Title: Family Connections: Cultural Adaptation and Feasibility Testing for Rural Latino Communities

NCT number: NCT04731506

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Biomedical
SECTION I

Therapeutic/Non-Therapeutic
Does your research involve a drug, medical device, technique or other intervention or strategy (including means like diet, cognitive therapy, behavioral therapy, exercise) to diagnose, treat or prevent a particular condition or disease: "THERAPEUTIC RESEARCH"?
Yes

1. Title of Protocol:
Family Connections: Cultural adaptation and feasibility testing of a technology-based pediatric weight management intervention for rural Latino communities

2. Responsible Personnel:
A. Principal Investigator (PI):
Silva, Fabiana B - COPH Health Promotion - 402-559-6363 - fabiana.silva@unmc.edu - alt #: 402-552-6363 - degree: PhD

B. Secondary Investigator (SI):
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C. Participating Personnel:

Ferreira Marta, Felipe E - COPH Health Promotion - 402-559-4325 - fferreiramarta@unmc.edu - alt #: 402-552-6363 - degree: PhD

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Rossi Squarcini, Camila F - COPH Health Promotion - 402-559-4325 - crossisquarcini@unmc.edu - alt #: 402-552-6363 - degree: PhD

Santos, Natalia B - COPH Health Promotion - 402-559-4325 - nsantos@unmc.edu - alt #: 402-305-5315 - degree: MPH - address: MCPH 2028 (Zip 4365) - phone: 402-559-4325

D. Lead Coordinator:
Favero Alves, Thais - COPH Health Promotion - 402-559-4325 - thais.alves@unmc.edu - alt #: 402-559-4325 - degree: MS - address: MCPH 1019 UNMC Midtown (Zip 4350) - phone: 9-4325

E. Coordinator(s):

F. Data/Administrative Personnel:

G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
Cooperative Group:
Center for Clinical and Translational Research (CCTR)
♦ Federal (e.g., NIH) Grant - Provide source: Sub-award - Research Project - PAR-16-241: Limited Competition: Renewal of Centers of Biomedical Research Excellence (COBRE)(P20)
Other Grant:
Departmental funding
Commercial - Provide company name:
Department of Defense
Other - Provide source (e.g. personal funding):

4. Deadline for IRB Approval:
♦ Yes - Explain and provide date: NIH Funding release is pending on IRB approval - 30 days after submission (aprox. Nov 1st, 2020)
No

5. Contract:
Is there a contract associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
No

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
Central District Health Department (CDHD),
Community Action Partnership of Western Nebraska (CAPWN),
East Central District Health Department (ECDHD),
Two Rivers Public Health Department (TRPHD)

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
Yes

List the sites.
UNMC
Central District Health Department (CDHD),
Community Action Partnership of Western Nebraska (CAPWN),

East Central District Health Department (ECDHD),
Two Rivers Public Health Department (TRPHD)
UNL

D. Does this study involve any international sites where the PI will either; 1) conduct 2) supervise or 3) receive / ship HBM or data to / from UNMC?
No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:
I certify that:

- **I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.**
- **I, and all listed research personnel, have the necessary qualifications, expertise, and hospital credentials to conduct this study in a manner which fully protects the rights and welfare of research subjects.**
- **There are, or will be, adequate resources and facilities to safely initiate, carry out and complete this research at the study sites specified in Section I.7. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address adverse events and any unanticipated problems involving risk to the subject or others. If the necessary resources become unavailable I will promptly notify the IRB.**
- **All listed research personnel, including external investigators, will be given a copy of the final IRB approved application and any other relevant study-related documents in accordance with their defined responsibilities.**
- **All listed research personnel, including external investigators, will be notified promptly of any changes in protocol, in accordance with their defined responsibilities.**
- **Research personnel, including data and administrative personnel who have access to protected health information (PHI) or subject identifiers will have adequate training in confidentiality and protection of PHI.**
- **The minimum amount of protected health information (PHI) or other identifiers necessary will be used and disclosed to conduct this research study (if applicable). I will implement reasonable safeguards to protect the PHI/identifiers at all times.**

- I and all other personnel listed in Section I.3A-E of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the UNMC Conflict of Interest Policy #8010 and HRPP Policy. I further certify that all potential financial conflicts of interest are appropriately managed in order to ensure protection of the rights and welfare of subjects.

I recognize that:

- As the PI it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol (including all amendments), all applicable federal regulations, state laws, and HRPP policies.
- It is my responsibility to ensure that valid informed consent/assent will be obtained, as appropriate, from all research subjects or their legally authorized representative(LARs).

I will:

- Ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to federal regulations, state laws, and HRPP policies.
- Promptly inform the IRB of internal adverse events, as well as any unanticipated problems involving risk to the subjects or to others, as required within the time frame defined by HRPP policies. I will analyze each internal adverse event/reported problem to determine if it impacts the risk-benefit relationship of the study, the safety of the subjects, or informed consent.
- Analyze each MedWatch/safety report to determine if it impacts the risk/benefit relationship of the study, the safety of the subjects, or informed consent.
- Promptly submit external adverse event reports in accordance with HRPP policies.
- Promptly inform the IRB if I become aware of 1) any complaints from research subjects, LARs, or others about research participation, 2) violations of federal regulations or state law, 3) violations of the HIPAA Rule, or 4) violations of HRPP policies.
- Promptly inform the IRB of the results of external audits performed by sponsors, Contract Review Organizations (CROs), cooperative groups, FDA, or other external groups.
- Not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.
- Promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.

- **Maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, FDA, and other Federal Departments or Agencies may inspect these records in accordance with granted authority.**

I understand that:

- **Continuing review by the IRB is required at least annually, or as per Federal Regulations and HRPP Policy, in order to maintain approval status. I will maintain IRB approval as long as this study is active.**
- **I am responsible for appropriate research billing in accordance with UNMC Clinical Trial Professional and Technical Fee Billing Policy #8008 or applicable Children's Hospital & Medical Center policy.**

Failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, applicable FDA regulations, the HIPAA Rule, applicable state law, HRPP policies, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB Approval of my research project and/or other administrative or legal actions.

Silva, Fabiana B - 2022-05-04 12:37:11.357

9. Principal Investigator Financial Interest Disclosure

A. As the PI, I declare:

♦ I have no financial interest in this research.

I have a financial interest in this research.

B. As the PI, I understand

♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:

♦ No Responsible Personnel have a financial interest in this research.

The Responsible Personnel listed below have informed me that they have a financial interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.

Silva, Fabiana B - 2022-05-04 12:37:11.357

11. Scientific/Scholarly Merit and Resource Review Certification

Scientific Reviewer:

Tibbits, Melissa K - COPH Health Promotion - 402-559-9447 - mtibbits@unmc.edu - alt #:

402-559-9447 - degree: PhD - address: Does not work on campus MCPH 1016 UNMC Midtown (Zip 4365)

As the Scientific Reviewer,
♦ I do not have a financial conflict of interest associated with this study.
I do have a financial conflict of interest associated with this study.

My signature certifies that:

- **this application has been reviewed for scientific/scholarly merit and available resources. It has been determined that the application merits consideration by the IRB based upon the following:**
- **The proposal has an acceptable level of scientific/scholarly merit which justifies the involvement of human subjects.**
- **The proposal has a sound research design in consideration of the stated objectives,**
- **The PI has the necessary qualifications, experience and credentials to conduct this research.**
- **The PI has or will have the necessary funding to support this research**
- **There is or will be adequate physical space required for the research interventions at all study sites specified in Section I.7. In addition, there is or will be adequate laboratory and administrative support, data storage capability, and any other resources necessary to complete this research.**
- **At all study sites specified in Section I.7, there is or will be emergency equipment, personnel, or services necessary to respond promptly to adverse events or unanticipated problems involving risk to the subject or others.**
- **I will promptly notify the IRB if the necessary resources to support this research become unavailable.**

Tibbits, Melissa K - 2020-10-14 10:17:00.000

Do you have any additional comments that you wish the IRB to consider during the review of this application?
No

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief (less than 2500 characters) abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
The purpose of this study is to conduct a mixed-methods study to determine the feasibility of delivering a culturally appropriate Family-Based Childhood obesity program (FBCO) via an automated telephone system (IVR) and two in-person group sessions to Latino/Hispanic (L/H) families (parents and children dyads) living in rural Nebraska will be invited to participate in focus groups and technology-usability tests (Aim 1) or randomized to a standard-care control group or an IVR/video delivered intervention (Aim 2). The proposed study will involve approximately 266 (Aim 1=35, Aim 2=116) L/Hs participants. The parent-child dyads (n=116) include adults (19 years of age or older, n= 58) and their children (6-12 years of age, n=58) living in rural Nebraska over a period of 12 months and 2 different stages of the project. In addition, we will involve 40 adults-parents from L/H families from the sampling region to participate in two rounds of focus groups (FG, n=80) with 6 parents taking part in usability tests (UT, n=6), and approximately 10 adults to participate in a Community Working Group (CWG, n=10) that will participate in two interviews (n=10) and advise in the study and assist in intervention adaptation, recruitment and retention. In Aim 1, we will adapt all intervention materials to better fit the rural L/H community profile, including translation of materials to Spanish, inclusion of culturally relevant content and images, and use of health communication strategies to address different levels of health literacy. Then, we will evaluate the acceptability, suitability, and usability of the adapted intervention materials and mode of delivery. In Aim 2, we will randomly assign family participants to either FC (n=29) or an enhanced standard-care (SC) group (n=29) and determine overall study reach, preliminary effectiveness in reducing child BMI z-scores, potential for program adoption, implementation, and sustainability through local health departments (RE-AIM outcomes). We will also evaluate health department perceptions of i-PARIHS constructs (Innovation, context,recipient characteristics), and FC participants view of the intervention (i.e. relative advantage, observability, trialability,complexity, compatibility).

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
Our primary specific aims are:

Aim 1: **To culturally adapt and determine the relevance, acceptability, and usability of**

a culturally adapted technology-delivered FBCO intervention for L/H families in rural Nebraska. Applying an iterative collaborative process, we will use a mixed-methods approach to culturally adapt FC to better fit the rural L/H community profile. A Community Workgroup facilitated by our rural partner organizations in Nebraska with a high population of L/H residents and theory-and data-driven approach using structured community input adaptation process will be conducted to develop and evaluate the relevance (ecological validity and equivalence), acceptability, and usability of all the adaptations made. We hypothesize that this process will lead to a program that is relevant, acceptable, and usable by L/H families in rural communities.

Aim 2: **To evaluate the feasibility and preliminary effectiveness of a technology-delivered FBCO intervention for L/H families in rural Nebraska using RE-AIM and i-PARIHS.** We will randomly assign participants to either FC (n=29) or an enhanced standard-care (SC) group (n=29) and determine overall study reach, preliminary effectiveness in reducing child BMI z-scores, potential for program adoption, implementation, and sustainability through local health departments (RE-AIM outcomes). SC participants will receive a workbook. FC participants will receive a workbook, 2 in person group sessions followed by 10 IVR calls over a period of 6 months. We hypothesize that a culturally adapted FC program will lead to a higher engagement (reach, retention and completion), significant higher proportion of L/H children reducing their BMIz scores at 6 months when compared to SC group, align (social validity) with health department perceptions of i-PARIHS constructs (Innovation, context, recipient characteristics), and that FC participants will view the intervention positively (i.e. relative advantage, observability, trialability, complexity, compatibility).

3. Background and Rationale

Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.

The burden of childhood obesity (CO) on L/Hs and rural communities. There are marked ethnic and rural-urban disparities in the prevalence of childhood obesity[1,2]. The prevalence of CO among L/H children is almost 60% higher than that of non-L/H Whites[1], and among children in rural areas is estimated to be 25%[3] to almost double[4] that of urban areas. Between 2000 and 2010 the number of L/H individuals in rural Nebraska counties increased by 63.3% and by 2050 Latinos are expected to represent 51.2% of rural Nebraskas population[5]. **Effective Family-based childhood obesity interventions low reach and engagement among L/Hs.** Identifying effective interventions to reduce health disparities and to address childhood obesity remains a top public health priority[6]. Previous findings reveal that culturally-adapted interventions appear to be more efficacious in the reduction of obesity in minority children[7-9]. A number of recent reviews[10-13] have shown that

family-based lifestyle interventions can lead to modest improvements in child BMI. In fact, the American Academy of Pediatrics, has issued its strongest recommendation grade (grade A) for Family-based childhood obesity (FBCO) interventions with parents as a focus for behavior modification for the management and treatment of obesity in children ages 6 to 11[14]. However, these interventions have been poorly accessed in L/Hs and other minority populations[12,13]. Nevertheless, a number of culturally tailored interventions for CO prevention and management among L/Hs have been tested[3,11]. These interventions have primarily included in-person face-to-face group-based delivery of content by a peer educator (community health worker - CHW) or health professionals (physicians and nurses) in a variety of urban community locations[3]. While these adaptations have led to modest BMI reductions, poor study designs, high attrition rates, small sample sizes and lack of representativeness (minorities and rural underrepresentation), diminish the potential impact of these interventions[11-13].

The potential of interactive technology to address barriers to reach and engagement among rural L/H families. The low rates at which evidence-based interventions are delivered suggests that simply recommending programs based in their availability and effectiveness, while necessary, is not sufficient given the myriad of barriers at the client, providers, team, and organizational-levels[15]. A lack of responsiveness to cultural needs and preferences negatively affects reach, adoption, implementation, suitability, and scale-up of interventions in community settings[16]. Interactive technologies may provide a possible solution to these challenges in that it offers an avenue for the delivery of FBCO relevant content at times and places convenient to families[17,18]. A meta-analysis showed that culturally-adapted interventions that promote lifestyle changes including parental involvement and the use of interactive technologies are the most promising in the reduction of obesity in minority children[19]. Our own work has demonstrated that technology-assisted FBCO interventions can lead to significant child BMI reduction using an interactive voice response (IVR) system to deliver the majority of the intervention content[20]. Additionally, L/Hs tend to make more use of mobile devices for both telephone usage and accessing the Internet than non-L/Hs[21]. A recent study with L/Hs living in rural and urban Nebraska found that over 82% of L/Hs have mobile devices and use it regularly to access information[22]. They have also indicated preference for receiving health information through verbal communication methods[22]. Thus, telephone systems that provide automated (i.e., IVR system) health education messages combined with in-person face to face strategies may be practical methods for providing culturally appropriate nutrition, physical activity, and weight loss information and engaging L/H families in rural communities. IVR has been used in a number of healthcare contexts to address a variety of health outcomes[20,23,24]. IVR has also been found to be acceptable and helpful[25], with over 76% of our participants perceiving the IVR system easy to use, 75% agreeing that IVR messages could help them lose weight[26], and nearly 80% indicating it should be included as part of standard care[20]. Previous IVR research has been conducted using rigorous RCT trial methodology in the areas of diabetes

prevention[27], diabetes self-management[28], dietary outcomes[29], and childhood obesity treatment[20,30]. However, there are no published reports on culturally adapted FBCO interventions that are delivered primarily via IVR that reach a large and representative sample of L/H families in rural communities.

Summary of significance and literature gaps. The proposed application is timely and important because: (1) effective FBCO interventions exist, yet they fail to attract and engage a representative sample of L/H families; (2) there is no evidence that these programs can be implemented and sustained in rural communities; (3) rural health departments and clinical settings lack the resources to deliver existing FBCO; and (4) IVR shows promise in addressing barriers and builds on L/Hs preferences. The **scientific premise** of this application is that the use of IVR to deliver culturally appropriate FBCO programing adapted through a community-driven approach will allow us to address existing rural family and setting-level barriers while capitalizing on the preferences of the intended audience.

Conceptual Framework. The theoretical basis for our study is the [31]revised Promoting Action on Research Implementation in Health Services (i-PARIHS) Framework[32] combined with the RE-AIM framework[33] (Figure 1). The implementation of effective programs can be viewed as a function of the characteristics of the proposed innovation, the target population (**beneficiaries-our addition to i-PARIHS**), delivery agents (**recipients**), the delivery context, and facilitation resources[32]. Our **innovation** is the cultural adaptation and customization of the materials from the Family Connections (FC) program[20]. **Contextually**, our community partners (CP; see letters of support) will be members of the community workgroup (CWG) and will play a central role throughout the process to improve the social validity[31,34] and feasibility of the innovation while considering factors such as leadership, experience with adopting and implementing interventions, and organizational context and cultural relevance. **Facilitation** of the **innovation** within the **practice context** will be guided by the research team using a consultee-centered training approach[35] as we have in the past[36]. We will use automated implementation of intervention content to ensure high fidelity (IVR calls) and keep implementation complexity low to address delivery system barriers (i.e. lack of resources, knowledge and training)[37] and L/H families participation barriers (i.e. lack of public transportation and cultural relevance, family and work responsibilities)[37], while targeting preferences for information receipt (i.e. verbal and written[22]). RE-AIM[33] will provide guidance on the outcomes (Figures 1 and 3) to ensure our innovation addresses issues of scalability at the individual and organizational level as well as the resources, infrastructure, and flexibility necessary for future implementation. Finally, cultural adaptation is an important part of the implementation process[16]. As such, we will make adaptations guided by a theory-driven approach that is both **selective** (focuses on areas with poor fit among L/Hs in rural communities) and **directed** (aimed at improving engagement and outcomes)[31,38]. We hypothesize that by incorporating community-informed

design features that tend to the cultural needs of L/H families, it will promote engagement and better outcomes independent of parents acculturation level.

INNOVATION

*This proposal represents a conceptual and methodological innovation in the FBCO intervention translation field. First, using both implementation science and cultural adaptation models we seek to understand factors that are related to those who would benefit from engaging in the intervention (beneficiaries) and those who would ultimately deliver the intervention[39] by adapting and testing the initial cultural relevance and effectiveness of a technology-delivered FBCO program concurrently with understanding the potential impact of our adaptations. The key thesis is that by understanding the underlying types and reasons for our adaptations we can improve the fit (ecological validity[31,40,41]) between the intervention and context to improve future engagement[31,42] and implementation[43]. Second, we propose to address multiple cultural sensitivity dimensions[7], including surface modifications (translation) to increase feasibility, and deep modifications (methods and content) to enhance impact[44]. Third, delivering FBCO programs through interactive technology is feasible[20], however, there is no evidence that these approaches can attract and keep engaged a representative sample of L/H families[13]. We will be the first to use IVR as part of a culturally adapted FBCO program for L/H families in rural areas. This is a significant departure from previous cultural adaptations of childhood obesity prevention and treatment trials that have relied primarily on multiple and frequent individual or small group sessions with mostly urban dwellers, delivered primarily by health professionals and CHWs[13]. While FC has used IVR technology, it was not specifically developed and adapted for L/H families in rural communities. Fourth, retention issues are more prevalent when interventions move from efficacy to effectiveness studies[45], and most FBCO programs[12] (including cultural adaptations[13]) developed and tested to date are restricted by their ability to geographically reach participants. For the existing technology-based FBCO programs, none has been able to show statistically significant reductions in child BMI nor attract or keep engaged a representative sample of L/H families[46].In contrast to other adaptation models[40,47,48], the identification of areas for enhancement in the proposed framework[31] occurs from the local context and experience of beneficiaries and recipients. Geographic and culturally relevant barriers are particularly more pronounced for L/H families in rural communities[37]. **Our intervention has the potential to bridge these gaps by allowing L/H families to participate in a culturally relevant FBCO program at a location and time that is convenient to them.***

CHARACTERISTICS OF THE SUBJECT POPULATION

4. Accrual

A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g.

UNMC, Nebraska Medicine, CHMC, UNO)?
Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?
The proposed study will involve approximately 272 (Aim 1=106, Aim 2=166) participants. Participants are required to complete study aims as described:

Aim 1:
We will involve 40 adults-parents from L/H families from the sampling region to participate in two rounds of focus groups (FG, n=80) with 6 parents taking part in usability tests (UT, n=6), and approximately 10 adults to participate in a Community Working Group (CWG, n=10) that will participate in two interviews (n=10).

Aim 2:
The parent-child dyads (n=116) include adults (19 years of age or older, n= 58) and their children (6-12 years of age, n=58) living in rural Nebraska over a period of 12 months and 2 different stages of the project randomized in two arms:
Standart Care= 29 dyads (58 participants)
FC intervention= 29 dyads (58 participants)

At the end of the intervention parents participating that participated in the intervention (FG, n=40) and CWG (n=10) will be invited to participate in focus groups for a post-program satisfaction and evaluation.

2. What is the statistical or other justification for the total number of subjects described above?
Aim 1 sample based in the literature recommended number per evaluation for focus group (5-10 participants) and usability tests (5 per test)[74].

Intervention testing sample size is based on the comparison of changes in BMI z-scores achieved by participants in FC-IVR with those achieved by participants in FC-workbook condition at 6 months post randomization14. A total of 56 (23 per group) parent-child dyads achieves 80% power (alpha 0.05) to detect a significant difference between the SC and IVR conditions, based on the relative BMI z-score differences (0.05) and standard deviation related to 6-month BMI z-score reduction for FC-IVR (0.06). To account for 25% rate at 12-month, we will recruit a total of 58 (29 per group) dyads.

5. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?

No

6. Age Range of Subjects
A. Will adults be enrolled ?
Yes

1. What is the age range of the adult subjects?
19 years of age or older.

2. What is the rationale for selecting this age range?
This is a prospective study of a family-base childhood obesity (FBCO) intervention program. Study participants will include both adults (>19 years) and children (6-12 years) living in rural counties located in the Nebraska, recruited through contacts at the Health Departments responsible for these counties. Parents/ are often the primary food providers and caretakers of children living in the home, so their diet selection and physical activity example often have the greatest impact on the children. Also stakeholders and community partners are adults that follow in this range.

B. Will children (18 years of age or younger) be included in this research?
Yes

1. What is the justification for inclusion of children in this research?
Overweight children are known to be at-risk for numerous weight-related health conditions such as diabetes, hypertension, and cardiovascular disease. The intervention are specifically targeted parents/guardians of overweight children and will be tested among parents and evaluating their children outcomes. In addition to obtaining written informed consent from the parents/caregivers, children will also provide assent prior to any study activities. The proposed protocol in this application is designed to protect the enrolled children and their personal data.

2. What is the age range for the child subjects, and what is the justification for selecting this age range?
The evidence-based Family Connection intervention[20] upon with this study proposes to adapt is specifically designed and targeted parents/guardians of overweight children 6-12 years old. Thus, study will include approximately 58 children following the inclusion criteria in this study: (a) age 6-12 years (b) BMI z-score ³85th percentile (c) self-Identified L/Hs living in target counties (d) assent to participate in the study.

3. Will this study enroll wards of the state?
No

7. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
Yes

a) Explain the nature of the restrictions and provide justification.
Latino/Hispanic families are the focus of this study. Based on our research eligibility criteria that target self-identified Hispanic or Latino participants, we anticipate that 100% of recruited subjects will be of Hispanic or Latino ethnic minorities, some monolingual in the Spanish language. Research staff who will conduct recruitment, informed consent, and study procedures will be required to speak this language fluently; therefore, potential subjects will not be excluded from research because of their inability to speak English. Conversely, all staff will be fluent in English so no L/Hs will be excluded from the study due their language preference. The community health workers and CWG will work with the investigative team to assist in developing and employing recruitment strategies that have demonstrated effectiveness for successfully engaging minority L/Hs into previous health programs. However, community members of Health Departments who are not minorities (e.g. others races/ethnicity) may participate as CWG members.

8. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
Critically ill patients
Students of the investigator
Employees of the investigator
Educationally disadvantaged individuals
Socially or economically disadvantaged individuals
Individuals with a stigmatizing illness or condition
Individuals from a marginalized social or ethnic group
Other.
♦ No vulnerable subjects will be specifically recruited

9. Inclusion Criteria
What are the specific inclusion criteria?
Intervention Adult Participants
1. Age >=19
2. Self-identified L/Hs living in target counties

3. Parent of a child aged 6-12 years with a BMI z-score ³85ths
4. Willing and able to give informed consent

Children Participants
1. Age 6-12 years
2. BMI z-score 85th percentile
3. Self-Identified L/Hs living in target counties
4. Assent to participate in the study

Community Working Group (CWG)
1. Rural health department administrators who participated in the preliminary study and development of the current application. They include our partners at CDHD (Teresa Anderson), ECDHD (Chuck Sepers), TRPHD (Jeremy Eschilman), and CAPWN (Betsy Vidlak).
2. Rural health department clinical staff (CHWs, Nurses, Clinicians, n=4) and state health department representatives (Josie Rodriguez, Nebraska Department of Health and Human Services [NDHHS]) who participated in the preliminary study and development of the current application (total n=5).
3. Adult community members (19 years of age or older) from the sampling region whose knowledge and experience provides insight into the preferences and needs of the local L/Hs (n=2).

10. Exclusion Criteria
What are the specific exclusion criteria?
Intervention Participants:
1. No telephone
2. Contraindication to physical activity or weight loss
3. Planning to move in the next 12 months
4. Currently participating in weight loss program
5. Pregnancy or planning to get pregnant in the next 12 months
6. Not willing to be randomized
7. Not willing to consent or assent to participate

Community Working Group - None

11. Pregnancy and Contraception Requirements
A. Are women of child bearing potential (WOCBP) included in this research?
Yes

a. Are there any specific contraception requirements for subjects?

No

1. Provide justification for absence of contraception requirements
♦ There are no interventions that are likely to be of risk to a fetus
Investigational drug(s) is (are) not systemically absorbed
Investigational drug(s) is (are) systemically absorbed, but there is no evidence from human studies, or from clinical experience, that there is risk to a fetus
Other

B. Are pregnant women included in this research?
Yes

C. Are breast feeding women included in this research?
Yes

Provide justification
All women, including child bearing potential (WOCBP), pregnant and breast feeding, can be a participant as member of the Community working Group (CWG) and in the focus groups. However we will exclude pregnant and breast feeding women from participating in the intervention testing. Being pregnant and/or breastfeeding could impact the parent main outcomes results (weigh loss) of feasibility test with small sample.

METHODS AND PROCEDURES

12. Methods and Procedures Applied to Human Subjects
A. Are there any evaluations or tests that will be performed for the purpose of determining subject eligibility which would not be routinely conducted as part of standard clinical care of the prospective subject?
No

B. Describe the research plan, including all procedures, interventions, evaluations and tests.
Intervention. Family Connections(FC)[20] focuses on parents as an agent of change. It includes two parent classes, followed by 10 IVR automated telephone support calls over 6 months. This intervention incorporates evidence-based principles[83-89] with the goal to provide parents with the skills and confidence to change the physical and social environment to be supportive of healthy behaviors. Program materials are provided in a parent workbook with activities to be completed at home that align with IVR calls to promote increased physical activity and consumption of fruits and vegetables in concert with

decreased sugary-drink consumption and screen time. The program starts with 2 small group support sessions spaced one week apart that guides participants through developing an action plan for parental behaviors, role modeling, and changes to the home environment that would facilitate healthy eating and physical activity. It is followed by 10 IVR calls (5-10 minutes) beginning with weekly (4), biweekly (4), and monthly (2) calls. We use the 5As model[90] to help train parents in setting physical activity and healthful eating goals with their family during our IVR calls. This model includes **A**ssessing behaviors and motivation, providing **A**dvice on healthy behaviors, collaboratively **A**greeing on goals, **A**ssisting parents with barrier identification and resolution, and **A**rranging for follow-up[90]. During each IVR call parents provide information on current physical activities, and food consumption. This information is compared to families goals for weight loss, physical activity, and food consumption and used to provide feedback on success in subsequent IVR calls. Calls also allow parents to select specific messages related to intervention content and help them prepare for relapse prevention (Calls 7-10) once the program is completed.

Community Workgroup (CWG) Development and Recruitment. We will convene a group of community members from organizations serving L/Hs to participate in a CWG[91]. Drs. Silva and Eisenhauer will work with our community partners to help identify and invite formal and informal community leaders to serve on the CWG. The CWG composition will include 10 community members from the sampling region[78] whose knowledge and experience provides insight into the preferences and needs of the local L/Hs.[79] CWG participants will be persons who have influence over their peers (i.e., opinion leaders), yet provide input on real-world issues and can leverage any necessary changes to minimize barriers to participants engagement and intervention implementation. Those will include our representatives from our partners, healthcare providers and L/H community members. Our team will also participate in the CWG to provide intervention content expertise[91]. CWG members will meet quarterly throughout the study and will provide structured qualitative and quantitative feedback on adaptations, recruitment and engagement strategies of L/Hs families. The CWG will help develop vertical and horizontal systems relationships and processes needed to successfully adopt, implement, and sustain the FC program. Topics for CWG meetings will include strategic development of referral pipelines, strategic recruitment and retention strategies, and implementation adaptation for local needs. Differences in feedback will be reconciled via group discussion until consensus is reached. Meetings will also be available via Zoom video chat technology to CAB members, which is freely accessible on the internet and feasible to use in low-band width internet locales via smartphone, PC, tablet, or laptops, to limit access barriers (weather, time) which might inhibit attendance.

Specific Aim 1: To determine the relevance, suitability and usability of a culturally adapted technology-delivered FBCO intervention for L/H families in rural Nebraska.

Figure 2 describes our adaptation approach using a structured community input[31,38,41,50]. We propose 4 phases of adaptation based on the Heuristic Framework for Cultural Adaptation [31]. Phase 1: We will conduct a pre-adaptation assessment of the intervention with CWG and L/H parents to identify intervention characteristics and parents preferences for potential adaptations. CWG (n=10) will complete the Cultural Relevance Questionnaire (CRQ)[41] and an individual interview, while parents (n=40) will participate in a focus group (FG). Phase 2: We will conduct surface (language, visuals) and deep (recruitment strategies, setting, delivery method, foods and recipes) modifications[31,38,44]. We will use two measures of readability[92,93] and a final series of edits to simplify language to 3rd4th grade level[94]. Phase 3: We will use a mixed method, task-based usability assessment[95] to evaluate IVR Calls & Workbook. We will recruit 3 to 6 participants with previous studies indicating that 5 may be the optimal number[96]. Participants will complete a short questionnaire and receive an introduction to think-aloud procedure[97]. A trained bilingual facilitator will lead each session using a semi structured interview guide, while Dr. Silva observes and take notes. Participants will be asked to perform standardized tasks, such as engaging with the IVR system, accessing information on the workbook, or setting a goal. After each attempted task, we will use open-ended questions to elicit participants (1) expectations for the features functionality, (2) ability to comprehend the information displayed, (3) ability to navigate to and from the feature, (4) satisfaction with the feature, and (5) how the feature might be improved[95]. To assess satisfaction, parents will complete the adapted Computer System Usability Questionnaire (CSUQ - ease of use, likability of the interface, and overall satisfaction). Each session will be video-recorded using QuickTime Player (Apple Inc, Cupertino, CA) and transcribed. Phase 4: we will conduct a post-adaptation assessment of using the same procedures and participants from Phase 1 to refine the adaptations. CWG will make final recommendations for adapted version to be tested under Aim 2. Data Collection: All participants (CWG and parents) will complete an informed consent prior to any study-related activity CWG (n=10) will complete structured (i-PARIHS) interviews (30-minutes) with Drs. Silva and Eisenhauer and the CRQ instrument (web-based) to provide pre and post feedback on adaptations. The CRQ is a theoretically-based instrument to evaluate cultural sensitivity (functional, conceptual and linguistic) and ecological validity (e.g. language and context). It provides information on: (a) language's suggestions or changes, (b) concept coherence (consistency and understanding of the intervention elements), (c) quality of delivery, and (d) positive/negative impressions. For our FGs, we will recruit L/H parents from four NE rural areas. FGs will take place at local community centers. Drs. Silva and Eisenhauer will coordinate the recruitment of parents (n=8-12 each, n=40 total). FGs will last close to two hours and will be facilitated by a trained bilingual facilitator. FGs will be led in the language most comfortable to all participants. We will collect feedback on the cultural relevance of the materials and delivery modes as well as the acceptability of the intervention. FGs and CWG interviews will be audio recorded and transcribed using a systematic process to clean and categorize similar FG/CWG comments for data analyses.

During the adaptation process we will use the expanded framework for reporting adaptations and modifications to evidence-based interventions (FRAME framework)[50] to record and characterize adaptations necessary to achieve appropriate contextual and cultural suitability. FRAME includes consideration of when and how modifications occurred, whether it was planned or unplanned, relationship to fidelity, and reasons and goals for modification. Data Analysis: See below.

Specific Aim 2: To evaluate the feasibility and preliminary effectiveness of a technology-delivered FBCO intervention for L/H families in rural Nebraska using RE-AIM and i-PARIHS. We will randomly assign participants to either the intervention or an enhanced standard care group (Figure 3). Sample Size Calculation. Sample size is based on the comparison of changes in BMI z-scores achieved by participants in FC-IVR with those achieved by participants in FC-workbook condition at 6 months post randomization[20]. A total of 46 (23 per group) parent-child dyads achieves 80% power (alpha 0.05) to detect a significant difference between SC and IVR groups conditions. To account for a 25% attrition rate at 6-month we will recruit a total of 58 (29 per group) dyads. Participant Recruitment and Baseline Assessment Procedures. Dr. Hines will coordinate the recruitment of the participants with the help of CHWs. We will recruit a total of 58 dyads (Table 1). Baseline visits will take place at local community centers using private rooms. Dyads will complete informed consent, height, weight and waist circumference assessments, as well as complete a computer-based survey. Randomization will follow a random-numbers table (families/staff unblinded). Standard-Care. Families randomized to this group will receive FC-workbook. No additional materials or intervention contact will be provided. CHWs will follow a retention protocol to ensure these individuals return to 6-month assessments. Intervention Delivery. Families randomized to this group will receive the adapted version of the intervention described above. Drs. Silva and Almeida will monitor IVR completion reports and assist the student-worker and CHWs in the on-going monitoring and engagement of participants during the intervention. Measurements and Data Collection. All measures (see table at PHS section for description) will be collected prior to intervention initiation and at 6 months post baseline (Figure 3). Weight will be assessed using a digital scale calibrated for accuracy prior to each assessment period using standard weights of a known quantity (e.g., 100-pound dumbbell). Height will be measured with a stadiometer, calibrated in 0.1-cm intervals. Waist circumference will be measured with a spring-loaded cloth tape measure at the level of the iliac crest using the average of the two closest measurements. Other Measures. Children and parents will complete measures of physical activity[98,99], eating behaviors[100], beverage intake[101], quality of life[102,103] acculturation[104,105], and health literacy[106]. Parents will also complete home environment[107] surveys. During the 6-month assessment parents will complete program satisfaction surveys and a short exit interview with a CHW. Feasibility will be assessed according to intervention relevant factors (RE-AIM dimensions, engagement, attendance and completion rates), cost-effectiveness, cultural

relevance (aim 1 measures) and acceptability identified in exit survey/interviews to determine whether intervention is appropriate for further testing. Qualitative Analysis. Qualitative interviews and FGs will be recorded and transcribed in English or Spanish. The PI, with assistance from Dr. Eisenhauer and Almeida will construct the interview codebook, with inductive codes added iteratively by in-depth reading of transcriptions until saturation is achieved. Transcripts will be double-coded in NVivo by Dr. Eisenhauer, Almeida and the PI. Inter-coder reliability using Cohens kappa (goal > 0.80) will be assessed. The research team has extensive experience conducting qualitative investigation[20,22,26,51,58,62,67], possesses local linguistic expertise (Drs. Silva and Almeida, speak Spanish), and will be aided by bilingual (English-Spanish) CHW staff. Statistical Analysis: The association of the intervention with the primary outcome of proportion of children reducing BMI z-scores will be tested using a chi-square test. The degree of association will be summarized using the odds ratio. If the assumptions of the chi-square test are violated, Fishers exact test will be utilized. Potential gender, and acculturation scores (external and familial language use, and social relations) differences will be explored via stratification. Comparisons between groups within gender will be done using Fishers exact test. Secondary aims outcomes include parent BMI, waist, PA, sweet beverages intake and eating behaviors, home environment changes and quality of life. The quantitative outcomes will be summarized using means and standard deviations or medians and inter-quartile ranges, as appropriate. If categorized, outcomes will be summarized using counts and percentages. Between group differences at 6-month will be capture using ANCOVA with the baseline measure as the covariate. If the ANCOVA assumptions are violated, a t-test (or if indicated, Wilcoxons sum rank test) between group change scores (6-month baseline measure) will be used. Potential parental engagement (% of reach, retention and completion) and acculturation scores (language and media use, and social ethnic relations) differences will be explored via stratification. Comparisons between groups will be done using Fishers exact test. Significance level is 0.05.

Sources of Data. Data for this research project will be collected from interviews, focus groups, surveys, and anthropometric measurements (Height and weight), specifically for research purposes. Interviews and focus groups will be audio recorded and usability testing will be video recorded, both will be transcribed verbatim for analysis. To analyze qualitative data, we will use a modified grounded theory approach.
This will involve identifying and naming key concepts from the interview, FG and UT transcripts, developing a codebook, and having two research team members code interviews independently, line by line. Dr. Silva will save the digital recordings off to a password protected encrypted file stored on the UNMC College of Public Health file server, secured by Windows access controls.
Drs. Silva and Eisenhauer will be the only individuals with access to these password-protected files. Upon saving the files to the encrypted file firewall protected UNMC database (OneDrive), the files will be deleted from the recording device. Dr. Silva will download a

copy to a dedicated folder in the UNMC database granting access to the files to Drs. Eisenhauer and Almeida for transcription. Speakers in Microsoft word documents will only be identified by numbers.

Outcome data for children and parents enrolled in the research are outlined in the table and assessments are projected to take ~35 minutes for children and ~60 minutes for parents. All the surveys utilized in this study will be in English and Spanish in paper format. Survey administrators will include the student-worker and four CHWs. The estimated time for each instrument is approximately 5 to 10 minutes. In Aim 2, participants will complete height and weight assessments using a calibrated weight scale, as well as a computer-based survey. The survey will include questions about socio- demographic information, physical activity, nutrition, health literacy and quality of life. All questionnaires and biomarkers will be entered in a password-protected database, without personal identification of participant and stored in OneDrive according to university IT guidelines. The information obtained from the surveys will also be encrypted and password protected. Drs. Silva, Estabrooks and Michaud will conduct error-checking procedures on all data to ensure their accuracy and safety.

As we have done in prior studies, a manual of procedures will be developed during the initial study start-up period that explicitly describes the specific procedures related to the delivery of focus groups, data collection and safety, and quality assurance for all study stages.

Implementation study measures:	Variables	Approx. minutes	Baseline	6-Month
Child				
Weight	Raw units (Kg), percentage, BMIz-scores	3 min	x	x
Height	Height (cm).	3 min	x	x
Waist Circumference	Waist Circumference (cm)	3 min	x	x
Blood pressure	Systolic and Diastolic pressure (mmHg)	5 min	x	x
Physical Activity (Godin-Child Questionnaire99)	Time of vigorous, moderate, mild exercise. Score and category (active/insufficient)	3 min	x	x
Nutrition (BRFSS fruits and vegetables100 and BEVQ101)	Fruit and vegetables servings and sugar sweetened beverage consumption	5 min	x	x
Quality of Life (PEDS-QL103)	Physical Health and Psychosocial Health Score, Sum Score	5 min	x	x
Health Literacy (New Signal Vital-NVS106)	Health literacy and Numeracy, Sum score of and categorized (limited/adequate)	3 min	x	x

Acculturation (Short Acculturation Scale for Hispanic Youth104)	External language use, familial language use, social relations scores, total score, rank (low/high)	3 min	x	x
Parent				
Weight	Raw units (Kg), percentage, BMI.	3 min	x	x
Height	Height in cm.	3 min	x	x
Waist Circumference	Waist Circumference in cm.	5 min	x	x
Blood Pressure	Systolic and Diastolic pressure (mmHg)	5 min	x	x
Physical Activity (Godin Leisure Time Exercise Questionnaire98)	Time of vigorous, moderate, or mild exercise. Sedentary Behaviors. Score and category (active /insufficient).	3 min	x	x
Nutrition (BRFSS fruits and vegetables100 and BEVQ101)	Fruit and vegetables servings and sugar sweetened beverage consumption.	5 min	x	x
Health Literacy (New Signal Vital-NVS106)	Health literacy and Numeracy, Sum score of and categorized (limited/adequate)	5 min	x	x
Quality of Life (BRFSS Healthy Days102)	General health status Number of Healthy Days	3 min	x	x
Home Environment (Comprehensive Home Environment Survey107)	Food, Physical activity, and Media home environment scores and total score.	10 min	x	x
Acculturation (Bidimensional Acculturation Scale105)	Language and media use, and social-ethnic relations scores, total score and rank (low/high).	3 min	x	x
Qualitative interview on process and program feedback	Feedback and Satisfaction with intervention components	20 min		X

- *all measures are available in both English and Spanish versions*

All questionnaires and biomarkers will be entered into a secure site through the Internet. All data will be entered in the firewall-protected server. The UNMC Research IT Office instructs investigators in its use and hosts the REDCap database of project data.

C. Select any of the following that apply to the research:
Phase I study
♦ Randomization
Placebo (or non-treatment arm)
Washout
Sensitive surveys or questionnaires
None of the above

Describe randomization process and schedule
Randomization will occur at enrollment and follow a random-numbers table (families/staff unblinded).

D. Identify:
1. All procedures, interventions, evaluations and tests performed solely for research purposes (eg, administration of an investigational drug or a new psychological assessment instrument; randomization)
With the exception of the standard care condition, all aspects of this study described above will be performed for research purposes. These include:

1. Eligibility and screening process
2. Monitoring of recruitment and retention of participants
3. Assessments / Measurements

2. All procedures, interventions, evaluations and tests performed for clinical indication but more frequently than they would be if the subject was not participating in the research (eg, extra blood tests; additional radiology exams)
We typically do not use assessments taken as part of normal clinical care, however, information provided by intervention and anthropometric tests performed (e.g. weight, height) are part of the usual care for both and children in a regular primary care practices.

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).
A mixed-methods feasibility study will be used to address our 2 Aims:

Specific Aim 1 Design and Analyses

Cultural relevance Analysis: We will conduct an assessment of both the original intervention and the adapted intervention by in-depth interviews and focus groups to assess changes proposed to match the characteristics and preferences of potential participants. The English and Spanish versions of the Cultural Relevance Questionnaire (CRQ) and i-PARIHS will be

used to evaluate original intervention by the Community Workgroup (CWG) as well as to guide interviews and focus group questions. CRQ evaluates cultural sensitivity (i.e., functional, conceptual and linguistic) and ecological validity (e.g., language and context) using a 5-point Likert scale and open-ended requests on each item to elicit qualitative observations. CRQ analysis will provide information on four overarching categories: (a) language's suggestions or changes, (b) concept coherence (consistency and understanding of the intervention elements), (c) quality of content delivery, and (d) positive/negative impressions. CWG members will evaluate adapted materials, and Dr. Silva will lead the training of the CWG on how to use the tool. Materials will be rated by CWG members on a scale of 1 (Components are not reflected within the intervention) to 5 (All of the components are reflected within the intervention). The evaluation of cultural relevance consists of three categories: 1) functional relevance, 2) conceptual relevance, and 3) linguistic relevance of the intervention for each module, where higher scores indicates a more culturally relevant material. Interviews and focus groups (FG) will be conducted to assess cultural relevance (cultural sensitivity and ecological validity), preferences of potential participants, and to see how satisfied participants and CWG are with (a) delivery mode (i.e. workbook, IVR, in-person group session), (b) relevancy of information provided, (c) frequency and duration of interactions, and (d) whether they would recommend the program. Interviews and FG will be scheduled and conducted by Dr. Silva and will be audio recorded and transcribed using a systematic process to clean and categorize similar comments for data analyses.

Readability Analysis. We will use two measures of readability: the FRY method and the Flesh Reading Ease Score (FRES). Our analysis will include a comparison of the readability level of the original English version and the new Spanish version using the collaborative functionalist approach.

Usability Analysis. We will use a mixed method, task-based usability assessment to evaluate our technology components (i.e., IVR and Videos). We will recruit 3 to 6 participants to complete a short questionnaire and receive an introduction to think-aloud procedure. This procedure allows testing observers to understand and track a participants thought processes as they navigate one randomly selected intervention session (i.e., IVR only, IVR plus workbook, or workbook only). A trained bilingual facilitator will lead each session using a semi-structured interview guide, while Dr. Silva observes and take notes. Participants will be asked to perform standardized tasks, such as engaging with the IVR system, completing workbook activities, or setting a goal. After each attempted task, we will use open-ended questions outlined in the interview guide to elicit participants (1) expectations for the features functionality, (2) ability to comprehend the information displayed, (3) ability to navigate to and from the feature, (4) satisfaction with the feature, and (5) how the feature might be improved. To assess satisfaction, participants will complete the adapted Computer System Usability Questionnaire (CSUQ) for ease of use, likability of the

interface, and overall satisfaction. Each session will be video-recorded using QuickTime Player (Apple Inc., Cupertino, CA) and transcribed. Deidentified transcripts will be imported into NVivo 10 (version 10; QSR International, Burlington, VT) for coding and analysis to address design, efficiency of use, and content and terminology.

Tracking and Monitoring of Adaptations. During the adaptation process we will use the expanded framework for reporting adaptations and modifications to evidence-based interventions (FRAME framework) to record and characterize modifications and adaptations necessary to achieve appropriate contextual and cultural suitability. FRAME includes considerations of when and how modifications occurred, whether it was planned or unplanned, relationship to fidelity, and reasons and goals for modification. We will align reasons and goals for adaptations to our overarching conceptual model and content and analyze meeting minutes, field notes, and decision-records along the components of the RE-AIM and iPARiHS models. This will provide information on adaptations that were made due to beneficiary characteristics (i.e., L/Hs), recipient and organizational characteristics, contextual factors, or facilitation factors.

Data Analysis. We will use triangulation of quantitative (CRQ, CSUQ and surveys) and qualitative (CRQ, CWG and FG feedback) methods from different sources (i.e., CWG members, providers, community partners staff, and L/Hs) to increase the likelihood that the refined intervention will meet the needs of participants while also adhering to the evidence-based principles at the core of the program. Focus groups will be audio recorded, and usability testing will be video recorded; both will be transcribed verbatim for analysis. To analyze qualitative data, we will use a modified grounded theory approach. This will involve identifying and naming key concepts from the interview, FG and UT transcripts, developing a codebook, and having two research team members code interviews independently, line by line. Co-Principal Investigator Dr. Silva will save the digital recordings off to a password-protected encrypted file store on the UNMC College of Public Health file server, secured by Windows access controls. Dr. Silva will be the only individual with access to these password-protected files. Upon saving the files to the encrypted file store, the files will be deleted from the recording device. Upon saving the files to the encrypted file firewall protected UNMC database (OneDrive), the files will be deleted from the recording device. Dr. Silva will download a copy to a dedicated folder in the UNMC database, granting access to the files to the student worker and Dr. Eisenhauer for transcription and analysis. Speakers in Microsoft Word documents will only be identified by numbers.

Specific Aim 2 Design and Analyses

Table 1 presents our implementation evaluation measures and analyses

RE-AIM	Measures	Data Sources [person collecting]	i-PARIHS Indicators
Reach	- Participation Rates - Characteristics Participants vs. Non-participants - Reasons for non-participation - IVR completion and dropout rates - Qualitative feedback on barriers/facilitators to participating	-Recruitment/enrollment/subject tracking logs (including reasons for non-participation or non-eligibility) [CHWs] -Demographic and clinical data from intake surveys (Redcap) [Student Worker, CHWs] -Qualitative interviews with participants, [PI Silva, CHWs]	Selected i-PARIHS constructs related to the RE-AIM dimensions will guide the qualitative interviews with patients and staff Selected constructs will include: Facilitation: IVR and group based sessions and workbook facilitation strategies; Innovation: adaptation to deliver strategies to L/Hs in the context of rural NE Recipients: perceptions of participants (Beneficiaries), and staff (Recipients) Context: documentation of the capacity (human and financial resources); assessment of support from the leadership at the state and local levels
Effectiveness	-Primary outcome (BMI z-score) and secondary clinical and self-management outcomes (Table 2) by control/IVR -Comparison of outcomes in subjects who withdraw vs. complete intervention	-Recruitment/enrollment/subject tracking logs (including completion, dropout and loss to follow-up rates/reasons) [CHWs] -Clinical data forms and surveys at 0,6 months [SW, CHWs]	
Adoption	- Staff and leaderships perceptions about delivering FBCO program via IVR and group sessions	-Qualitative interviews with staff and leadership [Dr. Eisenhauer , PI Silva]	
Implementation	- IVR completion reports; group session attendance and observation reports; proportion of content delivered as intended (fidelity) - Changes made during the implementation process (adaptation) tracked by the FRAME - Number of Calls completed and contact hours - Participant satisfaction - Qualitative feedback on barriers/facilitators from L/Hs/staff using i-PARIHS constructs	-IVR completion forms (IVR System) [Dr. Almeida] -IVR logged call duration (IVR System) [Dr. Almeida] - Participant Satisfaction survey [SW, CHWs] -Qualitative interviews with participants, staff [Dr. Eisenhauer , PI Silva]	
Maintenance	- Characteristics of completers vs non-completers - Intention to continue the intervention - Qualitative feedback on barriers/facilitators from participants/staff and leadership using i-PARIHS constructs	-Demographic and clinical data from intake surveys [SW, CHWs] -Clinical data forms at 0,12 months [CHWs] -Qualitative interviews with participants, facilitators, staff, and health authorities [Dr. Eisenhauer, PI Silva]	

Sample Size Calculation. Sample size is based on the comparison of changes in BMI z-scores achieved by participants in FC-IVR with those achieved by participants in FC-workbook condition at 6 and 12-month post randomization. A total of 46 (23 per group)

parent-child dyads achieves 80% power (alpha 0.05) to detect a significant difference between the FC-workbook and FC-IVR conditions, based on the relative BMI z-score differences (0.05) and standard deviation related to 6-month BMI z-score reduction for FC-IVR (0.06). To account for 25% attrition rate at 12-month, we will recruit a total of 58 (29 per group) parent-child dyads.

Cost Analysis: Costs will be assessed using time tracking spreadsheets and focused primarily on Aim 2 as it relates to the intervention delivery, though costs of participant recruitment will also be tracked using material and staff time to determine dollar amounts. Dr. Michaud will complete A simple cost benefit analysis by assessing intervention implementation costs at 6-month post baseline by BMI z-scores reduction categories of unchanged, ≤ 0.1, 0.1-0.25 and ≥ 0.25, respectively.

Qualitative Analysis. Qualitative interviews will be recorded and transcribed in English or Spanish. The PI, with assistance from Drs. Eisenhauer and Estabrooks, will construct the interview codebook, with inductive codes added iteratively by in-depth reading of transcriptions until saturation is achieved. Transcripts will be double-coded in NVivo by Dr. Eisenhauer. Inter-coder reliability using Cohens kappa (goal > 0.80) will be assessed. The research team has extensive experience conducting qualitative investigation, possesses local linguistic expertise (Drs. Silva speak Spanish), and will be aided by community partners bilingual (English-Spanish) CHW staff.

Statistical Analysis: Descriptive, parametric, and non-parametric statistical methods will be used to compare continuous and categorical variables among the intervention groups at baseline. Data will be examined for the presence of outliers, violations of normality (for those continuous variables) and missing data. Major violations of normality will be corrected with an appropriate transformation procedure or non-parametric methods . Multi-level mixed effect models will be employed to control errors of non-independence, heteroskedasticity caused by parent-child dyad heterogeneity, and potential covariates to control to detect the BMI z-score reduction differences between the two conditions. In its simplest form, the model generally can be shown as:

$$BMIzscore_{it}=\mu+\alpha_i+X_{ijt}'\beta+W_i\sigma+\Tau T_t+\theta d_i&\#8901;T_t+\nu_{it}.$$

All measures are obtained for 3 time periods: baseline, 6, and 12 months. The dependent variable is BMIz score for participant *i* at time point *t*. The unobserved participant-level heterogeneity that isnt time dependent is represented by α_i, is allowed to vary by parent-child-dyads and to be a random variable. The $\boldsymbol{X_{it}}$ are time-period-level covariates and the $\boldsymbol{W_i}$ are particpant-level covariates. The model also contains treatment group indicators $\boldsymbol{d_i}$, and

time period indicators T_t. Relative treatment effect between conditions will be captured by coefficient θ and is the variable of interest. Sensitivity analysis will be conducted to examine the robustness of the mixed effect model across different random-effect distribution specifications (e.g., normal, finite mixture of normal etc.). Additional outcomes (e.g., parent BMI, waist circumference, PA, sweet beverages intake and eating behaviors, acculturation, home environment changes and quality of life) will be analyzed using ANCOVA with the baseline measure as the covariate. If the ANCOVA assumptions are violated, a t-test (or if indicated, Wilcoxons sum rank test) between group change scores (6 or 12 month measure and baseline measure) will be used. Significance level for all tests is 0.05. Analyses will be performed using R 3.6 (R Core Team).

F. Does this study involve the collection of blood, urine, saliva or other human biological material (HBM)?
No

DRUGS, BIOLOGIC DRUGS AND DEVICES

13. Drugs and Biologic Drugs
1. Does this research involve the use of drugs or biologics?
No

14. Devices
1. Does this research involve a medical device(s)?
No

CONFIDENTIALITY AND PRIVACY

15. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
♦ On a secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO (including REDCap)
♦ On a secure cloud server - Specify the secured cloud serve: UNMC OneDrive
On a firewall protected database accessible through the internet - Specify who has administrative responsibility for maintenance of the server:
On an encrypted, password protected local hard drive
On an encrypted, password protected portable computer
On an encrypted, password protected flash drive
♦ In hard copy
Other

a. Please provide justification for use of hard copies
Data collection will be performed in rural areas that may have limited access to internet. Thus we may need to collect consents and survey printed forms (hard copies). Hard copies of data will be kept locked in a file cabinet in the locked office of the study coordinator or the locked office of the PI, at the College of Public Health.

b. Will hard copies will be transported from one site to another, on or off campus?
Yes

c. Describe how they will be secured during transport
Data will be transported in a locked briefcase or file box.

B. Will any of the following subject identifiers be recorded (at any time) in association with the research data?
Yes

1) Indicate the subject identifiers that will be recorded. Check all that apply.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
♦ Postal address information: street address, city, county, precinct, ZIP code
♦ Telephone numbers
Fax numbers
♦ Electronic mail addresses
Social Security numbers
Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
♦ Biometric identifiers, including finger and voice print
♦ Full face photographic images [and any comparable images]
No Identifier

2) Will a unique subject identifying number (e.g., S1, S2, S3), characteristic or code be used to link data to any of the identifiers listed above?
Yes

a. Where will the key (that links the unique subject identification code to the subject's name or other identifier) be stored?
The key will be housed on a password protected computer in a password protected file in an electronic location that is separate from participant data.

b. Does the code number include the subject's initials or other subject identifier as part of the code?
No

3) What is the justification for recording the specific subject identifiers listed above? Check all that apply.
♦ Schedule appointments
Collect continuous clinical information from the medical records
♦ Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
♦ Compensation
Other. Explain.

4) How long will the subject identifiers be maintained in association with the research data?
The recording will be maintained until the final report for the sponsor is generated and the associated manuscripts are published.

5) How will all of the identifiable research data be destroyed (e.g., all identifiers stripped from the data and destroyed, hard copies shredded etc) when the identifiable data is no longer required?
All electronic data will be destroyed with the assistance of the ITS and in accordance with UNMC Computer Use and Electronic Information Security Policy N0. 6051.

C. Will research data that contain subject identifiers be disclosed to:
Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

2. Investigators outside of UNMC, NM, UNO or CHMC?
No

3. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization

or entity (e.g., NCI cooperative groups)?
No

D. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

E. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future research that is not related to this study?
No

RISK/BENEFIT ASSESSMENT

16. Potential Risks
What are the potential risks associated with each research procedure, intervention, evaluation and/or test? If data are available, estimate the probability that a given harm may occur and its potential reversibility.
Considering the study rationale, population, procedures, and the risk: benefit profile as outlined, the overall risk level for participation in this study is considered **minimal risk.**

For the children and parents, it is possible that completing the assessments could cause stress or anxiety; however, the questionnaires contain minimally sensitive questions. Nonetheless, all community based project staff and university research assistants will be trained to deal with this anticipated anxiety and each individual will always have the right to refuse to participate or to answer any questions on the survey. Furthermore, children and parents from the target population of the proposed study could have relatively little recent experience with regular moderate intensity physical activity.

The risks associated with participation in focus groups, usability testing, interviews and surveys completion (CWG and Aim 1) are considered minimal. The research team will make it clear to participants that note taking and audio/video recording will be employed during the individual UT testing, focus group discussion and interviews, and obtain each member's agreement to this procedure during the consent process. In the FG sessions, participants

will be seated in a circle, to maximize face-to-face contact. Additionally, the audio/video equipment used to record the FG and UT discussions, and interviews will be placed in the most unobtrusive way in order not to inhibit participants interaction. FG and UT participants will receive assurance from the research team (in written and verbal form) that all information gathered, the recording and the resulting data, will be subject to the same rigorous safeguards and formal assurances of confidentiality and anonymity employed by other research techniques.

Parent from dyads participants from the target population of the proposed study will have relatively little recent experience with regular moderate intensity PA and may suffer from adverse health conditions such as hypertension, or high blood cholesterol. The dyads participants will be asked to initiate both a healthier diet and a graduated, moderate intensity exercise program. All PA programming will be tailored to individual family needs and levels of fitness. Each participant will begin with shorter bouts of moderate intensity PA and build to approximately 35 minutes for parents and 60 minutes for children of PA, 5 days per week by the conclusion of the 6-month trial. Although the initiation of inappropriate levels of high intensity PA could be harmful to such a population, small increases of moderate intensity PA over time has many benefits for this population, not the least of which is a reduced risk of mortality. Further, physical inactivity is a large risk factor for many adverse health events in this population and supervised moderate PA is safe even for older adults. Unfortunately, inappropriate levels of PA could lead to musculoskeletal injuries during or following PA, and potential cardiovascular, pulmonary, or related adverse events or hospitalizations, and in extreme cases death. Although, there is a larger risk from sustained physical inactivity, the risks of injury resulting from participating in the prescribed exercise regimens will be minimized in several ways. To avoid injury, participants will be instructed to devote the first and last 5 minutes of each physical activity session to warming-up and cooling-down, as well as setting realistic short term goals (i.e. parents:15 min. 3 days/week for 2 weeks; 15 min. 5 days/week for 2 weeks; 30 min. 3 days/week for 2 weeks; 35 min. 5 days/week for life). The purpose of the warm-up is to slowly bring the participants heart rate up the desired training heart rate. The cool-down is designed to slowly decrease the participants heart rate down from the training heart rate. The dietary recommendations are consistent with healthy eating patterns recommended by organizations such as the American Heart Association to produce a balanced diet and gradual weight loss, so are not anticipated to produce any risk beyond everyday living.

The research may also include risks to the privacy and confidentiality of protected health information or participants weight. The seriousness of this risk is low and several steps will be taken to ensure confidentiality. Further, based on the high security on internal computer hard and software, the likelihood of these risks are low. Each individual will have the right to refuse to participate or to refuse to provide a HIPPA authorization and such refusal will not affect a patients health care.

17. Risk Classification

What is the overall risk classification of the research?

♦ Minimal risk

Greater than minimal risk

18. Minimization of Risk

A. Describe how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety.

Adequacy of protection against risks: The proposed research presents no more than minimal risk to study participants. Families who meet the preliminary requirements will be required to sign a written informed consent form (parent) and verbal assent (child). The study and the consent form will be thoroughly described to each participant prior to enrollment. Any questions that arise and cannot be answered by trained recruiters on the spot will be routed to the principal investigator (Dr. Silva) and will be answered, with ample time for the patient to consider participation. Recruiters supervised by the Dr. Silva will ensure the participants comprehension of the study and obtain the participants signature. A copy of the document will be provided to the patient, and the original will be retained in the study file.

1. The risks of musculoskeletal injuries or cardiovascular events that accompany inappropriate increases in high intensity PA will be thoroughly described to each study dyad participant during the informed consent and assent process. All dyads participants will receive details to inform them of the studys purpose, protocols, and their responsibilities should they choose to participate.
2. The risks associated with data storage will be thoroughly described to each study dyad participant during the informed consent process. All dyads participants will receive details to inform them of the studys purpose, protocols, and their responsibilities should they choose to participate.

An assessment of potential adverse events will be used to document potential problems and if those problems were related to participation in the program. The risks of injury resulting from participating in the prescribed exercise regimens will also be minimized in several ways including:

1. Exclusion from the study of any person with overt contraindications for PA
2. Individualized exercise prescription based on the person's health background and history.
3. Careful instruction of participants through interactive technologies.
4. A gradual approach to increasing exercise amount and intensity of physical activity as recommended by the ACSM.
5. Targeting physical activity intensity in the moderate range, and tailoring the intensity level to the needs and abilities of each participant, including age.
6. Careful attention to warm-up and cool-down procedures as well as to the experience

of physical discomfort during exercise.

The risks to privacy and confidentiality will also be carefully described to each study participant during the informed consent process, and all uses and disclosures of protected health information will be detailed in the authorization document as well as the consent form. To keep the information safe and protected, the following steps will be taken:

1. Participants will receive a unique study ID number. Only approved personnel (Dr. Silva) can match the individuals to the study ID number and related results.
2. Strict security safeguards will be in place to reduce the chance of misuse or unplanned release of information. Steps we take include password protected access to databases, and storage of paper documents in a locked file cabinet.
3. Rules for publications: If research results are published, individual participants will not be identified by name or any other personally identifiable information.
4. If physical test results indicate possible health concerns, participants will be referred to the Study Healthcare Liaison, Dr. Eisenhauer, and this information may be shared with their primary physician if they wish to do so.

Additionally, during the parent informed consent process, potential CWG, FG and UT participants will be assured that the information shared during the think-aloud procedure or group discussions will be de-identified and anonymous. As such, participants will only use first names or nicknames when checking in to the UT or FG and when referring to self or others during the FG. To further protect confidentiality, the research team will remind participants at the start and end of the UT and FG that what is discussed during this process is to be kept confidential. To maintain this confidentiality, FG participants will be asked not to disclose the first names of participants outside the focus group. In the video recordings from the UT the camera will be positioned to not show participants face, only the interaction with phone/computer screen. Finally, the files of video recordings from the UT and audio recordings from the FG will be stored and protected under a locked room in a password protected computer file to further protect participant information from being shared.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis. If there is an independent Data and Safety Monitoring Board (DSMB) provide the charter, or describe (1) the composition of the DSMB membership, (2) the frequency of DSMB meetings and reports.

The study will monitor the medical safety of participants. At the screening stage, potential study participants will be monitored to determine safety to participate in the trial. Safety will also be monitored during the conduct of study assessments. Safety during the conduct of the study intervention will also be monitored. Finally, the study monitors adverse events to assess their potential relationship to the intervention. Events will be reported to the Data Safety Monitoring Board (DSMB).

A Data Safety Monitoring Board (DSMB) will be established and charged with the responsibility to monitor all aspects of the study. Dr. Eisenhauer will act as the Study Healthcare Liaison (SHL) and report to the DSMB for issues related to participant safety.

See uploaded file "Data and Safety Monitoring Plan."

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
The study will be audited beginning six months after the start of accrual of participants and then annually. Individual Roles and Responsibilities: Each audit will include monitoring of: compliance with informed consent and eligibility requirements, recruitment plan according to protocol, expected and actual accrual, protocol violations, participant withdrawals from the study, adverse events, baseline participant characteristics, interim analysis findings prepared by the study statistician (Dr. Kachman), and appropriate follow-up of data collection according to protocol. Dr. Kachman will prepare and sign off the relevant reports, with data void of participants names. The reports will then be signed off by the PI and submitted to the DMSB. The DMSB will be provided with a summarized report with access to raw data if needed.

See uploaded file "Data and Safety Monitoring Plan." for a summary of review/reporting activities outlined on page 3.

D. Describe the specific subject withdrawal criteria.
Subjects are free to withdraw at any point in the study. No withdraw by the study team are anticipated.

E. Describe the stopping rules for the research (e.g., the specific criteria for halting or early termination of the study).
There are none given the research minimal risk. Subjects can stop at any time.

F. Describe plans and resources available to promptly address any subject injury.
If a subject is injured or has a medical problem as direct result of being in this study, the subject will be instructed to immediately contact a member of the study personnel listed at the end of the consent form.

19. Potential Benefits to the Subject
Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?
Yes

Describe potential benefits to the subjects that may reasonably be expected from participation in the research, if any. If there are therapeutic and non-therapeutic components of the research, address anticipated benefits to subjects that may reasonably be expected from each of these components.

Parents and children in this study should receive many benefits by participating. Based on the literature cited in the Significance section participants who lose weight can expect the following:

1. Improved Cardiovascular Function.
2. Improved physical quality of life.
3. Decreased risk of future cardiovascular events.
4. Decreased risk of an obese adulthood.

Furthermore, all dyads participants may learn more about their own health. They will receive information regarding their weight, physical activity and dietary behaviors. This information could be helpful on their overall well-being and even identify potential health risks.

20. Potential Benefits to Society

Describe the potential benefits to society that may reasonably be expected to result from this research.

There is an urgent need to better understand and mitigate childhood obesity related disparities. However, despite growing number of publications and funding in this area, very little is understood and the disproportionate obesity related burden suffered by L/Hs children continues to grow. As such, more of the same type of research will not help solve this complex problem and our innovative collaborative approach seeks to help move the field further in its understanding of health disparities.

Additionally, the development of a successful intervention has the potential to provide a viable alternative that can be used in rural communities across the United States and abroad in rural Spanish speaking communities. Therefore, we believe findings from the proposed research will contribute to a limited body of knowledge regarding the feasibility and acceptability of delivering new culturally appropriate technology-delivered family-based childhood obesity (FBCO) programs to a population that is traditionally absent from the development process. Furthermore, we believe that by engaging the target population in this process we will have a higher chance that L/Hs families living in rural Nebraska will enroll and engage in future programs. Childhood obesity is one of the greatest health problems facing this rural population and the knowledge gained from the current proposal has the possibility of helping to slow down and even reverse the current obesity epidemic among rural L/Hs children.

Also, the proposed study will provide details on a novel application of a cultural adaptation model that could provide a blueprint for future intervention development and testing when considering translation to address health disparities. The importance of this knowledge has implications for both individual behavior change, but also for system application and

delivery. As noted previously, the risks to participating are minimal; therefore would be reasonable in relation to the anticipated benefits to research participants and others.

ALTERNATIVES TO PARTICIPATION

21. Alternatives to Participation

1. Describe the likely care the subject would receive at this institution were he/she not to participate in the research. If there are more than one reasonable courses of treatment briefly describe.

The subject can choose not to participate. The standard of care condition in this study is similar to the care an individual might receive when they are not participating in the research.

2. Is the potential benefit of the research at least as good as the potential benefits of the alternatives described above?

Yes

3. Are there any reasonably available alternatives outside this institution which would have the potential for providing benefit to the subjects outside the research context?

Yes

a. What are the reasonably available alternatives?

Families may seek out services that promote children weight loss without participation in the study.

4. Would any of the study procedures or courses of treatment in the protocol be available to the subject if they elected not to participate?

Yes

a. Explain.

Standard of care for childhood obesity is available in the community to the prospective subject should they choose not to participate.

5. Would the research intervention be available outside the context of research?

No

6. Are there any treatments that the subject would be denied as a consequence of participating in research that he/she would have received had he/she not participated?

No

7. How do the risks of the research compare with the risks of alternative procedures or courses of treatment described above?
The potential benefits of the Family Connection Program (e.g., weight loss, improved BMIz in children) are much greater than the current standard of care for childhood obesity, as evidenced by our published pilot data[20]. The risk associated with existing standard-care for childhood weight management is similar to those associated with the proposed intervention. They are minimal.

FINANCIAL OBLIGATIONS AND COMPENSATION

22. Financial Obligations of the Subject
A. Who will pay for research procedures, interventions, evaluations and tests? Check all that apply.
Sponsor
♦ Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
Department/Section funds
Other. Explain

B. Will any of these procedures, interventions, evaluations and tests will be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
No

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
No

23. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
Yes

1. Describe the form of compensation, dollar amount (if applicable) and the prorated compensation plan (if applicable).
Participant will receive a $25.00 gift card for completion of any focus group and $25.00 for completion of usability test and $25.00 for intervention assessments. To enhance retention, in addition to receiving full details on the results of their anthropometric measurements, both parents and child participants who complete each of the 3 study visits (0, 6 and 12 month) will receive a $25.00 gift card each as a thank you for their time for a possible total of $50.00

per family per visit - $150 total over 12 months if they complete all 3 visits.
CWG participants will be compensated for their involvement in this research study. A gift card of $25 will be provided for each assessment (survey), meeting, and interview completed.

PRIOR REVIEW

24. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
Yes

1. Describe why the study was withdrawn.
Yes. Last year we got closer to the NIH funding line with our R21 proposal and requested an expedited review in order to respond to the JIT request that was granted a pending-funding IRB approval under the protocol 634-19-EP. Unfortunately, due budget cuts our project was not funded at that time and the IRB protocol was re-classified as withdrawn in January 28, 2020.

2. Describe changes made to the research plan prior to the current submission.
Minor changes were made after NIH review following reviewers recommendation, such as:

- Expand study area by increasing number of communities participants (from 1 to 4 partners health departments) with increased the number of focus groups participants for Aim 1.
- Aim 1 modification to include more detailed approach on procedures for intervention cultural adaptation.
- Changes on research team composition.

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and disapproved?
No

SUBJECT IDENTIFICATION & RECRUITMENT

25. Method of Subject Identification and Recruitment
A. Will prospective subjects be identified through initial contact by the investigator?
Yes

1. Identified through: Check all that apply.
Clinic

Hospital inpatient units
Previous research participants
Investigator or clinic databases or registries
Hospital Opt-In Database (thru Nebraska Medicine, BMC or CHMC Conditions of Treatment)
School records
Support groups, or other Interest Groups
♦ Other. Explain. Health Departments referral list for stakeholders and CHW staff. Target population recruitment sample will be draw by CHW from their usual covered population.

2. Describe how the research staff has ethical access to the potential subjects?
The community health workers (CHW) have access to this target population, participants will be recruited through direct contact by CHWs that already work with those families. Stakeholders will be recruited for interviews based on list provided by each partner Health Department Districts and the State of Nebraska Health Department (DHHS) as the directors will inform whom may be a key informant in their organization - all employers contact are already public record information.

3. Who will initially screen potential subjects to determine eligibility?
Investigator with an existing clinical relationship
♦ Investigator with other legitimate access
Investigator whose professional responsibilities that require access to names of potential subjects
Honest broker (thru Nebraska Medicine or Bellevue Medical Center COT Opt-in database)
Research coordinator or other person without ethical access

B. Will prospective subjects make the initial contact with the research personnel to inquire about the study?
Yes

1. Potential Subjects learn about the research through: Check all that apply.
♦ Referral by clinician or other parties specifically for the research
♦ Printed advertisements (including bulletins, newsletters, posters, fliers, and magazine or newspaper ads)
♦ Radio and Television advertisements
♦ Electronic advertisements (including social media or other on-line venue)
♦ Word of mouth
♦ Public UNMC study database
Other. Explain.

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?
Yes

1. Provide the NCT#.
NCT04731506

2. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

26. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

27. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
Yes

1. Identify the type of waiver requested:
Waiver of signed consent where the principal risk would be associated with a breach of confidentiality (45 CFR 46.117(C)(1)(i))
♦ Waiver of signed consent where written consent is normally not required outside the research context (45 CFR 46.117(c)(1)(ii); 21 CFR 56.109(c))
Waiver of signed consent if the subjects are members of a distinct cultural group or community in which signing forms is not the norm (45 CFR 46.117(c)(1)(iii)

WAIVER OF SIGNED CONSENT WHERE WRITTEN CONSENT IS NORMALLY NOT REQUIRED OUTSIDE THE RESEARCH CONTEXT (45 CFR 46.117(c)(1)(ii); 21 CFR 56.109(c)
1. Do any of the research tests and procedures involve more than minimal risk to subjects?
No

2. Does the waiver apply to:
All subjects
♦ A subset of subjects - describe the characteristics of these subjects Only for participants of the focus groups and usability test.

3. Does the research involve any procedures for which written consent would normally be required outside of the research context?
No

28. Child Assent
A. Is a waiver of child assent requested?
No

29. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
Prior to their actual participation - during eligibility screening before assessment data is collected.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
We will collect 3 different types of consent for each phase of this study. The data collection steps related to Aim 1 (Focus groups and usability tests) will use narrative consent. For the data collection related to Aim 2 (clinical trial), we will still use an in-person printed signed informed consent. The narrative and the informed consent will be emailed or texted to them and then reviewed again by the research staff or CHWs to ensure understanding (during the screening and recruitment process, the CHW ask the potential participants if they would like to receive a copy of the consent by text, and communication by text will only occur with the participants that stated they want to receive a copy of the consent in this way). The remote inform consent will be emailed or texted to them via the DocuSign link and then reviewed again by the research staff to ensure understanding.
Sufficient time will be allowed for a complete understanding of the study and for the subject to ask questions about the study and his participation. All interested individuals will have the opportunity to review the informed consent at home, prior to phone screening, focus groups and usability tests, and then prior to their initial visit, if the individual has questions about what is stated in the informed consent, he/she will have the opportunity to discuss those questions with a member of the research team on a one-on-one basis. The individual may then choose to provide or not provide verbal consent for phone screening, focus groups and usability tests, and to sign or not to sign in-person the informed consent for the trial.

C. Who will be involved in the process of consent and what are their responsibilities?
All potential participants will receive a recruitment packet delivered by their Community Health Worker (CHW) to include the narrative consent for contacting potential participants, discussing the specifics of the study, answer any questions, obtain verbal consent for schedule screening, determine initial eligibility, assess whether the individual wishes to

participate, and if so, schedule an eligibility/in-person screening visit. Interested participants will be will receive a pre-assessment packet delivered CHW with the informed consent for the trial and instructions for their initial visit approximately 10 days before their initial visit. During the recruitment and screening, trained CHW will review the informed consent and answer any questions the patient may have about the program. The investigators listed as authorized to document consent have sole responsibility for obtaining and documenting the obtainment of informed consent, and once the informed consent is signed in person, they will conduct the screening measurements.

D. How much time will be allotted to the process of consent?
Individuals will have several days to review both the narrative informed consent for focus groups and usability tests, and the informed consent for the trial. They will have the opportunity to ask questions of the research staff, and will be given as much time as needed to review and ask questions in person at the initial screening visit.

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
Participants will be given as much time as needed time to ask questions about the consent process and provide feedback on their understanding of the study and procedures. Participants will also have the opportunity to discuss participation with family or friends.

F. Will non-English speaking subjects be enrolled in this research?
Yes

Describe the plan to conduct the process of informed consent in the language of the subject/parent(s)/guardian(s)/LAR
Our research team that will be responsible for the consent possesses local linguistic expertise (Drs. Silva and Almeida, are fluent in Spanish), and will be aided by RHDs bilingual (English-Spanish) CHW staff. Consent will be provided in their preferred language (English and/or Spanish).

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
Eligible participants must have capacity to give informed consent and children the assent. This will be determined by the study staff during the phone contact, as well as the in-person visit. Participants must be able to articulate in their own words what the study is about, and what they might be asked to do to participate. Only when the investigator is satisfied the subject comprehends all of the elements of informed consent will they provide verbal consent for screening, and sign the consent form for the trial.

30. Documentation of Informed Consent and Assent
Select who will obtain consent from the subject/parent(s)/LAR.
Almeida, Fabio

Brito, Fabiana B

Eisenhauer, Christine M

Favero Alves, Thais

Ochoa-Rojas, Daisy

Santos, Natalia B

31. Consent Forms and Study Information Sheets
Indicate the type of consent forms and study information sheets to be used in this research. Check all that apply.
♦ Adult consent form
Legally authorized representative (LAR) consent form
Parental/Guardian consent form
Youth study information sheet
♦ Child study information sheet
Adult study information sheet (decisionally-impaired)
Screening consent form
Addendum consent form
♦ Other. Explain. Narrative consent for focus group and usability test

32. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

RESOURCES

33. Describe the resources available to safely conduct this study at <u>each</u> study sites specified in Section I.7.
Health Departments (CDHD, ECDHD, TRPHD, CAPWN) will provide adequate space to allow for physical privacy when the participants discuss their informed consent and have

their risk assessments taken. All four Health Departments has an Automated External Defibrillator on site in the event of an emergent cardiac event. The PI (Dr. Silva) and at Dr. Eisenhauer will be at all for CWG in-person meetings and focus group, and the trained CHWs will present for participants in obtaining informed consent, conducting trainings for at home assessments. The PI and Dr. Eisenhauer are registered nurses, and the CHW are trained to provide first aid and emergency response action if needed. All investigators at each UNMC campus (Norfolk, Omaha) have password protected laptops, IT support, and private, locked office space. The principal investigator has two digital audio recorders. The grant will permit purchase of scales, stadiometers, iPads, and other equipment needed for baseline biomarker measures taken at the assessment points. A locked briefcase will be used to transfer hard copies of written study materials from the data collection site to the college.

Please see "Facilities and Other Resources" file from NIH proposal uploaded for more information.

LITERATURE REVIEW

34. References

Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.

Please see "Bibliography and References" file from NIH proposal uploaded.

SECTION III

SUBMISSION DEADLINE

A. Full Board Review:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (e.g., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. Expedited Review
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)
Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
Investigational Device Review Committee (IDRC) Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
♦ **Sponsored Programs Administration (SPA)/UNeHealth** grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
Other Review
None of the above organizational requirements apply to this study

SECTION IV

COVID-19

1. Written documentation
List all of the location(s) that will be used for informed consent, visits, or other procedures. Provide the name and title of the person(s) granting permission AND written documentation that the researchers have permission to conduct the study in all location(s) proposed.
Locations:

- Central District Health Department (CDHD),
- Community Action Partnership of Western Nebraska (CAPWN),
- East Central District Health Department (ECDHD),
- Two Rivers Public Health Department (TRPHD)

Please see Letters of Support uploaded from Teresa Anderson (Director, CDHD), Betsy Vidlak (Director, CAPWN), Charles Sepers (Chief Officer, ECDHD), Jeremy Eschliman (Director, TRPHD).

2. Describe mask, visitor, and other guidance or policies required by each site.
Please see our COVID protocol for conducting any contacts (uploaded). Our procol is based on the guidance from the CDC if you will be in close contact with or are conducting home visits and at the beginning of the study this protocol will be updated and revised (and in an ongoing basis as necessary) by the Community Work Group (CWWG) that includes directors and providers from local Health Departments and oversee the community strategies in this study.

Multiple areas of the state are experiencing community spread of the virus that causes COVID-19, but different parts of Nebraska are impacted differently. As different areas of the state experience hot spots or other unique risk factors, stricter guidelines may be needed to help minimize the spread of disease and protect the health of people residing and working in these areas. As in this study we will be working closely with the Nebraska Health Department (DHHS) as member of our CWG we will always follow their currently guidelines and the state directives (http://dhhs.ne.gov/Pages/COVID-19-Directed-Health-Measures.aspx).

3. Describe the source of PPE.
The study via it's funding will provide all necessary PPE (e.g. masks, eye protection, gowns and gloves) and any supplies necessary (e.g. hand sanitizer, wipes, infrared digital thermometer) for conducting this study and help minimize the spread of disease and protect the health of people residing and working in these areas.

4. Describe other plans to be instituted by investigators enhance safety of subjects, such as social distancing, remote visits, flexible scheduling, etc.

The possibility of of COVID-19 transmission highlight the importance and contributions of our study like ours that aims to develop and test a technology-based interventions do not require in-person sessions. Aligning with the importance of prioritizing public health activities while maintaining social distancing to reduce exposure to and transmission of COVID-19, and limiting in-person care. At the same time, it brings challenges of managing study related activities such as the anthropometric assessments.

This will require a multipronged and phased approaches and strategies for Face-to-Face Activities and following our community-based participatory research approach, this will be done together with our Community Working Group (CWG). We will expand in our proposed COVID protocol (uploaded) that we have been using in previous studies and leverage local accessible mobile technologies, evidence-based and culturally relevant approaches tailored for each community and area of this study.

Including explore telemedicine and other ways to use new technologies that may facilitate evaluation of intervention outcomes. As well, coordinate with partners to provide all equipment necessary and rapidly deploy and restock PPE, including masks, gloves, goggles, gowns, hand sanitizer, and cleaning supplies. Proactively planning and updating protocols with contingency plans that could include altering procedures, cross-training staff, and expand the using available technology to replace in person contacts such as RedCap and Qualdrics. For example, for those having face-to-face interaction with participants maybe a more comprehensive PPE may be indicated, depending upon the context, prevalence of COVID-19 in the community, degree of contact with the client, and healthcare activity pursued at their home or non-home residential settings.

This collaborative approach for development of study protocols and routines are aimed not only for the participants safe completion of research activities but as well to assisting state and local health departments to balance the competing demands of their COVID-19 response. Following and contributing to standardize and endorse readiness protocol for CHWs responding to COVID-19. Furthermore, the majority of the contact with participants and all the in-person assessments will be completed by CHWs. Their engagement in the study will be assured via direct contract with the community partners as proposed by them and agreed before the proposal and ensured necessary resources at the funding budget (see letters of support). CHW are equipped, trained and supported as part of a well-functioning health system. Existing CHWs are well trained to prevent, detect and respond to COVID-19 as part of their regular work activities, including home visits for contact tracing, isolation and quarantine follow-ups.

As basic principle for protocols designed to ensure the physical safety and health of participants, follow DHHS and CDC guidance. For example, while performing any research activity CHW, CWG and all research personnel will be required to wear facemasks to

prevent transmission. They will be advised to check for any signs or symptoms of illness before reporting to work and to notify their supervisor if they become ill. In addition, they will be reminded to not report to work when they are ill. Investigators will follow recommended work restrictions and monitoring based on staff exposure to patients with COVID-19. We are implementing a process of screening staff and participants for fever or respiratory symptoms before any in-person activities.

For qualitative data collection (focus group, interviews and Usability tests) if an appropriated space to permit social distancing are not available locally (and if recommended and approved by the CWG) we will deploy an alternative way to conduct live online data collection. This alternate approach unlike in-person enable people to take part, without the need to travel and expose to contact. We have budget for an IT analyst as part of the research team to help with any technology challenges that may arise. However, the added convenience of being able to participate from the comfort of your own home or place of your choice means that online focus groups are also easier to recruit for and result in higher response and engagement rates. Participants will be invited to log on to a live online session at a specified time. We will use Zoom (via UNMC SSO) due it be one of the most popular platforms to use due to its ease of use, and includes 256-bit GCM encryption which provides even greater data safety and security, meaning that data will still be UNMC security compliant. Sessions will be conducted by trained bilingual facilitators following the same process proposed by the in-person method and the records and transcript will follow the same security protocols (described in Sources of Materials section in Question 12-B).

5. Describe plans for site and/or equipment cleaning, and the source of appropriate cleaning supplies.
After each data collection staff will use of disinfectant wipes (for example, Clorox or alcohol 70% wipes) provided by study on all the equipment (scale, stadiometer) and devices (iPad) and perform hand hygiene again.
Any disposable PPE used should be removed outside of the home and discarded by placing in a plastic bag and into an external trash can before departing location. PPE should not be taken from the home in personnels vehicle. Staff will carry a supply of plastic bags for appropriated disposal of PPE.

Please see our COVID protocol for study assessment.

6. Describe when COVID-19 screening questions will be asked of each research subject, and by whom.
Screening questions for Community Health Worker (CHW) prior to assessment scheduling and visits:

1. Do you have a cough, fever, rash, runny nose, muscle aches or sore throat?
Yes ____ No_____

2. In the last month have you traveled to an area with a widespread outbreak, or had close contact with a person known to have: Novel Coronavirus (COVID-19), MERs-CoV, or Ebola?
Yes ____ No_____

3. Have you traveled outside of the country within the last month?
Yes ____ No_____

In addition, we will conduct a non-contact temperature checking using infrared digital thermometer and report the result in the form. CDC lists fever as one criterion for screening for COVID-19 and considers a person to have a fever if their temperature registers 100.4 or higher -- meaning it would be almost 2 degrees above whats considered an average normal temperature of 98.6 degrees.

Please see our COVID protocol for CHW - Appendix - Screening questions

ADDENDUM B
Research Involving Pregnant Women, Fetuses and Neonates of Uncertain Viability or Non-Viable

Title of Protocol

Family Connections: Cultural adaptation and feasibility testing of a technology-based pediatric weight management intervention for rural Latino communities

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1. Preclinical Studies and Studies on Non-Pregnant Women [45 CFR 46.204(A)]

A. Will Pregnant women/fetuses be included in the research?

No

6. Research Involving Neonates of Uncertain Viability [45 CFR 46.205]

A. Will the research involve neonates of uncertain viability?

No

7. Research Involvng Nonviable Neonates [45 CFR 46.205(c)]

A. Will the research involve nonviable neonates?

No