COVER PAGE: Clinicaltrials.gov results submission

Title: Pilot project: Evaluating a family-based nutrition and garden intervention in rural Guatemala

NCT number: 03689504

Version date: December 20, 2018

PROTOCOL TITLE:

Pilot project: Evaluating a family-based nutrition and garden intervention in rural Guatemala

PRINCIPAL INVESTIGATORS:

Study PI and contact information:

Peter Rohloff, MD, PhD
Chief Medical Officer, Wuqu' Kawoq
617-447-3034
peter@wuqukawoq.org

Site PI and contact information:

Elizabeth Yakes Jimenez, PhD, RDN, LD (UNM IRB)
Research Associate Professor, Departments of Pediatrics and Internal Medicine, UNM
Director, Nutrition Research Network, Academy of Nutrition and Dietetics
505-688-0718
eyjimenez@salud.unm.edu

VERSION NUMBER: 2.0

DATE: December 20, 2018

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	VA
x	Other: Rotary International

Is this a clinical trial under ICH-GCP E6? ☐ Yes X No

If yes, please confirm that the research team is familiar with and agrees to comply with the investigator requirements cited in ICH-GCP E6. ☐ Yes ☐ No

ICH-GCP E6 can be accessed by copying and pasting this URL into your browser: http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

Table of Contents

1. Objectives

The specific paaims of this pilot project are:

1) To evaluate the feasibility of studying whether implementation of family gardens paired with a nutrition intervention program in rural Guatemala will lead to improvements in maternal and child dietary diversity, child growth and household food insecurity compared to a nutrition intervention program alone.

2) Evaluate the implementation of the intervention through the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework.

We hypothesize that by augmenting a standard nutrition intervention with improved household food access through a garden intervention, child growth, dietary diversity and food security will improve compared to outcomes with the nutrition intervention alone.

2. Background

Children in Guatemala are at high nutritional risk, with a 47% prevalence of stunting (chronic malnutrition) and low full coverage with vitamin A supplements (UNICEF 2016). Only half of Guatemalan children receive a minimum acceptable diet (according to World Health Organization criteria measuring dietary diversity and meal frequency) from 6-23 months (UNICEF 2016). The indigenous Mayan population is disproportionately affected by poverty, food insecurity and malnutrition, with the prevalence of chronic malnutrition reaching as high as 70% in rural areas.

Wuqu' Kawoq/Maya Health Alliance (MHA) has conducted several studies to determine what nutrition interventions really work to prevent and treat chronic malnutrition. As a result of these studies, MHA established a home-based nutrition program whose goal is catch-up growth, improvement of minimum dietary diversity, minimum meal frequency, and minimum acceptable diet and increased caregiver knowledge. In a 50-child pilot, this intervention resulted in a mean change in height for age Z score (HAZ) from -3.67 ± 0.99 to -3.37 ± 0.89 over 6 months and an increase from 15-21% on minimum acceptable diet. of families In a subsequent RCT of this intervention, a trend toward improved growth at 6 months was observed, although the change was not statistically significant. However, minimum dietary diversity and minimum acceptable diet both improved significantly (risk difference 16.9 and 15.9%, respectively). The intervention also resulted in improved daily intake of legumes, eggs, and vitamin A rich fruits and vegetables (risk difference 16.5, 10.4, 12.7% respectively) (Martinez et al, 2018).

Agriculture is a major economic activity in Guatemala, with 70% of families working in this sector. Family agriculture has many obstacles, including lack of access to land and the expansion of cash crop (e.g., sugar cane, African palm) plantations. Most of the food that is grown locally is exported, rather than being used for local consumption.

Public and private organizations in Guatemala have worked to promote the production of food for consumption. However, very few of them have measured the impact of agricultural initiatives on nutritional status. Moreover, this is the first study in North Tecpán to evaluate the potential impact that adding a home food production (for

consumption) component to a health-oriented nutrition program can have on maternal and child diet quality and nutritional status and household food security.

3. Study Design

This is a quasi-experimental study with an intervention group and a nonrandomly selected control (standard care) group.

- The *standard-of-care group* will consist of subjects recruited from Maya Health Alliance's nutrition program in prioritized communities of *North Tecpán, Chimaltenango, Guatemala*. Subjects in the standard care group will receive the current standard child nutrition care (growth monitoring, deworming medication, micronutrient supplementation, nutrition education classes and home visits).
- The *intervention group* will consist of subjects recruited from MHA's nutrition program in prioritized communities of *San Andrés Semetabaj, Sololá, Guatemala*. Subjects in the intervention group will receive the standard child nutrition care plus an additional agriculture component (agriculture education classes, supplies to build a home garden near the family home and on-going agricultural support).

A quasi-experimental design was selected because it was determined that household level randomization would be culturally and logistically difficult.

Both sites are rural. The intervention and control communities are 90 minutes apart by car and have similar prevalence of chronic malnutrition in children and similar sociodemographic characteristics (education levels, economic activity, health services, school access and food access).

In addition to the primary study endpoints (defined below), we will use the RE-AIM framework (Glasglow 1999) to evaluate the implementation of the intervention at the caregiver, provider and community levels. Broadly, the five elements of RE-AIM are: reach, effectiveness, adoption, implementation and maintenance. For each element, a variety of factors affecting implementation will be assessed. A select number of constructs from the Consolidated Framework for Implementation Research (CFIR) (Damschroder 2013) will also be considered as implementation factors within the RE-AIM framework. Data for this implementation analysis will be gathered through program documentation and auditing, home visit surveys, focus groups with participants, key informant interviews and semi-structured community interviews. More details about the RE-AIM framework for this study, the implementation factors to be assessed and the instruments for assessing them are outlined in Appendix J.

4. Inclusion and Exclusion Criteria

The study involves enrollment of subjects into an add-on gardening intervention who are already participating in an intensive standard-of-care nutrition intervention by MHA staff. Therefore, clinical staff (community health workers) at MHA who run that nutrition intervention will ascertain initial interest in participation in this study from their clients enrolled in the nutrition intervention. Subjects will be approached in their homes to discuss potential participation in the study.

If clients express initial interest, the community health worker will provide that family's contact information to a study nurse, who is trained in human subject's research ethics and is a native speaker of Kaqchikel, the language spoken by the majority of the potential research subjects. This nurse will then conduct a home visit to potential subjects to explain the proposed research activities in more detail. If the family agrees to participate, then the nurse will administer the consent process and enroll them in the study.

Inclusion criteria are:

- Children who are already scheduled to be enrolled in MHA´s intensive home-based nutrition program (non-investigational, standard of care) who are 6-24 months of age at the time of enrollment with a height-for-age Z scores of <= -2 – Households of children with height-for-age Z scores of <= -2.5 will be prioritized.
- At least one caregiver willing to provide written informed consent
- Caregiver of a child enrolled in the study, including women who may be pregnant
- Planned residence in the study area for the next 18 months

Exclusion criteria are:

- Children with acute malnutrition (weight for length Z scores of <= -2.0)
- Children with a severe medical illness that affects growth (e.g., heart disease, kidney disease, genetic condition) as determined by a MHA/Wuqu' Kawoq staff physician.
- Caregivers with cognitive impairments that prevent them from being able to provide informed consent

Children who are ineligible for enrollment in the research study will receive standard care (the home-based nutrition intervention) from MHA.

5. Number of Subjects

The study will enroll 140 children and their primary caregivers into two study groups: standard-of-care (n=70 children and 70 caregivers) and intervention (n=70 children and 70 caregivers).

6. Study Timelines

Five to ten families per month will be enrolled into the study from each study community. We anticipate that recruitment will take ~7-14 months.

The research team will have contact with enrolled participants over the course of 18 months. The primary study data collection time points will be at 0 months (enrollment), 6 months (end of standard of care/nutrition intervention), 12 months, and 18 months. It is anticipated that each of these study data collection visits will last approximately 1 hour,

for a total of 4 hours. In addition to that, for the *intervention group only*, data will be collected at the first monthly agricultural home visit and at one additional agricultural home visit approximately 4 months thereafter. Each of these agricultural home visits will last approximately 1 hour for a total of an additional 2 hours. Combined, the total data collection time for the participant in the *intervention* group will be 6 hours.

The duration of the study interactions with the children and their caregivers is as follows:

- Standard child nutrition care (received by both groups) will last 6 months and will include nutrition classes for 5 weeks and one home visit a month. Standard nutrition care will involve approximately 16 hours of contact with MHA clinical personnel.
- The add-on agricultural/garden intervention (received by the intervention group only) will last 8 months and will include monthly agricultural classes and monthly home visits. The agricultural/garden intervention will involve approximately 16 hours of contact with MHA agricultural personnel, in addition to the time dedicated to the standard nutrition intervention.

A select number of participants (approximately 10) in the *intervention group* only will be asked to participate in one of two focus groups, approximately 90 minutes in length, between 6 and 9 months after the first enrollment. Participation in the focus groups will be fully voluntary and will not have any impact on the services or benefits received by the participants.

A small number of community leaders and Wuqu' Kawoq staff will be asked to participate in interviews, approximately 90 minutes in length, between 6 and 9 months after the first enrollment. Participation in the interviews will be fully voluntary.

The expected total duration of the study is approximately 3 years from the date of IRB approval.

7. Study Endpoints

The primary endpoints of this study are changes in the prevalence of:

- *Adequate diet quality*, as assessed by the World Health Organization (WHO) Infant and Young Child Feeding Indicators (IYCFI) (WHO, 2007) minimum dietary diversity, minimum meal frequency, minimum acceptable diet) for children and the Minimum Dietary Diversity for Women (MDD-W) indicator for caregivers. (FAO 2016)
- *Household food insecurity,* as assessed by the Global Food Insecurity Experience Scale (household referenced) (FAO 2017)

Secondary endpoints of the study include changes in: child length-for-age Z-score; child weight-for-age Z-score; child weight-for-length Z-score; child prevalence of stunting, wasting and underweight; and household total crop species diversity.

This study involved no more than minimal risk, so no safety endpoints are specified.

8. Research Setting

The study will be conducted in prioritized communities of North Tecpán, Chimaltenango and San Andrés Semetabaj, Sololá (see additional details in **Section 3. Study Design**). These are rural Mayan language speaking communities where MHA has been working providing primary care and nutrition services for several years. MHA collaborates closely with multiple other NGOs as well as Ministry of Health staff in the region.

All subjects will be recruited via MHAs existing nutrition care program, as described in **Section 4. Inclusion and Exclusion Criteria.** All recruitment, enrollment and study-related procedures will be conducted in the homes of the subjects. All study procedures will be conducted by MHA research staff. The study will be locally overseen and approved by MHA's IRB.

9. Resources Available

The study will be overseen by:

Elizabeth Yakes Jimenez, PhD, RDN, LD for the University of New Mexico/Academy of Nutrition and Dietetics. Elizabeth is a pediatric registered dietitian with a master's degree in public health nutrition and a PhD in epidemiology. She has worked in community and clinical settings conducting nutrition research and evaluation projects for approximately 15 years. She is the Director of Dietetics Practice-Based Research Network (DPBRN) for the Academy of Nutrition and Dietetics and a Research Associate Professor in the Departments of Pediatrics and Internal Medicine at the University of New Mexico Health Sciences Center.

Peter Rohloff, MD, PhD for MHA. Peter is the Chief Medical Officer at MHA and an Assistant Professor in Medicine at Harvard Medical School. He has 15 years of research experience in rural Guatemala, leads a core research team at MHA of 15 staff members, and speaks the relevant Mayan languages.

Research staff at MHA who will participate in the project include Andrea Paola Guzman Abril, a Licensed Nutritionist who will serve as the primary research coordinator; and a study nurse who will conduct research visits and collect research related data. Two MHA community health workers and a MHA agronomist will deliver the study interventions. These staff will work full-time on the project, except for the Nutritionist, who will devote 50% of her time.

Study staff will be employed for the entire timeline of the project, which includes sufficient time for data analysis after study completion. All personnel will complete Collaborative Institutional Training Initiative's International Modules (CITI) or the NIH's Human Subjects Training course before doing research in the field. A standard operating procedures manual for the study will be developed, and all study staff will receive training on study procedures.

MHA has a dedicated research office located in Tecpán, close to the study communities. The office has dedicated file storage cabinets for research documents, high-velocity internet, dedicated full-disc encrypted phones and computers, statistical software (STATA), and

online HIPAA-compliant file servers and a REDcap server. The study budget includes the purchase of a new vehicle for use by the study team. An IT technician and comptroller will provide support to the project as needed.

MHA will provide usual care for treatment of severe medical illness identified during the screening/recruitment phase.

10.Prior Approvals

The protocol is approved by the MHA IRB.

11. Multi-Site Research

N/A – this is not a multi-site study

12.Study Procedures

This study will be conducted in two different sites. These are rural, Mayan language-speaking areas where MHA has been working for several years to provide primary care and child nutrition services.

This is a quasi-experimental study with an intervention group and a non-randomly selected control (standard-of-care) group.

The *standard-of-care group* will consist of subjects recruited from Maya Health Alliance's nutrition program in prioritized communities of *North Tecpán, Chimaltenango.*

The standard-of-care child nutrition services include:

- Intake visit with research nurse to assess basic health history, demographics, WHO IYCFI, FIES and MDD-W for women
- Monthly growth monitoring
- Monthly micronutrient supplementation
- Deworming medication (every 6 months)
- Monthly home visits by community health worker (CHW) to provide individualized growth assessment to mothers
- Nutrition education classes with CHW (nutrition during pregnancy, breastfeeding, complementary feeding, chronic and acute malnutrition, hygiene and nutritious recipes)

The *intervention group* will consist of subjects recruited from MHA's nutrition program in prioritized communities of San Andrés Semetabaj, Sololá. The intervention group will receive all standard-of-care child nutrition services as described above, plus:

- Agriculture education classes with the study agronomist (home garden package, assessment of plant production, weed and pest control, water access, etc.)
- Home garden supplies including seeds and/or seedlings
- Monthly home visits from a study agronomist to provide assistance to build a garden near the family home and on-going support throughout the study

Study data will be independently collected by a study nurse for all enrolled subjects at 0, 6, 12 and 18 months:

- Basic health history and demographics Appendix A
- Child weight and length/height Appendix B
- Household Quick Poverty Score (QPS) Appendix C
- Food Insecurity Experience Scale (household) Appendix D
- WHO Infant and Young Child Feeding indicators (child) Appendix E
- MDD-W Indicators (caregiver) Appendix F
- Agriculture Inventory Survey (household) to measure crop diversity and crop utilization Appendix G

Note that child weight and length and WHO IYCFI are already routinely collected as part of evaluation data for the standard-of-care nutrition services.

Additional data will be collected by the study agronomist for the *intervention group only* during the first agricultural home visit and at one additional agricultural home visit approximately 4 months thereafter:

- Agricultural Home Visit Baseline Survey (Baseline Agricultural Practices; Gardening Experience and Motivation) Appendix H
- Agricultural Home Visit Follow-up Survey (Adoption of Methods; Level of Home Garden Maintenance; Hours Worked in Home Garden) Appendix I

13.Data Analysis

Descriptive statistics for each group will be calculated using Stata (StataCorp, College Station, Texas). Family poverty scores will be calculated with a validated numerical scoring system commonly used in Guatemala. Changes in primary and secondary study outcomes will compared between study groups using the chi-square test, paired t-tests (or the non-parametric equivalent) and linear and logistic regression as appropriate.

Within the intervention group, the rate of overall adoption will be compared descriptively across various demographic groups, and changes in primary and secondary outcomes will also be compared descriptively between adopters and non-adopters. Focus groups and interviews will be coded and analyzed thematically using select constructs from the Consolidated Framework for Implementation Research (CFIR) as a framework.

This is a pilot study to determine the feasibility of a garden intervention and to generate an initial effect size estimate for future, well-controlled studies. As such no formal power analysis will be performed.

14.Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A – this study poses no more than minimal risk

15.Withdrawal of Subjects

There are no safety/stopping rules, so we do not anticipate any withdrawal from the study unless requested by the participant, or in the case that a participant moves out of the study area.

Subjects can withdraw from the study at any time that they request. If subjects withdraw from the study, we will retain any existing collected data for analysis, as outlined in the consent form, unless the subjects specifically request otherwise.

If subjects wish to withdraw from the nutrition care services or the agricultural intervention, we will endeavor to continue data collection at the specified timepoints, if they are agreeable.

16.Data Management/Confidentiality

Data sharing between the Academy of Nutrition and Dietetics and UNM is covered under contract FP5579 (effective date 8/1/2018). Per this agreement, all data shared with UNM for this study will be de-identified and transferred using the secure transfer portal provided by UNM HSC Central IT. An account will be created for the contact at AND to login to the portal web site (https://securetransfer1.health.unm.edu). Data transfer via this link is protected with Secure Sockets Layer (SSL) capabilities/128-bit encryption. After the transfer, Elizabeth Jimenez will be granted access to the files transferred by the AND contact via the UNM HSC secure network storage.

All data transfer from MHA to AND, and from AND to MHA, will also occur using a secure transfer portal provided by AND. Data transfer via this portal is protected with Secure Sockets Layer (SSL) capabilities/128-bit encryption.

Research data and unique subject study IDs will be either captured on paper forms or directly entered into MHA's secure Redcap server interface using full-disc encrypted study Android phones or laptop computers (demographics, anthropometrics, quick poverty score, WHO IYCF indicators, MDD-W, crop diversity survey and the additional agricultural data to be collected by the study agronomist) or the Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII) database (WHO IYCF indicators, MDD-W). Both databases are HIPAA-compliant and secure. Study personnel will each be assigned a unique username and password to the Redcap and ANDHII interface. Only PIs or PI´s delegated research coordinator will be able to administer user accounts.

If data is captured on paper forms, it will be stored in a locked filing cabinet in MHA's central office, in a location distinct from consent forms.

For study data captured on paper forms, double entry in REDCap will be employed. Bimonthly data quality checks of paper forms and the study databases will be done by the research study coordinator. Native data field definition functions in Redcap and ANDHII will be used to ensure data quality at point of entry by research staff. During bimonthly database checks, any issues identified will be checked manually against an existing original paper forms if possible.

Study personnel will be trained to collect anthropometric and dietary diversity data using standard methods by a supervising study coordinator. All anthropometric measurements will be completed in triplicate during each study visit. Weight will be measured to the nearest 0.1 kg with the use of a Seca 310 hanging scale (Seca, Hamburg, Germany), and length/height will be measured to the nearest 0.1 cm with the use of a portable length board locally constructed according to UNICEF specifications. For data analysis, we will use the mean of the first two readings if they did not differ more than a pre-specified tolerance limit (length/height < 0.5 cm, weight < 0.2 kg). If they differed more than these pre-specified tolerance limits, the third measurement will be compared

with the first and second measurements and the pair of measurements that has the smallest difference will be used to calculate the mean.

On-going quality control via data review and random audits of in-field operations (recruitment, anthropometric techniques, dietary diversity, and exit visits) will be performed by the study coordinator. The auditor will perform a triplicate of height and weight measurements of the children and compare results to the measures obtained by the study nurse, at the same time evaluating the measuring technique. The auditor also will perform an independent dietary diversity interview with the children's caregiver, and compare results with the data obtained by the nurse or CHW. Timely feedback will be provided to the study staff as required. Study staff will also participate in monthly anthropometry standardization exercises during which the technique, precision, and reliability of their measurements will be evaluated and reinforced.

At enrollment in the study by the research nurse, each subject will be assigned a unique subject study ID number. This number will be registered on the paper consent form (stored in a locked file cabinet) and in an electronic study spreadsheet, hosted on MHA's HIPAA-compliant in-house file server. This will be the only link between identifiable subject information and their research data. Only the PIs or their delegated research coordinator will have access to this spreadsheet. Control of access to MHA's file server will be directly managed by the MHA PI (Rohloff) or a delegated research coordinator at MHA.

Identifiable data (consent forms, master lists linking subjects to study ID, birthdates) will be maintained through publication of primary study reports and manuscripts, and for an additional period of 5 years. In addition, fully deidentified data sets will be deposited in public data repositories at the time of report/manuscript publication. No identifiable data will be released at any point.

17.Data and Specimen Banking

No specimens will be collected during the study.

Identifiable data (master lists linking subjects to study ID, birthdates) collected during the study will be stored in secure, electronic databases (See Section 16.13). Consent forms will be stored in a locked filing cabinet in the MHA office in Guatemala. Identifiable data will be maintained through publication of primary study reports and manuscripts, and for an additional period of 5 years. In addition, fully deidentified data sets will be deposited in public data repositories at the time of report/manuscript publication. No identifiable data will be released at any point.

18.Risks to Subjects

The study procedures and activities are not more than minimal risk. The child nutrition services and many of the data collection procedures are part current standard of care at MHA. We do not, therefore, anticipate any adverse outcomes from these procedures and activities.

It is more likely, however, that a caregiver or community member might erroneously ascribe an adverse outcome to the trial. For example, this might occur if a child dies from pneumonia while in the trial, even though this would not be expected to be related to the trial itself. We will address this issue in the following way: The case would be reported by the study nurse and study coordinator to MHA PI Rohloff and MHA's medical director Dr. Waleska Lopez. Dr. Lopez will independently adjudicate the event and make a determination on the need for follow-up care. Dr. Rohloff will report the event to MHA's IRB Chair, Dr. Melvin, for independent review, and will

also include the event in a study adverse event log, which will be updated weekly and included in each continuing review of the project.

Additionally, we will attempt to minimize conflated adverse outcomes, by excluding all children with acute malnutrition or serious medical illness from the trial as outlined in **Section 4. Inclusion and Exclusion Criteria**. Any child with acute malnutrition or serious medical illness will be immediately referred to the MHA clinical team and will receive comprehensive clinical care.

Another potential risk from the study is that it might cause conflict between the study communities. This could occur because caregivers receiving the nutrition intervention might learn that others are also receiving the additional garden component. We attempt to minimize this risk by recruiting the intervention families from a different community than we recruit the standard-of-care families.

Finally, there is the potential of accidental disclosure of protected health information. Please see **Section 16. Data Management/Confidentiality** for procedures to minimize this risk.

19.Potential Benefits to Subjects

Individuals in both groups may benefit directly. Both groups will receive micronutrient supplementation, deworming medication, home visits and nutrition education, which we anticipate will have positive outcomes on diet quality, catch-up growth, decreased rates of severe stunting, and promotion of cognitive and motor development.

The agriculture intervention group will receive supplies to build a garden, home visits and agricultural education. We anticipate that this will increase their knowledge as well as food availability for their family, even after the study has finished (as the families will keep their garden supplies).

Over the long term, reversing the ill effects of stunting and food insecurity also contributes to improved school performance, adult earning potential, and reduced incidence of adult non-communicable diseases.

This study will help to fill an identified gap in research at the nexus of nutrition, food production and health. Specifically, this work will provide evidence about measurement and indicators used to evaluate diet quality, health impacts and food security when providing nutrition interventions paired with agriculture interventions in rural communities in the highlands of Guatemala.

The implementation evaluation component of this study will provide new knowledge about how various caregiver, provider and community-level factors can affect the implementation of a home gardens program for malnutrition, giving valuable insights into how and why the intervention achieved the level of success that it did.

In this way, the study will be help create a functional integrated nutrition and agriculture model that can be used by other organizations who are working or want to work in the treatment and prevention of malnutrition, while offering an understanding of the implementation challenges that

they would be likely to confront in the process. Thus, the benefits could conceivably multiply to many more children and their families in Guatemala than simply the study families.

20.Recruitment Methods

Potential subjects will already be planning to participate in MHA's individualized nutrition services in communities surrounding Tecpán, Guatemala (see **Section 4. Inclusion and Exclusion Criteria**).

Subjects (primary caregivers of children participating in the nutrition services) will be approached in their homes during a regular home visit by the community health worker, who will provide initial information about the study. If the subject expresses interest, then the community health worker will provide that person's information to a study nurse, who is trained in human subject's research protocols and a native speaker of Kaqchikel, the language spoken by most of the potential research subjects. This nurse will then conduct a home visit to potential subjects to explain the proposed research activities in more detail.

If more than one child in the home is already enrolled in the MHA nutrition intervention, then only the youngest of those children in the eligible age range will be enrolled in this study.

21.Provisions to Protect the Privacy Interests of Subjects

Subjects will be approached at a time that is most convenient to them, in their homes. We have learned from our previous work in these communities that the best times to conduct home visits are from 8:30 to 11:30 AM or from 2:00 to 4:00 PM.

Study personnel will introduce themselves and ask permission to enter a home before discussing the study, obtaining consent, conducting any surveys or taking anthropometric measurements.

Study personnel will be natively fluent in Spanish and the locally spoken language, or use an interpreter, to ensure comprehension for participants.

Study personnel will not participate in the nutrition services, and therefore will not have access to MHA electronic medical record data.

22.Economic Burden to Subjects

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
Quick poverty score	4	X	☐
Agriculture Inventory Survey	4	X	☐

Agriculture Home Visit Survey	2	X	☐
Focus Groups (Select Participants Only)	1	X	☐
Interviews (Select Leaders and WK Staff)	1	X	☐
		☐	☐
		☐	☐
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Basic health history and demographics	1	X	☐
Child weight and length/height	4	X	☐
WHO IYCF indicators	4	X	☐
MDD-W indicator	4	X	☐
Food Insecurity Experience Scale	4	X	☐
		☐	☐
		☐	☐
		☐	☐

There will be no direct costs to subjects for participation in the study. All services provided by MHA are given for free, including the standard of care nutrition and agricultural services that are under study in this protocol. Educational and intervention components will be conducted either in the subjects' home or in a nearby community facility and, therefore, no travel costs will be incurred.

23.Compensation

Subjects will not receive any monetary compensation for participation.

24.Compensation for Research-Related Injury

N/A - This research does not involve more than minimal risk to subjects.

25.Consent Process

Consent will be obtained by the study nurse, who is trained in human subject's research ethics and a native speaker of Kaqchikel, the language spoken by most of the potential research subjects If the potential participant agrees to take part in the study, the nurse will explain the consent process, obtain at least one caregiver's signature (or equivalent, see below for more explanation), and will enroll them in the study. The consent process will take place in participant's homes.

Subjects will not be required to provide immediate consent upon hearing about the study. The study nurse will be instructed to provide each subject with a waiting period of up to 14 days if requested before obtaining consent.

A small number of program participants, community leaders and Wuqu' Kawoq staff will be approached to participate in focus groups and community interviews, respectively, once the

study is already underway. For these groups, a verbal consent script will be read to the participants (Appendix C) allowing them to either accept or decline to participate.

Written consent will be obtained using the attached consent form (Appendix A). Consent will be obtained by a trained study nurse who has completed relevant human subjects ethics training and who is fluent in Spanish and Kaqchikel. Many of the anticipated participants will not be literate, and so the consent form will, in most cases, be read out loud to them by the study staff. A "teach back" process will be used to assess participant understanding of the consent form content.

If participants are unable to sign their name, the study nurse administering consent will sign the form documenting that consent was administered and note that the participant is unable to sign his/her name. This process will be witnessed and attested by a independent member of the study team. The potential participant will not be required to sign with an "X" or to place a thumbprint given the political context of this region of Guatemala. During the civil war, individuals who were not literate could be made to sign documents as an oppressive strategy for extracting land titles. Hence, this study will not perpetuate those practices.

The consent form and process will make it clear that consent to participate in the research will not in any way impact the quality or quantity of clinical services, including ongoing MHA primary care and nutrition services.

An attempt will be made to obtain consent from both guardians of the child. However, consent from one parent/guardian will be sufficient for enrollment in the trial, as this study involves no more than minimal risk. Children in the study are aged 6-24 months; therefore, they are not capable of providing assent.

Informed consent documents will be in Spanish. This is because Mayan languages are largely oral languages, and no subjects in the target area can reasonably be expected to read them. Similarly, very few professionals, such as the available pool of study staff, can read them. We will conduct extensive practice sessions with the nurse leading informed consent to ensure that her ongoing oral script accurately represents the Spanish written text, in the (highly likely) case of many caregivers being unable to read the text.

26.Documentation of Consent

Written informed consent will be obtained by a research study nurse. For more details on the consent process see **Section 20. Recruitment Methods and Section 25. Consent Process.** Briefly, subjects will be approached in their home and informed consent will be obtained at that time.

Many of the anticipated participants will not be literate, and so the consent form will, in most cases, be read out loud to them by the study staff. If participants are unable to sign their name, the study nurse administering consent will sign the form documenting that consent was administered and note that the participant is unable to sign his/her name. This process will be witnessed and attested by a independent member of the study team. The potential participant will not be required to sign with an "X" or to place a thumbprint given the political context of this region of Guatemala. During the civil war, individuals who were not literate could be made to sign documents as an oppressive strategy for extracting land titles. Hence, this study will not perpetuate those practices.

27.Study Test Results/Incidental Findings

Community health workers typically verbally share child growth results and progress and provide feedback on dietary diversity with caregivers as part of standard-of-care/child nutrition services; this will continue during the study.

Any incidental findings noted during the course of the study will be evaluated by MHA primary care medical team.

28.Sharing Study Progress or Results with Subjects

Local meetings will be held every 6-months to update each community about the study and progress. Additionally, the final study findings (in aggregate) will be shared with each community.

29.Inclusion of Vulnerable Populations

The population is highly vulnerable to coercion because of the potential for perceiving participation in the study to be a prerequisite to receiving services from MHA. The informed consent document and process will explain clearly that all families will receive the standard of care nutrition services and primary care services, whether they participate in the study or not.

There will be complete separation between nutrition services and agricultural intervention staff (community health workers, agronomist) and study research nurses. This is important, so the standard nutrition services can be delivered regardless of subjects' participation in the study.

No monetary compensation will be provided for research participation, to avoid coercive economic influence to participate.

Also, the majority of subjects will be Kaqchikel speakers with limited Spanish fluency. The study staff will be native speakers of to mitigate any language barriers. Teach back methods will be used to assess comprehension during the consent process.

Pregnant caregivers may participate in the study. The Pregnant Women Checklist has been completed below. Children 6-24 months will participate in the study. The Children Checklist has been completed below.

30.Community-Based Participatory Research

N/A- this study is not designed as CBPR. Clinical and programmatic leadership at MHA have close working relationships with local community authorities in all study communities. Local community authorities have been apprised of the planned work.

31.Research Involving American Indian/Native Populations

N/A This study does not involve American Indian/Native populations.

32.Transnational Research

Note that this project was developed by the Guatemala team, and will be reviewed and locally overseen by the MHA IRB. The Dietetics Practice-Based Research Network (Elizabeth Jimenez) will collaborating with the study team to provide technical assistance related to study design and implementation and data analysis and interpretation.

This study will be conducted in prioritized communities of San Andrés Semetabaj, Sololá and North Tecpán, Chimaltenango. These sites were selected because they are currently being served by MHA's primary care and nutrition services. MHA has been working in this area for several years, with a focus on providing culturally and linguistically appropriate care to the Mayan indigenous population. MHA has conducted several community-based research studies in the area, and their experience informed the development of this protocol. One significant difference with U.S. culture, noted in **Section 25. Consent Process**, is that there is historical trauma associated with asking non-literate individuals to sign with an "X" or thumbprint. We have taken this into account when designing the consent process.

Elizabeth Jimenez has extensive experience with conducting cross-cultural research, with previous experience collaborating with teams from Southeast Asia and East and West Africa. She is proficient in Spanish. The research team from Guatemala has extensive experience working in the study area (providing medical care and conducting research) and are fluent in Spanish (spoken and written) and Kaqchikel (spoken – primarily an oral language). All research team members from Guatemala involved in consent and research procedures will complete human research ethics training.
The consent process has been described above in **Section 25. Consent Process** and **Section 26. Documentation of Consent.**

Clinical and programmatic leadership at MHA have close working relationships with local community authorities in all study communities. Local community authorities have been apprised of the planned work. Local meetings will be held every 6-months to update each community about the study and progress. Additionally, the final study findings (in aggregate) will be shared with each community.

33.Drugs or Devices

N/A This research does not involve any drugs or devices.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

A. Waiver of Documentation of Consent

Complete this checklist if you intend to obtain consent verbally but will not be obtaining signatures from subjects on a consent form to document consent. Waivers of documentation of consent are commonly requested when using scripts, information sheets, or email or survey introductions to present the elements of consent instead of using a traditional consent form.

1. Are you requesting a waiver of documentation of consent for some or all subjects?

   ☐ All

   X Some. Explain: If participants are unable to sign their name, the study nurse administering consent will sign the form documenting that consent was administered and note that the participant is unable to sign his/her name. The potential participant will not be required to sign with an "X" or to place a thumbprint given the political context of this region of Guatemala. During the civil war, individuals who were not literate could be made to sign documents as an oppressive strategy for extracting land titles. Hence, this study will not perpetuate those practices.

   Verbal consent will be obtained for focus groups.

2. Provide justification for <u>one</u> of the following:

   a) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

   b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

      This research presents no more than minimal risk of harm to the subjects. Most of the study activities and procedures are part of the

standard-of-care nutrition services delivered by MHA, and the other activities and procedures are low risk (surveys and focus groups with adults and agricultural education) and do not require written consent outside the research context.

3. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

   ☐ Yes. Please attach a copy to your submission in Click.

   X No

II. **Vulnerable Populations**

A. **Children**

Complete this checklist if the subject population will include children.

1. Select the category of research that you believe this research falls within and provide justification for any associated criteria. If there are different assessments for different groups of children or arms (e.g., placebo vs. drug), include a memo to provide an assessment for each group.

   X Research not involving greater than minimal risk. *(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

   ☐ Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

   Provide justification for each of the following criteria:

   (1) The risk is justified by the anticipated benefit to the subjects:

   (2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

☐ Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Provide justification for each of the following criteria:

(1) The risk represents a minor increase over minimal risk:

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition

B. **Pregnant Women and Fetuses**

Complete this checklist if the subject population will include pregnant women and fetuses.

X This checklist does not need to be completed if the research is both minimal risk and is not conducted, funded, or otherwise subject to regulation by DHHS, DOD, EPA, or VA.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; ***or***, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

3. Any risk is the least possible for achieving the objectives of the research.