Study Title: The Impact and Implementation of a Mobile Messaging Intervention to Improve Infant and Young Child Nutrition in Senegal

NCT Number: NCT05374837

Document date: 07/08/22

Document name: Study Protocol

INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**

The Impact and implementation of a **M**obile **M**essaging intervention to **I**mprove **N**utrition among **I**nfants and young children in Senegal

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- **Protocol Version and Date:**

V5 07.08.22

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1.0 Research Design

1.1 Purpose/Specific Aims

The overall purpose of this study is to examine the impact (Aim 1), implementation and costs (Aim 2) of an mHealth infant and young child feeding (IYCF) messaging intervention in Senegal using an effectiveness-implementation hybrid (type 1) design. The specific aims include:

Aim 1. To determine the impact of an mHealth IYCF messaging intervention on IYCF practices and nutrition outcomes

Aim 2. To examine the implementation, costs and opportunities for scaling-up the mHealth IYCF messaging intervention

In addition to the two specific aims of the project, we aim to examine the food environments that our study participants interact with in order to better understand the factors that influence IYCF practices.

A. Objectives

This study will provide evidence related to the impact and implementation of an mHealth IYCF messaging intervention among subsistence farming communities in Senegal. The findings have the potential to inform best practices related to IYCF behavior change communication programs in the country targeting hard to reach populations.

B. Hypotheses / Research Question(s)

We hypothesize that parents exposed to the IYCF voice messaging intervention will adopt improved feeding practices leading to improved child dietary diversity and hemoglobin levels.

1.2 Research Significance

Suboptimal infant and young child feeding (IYCF) practices in the first 1000 days, from the time a child is conceived until the time they are 2 years of age, directly contribute to high rates of malnutrition and child mortality in Senegal.[1-4] According to global recommendations, infants should be exclusively breastfed for the first 6 months of life. Thereafter, they should receive a combination of continued breastfeeding and nutrient-rich and safe complementary foods until the age of 2 or beyond.[5] Most Senegalese children (93%) are not fed according to these guidelines, due to a lack of caregiver knowledge and food insecurity,[4] leading to growth faltering

and micronutrient inadequacies. Seventy-one percent of Senegalese young children are anemic, 7% are acutely malnourished, and 20% are chronically malnourished (i.e., stunted).[6] The peak period for growth faltering and micronutrient deficiencies in low- and middle-income countries (LMICs) is between 6-23 months, which coincides with the recommended introduction of complementary feeding.[5,7,8]

Interventions aimed at improving IYCF during the period of 6-23 months are considered essential nutrition actions by the World Health Organization (WHO) and are key policy priorities of the Senegalese Government.[5,7,9] Behavior change communication strategies aimed at increasing caregiver knowledge and addressing community cultural norms are effective in improving IYCF practices;[10,11] however, they often fail to reach caregivers of young children. In Senegal, counseling mothers about IYCF is the responsibility of community health workers (CHWs). However, their reach is limited due to time and geographical constraints as well as competing health priorities.[12-14]

Given the widespread mobile use and strong mobile networks in Senegal, there are clear opportunities for adopting mHealth interventions. Text messages and voice calls have been the most promising mHealth interventions to date,[15-18] but the processes and costs associated with these interventions have not been examined.[18] In this study, we plan to use an effectiveness-implementation hybrid design (type 1)[19] to conduct a rigorous evaluation of the impact, implementation and costs of a user-centered mHealth voice and text messaging intervention to improve IYCF practices in Senegal.

In our pilot research, we conducted focus groups (n=6) with mothers and fathers of young children, and completed a comprehensive survey of ~1200 households in Senegal, to identify key IYCF practices to target. We then developed 8 voice messages (based on the theory of planned behavior (TPB)[20]) targeting the identified IYCF practices and conducted a pre- and post-intervention pilot study to examine its feasibility and potential for impact with a small sample of mother, father and child (6-23 months of age) triads (n=47).[21] After the intervention, we found an improvement in the consumption of nutrient-rich foods and a greater proportion of children consuming a minimum acceptable diet (MAD),[21] an indicator of dietary diversity that is associated with nutrient adequacy, reduced stunting and underweight in children.[22] However, we were limited by a small sample size and a lack of control group, which this study is designed to overcome.

1.3 Research Design and Methods

This project involves five main components: 1) identification of role models in villages included in our pilot study[21] whose experiences related to IYCF will be recorded and included in the messaging intervention; 2) cognitive testing of the IYCF messages to ensure clarity; 3) a cluster randomized control trial (cRCT) of an mHealth IYCF messaging intervention (text and voice messages) that includes information about IYCF best practices that will be delivered to parents/guardians of children 6-23 months of age; 4) a process evaluation of the intervention implementation with the view to identify what worked (or did not work) and why; and 5) a description of the food environments in our study settings.

A. Research Procedures

Identification of role models: Positive deviance is a behavior change approach based on the observation that even in low-resource communities there are people who deviate towards preferred practices ("positive deviants").[23] These individuals have uncommon, but successful, strategies that enable them to find better solutions than their peer.[23] Including role models in IYCF interventions can increase their effectiveness.[24-26] With the assistance of community health workers (CHWs), we will identify "positive deviants" in the pilot villages from our formative work. These villages are culturally, linguistically, socially and economically similar to the villages included in our cRCT. In addition to the 8 scripted messages that we will use in this study (based on our pilot work), we will send an additional 8 unscripted role modeling messages, that describe strategies used by "positive deviants" to successfully adopt the key targeted behaviors. We will identify role models and record their messages in their villages between November 2021-May 2022.

Cognitive testing of messages: We will conduct cognitive testing of the messages in order to ensure that the information delivered in the messages is interpreted by its recipients in the way in which it was intended. Cognitive testing is a form of qualitative research that allows interviewers to probe for a deep understanding of the comprehension by asking participants to paraphrase the messages, discuss their associated thoughts and emotions, and offer suggestions for improvements.[27] Before beginning Aim 1, we will conduct semi-structured interviews, as part of the cognitive testing, with mothers and fathers (~30 participants) in pilot villages, using an iterative approach, until the point of theoretical saturation. In addition to these 8 primary messages, we will identify "positive deviants" in the pilot villages, with the assistance of community health workers (CHWs), who are successfully adopting the 8 target behaviors. We will record unscripted messages of the personal experiences of these role models that will be used to reinforce the 8 primary messages based on the TPB. This approach has been previously used by our Senegal team.[28] The cognitive testing will take place in the pilot villages between November 2021-May 2022.

cRCT sample. The villages in which we are conducting this study are subsistence farming communities with high levels of poverty and malnutrition in three regions of Senegal: Thies, Diourbel and Fatick. Each of the 104 villages that will be included in the study have been purposively selected to ensure that they have an established farming group, and that they are sufficiently geographically dispersed in order to minimize risk of contamination. We will use the list of the household members of the farming groups of each of the 104 villages included in the cRCT as our sampling frame. Based on Dr. Downs' previous experience, we will identify all households within the farming group that have a child 6-19 months of age at baseline (to ensure that the child is not >23 months at endline), and we will subsequently randomly select five mother, father and child triads to be included in our study sample. In some cases, the primary caregiver of the child may be a close relative rather than the birth mother. In these instances, the primary caregiver will receive the voice and text messages along with her husband or primary male caregiver. In total, we will sample 510 triads in 104 villages (~5 households/triads per village). Thus, our sample will include 510 mother, father and child triads. Baseline data collection will take place in May/Jun 2022, the intervention will be delivered between Jun-Sep 2022 and the endline data collection will take place in October 2022.

Process Evaluation sample: A smaller purposive sample of approximately 45 mothers and fathers, implementation project staff and CHWs will be included in Aim 2 of the project as part of the in-depth semi-structured interviews and focus groups conducted in the process evaluation. We will purposively select three villages from each region (n total = 9 villages) in order to maximize variation in village characteristics such as size, distance to urban settings, distance to markets, etc. Interviewees and focus group participants will be purposively selected from the list of all mothers and fathers receiving the voice messages in each of these villages to ensure variation in participant socio-demographics (e.g., household size, parity, age, etc.) as well as key people involved in the intervention's implementation. The process evaluation data collection will take place in between October and December 2022.

Food environment data: Alongside the main project, we will collect data to allow us to map the food environments in the 104 villages included in our R21 study at two different time points: dry and rainy seasons. These data will allow us to better understand the foods that households have access to during these seasons and how the attributes of those foods (e.g., their affordability and acceptability) influence IYCF practices and anemia status among infants and young children. In order to map the food environments in our study settings we will use a combination of food environment assessment tools that have been used by Dr. Downs and colleagues in different settings in East Africa and Asia. These tools involve observing the foods in markets, their price and their quality. They do not involve interaction with human subjects.

Study procedures:

Cognitive testing: We will conduct cognitive testing of all the messages prior to the intervention implementation (Aim 1) to increase acceptability and comprehension using semi-structured interviews and focus groups with ~30 mothers and fathers in the pilot villages. Detailed notes regarding the interviewees' IYCF message comprehension will be taken during the interviews and subsequently analyzed by members of the study team (Gueye & Downs) by assessing common themes/patterns in the message comprehension. Summaries that describe the issues noted for each message and how they were addressed will then be prepared and discussed as a team, in an iterative way until the point of theoretical saturation.

*Data collection for cRCT***:** We will conduct baseline and endline data collection in both the control and experimental group.

*Household survey***:** Consenting participants (mothers and fathers) will complete a household survey that will include information regarding demographics, household characteristics, household expenditures (including healthcare and food expenditures), food insecurity, and infant and young child feeding (IYCF) knowledge, attitudes, beliefs, norms, intentions and behavior. Either the mother or father will answer the questions related to demographics and household characteristics. Both mothers and fathers will separately answer IYCF knowledge, attitudes, beliefs, norms, intentions survey questions. Given that mothers are the primary caregiver of their young children, we will ask mothers to report on the frequency of consuming specific foods targeted in the intervention using a food frequency questionnaire (FFQ) as well as the list-based 24-hour dietary recall, described below. This is typical of collecting dietary data for infants and young children, given that the mother is generally the primary person feeding their children. This is particularly true in the Senegalese culture, where women are the primary caregivers of their

children. The enumerator will record all verbal answers to the household survey questions in an electronic tablet.

List-based 24-hour dietary recall: A list-based 24-hour dietary recall will be conducted with women to assess the dietary intakes of their children. This involves assessing whether their child consumed a list of foods and beverages (including breast milk) over the past 24 hours. Based on the dietary recall we will calculate the minimum acceptable diet (MAD) which measures the proportion of children aged 6-23 months who: had meal frequency the previous day that met the minimum standard for their age as defined by the WHO; AND consumed foods from at least 4 of the 7 food groups identified by the indicator.

Hemoglobin measurements: We will use Hemocue Hb301 machines to measure hemoglobin levels in children in order to determine anemia prevalence using the WHO cut-offs: mild 10 ≤ hb < 11 g/dl; moderate 7 ≤ hb < 10 d/dl and severe hb < 7 g/dl. Hemocue machines allow for non-invasive point-of-care assessments of hemoglobin levels using capillary blood from a finger prick. Standard procedures for their operation will be used based on the protocol used by the Senegal Demographic Health Survey and are described in detail below. [6] Children with severe anemia will be referred to a local health center/post to ensure that they can be treated by a health professional. We will also provide them with the cost of transportation to the local health center/post if there isn't one in their village. Referring children to the health center/post and providing resources for their transportation is aligned with the recommendations of the Comité National d'Ethique pour la Recherche en Santé (CNERS) local IRB board within the Senegalese Minstry of Health. The CNERS does not advise providing study participants that are found to have anemia with iron tablets. Based on our previous experience conducting hemoglobin measurements in Senegal, the CNERS IRB board advised us to refer children with severe anemia to the local health post where the health professionals can then make a decision on treatment.

A step-by-step procedure of the hemoglobin measurement using the Hemocue machine is outlined below:

- STEP 1: Preparation
  - Ensure that you have obtained consent.
  - Put on a new pair of gloves.
  - Open the Hemocue cuvettes box and set aside a cuvette; close the box.
  - Select the third and/or fourth finger of the non-dominant hand and rub (push) gently towards the fingertip to increase blood flow.
  - Clean the finger with an alcohol swab and allow to air dry.
  - Prick finger using lancet.
  - Wipe away the FIRST drop of blood with sterile gauze or cotton.
- STEPS 2: Hemoglobin testing and recording
  - Collect the THIRD drop of blood using the Hemocue® cuvette.
  - Press the corner of the cuvette to the blood drop.
  - Blood move to the center (circle) of the cuvette.
  - Place the cuvette in Hemocue reader.
  - Close drawer.
  - Press activation button.

    - Record the reading in the screen of the Hemocue reader on the Blood Sample Register next to the person's matching ID number.
- STEP 3: REFERRAL
    - In the event that an infant/child has severe anemia, they will be referred to the local health post. Prior to engaging in data collection, members of our study team will alert the local health posts of our study so that they are aware that they may receive referrals due to anemia. This approach is based on the recommendations of our local partners in Senegal as well as the CNERS IRB board.

Intervention description: A mobile voice messaging intervention aimed at improving IYCF practices will be delivered to mothers and fathers will young children (6-23 months). Eight voice messages were developed based on our formative research in the study regions. The voice messaging is based on key messages booklets for infant and young child feeding from UNICEF and the Senegalese '*Conseil national pour le développement de la nutrition'* (National Committee for Nutrition Development), ensuring that the messaging is consistent with both global and local recommendations. The theoretical underpinning of the way the messages are scripted is the Theory of Planned Behavior (TPB). [20] Using the TPB as the basis for the message framing, which places importance on the caregiver's beliefs about the behavior, their perceived efficacy of performing the behavior and the perceived benefits of performing the behavior,[20] we developed and piloted 8 primary messages. The messages contain information about the benefits and consequences of the behaviors, with the view to change attitudes, beliefs, intentions, community norms and, ultimately, behavior. The content of the messages will include 8 scripted messages related to: breastfeeding until two years of age, consuming a variety of foods within a given meal, limiting highly processed foods, the importance of animal sourced foods, consuming vitamin A rich fruits and vegetables, consuming leafy greens, handwashing and feeding infants and young children fruits and vegetables produced and foraged by the household.

In addition to the 8 scripted messages, we will send an additional 8 unscripted role modeling messages, that describe strategies used by "positive deviants" to successfully adopt the key targeted behaviors. The intervention will be delivered over a 16-week period, which falls within the duration observed in previously published IYCF messaging interventions that demonstrated positive impacts.[10] One voice and one text message will be sent each week over the 16-week period, which is aligned with both the previously published literature[10] as well as the community preferences identified through our formative work.

We will not provide participants with phones as part of this intervention. Cell phone ownership is very high in these communities. In most cases, adults have their own phones. In the event that the man or woman participating in the study do not have their own phone, we will ask them if there is a phone that they have access to in the household. In this situation, we will send the voice messages to that phone. However, if they do not have access to a phone we will not continue the recruitment process. There will be no costs to the participants receiving the messages. We will cover all costs of sending the messages and the minutes spent sending them. Using a combination of voice and text messages will enable us to ensure that messages reach phones in areas with poor mobile coverage, while also accounting for literacy levels. Baseline and endline surveys will be conducted in both the control and experimental groups. The control group will receive the 16 messages after the completion of data collection.

Randomization of intervention: Computer-generated random numbers will be used to randomize 104 villages in a 1:1 allocation, stratified by village size (number of households per village) and region (Thiès, Diourbel, Fatick), to receive either the intervention (experimental group) or usual care (control group). Randomization will be conducted following a baseline survey and, given the nature of the intervention, will not be blinded. The intervention will be delivered over a 16-week period.

Data collection for process and economic evaluation:

Process questions captured by messaging platform & endline survey: At the end of each voice message, participants will be asked a series of yes/no questions related to the content of the message. More specifically, they will be asked: if they understood the message, if they found the message helpful and whether they intend to adopt the behavior. The response to the message will be keyed into the phone (1= yes; 2=no). In the event that a participant states that they did not understand the message, we will make note of it and then follow-up with them after the endline survey. There will also be an option to call a local number, for a member of the study team, to gain additional information. The OuA platform (https://ouacompany.com) being used in this study will track whether the call was answered, how long it was listened to and the answers to the questions relating to message understanding, helpfulness and intent to change behavior. These questions will help inform the process evaluation component of the study and will be used to inform the semi-structured interview/focus group questions. As part of the endline survey, we will include an unprompted open recall of the messages by mothers and fathers, in order to assess exposure to the intervention. We will also include questions related to program satisfaction. These questions have already been field tested as part of the piloting of this intervention.

*Semi-structured interviews/focus groups***:** A sub-sample of mothers and fathers, as well project implementation staff and CHWs will participate in semi-structured interviews and focus group discussions to better understand the implementation process, including its strengths and weaknesses. The interviews will also be used to identify ways to integrate the messaging intervention into the existing activities of CHWs. The interview/focus group guides will be developed to gain insight into the fidelity, dose, reach, recruitment and context of the intervention. This will enable us to ascertain which aspects of the intervention worked and which aspects did not and why.

*Economic evaluation***:** The intervention costs will be documented throughout the duration of the intervention. Average costs per child in the experimental group will be estimated over the period of the intervention implementation. Healthcare utilization and costs will also be assessed in both the experimental and control groups using questions included in the household survey conducted as part of Aim 1. A cost-consequence analysis will be conducted in order to compare the intervention costs and outcomes (i.e., consequences).

Food environment data collection: We know from our previous work in these study settings that all villages have a small boutique and/or a daily market that sell food. In addition, we also identified 20 weekly markets where the 104 villages included in our study sample sell and

purchase food. These weekly markets tend to be larger and have more diversity of foods sold. For this project, we will conduct the following data collection in each of the village boutiques/daily markets as well as the 20 weekly markets that the members of the villages frequent:

- To assess **availability** dimension of food environment we will conduct the following assessments: market food diversity score and food vendor inventory to assess the diversity of foods being sold at the markets overall as well as by individual vendors. [8,10] We will also collect the GIS coordinates of all food outlets in order to be able to spatially map the food environments in the study communities. These metrics involve documenting all foods sold within the markets according to the different food groups in established dietary diversity scores. By assessing the diversity of foods available, we will identify gaps in the availability of food from key nutrient-rich food groups and examine how this influences the dietary diversity of infants and young children.
- To assess the **affordability** dimension of the food environment we will collect data on food prices of diverse nutrient-rich foods to calculate the cost of a healthy diet (CoHD).[11] This metric involves collecting the prices of foods that are included in the food based dietary guidelines for a given country, which is subsequently used to ascertain the minimum cost of meeting the national dietary recommendations. Once calculated, the CoHD will provide us with information about how much a healthy diet costs across the different study communities as well as across seasons. We will also be able to ascertain whether there is a relationship with the CoHD and IYCF practices and anemia among our study population.
- To assess the **acceptability** dimension of the food environment we will use the Produce Desirability (ProDes) tool [12] to examine the sensory properties (i.e., overall desirability, visual appeal, aroma, size, and touch) of the most commonly consumed fruits and vegetables in our study communities. Given that quality is often a key determinant of food choice, it is important to capture this element of the food environment. In addition to the ProDes tool, the Environmental Profile of a Community's Health (EPOCH) [13] assessment will be used to examine promotion and advertisement of foods within study villages as well as the weekly markets. This will enable us to better understand the type of messaging that study participants are receiving and which food groups are being promoted.

Potential Risks: The potential risks to study participants include temporary discomfort related to the assessment of hemoglobin levels using a finger prick. However, the hemoglobin assessment is a minimal risk procedure. There are no known side effects of participating in the intervention. The intervention consists of providing IYCF information to mothers and fathers of young children (6-23 months). However, it is possible that mothers and fathers could misunderstand the nutrition messages resulting in poor diet and nutrition practices. We will conduct cognitive testing prior to the delivery of the intervention in an effort to eliminate this risk.

There is also the inconvenience of the time required for listening to/reading the messages, responding to the surveys, and participating in the semi-structured interviews. The risks are limited to the immediate study period. With regards to severity, we do not anticipate any severe risks from participating in the study.

Adequacy of Protection Against Risk: While every possible step is taken to minimize risks, if participants have any concerns about any aspect of the study, consent documentation makes it clear that they can refuse to continue with the study at any time without penalty. The consent forms also contain the contact information for the CNERS local IRB and Mr. Gueye, the Project Coordinator, in case they wish to speak to the IRB or a member of the study team to discuss adequacy of protection against risks.

We will also minimize risk by making the nutrition education messages as clear as possible and making sure they are conveyed in a language that is easy to understand. We have also shared the messages with the C*onseil national pour le développement de la nutrition,* National Council for Nutrition Development*,* to ensure that they are in line with their efforts to improve nutrition education in Senegal. Dr. Downs has worked with them in the past as part of an initiative to train CHWs in farming communities in Senegal and has already established a relationship with them.

Considerations related to COVID-19: We do not anticipate engaging in any research activities until February 2022. Baseline data collection assessments for won't be conducted until May 2022 at the earliest. It is likely that the threat posed by the pandemic will be significantly lower at that time and a higher proportion of the Senegalese population will be vaccinated. However, given the uncertainty related to the COVID-19 pandemic, we are prepared to make modifications to our study protocol in order to protect human subjects. First, we will conduct all data collection outside. This is aligned with the data collection procedures that are typically used in these settings. Surveys are conducted outside of the home, in the household's private yard either sitting on a mat or in chairs. Given that the risk of virus transmission is incredibly low outside, we will ensure that all data collection is conducted outside, while maintaining the privacy of study participants. Second, enumerators will conduct the surveys at a six feet distance from the survey participants. This will allow us to maintain social distancing guidelines. While the enumerators conducting the household surveys will be able to maintain a six-foot distance between themselves and the study participants, this will not be possible for the anthropometric agent who will be testing hemoglobin levels using Hemocue machines. Third, if the risk of COVID-19 remains at the time of data collection, our enumerators will wear masks and gloves while conducting the surveys. Given the inability to maintain social distancing by the anthropometric agents, they may be provided with additional personal protective equipment (PPE) (e.g., N95 Masks) for their protection as well as the protection of study participants. Fifth, we will consult directly with the IRB at CNERS in Senegal to ensure that we are taking all the necessary precautions to protect both our enumerators but also our human subjects participants. Given that our intervention will be conducted on mobile phones, no adjustment to our intervention delivery would be required.

B. Data Points

We will collect data at baseline and endline. We will also collect process evaluation data after completing the endline data collection.

There is no long-term follow-up included in this study.

C. Study Duration

The total project duration is two years.

The cognitive testing interviews will take approximately 30-45 minutes to complete. These participants will be from villages in which we conducted pilot work and will not be included in the cRCT.

Participation in the cRCT will include a household visit (~45 minutes) before and after the delivery of the intervention. They will also receive voice and text messages for a period of 16 weeks. Each message will be less than 2 minutes in duration. Some participants will also participate in the process evaluation, which will involve an additional ~45 minutes as part of the semi-structured interview. In total, the maximum amount of time that a participant would be engaging in study activities is approximately 3 hours over the course of a six-month period.

D. Endpoints

The endpoint for this study will be after the endline data collection and process evaluation is completed and the control group has received the voice messages.

1.4 Preliminary Data

We previously conducted a pilot of a modified version of this intervention. In our pilot research, we conducted focus groups (n=6) with mothers and fathers of young children, and completed a comprehensive survey of ~1200 households in Senegal, to identify key IYCF practices to target. We then developed 8 voice messages (based on the theory of planned behavior (TPB)[20]) targeting the identified IYCF practices and conducted a pre- and post-intervention pilot study to examine its feasibility and potential for impact with a small sample of mother, father and child (6-23 months of age) triads (n=47).[21] After the intervention, we found an improvement in the consumption of nutrient-rich foods and a greater proportion of children consuming a minimum acceptable diet (MAD) (19% higher in intervention as compared to the control group),[21] an indicator of dietary diversity that is associated with nutrient adequacy, reduced stunting and underweight in children.[22] However, we were limited by a small sample size and a lack of control group, which this study is designed to overcome.

1.5 Sample Size Justification

We expect to enroll 510 mother, father and child triads in 104 villages (clusters) in the Thies, Diourbel and Fatick regions of Senegal as part of this study. We plan to include ~5 triads per village. Our sample size estimation was calculated based on our two primary outcomes: the prevalence of MAD and anemia.

The sample size estimate is informed by our prior cross-sectional research on over 1200 household surveys and our pilot data over a 4-week intervention period (unpublished data).[2] Attrition was 2%, anemia prevalence was 66% and MAD prevalence was 46.8%. Assuming a conservative intra-class correlation coefficient of 0.02,[3] 5% attrition (based on our pilot work and previously published community-based research projects in Senegal),[29,30] and a 2-sided significance level of 0.05, 102 clusters with 5 triads per cluster will provide 81.7% power to detect a 6% absolute difference in anemia and 88.8% power to detect an absolute difference of

7% in MAD. Our pilot study found a 19.2% increase in MAD. Even if we assume 10% attrition, we will still have 80% power to detect a 6% absolute difference in anemia and 87.3% power to detect an absolute difference of 7% in MAD. Improvements in anemia and MAD prevalence of 6% and 7%, respectively are clinically relevant and aligned with improvements in previously published studies.[31,32]

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

An mHealth messaging intervention will be delivered to the intervention group for this study, as described above. The intervention will be 16 weeks in duration and include both scripted and unscripted messages related to 8 key IYCF behaviors.

B. Dependent Variables or Outcome Measures

Table 1 provides an overview of our primary and secondary study outcomes.

Table 1. Study outcomes

Outcome type	Outcome	Description
Primary	Anemia prevalence	We will use Hemocue Hb301 machines to measure hemoglobin levels in children in order to determine anemia prevalence using the WHO cut-offs: mild 10 ≤ hb < 11 g/dl; moderate 7 ≤ hb < 10 d/dl and severe hb < 7 g/dl. A finger prick will be used to obtain a drop of capillary blood that is placed on a cuvette and inserted in the Hemocue machine to obtain an on-the-spot assessment of hemoglobin levels.
	Minimum Acceptable Diet	Minimum Acceptable Diet Prevalence, Primary, baseline and endline: The minimum acceptable diet indicator will be used to assess dietary diversity in children. A 24-hour open dietary recall will be conducted with mothers to assess their child's dietary intake over the previous day. The 24-hour recall will be used to calculate minimum dietary diversity (MDD) (consuming ≥4 of 7 food groups (grains, roots and tubers; legumes and nuts; dairy products; flesh foods; eggs; vitamin A rich fruits and vegetables; other fruit and vegetables)) and minimum meal frequency (MMF) (2x/day for breastfed infants 6-8.9 months; 3x/day for breastfed children 9-23.9 months; 4x/day for non-breastfed children 6-23.9 months). Children who meet the thresholds for both MDD and MFF are defined as consuming a MAD, based on the WHO/UNICEF IYCF indicator.

Secondary	Frequency of consuming key foods in past 7 days	Frequency of consuming key foods in the past 7 days, Secondary, baseline and endline: We will use a 7-day food frequency questionnaire (FFQ) to assess the frequency that children consumed specific foods targeted in the intervention over the course of the previous week. More specifically, the FFQ will ascertain the number of times that the following foods have been consumed: eggs, leafy greens, fish, milk, cowpea, nuts, orange colored fruits and vegetables, other fruits and vegetables, thick porridge, beef or mutton, pork, chicken and liver.
	IYCF practices	IYCF practice indicators, secondary, baseline and endline: We will use the WHO/UNICEF IYCF indicators to assess feeding practices. Mothers will be asked about feeding practices as part of the household surveys. These include: Bottle feeding 0–23 months; Continued breastfeeding 12–23 months; Exclusive breastfeeding under six months; Exclusively breastfed for the first two days after birth; Egg and/or flesh food consumption 6–23 months; Early initiation of breastfeeding; Ever breastfed; Introduction of solid, semi-solid or soft foods 6–8 months; Minimum dietary diversity 6–23 months; Mixed milk feeding under six months; Minimum meal frequency 6–23 months; Minimum milk feeding frequency for non-breastfed children 6–23 months; Sweet beverage consumption 6–23 months; Unhealthy food consumption 6–23 months; Zero vegetable or fruit consumption 6–23 months The proportion of children being fed according to the detailed descriptions of these indicators will be assessed based on the WHO/UNICEF IYCF indicator manual.
	IYCF knowledge, attitudes, norms and intentions	IYCF knowledge, attitudes, norms and intentions, Secondary, baseline and endline: IYCF knowledge, attitudes, norms and intentions will be assessed using survey questions based on the components of the intervention. Both mothers and fathers will be asked the survey questions as part of the household survey. The questions are grounded in the theory of planned behavior and based on previously published IYCF knowledge, attitudes, norms and intentions questions by Monterrosa et al.[1] The questions have been pilot tested by the project PI.

1.7 Drugs/Devices/Biologics

A. Schedule and Administration

Not applicable.

B. Drug/Device Accountability and Storage Methods

Not applicable.

1.8 Specimen Collection

A. Primary Specimen Collection

We will use Hemocue machines to assess hemoglobin levels; however, this does not involve specimen collection. It simply involves a few drops of blood which are placed on a cuvette and discarded directly after analyzing it within the Hemocue machine.

- **Types of Specimens**: Not applicable.
- **Annotation**: Not applicable.
- **Transport**: Not applicable.
- **Processing**: Not applicable.
- **Storage**: Not applicable.
- **Disposition**: Not applicable.

B. Secondary Specimen Collection

Not applicable.

1.9 Data Collection

A. Primary Data Collection

- **Location**: We will conduct cognitive testing of messages as well as household surveys (including hemoglobin measurements of infants and young children) outside of the homes of survey participants. In the local context of this study, households generally have a small dwelling and a surrounding yard/compound. Based on our team's previous experience working with these communities in Senegal, there is a preference for conducting surveys outside the home in the surrounding yard. This allows sufficient space while also allowing for privacy during the interviews.

- **Process of Data Collection**: We will work closely with a team of local enumerators from Senegal. We have previously worked with these enumerators in Senegal and they have extensive knowledge of the communities in which this study will take place. In addition to their previous experience working with these communities, the enumerators will be trained by the PI, supported by our local partners (Institut de Recherche en Santé de Surveillance Epidemiologique et de Formation) in Senegal; IRESSEF), to assist with data collection. Our local partners have experience working with the local enumerators and conducting similar work in these communities. The enumerators are not part of the research team but will be paid for their services, which is typical of research conducted in these settings.

- **Timing and Frequency**:

Cognitive testing: Participants included in the cognitive testing will only have one visit (~30-45 minutes) with the study team.

cRCT and process evaluation: Each participating household will have two visits from the study team. One visit for the baseline data collection and a second for the endline data collection. In addition, participants who will take part in the semi-structured interviews as part of the process evaluation, will have third study visits by our team.

In addition to the study visits to collect data, participants will receive voice and text messages to their cellular phones one time per week. Each message will be approximately 2 minutes in duration. The messages will continue for a period of sixteen weeks (total of 16 messages).

After the completion of the message two automated questions will be asked, including: Did you understand the message?; Did you find the message useful? Do you intend to adopt this behavior? The response to the message will be keyed into the phone (1= yes; 2=no). In the event that a participant states that they did not understand the message, we will make note of it and then follow-up with them at the time of the post-intervention survey. There will also be an option to call a local number to gain additional information. The OuA Platform being used in this study will track whether the call was answered, how long it was listened to and the answers to the questions relating to message understanding, usefulness and intention to adopt the behavior.

Food environment data: The collection of food environment data will coincide with the baseline and endline food environment measures.

- **Procedures for Audio/Visual Recording**:

Cognitive testing: The cognitive testing will only involve taking detailed notes of the interviews with participants. We will not audio-record the interviews.

Process evaluation: The process evaluation conducted alongside our cRCT will involve audio-recording interviews. We will use a recording device to record the interviews. However, if participants do not wish to be audio-recorded, we will instead take detailed notes. Consenting to being audio-recorded is not a requirement of participating in the process evaluation component of the study.

Only members of the study team will have access to the audio-recordings. After each interview has been completed, we will download the recording onto the PI's password protected computer and erase it from the recording device. The only identifiers that the recording will include is the participants' voice.

- **Study Instruments**:

rRCT survey instrument: We have included the survey instrument in this IRB application. The questions used in this survey include those from the WHO/UNICEF indicators, questions from the Senegalese Demographic Health Survey, the Food and Agriculture Organization Food Insecurity Experience Scale as well as questions related to knowledge, attitudes and behavior that we have already used in our pilot

study in Senegal. In addition, we will also complete a short village survey with each of the heads of the farming groups at baseline. This will help to provide us with information that will inform our analyses.

Food environment data: We have included the food environment assessments with our protocol.

- **Ethnographic Studies, Interviews, Or Observation**:

Cognitive testing: During the cognitive testing, we will ask participants the following questions for each of the IYCF messages:

1. Why did you answer that way?
2. What does the question mean to you?
3. Can you repeat the question in your own words?
4. How would you word it differently to make it easier for other respondents to answer?

Process evaluation: We have include the interview guide for the process evaluation as an attachment with our IRB application. The questions are guided by a previously published process evaluation framework.[33]

- **Subject Identifiers**:

Cognitive testing and process evaluation: We will not collect identifiers (with the exception of voice recordings for the process evaluation) as part of the cognitive testing and process evaluation.

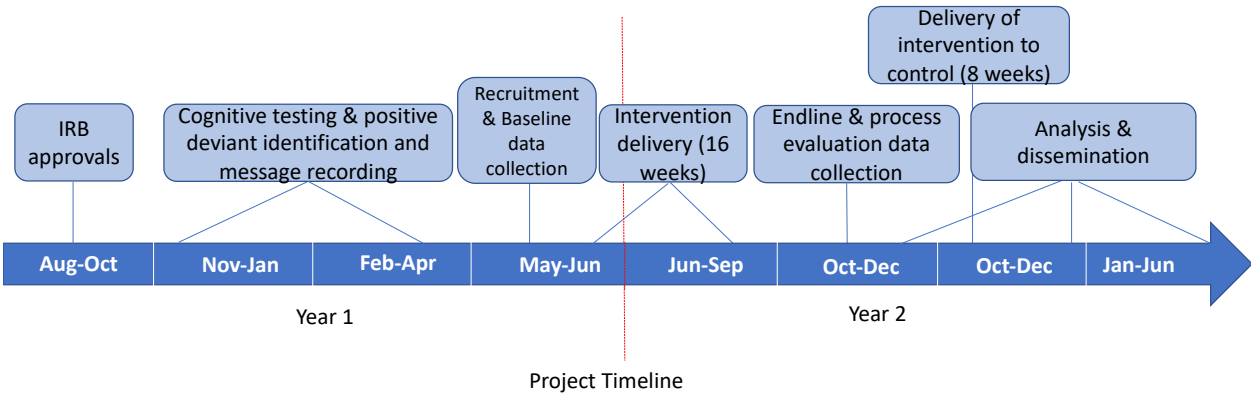
cRCT: We will collect identifiers (names, telephone numbers and GIS coordinates of household) for the cRCT and these will be retained only until the study activities are completed. Individuals will be assigned personal identification numbers in order to protect their identity. All electronic and hardcopy documents will refer only to the identification numbers and the names of the subjects will not be linked to their data once it has been downloaded from the survey platform.

B. Secondary Data Collection

Not applicable. We do not plan to use secondary data.

1.10 Timetable/Schedule of Events

We have included the study timelines below.



2.0 Project Management

We have the necessary resources for this project. It has been funded by the NIH.

2.1 Research Staff and Qualifications

Dr. Downs is the PI of this study. She has over 15 years of experience conducting research in low- and middle-income countries. She has been working in Senegal since 2014 and is familiar with the culture and customs. She has previously conducted field work in all of the study sites.

Dr. Sackey is from West Africa and has conducted research in similar contexts to Senegal.

We are working with the Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation (IRESSEF) in Senegal. Mr. Daouda Gueye is the Research Coordinator for this study. He will devote 50% of his time over the two year grant period to this project. He is Senegalese and has been doing evaluations of clinical trials in Senegal for the past 10 years.

Our research team will work with local enumerators for data collection. The local enumerators have previously worked with our partners and have conducted similar work in the study communities. We will conduct in-depth training with the enumerators prior to data collection in order to ensure that data are collected according to our protocol.

2.2 Research Staff Training

We will conduct training for the enumerators conducting the data collection as part of this study. During the enumerator training, we will use the Johns Hopkins School of Public Health Human Subjects Research Ethics Field Training Guide (2010) to train data collectors in human subjects research ethics, and will provide them with information about the project such that they would be qualified to provide information about the study and answer questions that participants may ask. There does not appear to be a similar training guide specific to Rutgers University.

Please note: Wherever possible, we will work with enumerators we have worked with in previous studies.

2.3 Other Resources

We received funding for this project through the National Institutes of Health Research. We have the necessary resources to engage in this research.

2.4 Research Sites

We have uploaded Form HRP-285 to this IRB application. The study sites for this project include: Thies, Diourbel and Fatick regions of Senegal. We will be conducting the study in 104 villages.

3.0 Multi-Center Research

Not applicable.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Cognitive testing: Our local partner will help us to identify potential participants for the cognitive testing of the IYCF messages. These individuals will be purposively selected to ensure that we include a sufficient number of mothers and fathers. Our local partners have close ties with the communities we will be working in and are able to easily identify potential study participants from their existing networks. In addition, we will use snowball sampling (if necessary) to identify additional participants. Once the potential participants have been identified by our in-country partners, our partners will describe the project to them and seek their consent to participate.

cRCT: We plan to recruit 510 mother, father and child triads in 104 villages in three regions of Senegal (Thies, Diourbel and Fatick) as part of our cluster-randomized control trial. Dr. Downs has previously worked in the study communities and has experience recruiting study participants from within them. We will employ the same methods as we have in the past in order to recruit participants to this study.

We will begin the recruitment process by first getting approval from the head of the village to conduct the study in the respective village. This is customary in these villages and is important for ensuring buy-in from the community. We will then ask for approval from the President of the village farming group. Each of the 104 villages included in the study have an established farming group. We will recruit participants from the farming groups in each of the villages. We have previously worked closely with the Presidents of each of the farming groups. We will ask the President of the farming group to share the list of households in the farming group. We will then identify all households in the farming group with a child between 6-19 months (at the time of the baseline data collection), and we will then randomly select five households per farming group to participate in the study. In order to facilitate our recruitment, we will plan initial fieldwork that will enable us to update our existing lists of households in the farming groups and the

number of households with children between 6-19 months at the time the intervention will begin (June 22). This will enable us to ensure that we have an up-to-date sampling frame. We will oversample to ensure that we are able to recruit 5 households/triads per village.

At the time of our baseline surveys, the President of the farmers group will then introduce us to each of the household heads. We will explain the study procedures to the household head, the woman and her husband before asking for their consent to participate in the study. Given the local customs in Senegal it is necessary to first explain the study to the household head, even though they will not be participating in the study. If the household head does not want members of their household to participate we will stop the recruitment process. Based on our previous experience, we were able to recruit participants from the study villages efficiently.

Informed consent will be collected during recruitment or immediately prior to participation in the baseline survey in the language spoken by the participant. The enumerators will meet with participants in their homes or another location in the community, as preferred by the participant. We will make every effort to obtain consent in privacy (without any peers or family members present, as described above). At the end of the recruitment and consent process, we will coordinate with the participant to schedule the timing and location of the survey. Based on our previous work in these communities, we anticipate a very high participation rate, and do not foresee difficulties in recruiting our study sample.

Process evaluation: A smaller purposive sample of approximately 45 mothers and fathers, implementation project staff and CHWs will be included in Aim 2 of the project as part of the in-depth semi-structured interviews/focus groups conducted in the process evaluation. We will purposively select three villages from each region (n total = 9 villages) in order to maximize variation in village characteristics such as size, distance to urban settings, distance to markets, etc. Interviewees will be purposively selected from the list of all mothers and fathers receiving the voice messages in each of these villages to ensure variation in participant socio-demographics (e.g., household size, parity, age, etc.) as well as key people involved in the intervention's implementation.

B. Recruitment Details

Cognitive testing: Our local partners and enumerators will recruit potential subjects using their existing networks. Initial contact with the potential subjects will be made face-to-face, but at a safe distance (i.e., 6 feet) in public outdoor spaces within the study communities. The following recruitment script will be used to recruit potential participants:

- *Verbal recruitment script:* Good morning/afternoon. My name is _____ and I am working with researchers at Rutgers University, a university in the United States, and the Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation. You were recommended as someone who might be interested in participating in an interview with us. We would like to learn about your understanding of infant and young child feeding messages. Are you interested in learning more about this project? If so, I can tell you more about the interview and answer any questions you have about the project. I also have an information letter about the project that I can go over with you. If you agree to participate in the project, I will organize with you to find a

good time to schedule a 30-45 minute interview.

cRCT and process evaluation: Our team of local enumerators will recruit study participants for the cRCT. They will first explain the study procedures to the household head, the mother and father before asking for their consent to participate in the study. At this time, we will also describe the intervention to the participant, providing them with information regarding the timing of the intervention as well as the details of what the intervention entails. The enumerators will meet with participants in their homes or another location in the community, as preferred by the participant. We will make every effort to obtain consent in privacy (without any peers or family members present, as described above). At the end of the recruitment and consent process, we will coordinate with the participant to schedule the timing and location of the survey. We will obtain consent for participation in the process evaluation at the time of cRCT consent. However, at the time of the endline survey we will ask participants again whether they are willing to participate in the semi-structured interviews.

- *Verbal recruitment script:* Good morning/afternoon. My name is _____ and I am working with researchers at Rutgers University, a university in the United States, and the Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation. We are doing research to measure the impact of a mobile messaging intervention about how to best feed your baby. Are you interested in learning more about this project? If so, I can tell you more about the project and answer any questions you may have. I also have an information letter about the project that I can go over with you. If you agree to participate in the project, I will organize with you to find a good time to schedule a 45 minute interview.

C. Subject Screening

- **Inclusion Criteria**

Cognitive testing: We will include adults who are parents to young children. We will not have restrictions based on ethnicity. In addition, we will only include people who have the ability and mental capacity to consent to their participation (i.e., not a member of a vulnerable group that is unable to voluntarily provide consent, such as a prisoner, or someone with limited mental ability, such as a person with dementia).

cRCT: Within each of the participating villages, the farming group will be used as the sampling frame for our sample. Thus, in order to be included in the study one of the members of the household will need to be a member of the village farming group. Additional inclusion criteria include: 1) mothers and fathers that have a child between the ages of 6 to 19 months at baseline and 2) have access to a mobile phone. Women and men included in the study will be 16 years of age or older. In order to be included in the study both the mother (or primary female caregiver) and father (or male primary caregiver) need to consent to participate.

We will only include people who have the ability and mental capacity to consent to their participation (e.g. not a member of a vulnerable group that is unable to voluntarily provide consent, such as a prisoner, or someone with limited mental ability, such as a person with dementia). The exclusion criteria includes households that do not have a child between the ages of 6 to 19 months old at baseline. In order to determine whether a household is eligible for

participation, we will ask the household head if there is a child 6 to 19 months in the household. If there is more than one child between 6-19 months, we will select the youngest child to participate in the study. We will then confirm the child's age using a vaccination card or birth certificate. We will also ascertain the age of the mother and father to ensure that they are 18 years of age or older.

Process evaluation: After the completion of the endline survey, enumerators will ask participants if they would be willing to participate in a semi-structured interview as part of the process evaluation. Of those that indicate their willingness to participate, we will purposively select participants in order to ensure that we include variation in terms of the socio-demographic characteristics of participants.

- **Exclusion Criteria**

Exclusion criteria include parents of children over the age of 24 months, those without access to a mobile phone and those that are cognitively impaired.

D. Privacy Protections

We do not anticipate any risks to participants or their privacy in the recruitment process. Furthermore, the recruitment process will be completed one-on-one with the participants such that their decision to participate or not will be theirs alone and any questions or concerns they have about the project will not be shared. The mother and father being recruited in the study will be recruited separately in the household compound. The enumerator will explain the study to both the parents together but will then take each potential participant aside in order to obtain consent. One enumerator will visit each household. If the layout of the household compound (which normally includes huts within a fenced off area of the compound) does not permit privacy from other family members, the enumerator will take the potential participant outside of the household compound in order to obtain consent.

We have previously worked in these study communities and have not had any problems in terms of the gender of the enumerators in terms of conducting surveys. We do not anticipate any problems in terms of allowing women to be alone with enumerators if they are male.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

Overall, we will have a total number of 1605 participants. This includes the cognitive testing (n=30), the cRCT (n=510 tryads; 1530 participants total) and the process evaluation (n=45).

Cognitive testing: We will recruit a total of 30 participants for the cognitive testing.

cRCT: We will recruit 5 mother, father and child triads in each of the 104 villages included in our sample. Our total sample will include 510 dyads. We will also ask the head of the farming group to complete a survey about the village.

Process evaluation: We will include a maximum of 45 participants in the semi-structured interviews/focus groups conducted as part of the process evaluation.

B. Total Number of Subjects If Multicenter Study
N/A

C. Feasibility

Based on our previous experience, we were able to recruit participants from the study villages efficiently. Our response rate in our previous large cross-sectional survey of ~1200 households was ~95%. Our enumeration teams (which will be composed of in the same way in our present study) were able to recruit and conduct extensive household surveys (~2 hrs in duration) with ten households per team, per day. We have planned for our enumeration teams to recruit and conduct household surveys with the same number of households in this study. However, the household surveys will be significantly shorter than our previous work (~45 minutes in duration).

Our mHealth messaging intervention will be 16 weeks in duration. Given the relatively short length of intervention time, as well as the low participant burden associated with participation, we do not anticipate having significant difficulties with participant retention. Our pilot study found an attrition rate of 2%. Our sample size calculation is based on an attrition rate of 5% and we have sufficient power to detect changes in our effect sizes (6% absolute difference in anemia; 7% absolute difference in MAD) even with 10% attrition.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

The enumerators will meet with participants in their household yards/compounds or another location in the community, as preferred by the participant. At the end of the recruitment and consent process, we will coordinate with the participant to schedule the timing and location of the survey.

- **Ongoing Consent**

This research is of short duration. The intervention is only 16 weeks. For this reason, we will not obtain ongoing consent throughout the research project.

- **Individual Roles for Researchers Involved in Consent**
  As mentioned, the consent process will be conducted by our team of local enumerators. They have extensive experience conducting research in these study communities.

The local enumerator will obtain consent in their local language (i.e., Wolof, Serere, or Pular). The enumerators have a substantial amount of experience doing these types of surveys and

interviews. Dr. Downs has been working closely with these enumerators since 2015. All of the enumerators have at minimum a Bachelor's degree and are proficient in French, Wolof and, in many cases, Serere and Pular.

- **Consent Discussion Duration**

We anticipate the consent discussion taking approximate 10-15 minutes to complete, based on our previous experience working in these communities.

- **Coercion or Undue Influence**

We will stress that participation in the study is voluntary and that potential subjects are under no circumstances obligated to participate.

- **Subject Understanding**

Subjects will be provided with a copy of the consent form that describes the study. They will also have contact information for members of the study team in the case where they wish to have additional information. Lastly, they will have the opportunity to ask questions during the recruitment process.

- **Protecting Privacy**

We will make every effort to obtain consent in privacy (without any peers or family members present, as described above).

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  We are not requesting a waiver of consent.

- **Destruction of Identifiers**
  We are not requesting a waiver of consent.

- **Use of Deception/Concealment**
  This research does not involve deception or concealment.

  a. Minimal Risk Justification
  N/A
  b. Alternatives
  N/A
  c. Subject Debriefing
  N/A

C. Documentation of Consent

- **Documenting Consent**

Written consent in the form of a signature will be obtained on the consent form. We have previously worked in these communities and have found people to be able to sign consent forms. Although the literacy levels in these communities are low, the majority of people are able to print their names. Those that are not able to print their names draw an X on the consent form.

- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**

N/A

4.5 Special Consent Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  We will obtain consent from parents/guardians of young children to participate in this research.

- **Non-Parental Permission**
  We will obtain consent from parents of young children. However, in some cases the child may be under the care of a legal guardian rather than parent. In these cases, we will obtain consent from the legal guardians.

- **Assent Process**
  We are including young children in this study; however, they are too young to provide assent. The infants included in this study will be between 6-23 months of age (i.e., less than 2 years old). At this age, children are incredibly limited in their ability to speak and from a developmental perspective cannot reasonably consulted to provide assent. For this reason, we are not seeking assent from infants and young children.

- **Documentation of Assent**
  N/A

- **Reaching Age of Majority During Study**
  N/A

B. Enrolling Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
  Our data will be collected in Senegal according to local IRB requirements. There are no specific laws pertaining to research involving minors that we need to adhere to.

C. Enrolling Non-English-Speaking Subjects

The participants in this study speak French, Wolof and/or Pular.

- **Process for Non-English-Speaking Subjects**

All information regarding the study will be communicated orally to participants in their local language (i.e., Wolof or Pular). Given the low literacy rates in these communities it is imperative that the consent form be explained orally. Moreover, Wolof – the language spoken by the majority of participants – is not a written language. Therefore, consent forms will be written in

French but explained in the local language. This is the approach recommended by the Senegal National Ethics Committee.

- **Short Form Consent for Non-English Speakers**

We will not be using the short form consent.

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
We will not enroll participants who lack decision-making capacity.

- **Assessing Adult Capacity to Consent**
  N/A
- **Selecting a Surrogate & Consent Process**
  N/A
- **Subject Assent**
  N/A
- **Selecting a Witness to the Surrogate Consent Process**
  N/A
- **Removing a Subject**
  N/A

E. Special Consent Considerations

As mentioned previously, the consent forms will be read out loud to potential participants given the low literacy rates in the study communities.

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

Study participants will not incur any costs related to participating in this project.

B. Compensation/Incentives

Subjects participating in cognitive testing will receive $5 USD for their participation.

C Compensation Documentation

We will make a list of all interviewees using unique identification numbers rather than their names (in order to not collect identifying information) and mark with a check next to their ID number once they have completed the interview and received their compensation.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**

This study poses only minimal risks to participants. The potential risks to study participants include temporary discomfort related to the assessment of hemoglobin levels using a finger prick. However, the hemoglobin assessment is a minimal risk procedure.

There are no known side effects of participating in the intervention. The intervention consists of providing IYCF information to mothers and fathers of young children (6-23 months). However, it is possible that mothers and fathers could misunderstand the nutrition messages resulting in poor diet and nutrition practices. We will conduct cognitive testing prior to the delivery of the intervention in an effort to eliminate this risk.

There is also the inconvenience of the time required for listening to/reading the messages, responding to the surveys, and participating in the semi-structured interviews and focus groups. The risks are limited to the immediate study period. With regards to severity, we do not anticipate any severe risks from participating in the study.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**

We do not anticipate any risk of harm from the intervention for subject's with existing conditions.

- **Other Foreseeable Risks of Harm**

There is the potential risk of loss of confidentiality. Risk of breach of confidentiality will be minimized in several ways. First, all participants will be assigned a coded identification number to assure that their identifying information is not linked to their data. A single list linking participant identification numbers with participant names will be kept in a locked electronic file on the computer of the PI. Research staff will operate under explicit guidelines to preserve confidentiality when speaking to participants. All materials with identifying information will be kept in locked files. Furthermore, confidentiality is enhanced by the use of computer-administered surveys, and data collection will be such that only an encrypted password will allow study researchers to access study data. No participant names or identifying information will be stored in the database – all data will be de-identified. All research staff will be trained in ethical guidelines governing research, including obtaining certification in the Collaborative Institutional Training Initiative.

While every possible step is taken to minimize risks, if participants have any concerns about any aspect of the study, consent documentation makes it clear that they can refuse to continue with the study at any time without penalty. The consent forms will also contain the contact information for the CNERS local IRB, Mr. Gueye, the Project Coordinator, and Dr. Downs in case they wish to speak to the IRB or a member of the study team to discuss adequacy of protection against risks.

- **Observation and Sensitive Information**

N/A.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects

None.

C. Risks of Harm to Non-Subjects

There will be no risks of harm to non-subjects in this study.

D. Assessment of Social Behavior Considerations

There are few possible risks of participating in this study. Some possible risks include misunderstanding of nutrition messages resulting in poor diet and nutrition practices. Participants may feel uncomfortable sharing their attitudes and beliefs but they are not obligated to share anything that they do not want to share. There may also be tension between participants trying to change their IYCF practices and people they know who advocate for other practices. This may cause strain in social interactions and relationships. There is also the inconvenience of the time required for listening to the messages, responding to the surveys, and participating in the semi-structured interviews (for participants in the process evaluation).

E. Minimizing Risks of Harm

We will minimize risk by making the nutrition education messages as clear as possible and making sure they are conveyed in a language that is easy to understand. We have also shared the voice messages with the *Senegalese* Committee for Nutrition Development to ensure that they are in line with their efforts to improve nutrition education in Senegal.

We will also engage participants in an open dialogue that takes into account their culture, education, and other factors to be inclusive of everyone. We will ensure that all participants fully understand the study, risks and benefits, as well as their right to cease participation in part or all of the study at any time.

- **Certificate of Confidentiality**

Given that this is a NIH funded study, this study has been automatically issued a certificate of confidentiality. We have included language that refers to this in our consent forms.

- **Provisions to Protect the Privacy Interests of Subjects**

All surveys will be done individually to protect the participants' privacy. We do not anticipate that the questions asked will be considered sensitive.

F. Potential Direct Benefits to Subjects

Potential benefits to participants include increasing their knowledge related to IYCF practices, which could lead to improvements in dietary quality (e.g., minimum acceptable diet) and nutrition outcomes (e.g., anemia) as well as improved growth and development in their young children.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations

- Children: We will include infants and young children in our study. Given their young age, they will not be providing assent. However, their parents will provide informed written consent.

5.4 General Data Protection Regulation (GDPR)
N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)
N/A

6.0 Data Management Plan

6.1 Data Analysis

Cognitive testing: As mentioned previously, we will take detailed notes during the cognitive testing. The notes will be subsequently analyzed by members of the study team (Gueye & Downs) by assessing common themes/patterns in the message comprehension. Summaries that describe the issues noted for each message and how they were addressed will then be prepared and discussed as a team, in an iterative way until the point of theoretical saturation.

cRCT: To estimate the impact of the mHealth messaging intervention on anemia and MAD, as well as our secondary outcomes, we will utilize a difference-in-differences approach. Linear regression models will be fitted for each outcome, with explanatory variables that include the intervention indicator, time (baseline and endline), and intervention by time interaction. The interaction term is of primary interest, as it summarizes mean changes in the outcome before and after the intervention in the treatment group compared with the control group. The intervention variable is as randomized (intention to treat). We anticipate that the parallel trend assumption will hold in this scenario since the various clusters and triads within clusters are similar to each other socio-economically; however, we will carefully test this assumption by applying the recently developed difference-in-difference model checklist[4]. We will analyze the data on the individual level and use generalized estimating equation (GEE) extensions of regression in SAS 9.4 to account for clustering. All models will adjust for sex of the child, socioeconomic status of the family and highest education completed by the mother. We will also conduct exploratory subgroup analyses based on baseline anemia status.

Process evaluation: A mixed-methods analysis of both the quantitative and qualitative process data will be led by Dr. Downs, in collaboration with the Senegal team. Key themes generated from the qualitative data related to the implementation challenges and opportunities for scale-up in different contexts will be identified in the analysis, guided by the process evaluation framework for cRCTs.[33] Total costs of the intervention, as well as average costs per child in the experimental group, will be estimated over the period of the intervention implementation. Where possible, a cost consequence analysis will be conducted that compares the average cost per child in the experimental and usual care group against the health consequences.[34,35]

Food environment data: We will use the food environment data to calculate the market food diversity index, the cost of health diet as well as the ProDesirability score for fruits and vegetables. These data will allow us to better understand the availability, affordability and acceptability of foods that our study participants have access to with the view to informing more comprehensive interventions in these communities.

6.2 Data Security

We will collect identifiers (names, telephone numbers and GIS coordinates) and these will be retained only until the study activities are completed and published. Individuals will be assigned personal identification numbers in order to protect their identity. cRCT data will be collected with a tablet using an electronic data collection platform such as ODK (https://getodk.org). All data collected in ODK is encrypted.

All electronic documents will refer only to the identification numbers and the names of the subjects will not be linked to their data at any time point.

We will have hard copies of consent forms and interview/meeting notes for our project. During transfer from the study collection site to the storage site, we will guarantee that the data collection forms and interview/meeting notes are kept secure by keeping them in the study team's possession during transport and not leaving them unattended in any vehicle. All audio recordings from the semi-structured interviews will be immediately uploaded to the PI's password-protected computer. None of the hard copies of data collection will contain names of participants during storage. Data will be uploaded, immediately after data collection to Rutgers Teams, as well as being saved on a password protected computer.

All interview notes and informed consent files will be stored at the IRESSEF office in Dakar in a locked file cabinet that only the study team will have access to. They will be scanned and saved on a password-protected computer as encrypted files/folders. Only members of the study team will have access to the study documents.

6.3 Data and Safety Monitoring

This intervention is minimal risk. For that reason, we have not included a DSMB.

A. Data/Safety Monitoring Plan

B. Data/Safety Monitoring Board Details

6.4 Reporting Results

A. Individual Subjects' Results

As part of the baseline and endline surveys for the cRCT we will conduct hemoglobin measurements of young children in order to assess their anemia status. We will immediately provide the parents with the results. In addition, any child who has severe anemia based on the hemoglobin results (hemoglobin measured <7g/dL) will be referred to a health post or community health worker. We have attached the referral sheet that we will use.

In addition, we will work with community health workers and health posts in our study communities to ensure that they have iron tablets in stock in the event that children are referred to the clinics.

B. Aggregate Results

Dr. Downs will create a short video that summarizes the findings which can help to disseminate the findings among participants with low literacy levels.

C. Professional Reporting

The results will be disseminated to the scientific community using a variety of methods (professional meetings and conferences, peer-reviewed journals, institutional press releases, progress and final reports to the NIH).

The Rutgers and IRESSEF team will work together to disseminate the study findings to key stakeholders, including the Ministry of Health, in Senegal. Policy briefs will be developed that describe the study findings as well as its value-for-money. The IRESSEF has a strong relationship with the Ministry of Health and will help facilitate the dissemination of the study findings through their existing networks. We will also work closely with the Senegalese National Council for Nutrition Development (C*onseil national pour le développement de la nutrition*), to disseminate the findings to Community Health Workers and NGOs working in the area of nutrition in Senegal.

D. Clinical Trials Registration, Results Reporting and Consent Posting

Given the nature of this study, it will be registered on Clinicaltrials.gov.

6.5 Secondary Use of the Data

We will not share the data with other researchers for secondary research purposes. As such, this language has not been included on the consent form.

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

We have obtained IRB approval from the Senegalese Ministry of Health. We have included these approvals in our updated submission.

9.0 Bibliography

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