 8.Baada ya kutoka chooni ☐ 9. Wakati wa kuoga ☐ Wakatimwinginetaja_____
Q 49. Je, unawaosha watoto wako mikono?	0 = Hapana 1 = Ndiyo ☐

Q 50. Kama jibuniNdiyo, niwakatiganiunawaoshawatotowakomikonokwasabuni?	1. Kabla ya kula 2. Baada ya kula ☐☐ 3. Baada ya kujisaidia 4. Wakati wa kuoga 99. Wakatimwinginetaja_____
Q 51. Je, katika kaya yako kuna chandalua watu wanajifunikia wakati wa kulala?	0 = Hapana 1 = Ndiyo ☐
Q 52. Je, kati yenu kuna aliyejifunika kwa chandalua jana usiku?	1 = Ndiyo ☐☐ 0 = Hapana 77 = Sijui
Q 53. Ni nani aliyejifunika kwa chandalua jana usiku?	2. Mtoto?..... ☐ 2. Mama wa mtoto?…….. ☐ 3. Baba wa mtoto?..... 4. Ndugu/umbu wa mtoto?..... ☐ 5. Bibi wa mtoto?..... ☐ 7. Familia yote?..... ☐ 8. Wana familia wengine?..... ☐ 99. Wenginetaja_____ ☐

ANNEX 3: Consent in English



Project INT6058"Contributing to the evidence base to improve stunting reduction programmes"

Sub-project titled: "Using stable isotope techniques to evaluate effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Dodoma region, Tanzania".

Consent form

Invitation

Dear Parent,

You have been invited to participate in the above-mentioned study together with your child. The leaflet you are reading/I am reading to you provide information about this proposed study that aims at evaluating the effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Dodoma region, Tanzania. Together with this leaflet is the Informed Consent Form. Please read/listen carefully the information in the leaflet, and if you accept you and your child to participate in this study, please put your signature, across the designated area in the Informed consent form. In case you need additional information or clarification you are welcome to ask for more explanations.

Purpose of the study

The purpose of this study is to evaluate the effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) the estimate volume and correlate results with nutrition status of the mother and the child. The study will also be able to compare mothers self-reports of exclusive breastfeeding to those determined using special water dose to mother dilution techniques. Finally the study will also be able to relate infant health to mode of feeding and volume of consumed milk.

The study will involve:-

- Taking anthropometric measurements
- Drinking special water
- Collecting saliva samples and

- Frequent visits to health facility for sample collection.

Procedure

If you agree to participate, please respond to our questionnaire and provide the required information. We will ask your permission to take your body measurements and collect saliva specimens for laboratory analysis. We would also like to determine whether you are exclusively breastfeeding your child. For us to be able to do this, we will request you to drink some liquid (special water). This liquid is safe and is not associated with any health hazard. Samples of saliva will be collected from you and your child starting from day 0(baseline), and on days 1, 2, 3, 4 and on 13 and 14.

Results obtained from this study will be used as evidence base for the effectiveness of Mwanzo Bora Nutrition Intervention Programmes and will subsequently be used to scale up interventions in other parts of the country. You will be informed of the results of this study at a dissemination meeting. The dates for this meeting will be communicated to you later. The study results will also be disseminated to various stakeholders including the Ministry of Health Community Development, Gender, Elderly and Children as well as through publications.

Voluntary participation

Please note that your participation in this study is voluntary and you have a right to refuse to consent. If you consent for you and your child to participate you have the right to withdraw your child from the study at any time if you wish to do so.

Benefits

Participants in the study will benefit directly by knowing their health and nutritional status. Also participants will benefit from medical and nutritional advice that will be provided. Also, results of this study will help us understand the relationship between breastfeeding, complementary feeding and mother's health to infant growth.

Risks of use of stable isotopic techniques

Special water is safe to use and do not present any hazard. It is naturally present in all biological materials such as foodstuffs that we eat; for example maize, bread, tomato, rice and sugarcane. Also, the application of stable isotopes do not require special environment for use or disposal. Special water that are going to be used in this study does not require invasive method of administration, it is taken orally.

Compensation for time

There will be no compensation for the time you and your child contributes to the study.

Confidentiality

Strict confidentiality will be maintained. Efforts will be made to ensure that participation in this study will only be known to the researchers who will be obliged to abide strictly with the study ethics. Participants will not be identified in any reports or publications of this study.

Results

The results of the study will be made available to you through planned dissemination meetings. Also, results of this study will be compiled in research papers for publication.

Contacts for further information

For any question you may have regarding this study, please contact Dr. E. E. Towo. He is the Co-Principal Investigator in charge of this study. He may be reached through the following address:

Dr. E. E. Towo
Tanzania Food and Nutrition Centre,
P. O. Box 977,
Dar es Salaam.
Tel: +255 22 2118137/9,
Fax: +255 22 2116713

If for any reason you want to talk to anyone else about this study call the office of the Chairperson, Research and Ethics committee, National Institute for Medical Research through the following address:

The Chairperson,
Research and Ethics committee,
National Institute for Medical Research
Ocean Road, P. O. Box 9653,
Dar es Salaam
Tel: +255 22 2121400;
Fax: +255 22 2121360.

Consent form

I have read the foregoing information, or it has been read to me*. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my further medical care.

Name of the mother _____

_____

Signature of the mother or thumb print*

Witness*

Name of the witness_____

_____

Signature of the Witness

Name of the Investigator_____

_____

Signature of Investigator

Date _____/_____/2017

*Optional unless subject is illiterate, or unable to sign

ANNEX 4: Consent form in Kiswahili

Project INT6058"Contributing to the evidence base to improve stunting reduction programmes"

Sub-project titled: "Using stable isotope techniques to evaluate effectiveness of Social and Behavioral Change Communication (SBCC) interventions in promoting exclusive breastfeeding (EBF) in Dodoma region, Tanzania".

Fomu ya kukubali kushiriki kwenye utafiti

Mwaliko Kwa Mama Mzazi

Mpendwa mama mzazi,

Wewe na mtoto wako mmealikwa kushiriki katika utafiti uliotajwa hapo juu. Fomu hii unayoisoma /Ninayokusomea inakupa taarifa zote kuhusu utafiti uliyopendekezwa, wenye lengo la kupima mafanikio ya afua za lishe zinazotekelezwa na mradi wa Mwanzo Bora kuinua kiwango cha unyonyeshaji watoto maziwa ya mama pekee katika mkoa wa Dodoma. Fomu hii imeambatishwa pamoja na maelezo ya kukubali kushiriki katika utafiti huu. Tafadhali soma/sikiliza kwa makini maelezo yaliyoko katika fomu hii na kama utakubali wewe na mtoto wako kushiriki katika utafiti huu weka sahihi yako kwenye fomu hii hapo chini. Tafadhali, kama unahitaji maelezo zaidi au ufafanuzi, unakaribishwa kuuliza.

Kusudi la Utafiti

Utafiti huu unafanyika ili kupima mafanikio ya afua za lishe zinazotekelezwa na mradi wa Mwanzo Bora katika kuinua kiwango cha unyonyeshaji watoto maziwa ya mama pekee katika mkoa wa Dodoma.Aidhaa, utafitihuupiautalinganishamatokeo ya kipimochamajimaalumkinachoonyeshakiasichamaziwaambayomtotoalikuwaananyonyana taarifa anayotoa mama kuhusu kumnyonyesha mtoto wake bila kumpa kitu kingine chochote.Vilevile,

utafiti huo utaangalia uhusiano uliopo kati ya afya ya mtoto, jinsi anavyolishwa na kiasi cha maziwa anayonyonya. Kwa ujumlautafitihuoutahusisha mambo yafuatayo:-

- Kupima vipimo vya uzito, urefu na mzunguko wa sehemu ya juu ya mkono
- Kunywa maji maalum
- Kuchukua sampuli za mate ya mama na mtoto
- Washirikikwendakliniki mara kwa mara kwaajili ya kuchukuliwa sampuli za mate

Taratibu za kushiriki:
Kama utakubali kushiriki katika utafiti huu, tafadhali jibu maswali yatokanayo na dodoso letu. If Kwaruhusayako, tutakupimawewenamtotowako uzito, urefu na mzunguko wa sehemu ya juu ya mkono, pia tutachukuwa sampuli za mate kwa ajili ya kupima kwenye maabara. Tutapenda pia kupima kama unamnyonyesha mtoto maziwa ya mama pekee bila kumpa kitu kingine chochote. Ili tuweze kufanya hivyo, tutakupa kiasi kidogo cha maji maalum ili unywe. Maji haya ni salama na hayana madhara yoyote kwenye mwili.Tutachukua sampuli za mate kwa mama na mtoto siku ya kwanza ya kuanza utafiti 0(takwimu za msingi), na siku zitakazo fuata siku ya 1, 2, 3, 4 na ya 13 na ya 14.

Matokeo ya utafiti huu yatatumika kama ushahidi wa afua zinazotekelezwa na mradi wa Mwanzo Bora na hatimaye kupanua wigo wa utekelezaji wa miradi hiyo katika mikoa mingine hapa Tanzania.Utajulishwa matokeo ya utafiti huo katika mikutano ya kuwasilisha matokeo. Tarehe na muda wa kufanyika mikutano hiyo utajulishwa baadaye. Pia matokeo ya utafiti huu yatawasilishwa kwa wadau wengine ikiwa ni pamoja na Wizara ya Afya, Maendeleo ya Jamii, Jinsia, Wazee na Watoto na pia kuandikwa kwenye machapisho mbalimbali ya kitaifa na kimataifa.

Hiari ya kushiriki:
Kushiriki kwako na kwa mtoto wako katika utafiti huu ni hiari. Unaweza kuamua wewe na mtoto wako kuingia na kushiriki katika utafiti huu au baada ya kushiriki ukaamua kumuondoa mtoto wako kwa sababu unazozifahamu wewe mwenyewe. Kumuondoa mtoto wako hakutamuathiri yeye kama mshiriki.

Faida zinazohusiana na kushiriki katika utafiti huu:
Zipo faida ambazo utazipata moja kwa moja kutokana na utafiti huu. Utaweza kujua hali ya afya na lishe ya mtoto wako na pia utapewa ushauri wa kilishe.

Hatarinausumbufu:
Hakunahatarizozotezinazohusiana na utafiti huu. Majimaalumyatakayotumika ni salamakwaafya ya binaadamu. Vyakulatunavyokulakamavilemahindi, nyanya, mchelenamiwa vina hayo majimaalumkwaasiliyake.

Motisha kwa kushiriki:
Hakuna motisha/ruzuku yoyote utakayolipwa kutokana na wewe na mtoto wako kushiriki katika utafiti huu.

Utunzaji wa taarifa za utafiti:
Taarifa zote za utafiti zitakuwa ni siri na jina lako pamoja na la mtoto wako halitajitokeza popote kwenye ripoti au makala zozote zitakazo andikwa. Ushiriki wako na wa mtoto wako katika utafiti huu utakuwa unafahamika kwa watafiti tu ambao wanatenda kazi zao kwa kuzingatia maadili ya utafiti kwa makini. Ikitokea kwamba maadili ya utafiti yamekiukwa kwa namna moja au nyingine, hatua za kinidhamu zitachukuliwa dhidi ya watafiti wanaohusika. Hata hivyo matokeo ya utafiti yatatolewa kwa watafiti na wataalamu wengine kwa ajili ya kuelimishana.

Kwa Mawasiliano na Maelezo zaidi
Kama una swali lolote au unahitaji maelezo ya kina, tafadhali wasiliana na Dr. E. E. Towo. Yeye ni msaidizi wa Mtafiti Mkuu. Unaweza kutumia anuani ifuatayo:

Dr. E. E. Towo
Tanzania Food and Nutrition Centre,
P. O. Box 977,
Dar es Salaam.
Tel: +255 22 2118137/9,
Fax: +255 22 2116713

Kama kwanamnamoja au nyingineunatakakuongeana mtu mwingine kuhusu utafiti huu, tafadhali wasiliana na Mwenyekiti, Kamati ya Kitaifa ya Maadili ya Utafiti, National Institute for Medical Research Kupitia anuani ifuatayo:

The Chairperson,
Research and Ethics committee,
National Institute for Medical Research
Ocean Road, P. O. Box 9653,
Dar es Salaam
Tel: +255 22 2121400;
Fax: +255 22 2121360.

Kukubali kushiriki kwenye utafiti

Nimesoma taarifa hii/nimesomewa taarifa hii* na nimepata fursa ya kuuliza maswali, na kila swali nililouliza limejibiwa vizuri na nimeridhika. Ninakublikwahiariyangumwenyewemiminamtotowangukushirikikatikautafitihuunaninahaki ya kujiondoanakumuondoamtotowanguwakatiwowotenitakapojisikia kufanya hivyo.

Jina la mama _____

_____

Saini ya mama au dole gumba

Shahidi*

Jina la Shahidi_____

_____

Saini ya shahidi

Jina la Mtafiti_____

_____

Saini ya Mtafiti

Tarehe _____/_____/2017

Saini ya Mtafiti

Kama mshiriki hajui kusoma na kuandika.

ANNEX 5: Data Sheet for Mother- Baby Pair

Project INT6058"Contributing to the evidence base to improve stunting reduction programmes"

Assessment of Exclusive Breastfeeding using dose to mother (dose-to-mother) deuterium dilution technique data sheet

Mother- baby pair ID_____

Variable	Mother	Baby
Date of dosing (Day 0)		
Study ID		
Date of birth		
Body weight (kg) Day 0		
Body weight (kg) Day 14		
Height/length (cm)		
Date and Time of baseline saliva sample		
Dose number		Not applicable
Time dose taken		Not applicable
Date and Time Day 1 saliva sample		
Date and Time Day 2 saliva sample		
Date and Time Day 3 saliva sample		
Date and Time Day 4 saliva sample		
Date and Time Day 13 saliva sample		
Date and Time Day 14 saliva sample		

ANNEX 6: Detailed budget

Budget for Implementing project INT 6058/RAF 6030

Pre-study Activities –Iringa &Njombe	**Unit of Measure**	**Number of Personnel**	**Unit Cost**	**Quantity**	**Unit/day**	**Total in Tshs**
Development of the study protocol	Person	5	60,000	1	5	1,500,000
Ethical clearance fee	Protocol	1	800,000	1	1	800,000
Production of 8 copies of study protocol	Protocol	1	6,000	8	1	48,000
Preliminary visit to the proposed study area	Person	3	120,000	1	4	1,440,000
Printing papers	Rim	1	10,000	10	1	100,000
Gloves	Box	1	15,000	20	1	300,000
Pen	Box	1	15,000	2	1	30,000
Cotton balls	Box	1	4,000	20	1	80,000
Driver	Person	1	80,000	1	4	320,000
Fuel	Litre	1	2,500	230	1	500,000
Sub – total						**5,118,000**

Data collection Iringa DC and Kilolo in Iringa	Unit of Measure	Number of Personnel	Unit Cost	Quantity	Unit/day	Total in Tshs
Dose administration, Collection of saliva samples	Person	6	120,000	1	35	25,200,000
Questionnaire administration	Person	2	100,000	1	35	7,000,000
Driver	Person	1	80,000	1	35	2,800,000
Fuel	Ltr	1	2,500	230	1	575,000
Sub – total						**35,575,000**

Data collection Njombe DC and Wanging'ombe in Njombe	Unit of Measure	Number of Personnel	Unit Cost	Quantity	Unit/day	Total in Tshs
Dose administration, Collection of saliva samples	Person	6	120,000	1	40	28800,000
Questionnaire administration	Person	2	100,000	1	40	8,000,000
Driver	Person	1	80,000	1	40	3,200,000
Fuel	Litre	1	2,500	250	1	620,000
Sub – total						**40,620,0000**

Data Analysis	Unit of Measure	Number of Personnel	Unit Cost	Quantity	Unit/day	Total in Tshs
Analysis of saliva for deuterium enrichment	Person	6	50,000	1	20	6,000,000
Analysis of Questionnaire	Person	4	50,000	1	10	2,000,000
Report writing	Person	6	50,000	1	10	3,000,000
Sub – total						**11,000,000**

SUMMARY OF THE BUDGET

Pre-study activities in Iringa and Njombe	5,118,000
Data collection in Iringa DC and Kilolo in Iringa	35,575,000
Data collection-Njombe DC and Wanging'ombe in Njombe	40,620,000
Data analysis, saliva samples analysis and report writing	11,000,000
Grand Total	**92,313,000**