THE PROMOTION OF NUTRIENT-DENSE FOODS IN ANDASIBE, MADAGASCAR

A Thesis
by
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Abstract

THE PROMOTION OF NUTRIENT-DENSE FOODS IN ANDASIBE, MADAGASCAR

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Purpose: Due to a lack of resources, especially for mothers and children, Madagascar has high levels of poverty and malnutrition. Nutrition education has shown to be an effective approach to increasing health in low-resource areas worldwide. The purpose of this study was to pilot a tailored, four-week nutrition education program to improve diet diversity and health promoting practices in Andasibe, Madagascar.

Methods: Twenty caregivers were recruited from Andasibe, Madagascar. Diet diversity and nutrition knowledge were assessed using a pre/post-test design. Nutritional status was assessed using height, weight, mid-upper-arm circumference measurements, and Raman spectroscopy technology. The intervention consisted of weekly individualized counseling sessions with education materials. Data were analyzed using descriptive statistics and paired sample t-tests to determine changes post education.

Results: Significant increases were found in the consumption of vitamin A-rich foods for adults ($p \leq 0.01$), and the use of treated water to wash fruits and vegetables before consumption ($p \leq 0.01$). All but one caregiver (95.0%) made dietary changes by increasing diet diversity (consuming fruit, vegetables, legumes) and by focusing on colorful foods. Most caregivers were outside of normal limits for BMI (60.0%) but were within normal limits for mid-upper-arm circumference (75.0%).

Conclusions: Findings suggested nutrition education was effective in increasing nutrition knowledge in Andasibe, Madagascar. Findings suggested that an individualized approach to nutrition education in a low resource country can improve diet diversity, nutrition knowledge, and health practices with potential to increase the consumption of specific foods associated with micronutrient deficiencies.

Keywords**:** nutrition education, diet diversity, malnutrition, vitamin A, iron

Foreword

Chapter two of this thesis will be submitted to the *Health Education Journal,* a peer reviewed journal with a focus on that of health education and health promotion. The journal is a member of the Committee on Publication Ethics (COPE) and is published by SAGE publishing. The manuscript article has been formatted to fit the guidelines for this journal.

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Chapter 1: Introduction

Literature Review

Madagascar is a country with high levels of poverty and malnutrition (Farris et al., 2019) leading to significant health consequences, especially for mothers and children. Malnutrition is responsible for 45.0% of all child deaths worldwide and affects not only health, but the capacity for contribution to society (Black et al., 2013). Stunting rates (defined as the hindrance of growth, development, or progress of the body) in Madagascar are very high, at 53.0% with 27.0% of women of childbearing age suffering from undernutrition (BMI <18.5) (Mathys et al., 2015). Micronutrient deficiencies, such as iron, iodine, and vitamin-A, also pose a serious threat to health (Gavaravarapu et al., 2017), and are avoidable but widespread in Madagascar, particularly for 78.0% of the population who make the equivalent of $1.90 per day (World Bank Group, 2019). High levels of poverty contribute to food being financially inaccessible or unaffordable for many (United Nations FAO, 2018). Some Malagasy report employing coping mechanisms such as choosing between eating or having medicine for a sick family member and selling livestock and vegetables for money to purchase cheaper foods for themselves (Farris et al., 2019).

Diet diversity has been associated with increased nutrient intake and better maternal and child nutrition status in developing countries with resource-limited conditions. Research has shown that nutrient-dense foods are available in Madagascar despite the high rates of malnutrition and stunting in the region. The traditional Malagasy diet consists of mostly carbohydrates, supplying 77.0% -79.0% of total calories (Rakotosamimanana et al., 2014), which is higher than health recommendations of 45.0% - 65.0% (Institute of Medicine, 2005). Rice is the most commonly consumed carbohydrate, providing high levels of satiety at

a low cost (Rakotosamimanana et al., 2014). The consumption of vegetables and fruits are not as valued as the consumption of rice, due to their low-energy density, though they are crucial for the maintenance of good health status (Farris et al., 2019). The World Food Program (WFP) and the United Nations International Children's Emergency Fund (UNICEF, 2010:65) reported that in Madagascar, plant-based proteins were consumed only once per week on average and animal sources were consumed twice per week. Another study found most Malagasy consume animal-source foods only for celebrations or once to twice per month, and there were some participants who could not afford to eat it at all (Farris et al., 2019).

Seasonal variations also affect consumption patterns. During the lean season, rice is more expensive, and often plantain bananas and cassava root are consumed instead (Mathys et al., 2015). Cassava root, typically boiled and eaten with sugar, coconut, and salt, is very low in protein, lipids, vitamins and minerals, but consistently high in carbohydrates, providing more sources of non-nutrient-dense foods (Rakotosamimanana et al., 2014). While the consumption of fruits and vegetables also varies widely due to seasonality, consumption rates remain low regardless of season, varying from 6-21.0% depending on the time of year (Faber and Laubscher, 2008). Lack of financial resources is consistently the main reason the Malagasy report for not purchasing varying types of food (Asgary et al., 2015).

In addition to income, one explanation for the low consumption rates of fruits and vegetables could be the beliefs the Malagasy have that they are unsatiating. Beliefs about food and nutrition also influence dietary choices in Madagascar. One study found that beliefs about the nutritional benefits of food had a larger impact on consumption than the actual nutritional quality of the foods (Rakotosamimanana et al., 2014). Unless participants believed

that foods were healthy, they would neither purchase nor prepare them, regardless of cost. Moreover, a recent study showed a misconception around the concept of health in general. Participants reported that "nutritious foods" meant foods were clean, tasted good, and were well cooked (i.e. rice, meat, and cassava), and certain fruits and green leafy vegetables were considered "non-nutritious foods" due to their low cost. This misconception has contributed to a lack of diet diversity (Farris et al., 2019). Lastly, studies show the Malagasy are interested in learning more about diet diversity. One study by Asgary et al. (2015) conducted qualitative interviews on mother's displaying signs of food insecurity. Participants were unable to identify foods or the lack thereof to prevent malnutrition, and were concerned about eating the same foods all the time (rice, yucas, and bananas), and were concerned the lack of variety in their foods could make them sick (Asgary et al., 2015).

A variety of actions are needed to combat malnutrition in Madagascar, including nutrition education on diet diversity with special attention paid to vulnerable groups like women and children. Lower education has been found to be associated with less than daily fruit intake in the Malagasy population (Metta et al., 2014). However, those who see their healthcare providers regularly are 59.0% more likely to have adequate fruit and vegetable intake, yielding support for the education of the healthcare workers in Madagascar as well as the caregivers in the community (Metta et al., 2014).

Several studies have reported on effective nutrition education strategies to encourage diet diversity. According to the United Nations Millennium Project (2005) comprehensive community-based nutrition education increases the intake of vitamins and minerals through the intake of micronutrient-rich foods (Sanchez et al., 2005). In addition, focusing on the types of foods consumed and not on specific nutrients, while also incorporating multiple and

familiar food models and food utensils has also proven effective (Semba et al., 2008). In a study by Mushaphi et al. (2017) conducted in South Africa, a nutrition education program aimed at the feeding practices of caregivers for children aged 3-5 years old helped to increase daily vegetables and fruit, while also increasing the number of meals consumed daily. Furthermore, a study conducted by Khan et al. (2013), used individualized nutrition counseling to change feeding practices of limited-resource caregivers. The study reported increased intake of fruits, vegetables, starchy foods, and the number of meals consumed, showing an overall improvement in diet quality (Khan et al., 2013). Finally, Sethi et al. (2003) and Rao (2015) also demonstrated that nutrition education intervention, no matter the duration, can be extremely successful using a combination of communication approaches with repeated reinforcement.

These studies show that counseling, nutrition education, and behavior change communication tailored for caregivers and community health workers can improve the feeding behaviors and growth rates of those struggling to obtain adequate resources (Khan et al., 2013). The aim of the proposed study is to provide a tailored, four-week nutrition education program to improve diet diversity and health promoting practices of caregivers and community health workers, using multiple channels of communication in Andasibe, Madagascar. We aim to test the hypothesis that nutrition education will improve diet diversity, nutrition knowledge, and ultimately nutritional status.

Goals and Objectives

My ultimate goal was to assess and improve the nutritional status, diet diversity, and nutrition knowledge of caregivers living in Andasibe, Madagascar. The following chapter of my thesis includes detailed objectives of how I addressed this goal.

1. Using a pre/post-test design, conduct measures at the beginning of the intervention to obtain baseline data and at the conclusion to assess changes in diet diversity and nutrition knowledge and status.

    a. Nutritional status will be assessed using height, weight, and mid-upper arm circumference measurements. Additionally, resonance Raman spectroscopy technology, a non-invasive biomarker of fruit and vegetable intake, will measure carotenoid status in skin (Zidichouski et al., 2009).

    b. Diet diversity will be assessed using a previously validated dietary diversity questionnaire (DDQ) (Mathys et al., 2015).

    c. Nutrition knowledge and behaviors of caregivers will be assessed using a previously validated nutrition knowledge questionnaire.

2. Provide a 4-week nutrition education intervention to caregivers consisting of weekly individualized counseling sessions.

    a. Individualized counseling will be based upon results from the dietary assessments and will focus on healthful nutrition through the intake of vitamin-rich foods and food safety practices for caregivers and their young children. Education will be comprised of verbal discussions with written handouts and pictures to demonstrate the recommended size and type of foods to consume (WHO, 2020) for reinforcement.

3. Collaborate with local community healthcare workers in assessing dietary patterns and providing nutrition education, in order to become demonstrators of healthful nutritional practices, and to sustain the dissemination of education beyond the research project.

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Chapter 2: Manuscript Article

Abstract

Purpose: Due to a lack of resources, especially for mothers and children, Madagascar has high levels of poverty and malnutrition. Nutrition education has shown to be an effective approach to increasing health in low-resource areas worldwide. The purpose of this study was to pilot a tailored, four-week nutrition education program to improve diet diversity and health promoting practices in Andasibe, Madagascar.

Methods: Twenty caregivers were recruited from Andasibe, Madagascar. Diet diversity and nutrition knowledge were assessed using a pre/post-test design. Nutritional status was assessed using height, weight, mid-upper-arm circumference measurements, and Raman spectroscopy technology. The intervention consisted of weekly individualized counseling sessions with education materials. Data were analyzed using descriptive statistics and paired sample t-tests to determine changes post education.

Results: Significant increases were found in the consumption of vitamin A-rich foods for adults ($p \leq 0.01$), and the use of treated water to wash fruits and vegetables before consumption ($p \leq 0.01$). All but one caregiver (95.0%) made dietary changes by increasing diet diversity (consuming fruit, vegetables, legumes) and by focusing on colorful foods. Most caregivers were not within normal limits for BMI (60.0%), but we within normal limits for mid-upper-arm circumference (75.0%).

Conclusions: Findings suggested nutrition education was effective in increasing nutrition knowledge in Andasibe, Madagascar. Findings suggested that an individualized approach to nutrition education in a low resource country can improve diet diversity, nutrition

knowledge, and health practices with potential to increase the consumption of specific foods associated with micronutrient deficiencies.

Keywords**:** nutrition education, diet diversity, malnutrition, vitamin A, iron

Introduction

Malnutrition is responsible for 45.0% of all child deaths worldwide and affects not only health, but the capacity for contribution to society (Black et al., 2013). It is in the early stages of pregnancy that nutrients from adequate nutrition are stored and utilized for the end of gestation and into lactation and breastfeeding (Berggren et al., 2015). The physiological implications of malnutrition (including wasting, stunting, and decreased mental and physical function) (USAID, 2017) are most impactful during pregnancy and the first two years of a child's life (Metta et al., 2014). Further, vitamin A blindness and iron deficiency anemia are two of the most common effects of malnutrition world-wide, especially in resource-limited countries (USAID, 2017). Vitamin A deficiency and iron deficiency anemia often develop simultaneously from an inadequate intake of fruits and vegetables rich in vitamin A, and contribute to decreased immunity, cognitive dysfunction and decreased physical strength (Müller and Krawinkel, 2005). With the decreased intake of fruits and vegetables there is an estimated higher consumption of processed foods which provide increased satiating power (Black et al., 2013; Rakotosamimanana et al., 2014) for lower economic strain (Rakotosamimanana et al., 2014). This can lead to malnutrition in the context of overweight and obesity, a global problem that increases risk for comorbidities including type 2 diabetes and cardiovascular diseases (Black et al., 2013). This global health issue effected an estimated 7.0% of children under the age of 5 years in Africa (2011), which is an increase

from estimated 4.0% in 1990 (Rakotosamimanana et al., 2014). The development of malnutrition and becoming overweight results in decreased health and increased risk of disease overall (Black et al., 2013).

Madagascar is a country with high levels of malnutrition and increased risk of disease, (Farris et al., 2019) which leads to significant health consequences, especially for mothers and children (UNICEF, 2010). Madagascar has the world's fourth highest rate of chronic malnutrition, with almost one child in two under five years of age suffering from stunting (defined as the hindrance of growth, development or progress of the body) (World Bank, 2019). Malnutrition is common in adults as well, with 37.0% of women of childbearing age suffering from anemia (World Bank, 2019) and an estimated 27.0% suffering from undernutrition (BMI <18.5) (Sharp, Maryanne; Kruse, 2011). Micronutrient deficiencies, such as iron, iodine, and vitamin-A (Gavaravarapu et al., 2017) pose a serious threat to health and are avoidable but widespread in Madagascar, particularly for 78.0% of the population who make the equivalent of $1.90 per day (World Bank Group, 2019). High levels of poverty contribute to food being financially inaccessible or unaffordable for many (United Nations FAO, 2018). Previous studies suggest many Malagasy engage in poverty coping mechanisms, and must sometimes choose between purchasing food or medications for example, or selling valuable/costly food products (e.g. livestock) to purchase lower-cost foods for themselves (Farris et al., 2019).

Poverty coping mechanisms result in lower diet diversity, which can result in reduced nutrient intake and poorer maternal and child nutrition in developing countries (Mathys et al., 2015). Diet diversity has been associated with increased nutrient intake and better maternal and child nutrition status in developing countries with resource-limited conditions (Khatoon

et al., 2011). Research has shown that nutrient-dense foods are available in Madagascar, but not readily consumed (Rakotosamimanana et al., 2014; Sawadogo et al., 2006). The traditional Malagasy diet consists of mostly carbohydrates, supplying 77.0% - 79.0% of total calories, (Rakotosamimanana et al., 2014) which is higher than health recommendations of 45.0% - 65.0% (Institute of Medicine, 2005). Rice is the most commonly consumed carbohydrate throughout Madagascar, providing high levels of satiety at a low cost (Rakotosamimanana et al., 2014). Vegetables and fruits which are crucial for the maintenance of good health, are not as valued or consumed as frequently as rice (Farris et al., 2019; Rakotosamimanana et al., 2014). While the consumption of fruits and vegetables can vary widely due to seasonality, a previous study conducted in rural and urban areas of Antananarivo and Antsiranana (where income is higher compared to more rural regions of Madagascar) reported that consumption rates in Madagascar remain low regardless of season, varying from 6.0% - 21.0% of energy intake throughout the year (Rakotosamimanana et al., 2014). Malagasy animal and plant-based protein consumption is also low with most consuming roughly 80.0% of estimated protein needs per day (Rakotosamimanana et al., 2014; Institute of Medicine, 2005). The United States Agency for International Development (USAID) reports that plant-based proteins are consumed only once per week on average (UNICEF, 2010), while animal sourced protein consumption varies from twice per week (UNICEF, 2010), to once or twice per month, to not at all (Farris et al., 2019; UNICEF, 2010).

These eating patterns can result in high carbohydrate and low protein consumption throughout Madagascar and may be tied to local beliefs or values placed upon various food sources. One study conducted in rural and urban areas of Madagascar found that beliefs

about the nutritional benefits of food had a larger impact on consumption than the actual nutritional quality of the foods (Rakotosamimanana et al., 2014). Unless participants believed that foods were healthy, they would neither purchase nor prepare them. Moreover, a recent study conducted among the rural villages along the east coast of Madagascar showed some Malagasy had misconceptions about health and the nutritional value of foods (Farris et al., 2019). Participants reported that "nutritious foods" meant foods were clean, tasted good, and were well cooked (i.e. rice, meat, and cassava), and certain fruits and green leafy vegetables were considered "non-nutritious foods" due to their low cost.

In addition, many Malagasy families chose foods and form opinions on "nutrition values" based on the cost of the food items (Rakotosamimanana et al., 2014). A study by Rakotosamimanana et al. (2014) found that price was reported 80.0% of the time by participants as a factor for purchasing food (Rakotosamimanana et al., 2014). However, while the perception of health and nutrition are important, there are opportunities for nutrition education regarding inexpensive, nutrient-dense foods to improve diet diversity. For example, studies show many Malagasy are interested in education on diet diversity and health (Farris et al., 2019; Asgary et al., 2015), and education has been shown to positively impact behavior (Mushaphi et al., 2017). Different strategies are needed for increasing knowledge base and improving diet diversity. The United Nations Millennium Project (2002) reported on effective nutrition education strategies to encourage diet diversity. These strategies include: comprehensive community-based nutrition education (Sanchez et al., 2005), focusing on the types of foods consumed and not on specific nutrients while incorporating multiple and familiar food models and food utensils (Sanchez et al., 2005), incorporating caregivers into education (Mushaphi et al., 2017), individualized nutrition

counseling (Khan et al., 2013), and a combination of communication approaches with repeated reinforcement (Sethi et al., 2003); Rao, 2015). These studies show that counseling, nutrition education, and behavior change communication tailored for caregivers and community health workers can improve the feeding behaviors and growth rates of those struggling to obtain adequate resources, particularly in impoverished, malnourished places like Madagascar (Khan et al., 2013).

The aim of this study was to pilot a tailored, four-week nutrition education program to improve diet diversity and health promoting practices of caregivers in Andasibe, Madagascar. We aimed to test the hypothesis that nutrition education would improve diet diversity, nutrition knowledge, and ultimately nutritional status of caregivers and their children of less than 10 years of age. To achieve this goal and test this hypothesis, we evaluated the following: 1) nutritional status through anthropometric measurements; 2) diet diversity for fruit and vegetable consumption using a dietary diversity questionnaire; 3) changes in nutrition knowledge and behaviors of caregivers using a nutrition knowledge questionnaire.

Methods

This exploratory cross-sectional pilot study was conducted in Andasibe, Madagascar. Andasibe is located in the Alaotra-Mangoro region of eastern Madagascar and is surrounded by several protected natural wildlife and forest reserves. The quantitative survey methodology for this study followed previous studies that conducted nutrition education in low-income, resource-limited countries (Rakotosamimanana et al., 2014; Farris et al., 2019;

Asgary et al., 2015). A mixed methods approach with an individual survey followed by qualitative discussion was chosen to explain and interpret findings.

Participants and Setting

Participants were recruited from the village of Andasibe, Madagascar which contains approximately 400 households with 5,000 inhabitants (Association Mitsinjo, 2019). Inclusion criteria for individuals targeted for this pilot study included women under the age of 70 years who were the primary caregivers for a child(ren) aged 0 - 10 years, living in the Andasibe village. In addition to the research team, the study team also included one native Malagasy who was trained in survey protocol and interview techniques. Permission to conduct surveys and provide education was granted from the Ministry of Health and the Andasibe village chief prior to data collection. All study participants granted verbal consent, and the study was approved by [blinded for review] the Institutional Review Board (IRB) (Appendix A).

Data Collection

Data collection occurred during June 2019. Measures were included to assess nutritional status, diet diversity, and nutrition knowledge and behaviors of caregivers living in Andasibe, Madagascar using a pre/post-test design.

Nutrition Status

Baseline and end measurements for nutritional status were assessed using height, weight, mid-upper-arm circumference, and resonance Raman spectroscopy levels (RRS). RRS technology measures carotenoid status in skin as a non-invasive, less expensive biomarker of fruit and vegetable intake (Zidichouski et al., 2009). For consistency of results, the Pharmanex® BioPhotonic Scanner (S3) device was calibrated each day before use by

running a D*ark Cap Scan* (a scan conducted with the dark cap securely fixed over the scanner lens) per device instructions (Nu Skin Enterprises, 2019).

Diet Diversity

Diet diversity was assessed using a previously validated dietary diversity questionnaire (DDQ) (Mathys et al., 2015; Ruel et al., 2010). Participants were asked to recall the foods and drinks they consumed in the past 24 hours. Items were categorized into nine food groups: 1) cereals, white roots and tubers; 2) vitamin A-rich fruits, vegetables and tubers; 3) "other" fruits and vegetables; 4) dark green leafy vegetables; 5) organ meat; 6) flesh meat, fish and seafood; 7) eggs; 8) legumes, nuts and seeds; 9) milk and milk products, with a resulting numeric score given for the consumption of foods in each category (Sawadogo et al., 2006).

Health Knowledge and Behaviors

Lastly, health knowledge and health behaviors were assessed using a previously validated questionnaire (Farris et al., 2019; Rakotosamimanana et al., 2014; Headrick et al., 2014; Food and Agriculture Organization, 2012), (Appendix B) which was comprised of three main sections: 1) drivers of food practices including food selection, food preparation, and hygiene practices; 2) foods believed to be nutritious and beliefs around nutrition; and 3) agriculture and economic practices . Five open-ended questions were added to evaluate program acceptability and behavior changes that might not have been captured with the survey (Appendix C). The open-ended questions were developed in partnership by the research team and the Malagasy translator, and consisted of the following: 1) What was the most helpful or enjoyable aspect of the nutrition education you received; 2) Was there any part of the education that you did not like or that was not helpful? If so, how could we make

it better; 3) Did you change any part of your diet because of the education you received? If so, what was it; 4) If you wanted to make changes but were not able to, can you tell us some of the barriers that prevented you from doing so; 5) What would you like to learn more about in the future? To accommodate for variability in literacy level, the survey was developed in English only and then read aloud in Malagasy to each participant. Survey response time was between 15 to 30 minutes. Responses were translated as given by the Malagasy team member, and then recorded verbatim onto paper surveys. All 20 participants were recruited on the first day of data collection in Andasibe.

Nutrition Education

The 4-week nutrition education program, *Salama Fahasalamana* (translation: Hello Health) included 30-minute individualized nutrition instruction via weekly one-on-one counseling sessions (Table 1). Individualized counseling was based upon the results of the initial dietary assessment and education was comprised of verbal discussions with written handouts for reinforcement. Handouts were developed in English and then translated into Malagasy and reviewed by two bilingual persons to assure translational accuracy and cultural appropriateness. The handouts were utilized to focus the nutrition messaging around the following topics:

Handout 1 (for caregivers with children aged 0-1 years): the continuation of breastfeeding, starting complementary foods, encouraging soft fruits and vegetables in the diet, the importance of food and handwashing, and encouraging vitamin-rich foods (Appendix D).

Handout 2 (for caregivers with children aged 1-10 years): breastfeeding until two years of age, consuming three meals per day with two healthy snacks, discouraging

low-nutrient foods, encouraging vitamin-rich foods, the importance of food and handwashing (Appendix E).

The individualized sessions were comprised of verbal discussion with pictures to demonstrate the recommended size and type of foods to consume, based off the World Health Organization (2020) dietary recommendations, in order to increase nutrient diversity. Implementation strategies were discussed to incorporate fruits and vegetables into predominantly rice meals, to remain culturally appropriate.

Table 1. *Salama Fahasalamana* Curriculum and Project Measures – Education Topics, Learning Objectives, Activities and Materials

Topic	**Learning Objectives**	**Measures & Activities**	**Education Materials**
Week 1: Importance of breastfeeding and consuming nutrient-dense foods	(1) List examples of nutrient-dense and low-nutrient foods (2) Identify the benefits of breastfeeding until 2 years of age	Baseline measurements collected Nutrition counseling based on results of DDQ* and knowledge questionnaire	Handout 1 Handout 2
Week 2: Consuming lower cost, in-season fruits and vegetables Importance of foods that provide energy for strength and eye health	(1) Identify less expensive fruits and vegetables available at the local market (2) List foods that keep you strong and keep your eyes healthy	Individualized counseling, addressing participant questions and concerns	Handout: Healthy Foods and Their Benefits (Appendix F)

Topic	**Learning Objectives**	**Measures & Activities**	**Education Materials**
Week 3: Importance of clean water and good hygiene practices Reinforcement of consuming nutrient-dense foods	(1) Demonstrate proper handwashing to reduce the spread of bacteria (2) Identify the importance of washing hands and food with *treated* water (3) Replicate a simple and nutritious snack for the family	Individualized counseling, addressing participant questions and concerns, handwashing demonstration, food demonstration, and tasting of a nutritious snack	Handout: The Importance of Handwashing (Appendix G) Nutritious snack provided using locally available ingredients
Week 3: Community engagement and collaboration for continued nutrition education and sustainability Reinforcement of previous education topics	(1) Identify methods of continuing nutrition education in Andasibe (2) Discuss cultural similarities and differences in implementing nutrition education	Individualized counseling, addressing participant questions and concerns Discussed nutrition education methods with community health workers the medical doctor for the area, and the lead midwife	Provided to regional health professionals: Handout 1 Handout 2 Healthy Foods and Their Benefits The Importance of Handwashing
Week 4: Program acceptability Goal setting and changes in baseline measurements	(1) Recognize dietary changes made and set goals for increasing health behaviors	End measurements collected, and program acceptability and behavior change measurements collected, individualized counseling, addressing participant questions and concerns	Program incentives (dry beans, carrots, zucchini) distributed

*DDQ (Diet Diversity Questionnaire)

Data Analysis

The survey data were analyzed using descriptive statistics and paired sample *t-tests* in Microsoft Excel (2010). Descriptive statistics were analyzed by compiling the frequency count of questions asked, and all percentages were based on the sample size for the question asked. Data were grouped using pivot tables for organizing trends of data. Paired sample *t-tests* were used to evaluate if a significant change occurred after the nutrition education intervention. A p value of $<.05$ was considered statistically significant. Open-ended responses on program acceptability and behavior change were coded by two researchers, common responses identified, and frequency of common responses calculated.

Results

Demographics and Nutrition Status

A total of 20 caregivers participated in the study (Table 2). All caregivers were female and were titled the grandmother or mother of the household (n = 20, mean age = 37.5 years). The average number of adults residing in a household was reported as 2.3 (+/- 0.9), while the average number of children was 2.2 (+/- 1.0). Most participants reported growing their own crops and/or raising their own livestock (n = 14, 70.0%) and of those, participants reported eating and selling the crops and/or livestock (n = 7, 50.0%), strictly selling them (n = 4, 29.0%), and strictly eating them (n = 3, 21.0%).

Table 2. Participant Characteristics of Malagasy Caregivers (n=20).

Average Age (years)	
37.5	(SD [a] +/- 14.7)

Paid Work and Profession [f]	Number	Percent
Currently Employed	12	60.0%
Currently Unemployed	8	40.0%
Business/trade (not animal)	6	43.0%
Business/trade (animal)	1	7.0%
Farmer	4	29.0%
Teacher	2	14.0%
Secretary	1	7.0%
Caregiver's Highest Level of Education	Number	Percent
Primary	8	40.0%
Secondary	7	35.0%
High School	3	15.0%
University	2	10.0%
Child School Attendance	Number	Percent
No	3	15.0%
Yes	17	85.0%
Public	13	72.0%
Private	5	28.0%
Number of children in household under 5 years		
0	3	15.0%
1	13	65.0%
2	2	10.0%
3	2	10.0%
Number of children in household over 5 years		
0	3	15.0%
1	15	75.0%
2	1	5.0%
3	1	5.0%
Hours Spent Handling Food	Average	
Obtaining Food	0.7	
Preparing Food	1.5	
Anthropometrics	Average	
Weight (kg)	50.8	
Height (cm)	151.1	
BMI [b]	22.2	
Underweight	5	25.0%
WNL [c]	8	40.0%
Overweight	7	35.0%
MUAC [d] (mm)	26.5	
Low		25.0%
WNL [c]		75.0%
RRS [e] Score (N=20)	Pre-Survey	Post-Survey
Average Score *P* value: 0.928	21,138.8 (± 9,025.5)	20,999.9 (± 9,484.9)

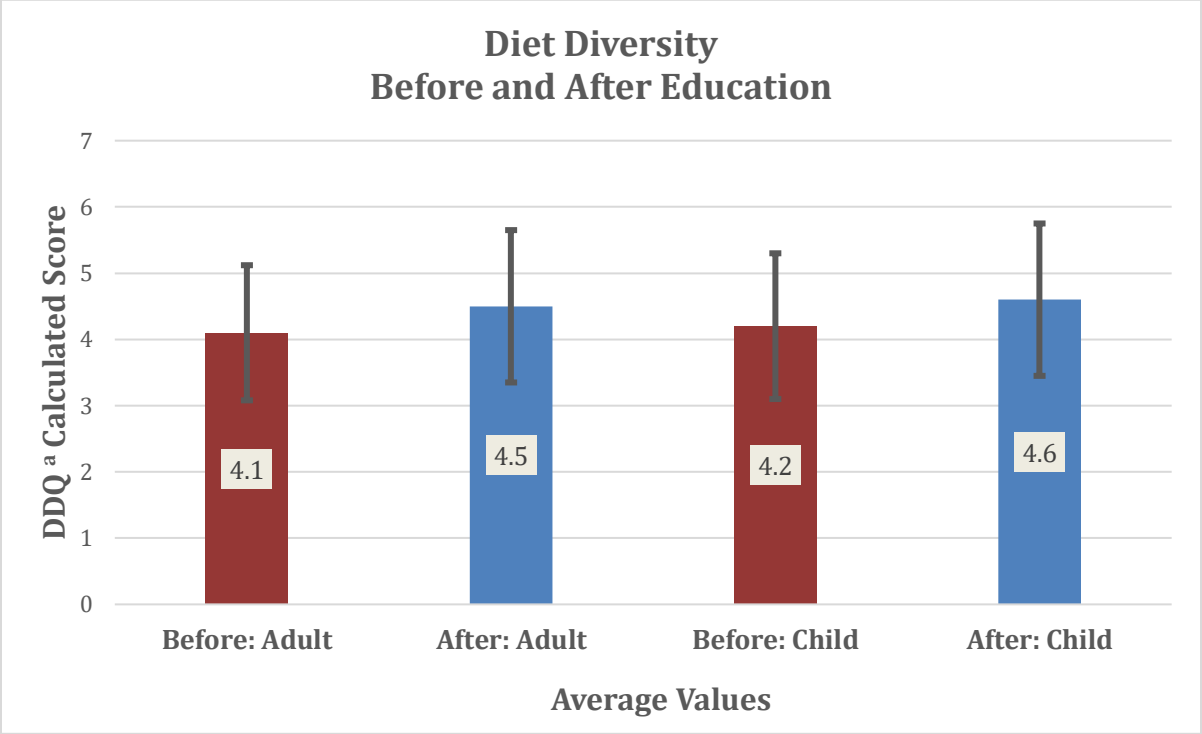
RRS [e] Score Classification	Pre-Survey	Post-Survey
< Low Intake	2/20 (10.0%)	2/20 (10.0%)
Low Intake	13/20 (65.0%)	15/20 (75.0%)
Moderate Intake	5/20 (25.0%)	3/20 (15.0%)

[a] SD (Standard Deviation)
[b] BMI (Body Mass Index)
[c] WNL (Within Normal Limits)
[d] MUAC **(**Mid-Upper-Arm Circumference)
[e] RRS (Resonance Raman Spectroscopy)
[f] (Percentages do not equal the number comprising
each sample because participants were able to select multiple professions.)

Diet Diversity

Comparing diet diversity pre- versus post- education and intervention using the results of the dietary diversity questionnaire, significant changes were found in the consumption of vitamin A-rich fruits and vegetables for adults (Table 4), though significant changes were not found for children ages 2-10 years. There were no significant changes found in the overall diet diversity scores of neither children nor adults (Figure 1), though an increase in average scores was noted. There were also no significant changes found in the RRS scores of adults (Table 2). The RRS scores were categorized into levels of fruit and vegetable intake according to the RRS S3 scanner user manual. Scores of <10,000 were classified as *less than low* intake; 10,000 – 29,000 were classified as *low* intake; scores of 30,000 – 49,000 were classified as *moderate* intake; scores of 50,000 – 90,000 were classified as *above average* intake (Nu Skin Enterprises, 2019). There were no participant scores in the range of *above average* intake (Table 2).

Figure 1. Frequency Distribution of Changes in Diet Diversity by Participants (n=20).



[a] (DDQ) Dietary Diversity Questionnaire

Health Knowledge and Behaviors

When asked to select the three most important factors to consider when *shopping* for food items, participants reported health (30.0%), cost (21.7%), and child food preferences (18.3%) most commonly. However, when asked to select the three most important factors to consider when *preparing* food, participants reported providing energy (26.7%), ensuring it is clean (26.7%), and containing vitamins (25.0%). Diet diversity was selected *least* often by participants as important when preparing meals for their families (3.3%) but was selected more frequently as important when shopping for food (13.3%).

The most common method reported for food preparation was boiling in water (85.0%), with a small number of participants who reported frying their food in oil (15.0%).

Participants also reported storing food in their homes (n = 11, 55.0%), specifically fruit (19.1%), rice (14.3%), and beans (14.3%) were listed most often. When asked to name foods that a child should eat to prevent becoming malnourished or sick, participants most frequently reported starchy and non-starchy vegetables (33.8%), starchy grains (15.5%), and fruit (14.1%).

Table 3. Frequently Reported Foods Identified by Caregivers as Nutritionally Good and *Not* Nutritionally Good (n=20).

Food Items Prior to Nutrition Education	**Food Items after Nutrition Education**
Reported as Nutritious	
Pre	**Post**
Carrots/Potatoes/Tomatoes (21.7%)	Carrots/Potatoes/Tomatoes (24.3%)
Fish (10.0%)	Leafy Greens (10.8%)
Meat (8.3%)	Beans (10.8%)
Reported as Non-Nutritious	
Pre	**Post**
Cassava Root (32.0%)	Processed Crackers (21.3%)
Sweet Potatoes (14.0%)	Cassava Root (17.0%)
Leafy Greens (8.0%)	Pasta (14.9%)

Responses calculated by asking caregivers to list the top three foods believed to be nutritious and non-nutritious. Percentages based on responses of agreement.

When asked about foods believed to be nutritious, the most commonly reported answer was vegetables such as carrots/potatoes/tomatoes, which did not change after nutrition education (Table 3). However, the next commonly reported food items shifted from animal proteins (prior to education) to leafy green vegetables and plant proteins (after education). When asked to name foods believed to *not* be nutritious, participants reported

cassava root both prior to and after nutrition education but shifted their other food answers from vegetables (sweet potatoes and leafy green vegetables) to processed food items like crackers and pasta (Table 3).

When asked where household water was collected, all participants reported collecting tap water from local community wells to keep in storage containers. All participants reported using this water for drinking, bathing, cooking, washing fruits and vegetables, washing meat to cook, and washing household dishes and utensils, while some also reported using this water for washing clothes (50.0%), giving to animals (45.0%), and washing the floor (20.0%). All caregivers washed their hands, "more than once a day", and the most frequent instances were after using the bathroom (14.9%), before food preparation (14.9%), and before eating (14.0%). Most participants reported always keeping soap in the house (85.0%), and most reported always washing their hands with soap (75.0%). All participants also reported using soap for bathing their bodies, washing clothes and kitchen items (95.0%), washing their hair (60.0%), and washing hands for market (n = 1, 5.0%).

There were no significant changes in the treatment of drinking water (Table 4), due to many caregivers already participating in water treatment practices. However, there was a significant change in washing fruits and vegetables with treated water after nutrition education ($p = 0.01$). Of those who began using treated water, 33.0% used boiled water, and 67.0% used sur'Eau-treated water. Sur'Eau is a locally available chlorine solution used for water treatment in Madagascar and several other countries, implemented by the Humanitarian Aid Organization (UNICEF, 2013).

Table 4. Changes in Nutrition Knowledge and Health Behaviors by Participants (n = 20).

Question	Pre-evaluation Percentage	Post evaluation Percentage	Pre-evaluation Mean (SD) [a]	Post evaluation Mean (SD) [a]	*P* value
Do you treat your drinking water with anything before you drink it? N=20 1=No 2=Yes	 5.0% 95.0%	 0.0% 100.0%	 2.0 (+/- 0.2)	 2.0 (+/- 0.0)	0.330
How often do you treat the water? N=19 1=Sometimes 2=Often 3=Always	 11.0% 5.0% 84.0%	 5.0% 10.0% 85.0%	 2.6 (+/- 0.9)	 2.8 (+/- 0.5)	0.385
Do you wash your fruit and/or vegetables with treated water? N=20 1=No 2=Yes	 100.0% 0.0%	 70.0% 30.0%	 1.0 (+/- 0.0)	 1.3 (+/- 0.5)	0.010**
Consume Vitamin A-rich F&V [b] (caregiver)? N=20 1=No 2=Yes	 50.0% 50.0%	 10.0% 90.0%	 1.5 (+/- 0.5)	 1.9 (+/- 0.3)	0.008**
Consume Vitamin A-rich F&V [b] (child 2-10)? N=16 1=No 2=Yes	 44.0% 56.0%	 13.0% 88.0%	 1.6 (+/- 0.5)	 1.9 (+/- 0.3)	0.055

(*p<.05, **p<.01, ***p<.001)
[a] (SD) Standard Deviation
[b] (F&V) Fruit and Vegetables

Qualitative Analysis Open-Ended Questions

All 20 caregivers participated in the open-ended response questions on program acceptability and behavior change. More than half of the caregivers perceived the education on handwashing and water treatment and the information on the importance of consuming

colorful vegetables as the most helpful and/or enjoyable aspect of the nutrition education. All but one of the 20 caregivers (95.0%) reported making at least one dietary change due to the education received. The majority (80.0%) of dietary changes made were an increase in diet diversity (now consuming more fruit, green leafy vegetables, or legumes) with a focus on colorful foods. The main barrier reported for not making further behavior changes was financial constraints (95.0%). Participants reported wanting further education on health, cooking methods, farming methods and agricultural techniques, as well as educating and raising healthy children. There were no reports of disliked or unhelpful information.

Discussion

The aim of this study was to pilot a tailored, four-week nutrition education program to improve diet diversity and health promoting practices of caregivers in Andasibe, Madagascar. In accordance with the hypothesis that nutrition knowledge and ultimately nutritional status would be improved among participants and their children, this pilot study suggested that tailored nutrition education was an effective tool for increasing diet diversity and health promoting practices in low-resource areas such as Madagascar. In the baseline survey and a previous study (Farris et al., 2019), diet diversity was not found to be of importance to Malagasy caregivers. However, the results of the current study support the hypothesis that nutrition education would improve diet diversity. A significant increase was found in diet diversity by providing nutrition education on the importance of vitamin A rich foods and specific examples of foods high in vitamin A. Vitamin A contributes to the health of the eyes, which heavily impacts night vision (Chakravarty, 2000) and deficiency is linked to undernutrition and child death (USAID, 2017). Although the increase in the consumption

of vitamin-A rich foods in children was not significant, determined by the dietary diversity questionnaires, this could be due to the smaller sample size of children in the appropriate age range of 2-10 years Interventions which encourage the consumption of vitamin A rich foods are warranted.

In addition to the questionnaires, resonance Raman spectroscopy scores were also used to assess vitamin A intake as a measure of carotenoid levels in the skin. Study results did not show significant increases in RRS scores; however, this could be attributed to the short duration of the 4-week intervention period. Despite the lack of RRS score change, participants provided positive feedback and reported eating higher levels of fruits and vegetables rich in vitamin-A. Based off participants' report, the biggest diet change made was eating more colorful foods after receiving nutrition education. Participants also reported adding many vitamin A-rich foods into their diet, specifically dark green leaves, pumpkin, and sweet potatoes. Participant open-ended responses showed the incorporation of more fruits and vegetables into the diet, further supporting the significant increase in diet diversity shown by dietary diversity questionnaire responses, though this was not reflected consistently in RRS scores. Emphasis on an intervention with a longer duration of study is warranted to obtain a more accurate reading of carotenoid levels over time.

Cleanliness was considered an important factor for food preparation. Previous studies have shown that the Malagasy are aware that boiling their food ensures that it is cooked throughout and free from contamination (Farris et al., 2019; Rakotosamimanana et al., 2014). However, there are many water soluble nutrients like vitamins C, B_1, B_2, B_5, B_6, and B_{12} that leach out into the cooking water and are discarded before they are consumed, possibly

contributing to a population deficient in some of these specific nutrients (Rakotosamimanana et al., 2014). The Malagasy also reported that the vitamins in food were important to consider for food preparation, which showed a knowledge link between the types of food that they prepare and their perception of nutrient content. However, since diet diversity was chosen as the least important factor when shopping for and preparing foods, this proved that there is still need for further education on the importance of consuming vitamin-rich foods prepared in a way that maximizes physiological nutrient utilization. One food that would increase diet diversity and nutrient consumption is dark leafy greens which are plentiful in Andasibe at low cost (Farris et al., 2019). However, in this study and a previous study leafy greens are often sold to buy rice instead (Farris et al., 2019). Rice and carbohydrate-rich foods like cassava are consumed most because they are viewed as energy-dense and satiating, however they are low in nutrient density. This further emphasizes a need for nutrition education intervention highlighting the importance of consuming nutrient-dense foods with a goal of increasing diet diversity and intake of nutritious foods.

A misconception of the definition of *nutritious* food has been shown in this study and previous studies in Madagascar (Farris et al., 2019; Rakotosamimanana et al., 2014). This study revealed that knowledge can be impacted through targeted nutrition education. For example, leafy greens were most frequently listed as *non-nutritious* before education but identified to be *nutritious* post education. Packaged crackers were also listed most frequently for non-nutritious foods post education. Although leafy greens cannot be considered nutritionally complete unless eaten with other food groups (Rakotosamimanana et al., 2014), they do contain vitamins and minerals that have been shown to improve vitamin A status when eaten with other fruits and vegetables (Faber and Laubscher, 2008). Beans, for example

are among the foods that should be paired with dark leafy greens for a non-meat source of protein in the Malagasy diet (Mushaphi et al., 2017). In Andasibe, beans are more affordable and available when compared to animal sources (USAID FEWS NET, 2018), and the current study identified them as good protein sources as part of the nutrition education provided. Studies have reported that Malagasy recognize the importance of consuming meat and seafood, but consumption is scarce due to its higher cost (Farris et al., 2019; Rakotosamimanana et al., 2014; Asgary et al., 2015). In this study, beans were more frequently listed as a nutritious food post education instead of meat and fish. This finding reinforces that nutrition education may shape how individuals spend their limited income to target nutritionally dense foods, ultimately impacting health using the resources available.

This study contributes to the knowledge available on nutrition education in low-resource areas. Lower education has been found to be associated with low fruit intake in the Malagasy populations (Metta et al., 2014), however, this study suggests that behavior change can occur through the provision of knowledge. These findings support previous research by Davis-Kean (2005) where increasing parental knowledge was more beneficial for behavior change than providing supplemental assistance, and research showing higher levels of parental education correlate to increasing child knowledge and improving behavior (Davis-Kean, 2005). Nutrition education is warranted for Malagasy parents, enabling them to increase their own health and the health of their children.

The education provided in the current study had a significant impact on the number of households that began treating their water to wash their fruits and vegetables before consumption. The tap water used in Andasibe was obtained from local community wells,

unique to Andasibe because most villages in Madagascar must collect surface water from lakes, rivers, and streams (UNICEF, 2010) for household use. Treating the water before using it to wash food products is crucial because the tap water in Madagascar could contain possible runoff from animal and human feces as well as other contaminants (UNICEF, 2010) leading to many unfortunate health consequences. Reports have shown that roughly 58.0% of Malagasy households practice open defecation (UNICEF, 2010) with no means of waste management. Poor sanitation practices have been linked to increased morbidity (UNICEF, 2010) meaning the improvement of water treatment practices could impact spread of disease in the Malagasy population. Toxoplasmosis, a disease caused by the *Toxoplasma gondii* parasite (Flegr et al., 2014), has potential to cause encephalopathy in the human fetus of an infected mother. This disease, primarily spread by feline defecation (Flegr et al., 2014), is a concern for the Malagasy population given that wild and domestic cats and dogs are prevalent without boundaries (Czaja et al., 2015). According to a study that analyzed toxoplasmosis antibodies in pregnant women in Madagascar, 84.0% of women of childbearing age had been exposed to latent toxoplasmosis (Lelong et al., 1995). This further emphasizes the importance of handwashing and food washing with treated water in Madagascar communities. Washing foods with water that has been cleaned, either through boiling or the use of Sur'Eau drops is of low cost for the Malagasy people. However, financial constraints were reported as the main barriers to making lifestyle changes. Because of these barriers, education on lower cost, nutrient-dense foods is crucial to changing the lifestyle habits of this population.

Study Strengths and Limitations

This pilot study did have many limitations. One limitation was that the sample size was not randomized, and though convenience sampling is most useful for pilot testing, it means the results collected may not be generalizable to the entire country of Madagascar. Andasibe is home to the Andasibe-Mantadia National Park, an environmental factor that could influence behavior and way of life when compared to other low-resource areas of Madagascar. Other areas of Madagascar vary in climate, available resources, culture, and food availability. Also, as with all survey data, there was susceptibility to bias. The pre and post knowledge questionnaire could contain slight variances from what the Malagasy reported due to differences between the Malagasy and English languages and cultural food differences.

A second limitation that must be considered is the short duration of this pilot study. According to a debate and analysis study by Gardner et al. (2012), an estimated time of 10 weeks is needed to implement and sustain a lifestyle change. Another study conducted in a resource-limited area of Pakistan found an improvement in eating behaviors among caregivers and a decrease in child wasting after the completion of a three month nutrition education intervention (Khan et al., 2013). While participants in the current study reported making dietary changes, identified by qualitative responses and post-education dietary diversity questionnaire reports, a long-term evaluation is needed to assess the change in nutritional status or dietary habits of the study population. This approach should also be applied and evaluated in a larger representative sample of Malagasy caregivers to test its effectiveness for multiple regions of Madagascar.

One strength of the current study was the collaboration with and training of Malagasy community health professionals in the Andasibe region to promote sustainability. While this part of the project was not measured, the education material created and used in the current study was shared for the dissemination of education beyond the research project. This is the first study to implement a nutrition education intervention in the Andasibe region of Madagascar and provide specific education for circumstantial need. A second strength is that the research team previously conducted a community health assessment to determine specific health education needs. This allowed the current study to provide education on culturally appropriate changes to have positive impacts on overall health. Duplication of this small plot study is warranted in other low-resource areas of Madagascar to provide further nutrition education and implement behavior change communication tactics to ultimately increase nutrition knowledge and overall health behaviors.

Conclusion

Nutrition education interventions can be successful in increasing dietary diversity and water treatment practices among caregivers living in low-resource areas. The results suggest that there is great potential to positively change eating behaviors and health practices in resource-limited communities by providing weekly individualized counseling over a four-week period, though longer intervention projects are warranted. Opportunities for further education include increasing knowledge of nutrient-dense foods and expanding food choice beyond carbohydrate-rich foods chosen for high satiety levels, the importance of diversifying the diet [through the intake of locally grown fruits and vegetables] for increased nutritional intake, and providing ways to sustain education efforts beyond project implementations. The

findings from the current study support the evidence that behavior change communication can improve diet diversity and increase nutrition knowledge.

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Chapter 3: Conclusion

The purpose of this study was to pilot a tailored, four-week nutrition education program focused on improving diet diversity and health promoting practices in Andasibe, Madagascar. Twenty caregivers were recruited from Andasibe, Madagascar. Diet diversity, nutrition knowledge, and health behaviors were assessed using a pre/post-test design. Nutritional status was assessed using height, weight, mid-upper-arm circumference measurements, and Raman spectroscopy technology. Despite limited sample size, findings suggested nutrition education was effective in increasing nutrition knowledge in Andasibe, Madagascar. Findings suggested that an individualized approach to nutrition education in a low resource country can improve diet diversity, nutrition knowledge, and health practices with potential to increase the consumption of specific foods associated with micronutrient deficiencies like vitamin A. Significant increases were found in the consumption of vitamin A-rich foods for adults ($p \leq 0.01$), and the use of treated water to wash fruits and vegetables before consumption ($p \leq 0.01$). All but one caregiver (95.0%) made positive dietary changes due to the education they received. The majority (80.0%) of dietary changes made were an increase in diet diversity (now consuming more fruit, green leafy vegetables, or legumes) with a focus on the consumption of colorful foods. Most caregivers were within normal limits for BMI (40.0%) and mid-upper-arm circumference measurements (75.0%).

The main barrier reported for not making further behavior changes was financial constraints (95.0%). Although nutrition education was provided on buying fruits and vegetables when they are in season and less expensive, this is a change that will happen over time for most families. It takes roughly between two and three months to make a sustainable lifestyle change. Since the nutrition education team was in Madagascar for just four weeks,

an education intervention with a longer duration is warranted. At the end of the four-week study, participants were asked to answer freely about education topics they would like to learn about in the future and feedback regarding the project. Participants reported wanting further education on health, cooking methods, farming methods and agricultural techniques, as well as educating and raising healthy children. There were no reports of disliked or unhelpful information.

These findings suggest that an individualized approach to nutrition education in a low resource developing country can improve diet diversity, health and nutrition knowledge, and overall health practices like water treatment. Further, it can increase the consumption of specific foods which are associated with micronutrient deficiencies like vitamin A. Increased knowledge can impact the spread of malnutrition and chronic disease, providing more opportunities for the Malagasy to reach their full health potential. More research is needed on the impact of a long-term nutrition education intervention in Andasibe. Replication is also warranted in other low-resource areas of Madagascar.

Appendix A: IRB Approval

General Information

1. General Information

*Questions marked with * are required.*

1. Project Title

   Investigating Maternal Health in the Andasibe Region of Madagascar

2. **Brief Summary**. Provide a short non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. You will be asked for more specifics around background/rationale and research question(s) further in the application. This should only serve as a brief synopsis and not the full description of your study.

   Adequate nutrition is critical for positive maternal and child outcomes in developing countries. Undernourished pregnant mothers have higher risks of pregnancy complications or mortality, and poor nutrition while pregnant and/or breastfeeding can result in child health consequences such as mortality, stunting, nutrient deficiencies, and lower learning capacities of children, ultimately impacting socioeconomic development of the country. Diet diversity and health promoting practices have direct links to health outcomes. Due to high levels of malnutrition in Madagascar, in-depth knowledge of dietary and child-bearing practices, interventions promoting health practices, and identifying further pathways for intervention are warranted. This project aims to improve the nutritional status of mothers and children living in resource-limited Andasibe, Madagascar through a comprehensive assessment of the potential pathways of malnutrition, and a 4-week nutrition education intervention.

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc)?

   No

2. List all project personnel beginning with the principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who will obtain consent, interact with subjects for research purposes, or have access to subject's private identifiable information.

List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.

Liaison	Last Name	First Name	Department Name	Role	Detail
Appalachian State University (ASU)					
	Farris	Alisha	Nutrition & Health Care Mgt.	Principal Investigator	view
	Farris	Zachary	Health and Exercise Science (HES)	Co-investigator	view
	Caldwell	Olivia	Nutrition and Health Care Management	Research Assistant	view
	Collins	Alison	Nutrition and Health Care Management	Research Assistant	view

	Hawkins	Kelsey	Nutrition and Health Care Management	Research Assistant	view
	Jameson	Erin	Nutrition and Health Care Management	Research Assistant	view
	Jennings	Eavan	Nutrition and Health Care Management	Research Assistant	view
	Owen	Emily	Nutrition and Health Care Management	Research Assistant	view
	Phillips	Hannah		Research Assistant	view
	Polich	Emily	Nutrition and Health Care Management	Research Assistant	view
	Tibbett	Michelle	Nutrition and Health Care Management	Research Assistant	view
	Wang	Ilya		Research Assistant	view

NOTE: All project personnel must complete human research ethics training. The IRB website has directions for accessing this online training.

If this research is based in a center, institute, or department (Administering Department) other than the

one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Nutrition & Health Care Mgt.

Conflict of interest relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, involve the potential for compromising, or have the appearance of compromising a researcher's objectivity in fulfilling research responsibilities. Please refer to Appalachian's at: Conflict of Interest Policy.

4. Is a spouse or immediate family member listed in the research team?

Yes

Please explain

The PI and Co-Investigator are married.

Does the sponsor have any direct financial or other relationship with the University (i.e., gifts, serve on University boards)?

No

Do any members of the research team have a financial or equity interest or other relationship with the sponsor?

No

3. Funding Sources

1. Is the project internally funded (departmental, URC, OSR, etc.)?

Yes

List internal source of funding:

URC funds a portion of the project, Objective 2 only (PI: Zach Farris)

Is this project funded (or proposed to be funded) by a contract or grant from an organization external to Appalachian State University?

Yes

Sponsor Name	AGrants Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Allen Foundation	19-0118	Foundation				view

3. Is there another proposal supporting this submission (check all that apply)?

- ✖ Grant Application not managed in Sponsored Programs
- ✖ Master Protocol for Multi-site Study
- ✖ Student Dissertation or Thesis Proposal
- ✖ Other Study Protocol

Screening Questions

The following questions will help you determine if your project will require IRB review and approval. The first question is whether this is RESEARCH

Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer Yes unless the information is also ABOUT them.

Yes

Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository). OR Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations?

No

The following questions will help build the remainder of your application.

Are any personnel, organizations/entities, facilities or locations not affiliated with Appalachian State University engaged in this research? IF YOU ARE CONDUCTING RESEARCH OFFSITE OR REQUESTING A RELIANCE AGREEMENT, PLEASE ANSWER "YES"

Yes

5. Collaborations, Offsite, or Multi-site Study Information

1. Will this study be conducted in locations outside the United States?

Yes

2. List the country/ies in which you plan to conduct your research.

Madagascar

Are any of the countries on the U.S. State Department Travel Warning List? See list found at http://www.travel.state.gov/content/passports/english/alertswarnings.html (look for "Travel Warnings").

Yes

3. If you are conducting research off campus or with permission of an outside entity, please indicate the appropriate location:

No Answer Provided

4. Is ASU the Lead Site or Coordinating Center or Sponsor of a multicenter project?

No

Lead Site/Coordinating Center addendum

5. Is Appalachian State University taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of ASU?

No

Are you requesting that Appalachian rely on an external IRB for continuing review and approval ofthis study?

No

Researchers are reminded that additional approvals may be needed to use external facilities or to access the subject population. Please refer to our Letters of Agreement templates.

Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fe and review requirements. This would not apply in a study that involves drugs or devices, involves g minimal risk, or involves medical procedures or deception or minors, except in limited circumstance Additional guidance is available at the Research Protections SOP.

1. Would you like your application evaluated for a possible exemption?

No

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e, why is the study nee complete background and literature review are in an accompanying grant application or oth proposal, only provide a brief summary here. If there is no proposal, provide a more extensi and literature review, including references.

The Allen Foundation grant application (PI: Alisha Farris; funding undecided until Jun application (PI: Zach Farris; funding granted), provide some background and rationale More background and rationale is provided below.

Malnutrition and micronutrient deficiencies are prevalent in Madagascar, with serious health consequences, especially for mothers and children. Malnutrition is directly or indirectly responsible for 45% of all child deaths worldwide and affects the psychomotor development and learning capacities of children, with a long-term impact on the socioeconomic development of the country. Reproduction causes mothers to have specific nutritional needs to ensure the growth and development of both mother and child. Intrauterine growth retardation, low birth weight, and infant malnutrition contribute to a high risk of maternal and infant mortality. Once born, only 41.9% of children aged 6–23 months are exclusively breastfed, and from the age of six months, breast milk is no longer able to meet the energy and micronutrient needs of children, making consumption of adequate complementary foods essential. When solid foods begin, diet diversity for the mother and child remain a concern. Another concern for maternal/child health is the spread of Toxoplasmosis. The modes of infection and transmission remain poorly understood, particularly for poor, remote communities but occurrence is high accounting for many complications of birth and pregnancy.

Diet diversity has been associated with increased nutrient intake and better maternal and child nutrition status in developing countries. Although nutrient-dense foods are available, diets are centered on nutrient deficient foods such as rice that are low in vitamins and minerals. Despite resource-limited conditions, targeted nutrition education has been shown to increase diet diversity and

nutrition status in developing countries. Due to high levels of malnutrition in Madagascar,
in-depth knowledge of the dietary and child-bearing practices of mothers, interventions promoting health practices, and identifying further pathways for intervention are warranted. Lastly, investigating the pathways of Toxoplasmosis are also warranted to mitigate the spread of this serious and preventable public health concern.

The objectives are: 1) describe the dietary practices and perceptions of mothers during pregnancy, lactation, breastfeeding, and complementary food introduction; 2) describe birthing practices of midwives and community health workers to determine differences in maternal health outcomes; 3) to conduct household surveys on hand washing and food preparation and sample fruits, vegetables, and water sources in the community to quantify and map the prevalence of Toxo oocytes (eggs) across Andasibe; and 3) to provide a tailored, four-week nutrition education program to improve diet diversity, health promoting practices.

A.1.2. State the research question(s) (i.e., specific study aims and/or hypotheses).

The study aims are to: 1) describe the dietary practices and perceptions of mothers during pregnancy, lactation, breastfeeding, and complementary food introduction; 2) describe birthing practices of midwives and community health workers to determine differences in maternal health outcomes; 3) to conduct household surveys on hand washing and food preparation and sample fruits, vegetables, and water sources in the community to quantify and map the prevalence of Toxo oocytes (eggs) across Andasibe; and 3) to provide a tailored, four-week nutrition education program to improve diet diversity, health promoting practices.

Describe how you will disseminate your findings as "generalizable knowledge" . (Publications, presentations, etc).

The findings will be analyzed and disseminated as research publications and presentations for faculty and students involved as research assistants.

A.2. Subjects

Total projected number of subjects proposed across all sites by all investigators for the entire course of the study.

500

Total projected number of subjects to be studied by the Appalachian State University investigator(s) for the entire course of the study

500

If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here. (Note: this does not pertain to experimental vs control groups--just whether different populations or groups are being selected for recruitment.)

A.2.3.

This study is being conducted in four separate parts:

1. Maternal and Child Nutrition Survey - will recruit approximately 200 mothers with a child 2 years of age or younger who live in the Andasibe region.

2. Toxoplasmosis Survey - will recruit approximately 200 participants who live in the Andasibe region.

3. Nutrition Education Program - will recruit approximately 25 mothers aged 45 of younger, with a child aged 10 or younger.

4. Midwife and Community Health Worker practices Interview - will recruit approximately 75 individuals who hold this responsibility in the community.

Do you have specific plans to enroll subjects from these vulnerable or select populations: Do not check if inclusion of a group is purely coincidental and has no bearing on the research. For example, you should check "Pregnant women" if you specifically intend to recruit women who are pregnant. Do not check if you are conducting a survey of the general public, not aimed at pregnant women. See SOP 1201: Vulnerable subjects in research.

✘ Children (under the age of majority for their location)
Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.
✘ Pregnant Women
✘ Nonviable neonates or neonates of uncertain viability
✘ Prisoners, others involuntarily detained or incarcerated, or parolees
If an enrolled participant becomes incarcerated during the course of the research, they must be removed from the research project until such time as the IRB (and OHRP for NIH funded projects) approves the study to include prisoners, unless there is an immediate risk to the participant from ending treatments under the protocol.
✘ Student athletes, athletic teams, or coaches

Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply.

✘ Decisionally impaired individuals
(e.g., Mini mental state examination (MMSE), Montreal cognitive assessment (MOCA))
✘ Foster children
✘ Non-English-speaking

Students

Some research involving students may be eligible for waiver of parental permission (e.g., using departmental participant pools). See SOP 32.9.1

Employees

✖ Abusive Relationships

Age range of subjects:

Minimum age of subject enrolled	18
	years
Maximum age of subject enrolled	99
» If no maximum age limit, indicate 99	
	years

A.3. Inclusion/exclusion criteria

A.3.1. List required characteristics of potential subjects (inclusion criteria).

1. Inclusion criteria for the Maternal and Child Health Survey - mothers with a child aged 2 and younger who live in the Andasibe region.

2. Inclusion criteria for the Toxoplasmosis Survey - mothers with at least one child who live in the Andasibe region.

3. Inclusion criteria for the Nutrition Education Program - mothers under the age of 45 with at least one child aged 10 or younger who live in the Andasibe region.

4. Inclusion criteria for the Midwife and Community Health Worker Interview - midwifes and community health workers who practice in the Andasibe region.

A.3.2. List required characteristics of potential subjects (exclusion criteria).

Any person not meeting the above criteria will be excluded from the study.

A.3.3. Justify any exclusion based on race, gender or ethnicity

Exclusions will be made based on gender. These studies being conducted are centered on maternal and child health, and the evaluation of specific practices that only females can speak to such as pregnancy, breastfeeding and childbirth.

Additionally, mothers are considered to be gatekeepers to the home for purchasing, cooking, and preparing foods and drink items. Therefore, they are the most knowledgeable about these practices, and have the greatest influence on such behaviors.

A.4. Study Procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

No

A.4.2. Select all health or performance collection activities (non-clinical) that apply.

✗ Health assessment information, other than questionnaires (such as blood pressure or lipid panels)	
✗ Recording for presentation purposes	
✗ Body Composition (eg, BodPod)	
✗ Use of CO2 to induce anxiety	
✗ V02 max test	
✓ Other physical performance measures	
✗ Other physiological procedures not listed	
List:	Height, weight, mid-arm circumference measurement, and RRS technology

Will this study use any of the following non-clinical methods?

✓ Pencil and paper questionnaires or surveys	
✗ Electronic questionnaires or surveys	
✓ Interview questionnaires or surveys	
✗ Telephone questionnaires or surveys	
✗ Focus groups	
✗ Diaries or journals	
✗ Audiorecording	
✗ Videorecording or filming	
✗ Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)	
✗ EyeTracker	
✗ Photovoice	
✗ Still photography	
Describe	--

A.4.2. Are subjects assigned or randomized to study "arms" or groups?

No

Will you be using any methods or procedures commonly used in biomedical or clinical research. Examples include but are not limited to: * Using a Medical Device/Mobile App * Non-Medical device to affect structure/function or treat a condition * Drawing blood * Performing lab tests or biological monitoring * Conducting physical exams * Administering drugs or other substances * Conducting a clinical trial

June 4, 2019 until July 1, 2019 for all projects.

Describe research procedures as they relate to human participants. Information must be sufficiently detailed to explain what participants will be asked to do, duration of procedures, and frequency of procedures. PLEASE NOTE: this field will not support uploading diagrams or images. Please upload them as separate attachments at the end of your application.

introduction, and pregnancy and/or breastfeeding experiences. They will also be asked to allow us to measure their weight, height, mid-arm circumference, and to scan the mother's hand with a RRS technology device that is a non-invasive bio-marker of fruit and vegetable intake and measures skin carotenoid concentrations using a Pharmanex BioPhotonic ScannerTM, a portable RRS device. The participant will place his/her palm against the light window of the scanner and hold it there for 90 seconds. The scanner will emit a light and display a score in Raman counts of 0-70,000+. Each participant will be measured (weight, height, mid-arm, and RRS) twice and the result will be averaged. Participants will be assigned a participant code based on region location and responses will be de-identified.

2. Procedures for the Toxoplasmosis Survey - mothers with at least one child will be asked to complete a one-time questionnaire on food and household behaviors on water, food, and hygiene practices. Permission will also be requested to use sterile sampling supplies to swab fruits, vegetables, soil, and sources of water. All samples will be stored in small, sealed vials (5mL and 2mL) containing RNAlater. Each sample will be labeled and marked with the location (GPS coordinates), description of site, item sampled, and time of day. Samples will be given to Dr. Sarah Zhody, Assistant Professor at Auburn University for analysis. ASU will only be collecting samples, and will not be involved in any analysis of the samples. Participants will be assigned a code based on region location and responses will be de-identfied.

3. Procedures for the Nutrition Education Program - mothers under the age of 45 with at least one child aged 10 or younger will be asked to participate in the nutrition education program. To participate, mothers will complete a pre (week 1) and post questionnaire (week 4) on what the mother and child eat and how often, nutrition knowledge, and health behaviors. They will also be asked to allow us to measure their weight, height, mid-arm circumference, and to scan the mother's hand with a RRS technology device that is a non-invasive bio-marker of fruit and vegetable intake (same procedures as #1). They will be asked to complete these measurements two times, once at the beginning of our study, and once again in 4 weeks. The same participants will also be asked to meet with researchers weekly one-on-one for about 15-30 minutes to be provided individual diet and health recommendations and to attend one group meeting after three weeks, to share and discuss nutrition and health concerns and to learn about healthy behaviors. Participants will be assigned and provided a code based on region location. The code will be used to link participants data for the pre/post measures.

4. Procedures for the Midwife and Community Health Worker Interview -

midwifes and community health workers will be asked to complete a one time set of interview questions on their current practices when working with pregnant mothers, and during the delivery process. Participants will be assigned a code based on region location and responses will be de-identified.

All recruitment, consent, interviews, and surveys will be completed with the assistance of a translator to assure that all procedures are explained thoroughly and well understood.

If there are procedures or methods that require specialized training, list who will perform these procedures, and their qualifications for the procedures/instrumentation used.

The skin carotenoid concentrations using a Pharmanex BioPhotonic ScannerTM, a portable RRS device, will require specialized training.

The lead PI and Emily Owen, a graduate research assistant will be trained in using the RRS device and will perform these measurements. Both will have undergone a training by a Pharmanex representative to use the technology.

A.4.8. Are there cultural issues, concerns or implications for the methods to be used with this study population?

Yes

Please explain

Before research procedures begin, all projects will be discussed with the village fokotany (mayor) and permission will be granted to conduct the study. This is in accordance with Malagasy culture and tradition. Additionally, verbal consent a less formal consent process is preferable to Malagasy culture and will also be used instead of written consent.

A.5. Benefits to subjects and/or society

A.5.1. Describe the benefit to society based on scientific knowledge to be gained

These study results will provide a wealth of baseline knowledge of the food practices and health care of mothers and children, a very vulnerable population in Madagascar.

These projects will provide knowledge that will help tailor interventions or programs toward improving health while also providing pathways to mitigate the spread of many serious illnesses.

This could have profound effect on maternal and child mortality, but also micro-nutrient deficiencies in the future.

A.5.2. Does this study have the potential for direct benefit to individual subjects in this study?

No

Explain

No direct benefits will be immediately identifiable, but longer term indirect benefits for health and health care may be impacted.

A.5.3. Are there plans to communicate the results of the research OR results of any clinical tests administered for the research back to the subjects?

Yes

If yes, describe

Results will be communicated back to the mayor of the region in very general terms such as: most people need to eat more vegetables daily, or people should be washing their fruits and vegetables prior to eating them to lessen the chance of a food borne illness.

Since all data will be de-identified, individuals will not be identified when results are communicated.

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Please select the categories of risk:

There are no foreseeable risks to this research for participants.

A.6.3. Overall Assessment of level of risk (i.e. greatest level of risk based on all procedures):

Describe any items (risk categories) checked above and what will be done to minimize these risks. We have provided IRB-approved risk language for certain procedures starting with question 5. Note: If you have safety risks which could be identified or managed by the data you are collecting on individual participants, you will be asked to elaborate in Section A.7.

	Risks (including physical, emotional, social, legal or financial) are the same as encountered in daily life or during the performance of routine physical or psychological examinations or tests (minimal risk).

Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling, if applicable.

Not applicable.

The following options are IRB-approved risk language statements for certain biomedical/clinical procedures. Only check "yes" if you wish to have this language added to your IRB. You do not have to check "no."

A.6.5. Risk language for DEXA scans:

No

A.6.6. Risk language for pQCT scans:

No

Risk language and minimization of risks for VO2 Max procedures (selecting this language confirms you will follow the listed procedures):

No

Use of CO2 (35% / 65%) to induce anxiety (selecting this language confirms you will adhere to the procedures described for risk minimization):

No

A.6.8. Risk from EyeLink 1000 or other EyeTracking device:

No

Risk language and risk minimization for muscle biopsy procedures (selecting this language confirms adherence to the procedures listed below):

No

A.7. Data and safety monitoring

When appropriate, describe the plan for monitoring the data to ensure the safety of participants (i.e. physical or psychological risk factors). These plans could range from the investigator monitoring subject data for any safety concerns to a formal data safety monitoring plan, depending on the study. For studies that do not raise obvious safety concerns, you may still describe your plans for monitoring the study as it progresses, or mark N/A.

n/a

Are there criteria that will be used to stop the ENTIRE STUDY prematurely (e.g., safety, efficacy, unexpected adverse events, inability to recruit sufficient number of subjects, etc.)?

No

A.8. Data analysis

Explain how the sample size is sufficient to achieve the study aims. This might include an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies), or a formal power calculation.

Since this study is exploratory by nature, a small sample size will be sufficient to accomplish study aims.

The midwife and community health worker interviews are qualitative, and the other survey projects will be a convenience sample of as many individuals as are available.

A.9. Identifiers

Check all of the following identifiers you will be collecting. This does not apply to information on consent forms.

✗ Names
✗ Telephone numbers
✓ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
✗ Fax numbers
✗ Electronic mail addresses
✗ Social security numbers
✗ Medical record numbers
✗ Web universal resource locators (URLs)
✗ Internet protocol (IP) address numbers
✗ Biometric identifiers, including finger and voice prints
✗ Full face photographic images and any comparable images
✗ Recordings of Voice
✗ Other
Enter other here: --

A.8.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

✓ with the research data (i.e., in the same data set and/or physical location)
✗ separate from the research data (i.e., coded with a linkage file stored in a different physical location)
Describe: All participants will be assigned a code based on their region of Andasibe (north, east, south, west). This code will not make participants readily identifiable as many individuals will be recruited from each region.

A.10. Confidentiality of the data

A10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

Participants will be assigned a code for ease of data entry, but their responses will remain de-identified.
For the Nutrition Education Program specifically, participants will be assigned and provided with a code. This code will be used again when researchers collect post measures so the data may be paired, but still remain de-identified.

A10.2. Describe how data will be transmitted among research team (i.e., personnel listed on this application).

The data will be collected using paper questionnaires and entered into excel files on password protected computers.
The paper questionnaires will be transported back to the U.S. with the PI and then kept in a locked filing cabinet in the PI's office.

A10.3. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc.?

No

A10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study? Please note that all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable information is automatically issued a Certificate of Confidentiality (CoC). You should also select "Yes" if your study is NIH funded and has been issued a CoC under this updated NIH policy.

No

A10.5. If this study is limited to data collection by survey or interview, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

There will be very little potential for identification of participants. Even so, when survey results are discussed they will be discussed as descriptive statistics of the study population, not as individual responses.
For the interview participants, individual anonymous responses may be used as quotations when discussing results. However, the specific town or village will not be used in conjunction a quote.

A10.6. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

A.11. Data sharing and transmission

Data security for storage and transmission:

Electronic Data

If other, explain: --

Hard copy data and/or specimens

Data anonymized by research team so source data cannot be determined

Locked suite or office

Locked cabinet

Using participant codes on all collected data and maintaining the key linking participant codes with identifiable information in a separate location from data

If other, explain: --

A.11.2. How long will the data be stored?

Years after study completion

How many years?

3

A.12. Post-study disposition of identifiable data or human biological materials

Describe your plans for destroying data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

Examples:

_ Paper will be shredded by: (date)
_ Biological Samples will be destroyed by: (date)
_ Destroy electronic files from computer/PDAs/removal media (CDs, diskettes) by: (date)

Paper will be shredded by July 30, 2022.

Part B. Direct Interaction

B.1. Methods of recruiting

Check all the following means/methods of subject recruitment to be used:*

✔ In person (i.e. approaching individual participants)

Describe how subjects will be identified

Participants will be randomly approached by walking through villages and using the screening tools.

To recruit midwives and community health workers, the researchers will inquire with the mayor to help identify individuals and then permission will be sought to participate.

For any selections made, please describe the procedures. (Respond "N/A" if "None of the above" is selected.)

n/a

For any information collected for these purposes, please describe when and how you will destroy the data if the participant declines to participate or is not eligible. (Respond "N/A" if "None of the above" is selected.)

n/a

Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

Participants will be randomly recruited using a convenience sample from each region of Andasibe. Sample size estimation is based upon participant recruitment numbers from previous research data in the Andasibe region, using the same time frame of one month.

Describe how you will protect the privacy of potential subjects during recruitment

After speaking with the mayor of the region, many individuals will become aware of research project and needed participants through word of mouth. The screening tool does not ask sensitive information and participants will be free to refuse.

Describe how subjects will be contacted, if not addressed above

n/a

Describe who will do the recruiting

All participants of the research team will be involved in recruiting.

B.1.10. Describe efforts to ensure equal access to participation among women and minorities

Women will be exclusively recruited, and all participants will be Malagasy.

B.2. Protected Health Information (PHI)

Protected Health Information (PHI) is any identifiable information about the subject's health that relates to their participation in this research and is obtained from sources ***other than the subject*** *, such as medical records, health care providers, insurance plans, etc. more*

B.2.1. Are you requesting a waiver or limited waiver of HIPAA authorization?

If you need to access Protected Health Information (PHI) to identify potential subjects

who will then be contacted, you will need a limited waiver of HIPAA authorization. If you will be accessing medical records but not contacting patients (e.g., retrospective chart review),you should request a full waiver.

No

B.2.2. Will you need to access PHI for reasons OTHER than the identification of potential subjects (e.g., ongoing use of medical records to conduct the study), as addressed above? In this case you will need a HIPPA Authorization by obtaining permission from the participants.

No

B.4. Incentives for participation

B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate?

Yes

Please describe

For the nutrition education portion of the study, participants will receive 1 pound of beans and 1 pound of vegetables at the conclusion of the study.

Specify the schedule for distributing incentives and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.

The incentive will be provided when the researcher returns to collect post survey information at the conclusion of the nutrition education program.

Those who do not complete the post survey will not be eligible to receive the incentive.

B.4.2. Are there incentives for ELC's via the Psychology Pool (Sona)?

No

B.4.3. Are you collecting Social Security Numbers or Banner IDs for payment and/or tax-related purposes? (Note: you must collect SSNs or Banner IDs for payments more than $99.99 or $599 annually)

No

Part D. The Consent Process

D.1. Obtaining informed consent from subjects

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain

circumstances. If you will be requesting a waiver, you will be asked to provide relevant information in the section below on waivers.

Will children under the age of majority in their locale (18 years in NC) be enrolled in the study?

No

Will adult subjects be enrolled in your study?

Yes

Explain the process for obtaining consent from the subject or the subject's legally authorized representative, if relevant.

Verbal consent will be obtained using the uploaded documents. All study procedures will be explained, including risks, benefits, and the ability to stop participating at any time.

Data collection will not begin until verbal consent has been obtained.

D.1.1. Will decision-impaired subjects be enrolled in your study?

No

D.1.2. Are you planning to obtain consent from any Non-English speaking subjects?

Yes

Describe how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their legally authorized representative (LAR).

All consent and study procedures will be communicated via a translator. Each project will be assigned a translator native to Madagascar.

All study materials will be reviewed with the translator prior to recruitment to clarify any confusing or incorrect wording to ensure accurate translation.

How much time will participants be given to decide whether they want to participate (i.e., how much time will they be given between presentation of research/request for consent and start of procedures)?

Participants will be given as much time as they require to decide until the research team leaves Andasibe. Data collection will only begin with those ready to consent at the time of explanation. For those who are not ready, we will return at a later date to inquire about their decision.

D.1.4. Select factors that might interfere with informed consent:

Participants or their authorized representative (parent) may not speak and/or read English

Please explain other factors.

--

For selected factors, describe any efforts to mitigate

All consent and study procedures will be communicated via a translator. Each project will be assigned a translator native to Madagascar. All study materials will be reviewed with the translator prior to recruitment to clarify any confusing or incorrect wording to ensure accurate translation.

Describe any steps that will be taken to minimize coercion or undue influence during the consent process. These might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician).

Data collection will only begin with those ready to consent at the time of explanation. For those who are not ready, we will return at a later date to inquire about their decision. It will also be explained that even once they consent, they can decide to stop participating at any time.

D.2. Waiver of written documentation of informed consent

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

D.2.1. Are you requesting a waiver of any aspect of written (signed) documentation of informed consent?

No Answer Provided

D.3. Full or partial waiver of consent elements

The default is for subjects to give informed consent. A waiver for elements of informed consent might be requested for the following reasons: 1) Research involving only existing data or human biological specimens; 2) Deception; i.e., the research design requires withholding some study details at the outset; 3) parental permission may be waived. If none of these circumstances apply, click Save and Continue to move to the next section of the application process.

D.3.1. Are you requesting any of the following:

- ✗ a waiver of informed consent in its entirety
- ✓ a waiver or alteration of some of the elements of informed consent
- ✗ a waiver of parental consent for college students under the age of majority

Describe which elements you wish to waive or alter

Participants will all provide verbal informed consent. Data collection will

not begin until participants have verbally agreed to the consent form via a translator.

To justify a waiver of the requirement for informed consent, you must affirm, by checking each of the following items, that it applies to this study. Provide a brief explanation.

The research involves no greater than minimal risk to subjects or to their privacy

Explain
All project measures are non-threatening and non-sensitive questions. All responses are anonymous.

The waiver will not adversely affect the rights and welfare of subjects (Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)

Explain
All participants are still consenting to all procedures, simply with a verbal consent instead of written. No information is being withheld from participants.

The research would be impracticable to conduct without the waiver

Explain how the requirement to obtain consent would make the research impracticable, e.g., most of the subjects are lost to follow-up or are deceased.

When appropriate, there are plans to provide subjects with pertinent information after their participation is over. (e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)

The risk to privacy is reasonable in relation to the importance of the knowledge to be gained

Please explain why it would not be possible to conduct the study with only de-identified data (i.e. without any identifiers listed in A.9.)
Only anonymous, de-identified data will be collected.

D.3.2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

n/a

D.3.3. Does this request for waiver support a study design that involves deception or withholding of information?

No

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies

regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 2 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

Certifying Signatures:

Signature: Electronic Signature Received PM **Date:** 2/15/2019 02:34:10

Alisha Farris

Appendix B: Knowledge and Behavior Questionnaire

2019 One Health Research

Appalachian
STATE UNIVERSITY

Nutrition Education Survey and Food Recall

Interviewer Initials:
Location:
Household #:
Date:

Demographic Questions

1	In what month and year were you born?	Month _____ Year _____
2	Please tell me how old you are. What was your age at your last birthday?	Age:
3	What is your profession? Do you perform paid work or service on a regular basis? If so, what is it?	Yes = 1 No = 0 Profession: _____
4	How many adults live in your household?	Adults: _____
5	How many children in your household are over 5 years of age?	Children: _____
6	How many children in your household are under 5 years of age?	Children: _____
7	Do your children attend school? If yes, is it public or private school?	Yes = 1 No = 0 Public = 2 Private = 3
8	What is your highest level of education (primary, secondary, high school, university)?	Primary = 1 Secondary = 2

		High School = 3 University = 4
9	How many hours per day do you spend obtaining and preparing food for your family?	Obtaining: _____ Preparing: _____

10. Are you currently employed and/or a student?

□ Yes [1]

□ No [2]

11. What is your primary profession? (Check all that apply)

□ Business/ trade (not animal) [1]

□ Business/ trade (animal) [2]

□ Civil servant [3]

□ Other professional [4]

□ Farmer [5]

□ Animal care [6]

□ Mistinjo (office or education) [7]

□ Tourist Guide [8]

□ Hotel Employee [9]

□ Jirama [10]

□ Teacher [11]

□ Health care [12]

□ Student [13]

□ Homemaker [14]

□ Other: [15]

Food Beliefs Questionnaire

12	Which 3 words would you use to describe "nutrition"?	• Expensive • Clean • Balanced • Satiating • Nutritious • Well Cooked • Tasty •Other:_____
13	Name 3 foods you believe are nutritious?	1_____ 2_____ 3_____
14	Name 3 foods you do **not** believe are nutritious?	1_____ 2_____ 3_____
15	When you do your food shopping, which of these are the 3 most important to you?	• Diversity of food • Cost • Availability • Children liking • What you normally buy • Health
16	When you prepare meals for your family, which of these 3 are most important to you?	• Cleanliness • Vitamins in the food • Satiety • Diversity • Children liking • Energizing
17	Do you grow your own crops or raise your own livestock?	YES or NO (If No, skip to question 8)
18	Does your family eat the crops and/or livestock or sell them for money?	
19	Are there food related fady that you are aware of in the community?	YES or NO (If No, skip to question 11)
20	What are the food related fady that exist?	
21	Who observes the fady and who does not?	

22	Which of the following methods do you use to prepare and cook your food? (Circle all that apply)	• Boiling in water • Frying in oil • Grilling over open flame • Baking in oven • Raw, not cooked
23	What foods should an infant or child eat so that he/she does not become malnourished or sick?	
24	What foods should an adult eat so that he/she does not become malnourished or sick?	
25	Do you preserve foods in your home?	YES or NO (if No, skip to the next section)
26	List the foods you preserve and the reason that your preserve them.	Food: _____ Reason: _____ Food: _____ Reason: _____

Dietary Diversity Questionnaire (photos of food and food models will be used for visual aid)

Please describe the foods (meals and snacks) of each food that you ate or drank yesterday during the day and night, whether at home or outside the home. Start with the first food or drink of the morning.

Interviewer: Write down all foods and drinks mentioned. When mixed dishes are mentioned, ask for all items included. When the respondent has finished, probe for meals, snacks, and condiments not mentioned.

Breakfast	Snack	Lunch	Snack	Dinner	Snack

When recall is complete, fill in the food groups based on the information recorded above. For any food groups not mentioned, ask the respondent if a food item from this group was consumed.

	Food Group	Examples	Yes = 1 No = 0
1	CEREALS	corn/maize, rice, wheat, sorghum, millet or any other grains or foods made from these (e.g. bread, noodles, porridge or other grain products)	
2	WHITE ROOTS AND TUBERS	white potatoes, white yam, white cassava, or other foods made from roots	
3	VITAMIN A RICH VEGETABLES AND TUBERS	pumpkin, carrot, squash, or sweet potato that are orange inside + *other locally available vitamin A rich vegetables (e.g. Red sweet pepper)*	
4	DARK GREEN LEAFY VEGETABLES	dark green leafy vegetables, including wild forms + *locally available vitamin A rich leaves such as amaranth, cassava leaves, kale, spinach*	
5	OTHER VEGETABLES	other vegetables (e.g. tomato, onion, eggplant) + *other locally available vegetables*	
6	VITAMIN A RICH FRUITS	ripe mango, cantaloupe, apricot (fresh or dried), ripe papaya, dried peach, and 100% fruit juice made from these + *other locally available vitamin A rich fruits*	
7	OTHER FRUITS	other fruits, including wild fruits and 100% fruit juice made from these	
8	ORGAN MEAT	liver, kidney, heart or other organ meats or blood-based foods	
9	FLESH MEATS	beef, pork, lamb, goat, rabbit, game, chicken, duck, other birds, insects	
10	EGGS	eggs from chicken, duck, guinea fowl or any other egg	
11	FISH AND SEAFOOD	fresh or dried fish or shellfish	
12	LEGUMES, NUTS AND SEEDS	dried beans, dried peas, lentils, nuts, seeds or foods made from these (eg. hummus, peanut butter)	
13	MILK AND MILK PRODUCTS	milk, cheese, yogurt or other milk products	

27. Do you have a child aged 0-2 years? Yes _____ No _____

Answer the following for one of those children. What age is the child you are answering questions about today? _____ months

Yesterday, what was your child fed and how often?

Breakfast	Snack	Lunch	Snack	Dinner	Snack

28. Are you breastfeeding your child? Yes _____ No _____
How old do you think your child will breastfeed until? _____
How confident are you in this? (circle one below) _____

1) Not confident
2) Unsure
3) A little confident
4) Pretty confident
5) Very confident

29. Do you have a child aged 2-10 years? Yes _____ No _____
Answer the following for one of those children. What age is the child you are answering questions about today? _____ years

Did your child eat different foods from you yesterday? If so, list differences here:

Breakfast	Snack	Lunch	Snack	Dinner	Snack

30. Where do you get water from? _____

31. What do you use the water in your storage containers for? (Check all that apply)

□ Drinking [1]
□ Bathing [2]
□ Cooking [3]
□ Washing fruits and vegetables [4]
□ Washing meat to cook [5]
□ Washing household dishes and utensils [6]
□ Washing clothes [7]
□ Giving to animals [8]
□ Other: [9]

32. How do you take water from your storage container?

□ Bucket [1]
□ Cup [2]
□ Hands [3]
□ Pour directly from storage container [4]
□ Other: [5]

33. Do you treat your drinking water with anything before you drink it?

□ Yes [1]
□ No [2] (Skip to question 36)

34. If yes, how often do you treat your water?

□ Sometimes (≤ once per week) [1]
□ Often (> once per week) [2]
□ Always (every time you drink water) [3]

35. If yes, how do you treat the water?

□ Boil [1]
□ Filter through cloth/gauze [2]
□ Settle [3]
□ Chlorine/Sur'eau [4]
□ Other: [5]

36. Do you wash your fruit and/or vegetables with anything before you eat or prepare them for eating?

□ Yes
□ No (Skip to question 39)

37. If yes, how often do you wash them?

□ Sometimes (≤ once per week) [1]

□ Often (> once per week) [2]

□ Always (every time you eat or prepare them) [3]

38. If yes, what do you use to wash them? [Do not prompt with answers]

□ _____

39. How often do you wash your hands?

□ More than once a day [1]

□ Once a day [2]

□ 3 to 5 times a week [3]

□ Once a week [4]

□ Never [5]

□ Other: [6]

40. When do you wash your hands? (Check all that apply)

**Note for interviewer --- Do not list options, but probe "are there any other times you wash your hands?" to get all instances. If needed, clarify if hands are washed before or after activities.

□	Before food preparation [1]	□	Before eating [11]
□	After food preparation [2]	□	After eating [12]
□	Before food collection [3]	□	Before breastfeeding [13]
□	After food collection [4]	□	After breastfeeding [14]
□	Before using the bathroom [5]	□	Before using animal feces [15]
□	After using the bathroom [6]	□	After using animal feces [16]
□	Before dealing with kids [7]	□	Before farming in the field [17]
□	After dealing with kids [8]	□	After farming in the field [18]
□	Before working with livestock [9]	□	Other: [19]
□	After working with livestock [10]		

41. Do you have soap in your household?

□ Always [1]

□ Sometimes [2]

□ Never [3] (Skip to measurements)

42. If yes, how often do you wash your hands with soap?

□ Always [1]

□ Sometimes [2]

□ Do not wash hands with soap [3]

43. What else do you use the soap for? (Check all that apply) *Don't read options out loud.

□ To wash for market [1]

□ Washing clothes [2]

□ Washing kitchen items [3]

□ Bathing bodies [4]

□ Washing hair [5]

□ Other: [6]

Mother

Weight (kg)	#1:	#2:	Average of measurements:
Height (cm)			
MUAC (mm)		RRS:	

Appendix C: Qualitative Data Collection

Qualitative Post-Data Questions

1. What was the most helpful and/or enjoyable aspect of the nutrition education you received?

2. Was there any part of the education that you didn't like or that wasn't helpful? If so, how could we make it better?

3. Did you change any part of your diet because of the education you received? If so, what was it?

4. If you wanted to make changes but weren't able to, can you tell us some of the barriers that prevented you from doing so?

5. What would you like to learn more about in the future?

Appendix D: Handout 1

Ny mpitaiza zaza 0 – 1 taona

Ny fampinonoan-dreny

Tsara ho an’ny zaza, tsara ho an’ny reniny.

Tsy misy tsara noho ny mampinono.

Raha mety dia tsara raha tohizana mandrapaha-feno 2 taona ny zaza.

Tsara ho an’ny zaza satria:

- Misoroka ny fivalanan’ny zaza ary miaro azy amin’ny aretina samihafa
- Mora levonina

Tsara ho an’ny reny satria:

- Tsy vidiana
- Tsotra sady mahasalama

Ny sakafony voalohany

Rehefa feno enim-bolana (6 volana) ny zaza dia omena sakafo mivaingana.

Voankazo maivana, legioma, voamaina, ary vary no tsara indrindra.

Safidio ny sakafo be otrikaina (vitamine) ! Ireo sakafo tsara anombohana izany dia ny:

- Voankazo potserina: papay, manga, ary akondro.
- Vomanga, ovy

Tohizo hatrany ny fampinonoana ny zaza mandrapaha-fenony 2 taona.

- Legioma: korzety na karoty voapotsitra

Ny fanasana tanana sy ny sakafo

Sasao ny tanana rehefa avy mivoaka (avy ao an-kabone), avy any an-tsaha, vao miditra ny trano, na koa rehefa maloto fotsiny. Zava-dehibe ny fanasana ny tanana sy ny sakafo mba hitandrovana ny fahasalamana!

Ny fanasana ny tanana dia miaro amin'ny fivalanana sy ireo aretina maro samihafa .

Hirao in-2 ny "zaza manasa tanana" mba hampadio tsara ny tanana . 20 segondra dia ampy hanadiovana ny tanana amin'ny rano sy ny savony.

Sasao vao avy mikohaka, mievina, na koa avy manisin-delo mba tsy harary.

Sasao ihany koa ny voankazo sy ny legioma! Mbola maloto izy ireny ka mety hankarary.

Appendix E: Handout 2

Eat more Fruits and Vegetables

Fruits and Vegetables are colorful, tasty, and full of vitamins!

Enjoy a variety of colors for good health!

- **Eat different ones every day for the best health**

Cheaper fruits and vegetables to add to rice are:

- Green leaves - all kinds!
- Onions, Tomatoes, Carrots
- Potatoes and Cabbage
- Beans - all kinds!
- Bananas and Litchi
- Oranges, Mangos, Pineapple
- Avocado

Limit packaged foods like crackers, chips, candy. They do not have vitamins.

Breastfeeding

Good for baby, good for mom.

Some is better than none.

If you can, keep breastfeeding until your child is two.

Good for baby:

- Prevents diarrhea keeps your baby from getting sick
- Easy on the stomach

Good for mom:

- Cheap!
- Easy and healthy

Handwashing & Food Washing

Wash hands after going to the bathroom, gardening, being outside, and when they are dirty. Washing foods and your hands are both important to keep you healthy!

Washing hands can prevent diarrhea and many other illnesses.

Sing the "Alphabet Song" to make sure you wash long enough. 20 seconds with soap and water is all you need to be clean!

Wash after coughing, sneezing, or blowing your nose so you don't get sick. Wash your fruits and vegetables too! They have dirt on them that can make you sick.

3 Meals and 2 Snacks Every Day

Eating good foods keeps you healthy and strong! 3 big meals and colorful snacks will keep you happy and give you energy to work and play.

First build a healthy meal

- Rice, then fruits and vegetables, then protein

Eat these foods to make you strong and help you feel full. They help you eat smart to play and work hard.

- Fruits, vegetables, and rice
- Beans, eggs and meat

Eat these foods to protect your eyes and keep them healthy.

- Carrots, leafy greens

Appendix F: Healthy Foods Handout

Handout on Healthy Foods and Their Benefits

Healthy Foods and Their Benefits: They Make you Happy and Healthy

Pair these cheap fruits and vegetables with rice to make you strong and healthy!

** it is better to eat a fruit or vegetable for snack, not biscuits

** eat all fruits and vegetables that are in season

- Eat dark green leaves to make you strong and to have healthy eyes
    - Sweet potato leaves
    - Pumpkin leaves
    - Cassava leaves
    - Anamamy
    - Pitsaye
    - Anamala
    - Tarro leaves
- Eat lentils and beans to make you strong and give you lots of energy
- Eat bananas to keep your heart strong and help prevent disease
- Eat pumpkin to make you strong and for healthy eyes
- Eat carrots to make you strong and for healthy eyes
- Eat oranges and pineapples to keep your heart strong and help you stay healthy from disease
- Eat sweet potatoes to make you strong and for healthy eyes
- Eat tomatoes to keep your heart strong and help you stay healthy from disease
- Eat onions for flavor

Appendix G: Handwashing Handout

Handout on the Importance of Washing

The Importance of Washing

- **It's most important to treat your water to get rid of dirt and germs that make you sick**
- **Treat your water with chlorine/Sur'eau or boil it so it is safe to drink**
- **Use treated water to wash fruits, vegetables, and drink to prevent you from getting sick**
- **Wash vegetables and fruits with treated water before cooking or preparing them in any way**

Vita

Emily Owen is originally from McDonough, Georgia. She is the daughter of Michael and Dawn Levins and Russell Owen. She graduated from Ola High School in 2014. Emily then attended the University of Georgia where she graduated with her bachelor's in Dietetics in May of 2018. Emily is a graduate student at Appalachian State University earning her master's in nutrition and completing her dietetic internship in Lincolnton, North Carolina. Emily moved to Boone, North Carolina, to attend Appalachian and live out her dream to study global nutrition. The nutrition education she provided was a small aspect of the conservation efforts made by the Mad Dog Initiative year after year in Madagascar's beautiful rain forest communities. Emily hopes to return to Madagascar to continue providing nutrition education for the people in Andasibe by partnering with Association Mitsinjo, an organization focusing on conservation and sustainable development initiatives for the village of Andasibe. In addition to traveling back to Madagascar, she is passionate about nutrition education and hopes to become a nutrition education specialist as she continues with her career as a registered dietitian.