IRB Protocol of Study to Culturally Adapt Healthy Dads Healhty Kids for Latino families

NCT03532048

BCM IRB Protocol: H-38237

PI: Teresia O'Connor

Note: Study 3 represents the protocol for the Feasibility Trial registered on ClinicalTrials.gov

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-38237
Status: Approved
Initial Submit Date: 2/10/2016
Approval Period: 10/14/2019 - 10/13/2020

Section Aa: Title & PI

A1. Main Title

HEALTHY DADS, HEALTHY KIDS LATINO- ADAPTATION AND FEASIBILITY OF A LIFESTYLE INTERVENTION FOR LATINO FAMILIES

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Organization: NATIONAL INSTITUTES OF HEALTH (NIH)

A6a. Institution(s) where work will be performed:

CNRC: Children's Nutrition Research Center
Texas Children's Health plan: Center for Children and Women

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

Yes

A9. ClinicalTrails.gov Registration

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Latino children have a high prevalence of overweight/obesity (OW/OB) with 39.7% of Latino 6-11 year old children OW/OB, compared to 32.6% of general US children. Being OW/OB places Latino children at risk for obesity-related medical conditions and remaining overweight into adulthood. Latino men in the US have a 78.6% prevalence of OW/OB, compared to 71.3% of the US male population. Latino adults carry a high burden of obesity related diagnoses, such as type 2 diabetes, and are less likely than non-Latino whites to receive optimal treatment for those conditions. Weight loss for adults and obesity prevention for children can help reduce the risk of both cardiovascular disease and diabetes among Latinos, yet studies have been of poor quality and interventions have targeted or attracted more women, with few weight loss interventions developed to target Latino families. In order to reduce the health disparities of obesity among Latinos, effective and innovative obesity programs are urgently needed. Capitalizing on effective programs and culturally adapting the program for Latino families is a promising approach.

Healthy Dads, Healthy Kids (HDHK) is an evidence based, healthy lifestyle program developed by investigators in Australia to promote healthy eating, physical activity (PA), and weight loss for OW/OB fathers, and healthy lifestyle behaviors among their 5-11 year old children for obesity prevention. The 3 month, award winning program, based on social cognitive and family systems theories, is the only program to target fathers to reach their personal weight loss goal and positively influence their child¿s eating and PA behaviors. HDHK has been evaluated in a randomized controlled efficacy (1) and effectiveness trials (2) in Australia; and recently in a community sustainability trial delivered by local facilitators in a large-scale rollout in one region in Australia (unpublished). The trials (1-2) have demonstrated significant and clinically meaningful effects on father¿s weight loss, and fathers¿ and children¿s lifestyle behaviors. HDHK primarily targets fathers, but includes children in most sessions, and mothers in some sessions to reach the whole family. Prior research supports the underlying premise of targeting fathers. Greater quantity and quality of paternal active involvement in their children¿s lives has been associated with many positive child outcomes, including cognitive development, social competence, academic achievement, and emotional well-being. Emerging evidence also supports the importance of targeting fathers in child obesity prevention programs. Evaluations of such programs require validated instruments to assess parenting as a mediator for child behavior change.

The HDHK has features that make it appropriate for adaptation for Latino families, such as emphasizing paternal role-modeling, family cohesion and engagement together in lifestyle behaviors. Latino cultural attitudes, such as respeto (respect for authority figures, e.g. parents), familism (family cohesion), and simpatia (harmonious interpersonal relationships) have been associated with their parenting behaviors and Latino mothers¿ and fathers¿ coparenting relationship. Taken together, these findings illustrate the importance of appropriately culturally adapting HDHK for Latino families before assessing its feasibility , and in later studies it effectiveness, among Latino fathers and their children. Cultural adaptation includes systematic modifications of an evidence based parenting program to enhance the language, cultural context and content to improve recruitment and retention and promote desired parenting and child outcomes among the new target population. Latino families need innovative obesity prevention programs. Culturally adapting and then testing the feasibility of this evidence-based program to target Latino fathers¿ and children¿s lifestyle behaviors together is a novel strategy to promote improved weight status for both and help reduce obesity-related health disparities for the Latino population.

This work will lead to the future submission of a clinical trial R01 application to assess the efficacy of the Latino HDHK program in a fully powered randomized controlled trial.

Background on add-on study fro Study 3: Arterial stiffness as measured by carotid-femoral and carotid-brachial pulse wave velocity is a non-invasive assessment that can be done in community settings. It has been associated with higher cardio-vascular disease (CVD) risk both among high-risk groups and community populations. However, it is not known if arterial stiffness is modifiable with lifestyle interventions intended to improve dietary intake, increase physical activity and promote weight loss in adults or prevent obesity among children. The culturally adapted version of Healthy Dads Healthy Kids offers an opportunity to assess whether a lifestyle intervention can result in change in arterial stiffness, which may result in lower

CVD risk among participants in a future fully powered trial. First, the feasibility and acceptability of obtaining this assessment among a sub-sample in the feasibility trial needs to be assessed.

1. Morgan PJ, Lubans DR, Callister R, et al. The 'Healthy Dads, Healthy Kids' randomized controlled trial: efficacy of a healthy lifestyle program for overweight fathers and their children. Int J Obes (Lond). 2011;35(3):436-447.

2. Morgan PJ, Collins CE, Plotnikoff RC, et al. The 'Healthy Dads, Healthy Kids' community randomized controlled trial: A community-based healthy lifestyle program for fathers and their children. Prev Med. 2014;61:90-99.

Section D: Purpose and Objectives

SA 1: Culturally adapt the HDHK curriculum for a US Latino population with input from Latino fathers and mothers, an expert panel of Latino parenting researchers (co-investigators), and the developer of HDHK (Morgan, Co-I). (Study 1)

SA 2: Identify food and PA parenting scales for Latino fathers and assess the psychometric validity and reliability of scales in a cross-sectional study and sensitivity to change in the feasibility study, to prepare to assess parenting practices as a mediator of child behavior change in the future clinical trial of HDHK. (study 2)

SA 3: Assess the feasibility (as measured by retention, engagement, and satisfaction) of the culturally adapted HDHK program among a sample of Latino fathers and their 5-11 year old children (n=40), in a randomized (wait-list) controlled trial (RCT).

Exploratory Aim: Assess the feasibility of methods for assessing weight, BMI or BMI z-score, physical activity, and dietary intake among the Latino fathers and their children, and parenting practices among the Latino fathers to prepare for a future fully-powered RCT.

Exploratory Aim 2:a) Assess the feasibility and acceptability of obtaining carotid-femoral and carotid-brachial pulse wave velocity assessments among a sub-sample of fathers and children in the feasibility trial of Papas Saludables Ninos Saludables. b) Explore if change in carotid-femoral and carotid-brachial pulse wave velocity varies between participants who demonstrate weight change or lifestyle change versus those who do not.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Child (3-12 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
This protocol offers minimal risk to the participating children. Children will be recruited for Study 3 with their families will be recruited in the Harris County (Houston) community on a strictly voluntary basis. Participation will be based on Latino families' willingness to participate. Written informed consents will be obtained from all participating parents, along with parental permission for child to participate, and child assent, when age appropriate.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Study One (SA 1) consists of qualitative studies (focus groups and interviews) with Latino parents to assist with culturally adapting the HDHK curriculum for a US Latino population.

Study Two (SA 2) is a cross-sectional study of a multi-ethnic/racial sample of fathers to complete a secure internet survey on physical activity and food parenting practices. Two weeks later, a sub-set of fathers will be asked to complete the surveys again.

Study Three (SA 3 and Exploratory Aim) is a feasibility study where Latino fathers and their families enroll and will be randomized to participate in the HDHK program immediately (Intervention group) or wait-listed several months to participate (Control group).

Inclusion Criteria:

Study 1: 1) Latino fathers and mothers with at least one healthy child between the ages 5-11 years old whose child is seen at the TCHP Center Clinic, 2) able to read and write in either Spanish or English. 3) Latino families who live in the Greater Houston area.

Study 1 Child Focus Group: 1) healthy Latino child between the ages 5-11 years old seen at the TCHP Center Clinic, 2) able to read and write in either Spanish or English.

Study 2: 1) Father of child between the ages of 5-11 years, whose child is able to participate in regular physical activities and eat regular foods, 2) able to read and write in either Spanish or English (although audio assistance of survey will be available for those that have lower literacy levels).

Study 3: 1) Latino fathers, mothers (if available) over the age of 18, with at least one healthy child between the ages 5-11 years old, and target child between the ages of 5-11 years old, 2) Child is a patient at one of the TCHP Center for Children and Women Clinics, 3) parents able to able to read and write in either Spanish or English. 3) Latino families who live in the Greater Houston area. 4) Latino fathers and children willing to wear an accelerometer for a 7 day study period at baseline and 4 months later. 4) Latino fathers with a BMI > 25, 5) Fathers pass the American College of Sports Medicine (ACSM) health screener to participate.

For all studies, we will define a father as an adult "father figure" in the child's life. This can include a biological father, step father, adapted father, grandfather, older adult brother, uncle or other male figure who is a father figure for the child and helps with caring/raising the child.

Exclusion Criteria:

Exclusionary criteria for the study Study 1: 1) child or parent with a disease affecting their dietary intake (severe GI disease or multiple food allergies), physical activity behaviors (e.g., physical disability, severe asthma), cognitive functioning (e.g., Down¿s syndromes, Fragile X), or psychiatric functioning (e.g. schizophrenia in parent); 2) unable to read and write in English or Spanish; and 3) plans of moving away from Harris County in the next year

Study 3: 1) child or parent with a disease affecting their dietary intake (severe GI disease or multiple food allergies), physical activity behaviors (e.g., physical disability, severe asthma), cognitive functioning (e.g., Down¿s syndromes, Fragile X), or psychiatric functioning (e.g. schizophrenia in parent); 2) unable to read and write in English or Spanish; 3) plans of moving away from Harris County in the next year; 4) unwilling to wear accelerometers for a 7 day study period at baseline and 4 months later; 5) Fathers BMI>40; 6) fathers who have lost more than 10 pounds recently, are in a current weight loss program or taking medications to lose weight; and 7) Fathers who fail ACSM health screening and do no provide a MD letter approving participation in the program.

F2. Procedure

Overview of HDHK for reference: The Australian version of the HDHK program consist of nine weekly 90-minute sessions (attached table) on healthy eating and PA, as well as parenting. All the sessions involve both the fathers and their children, and one also invites mothers to attend. The sessions allow for part of the session to be delivered separately for the fathers and the children. However, the majority of the time during these sessions the fathers and the children engage in fun physical activities together, learning new skills to try at home.

Study One: In study 1, the HDHK materials will be adapted for US families (e.g. Australian slang will be changed, eating and activity recommendations verified to meet US guidelines, kilojoules changed to calories, etc) and translated into Spanish. Latino fathers (n=20) and mothers (n=10) will be recruited from the community to serve on a Panel of Latino Parents as key informants to help advise on the cultural adaptation of HDHK. Latino fathers and mothers will be contacted up to five times for interviews and/or focus groups (four times in year 1 and once in year 3) to provide feedback on different program components for cultural relevance and appropriateness for Latino families. The Panel of Latino Parents will be asked to provide demographic information (see attached in Section S) and iteratively review and provide feedback to inform the program content. Contact one will be in the form of a Focus group, Contact two will be interviews coupled with surveys, and contact three for the fathers will be an additional interview to explore how much time he spends with his kids, hi work schedule and his attitudes about his health and weight. Contact three with the mothers of the parent panel will be further specified at a later date (pending information obtained from first two contacts and expert panel suggestions).

The guide of the first focus group is attached, but exactly what is asked will vary slightly based on the dynamics of each group. We plan on splinting the parent panel of 10 Latino fathers and 10 Latino mothers into 3-4 groups for the first focus group to accommodate their language preference and schedule. The focus groups will be conducted at one of the TCHP Center locations or at the CNRC in the medical center.

The specific questions asked during the subsequent focus groups and interviews will depend on the first round of adaptations by the BCM research team, and guide/scripts will be added to IRB protocol when available and prior to focus groups or interviews starting. Parents will be consented at the first visit and re-consent will only be obtained later in the study if subsequent changes results in amendments that affect participation in protocol or affect subjects in other ways. The first focus group session will consist of reviewing the HDHK program goals, curriculum outline and content of sessions of the HDHK program, in English or Spanish. Future discussions will be held regarding the Ecological Validity Model dimension (including: (1) language, (2) persons, (3) metaphors, (4) content, (5) concepts, (6) goals, (7) methods, and (8) context) and how these apply to HDHK, including components they feel do not engage them or do not apply to them. They will be asked to offer alternative content or methods of delivering the same content that is more applicable to them. They will also be asked to make suggestions of new content areas they feel should be covered by the program to help them engage with their families in being more active and eating healthier. Issues regarding co-parenting, communication between the father and his partner (often child¿s mother), and cultural values such as simpatia, collectivism, respeto, and familism will specifically be explored.

Contact two will be either 1) cognitive interviews to assess their understanding of each of the Food and PA items selected for study 2; or 2) an on-line survey with follow up interview. If parent desires, they can participate in both, if within the limit of five contacts during the study.

Cognitive interviews: Up to 20 Latino fathers from the parent panel will be interviewed, in iterative rounds of cognitive interviews to assess resulting changes in survey questionnaire from previous cognitive interview findings. They will also be asked to comment on the possible response options, and instructions of the survey instrument. The full survey questionnaire and cognitive interview script is attached in section S. The survey questionnaire and cognitive interview will be provided in English or Spanish depending on the participants¿ preference.

On-line survey with follow up interview: Up to 21 fathers and mothers will be interviewed to assess parent¿s a) preferences for program names, logo and colors; b) understanding of Sport Skill Play cards that have been culturally adapted to Latino families; and c) barriers and facilitators for taking part in Healthy Dads Healthy Kids. The play cards consist of instruction cards and 15 play cards. The play cards will be sent to the parents in advance to review as they take the on-line survey remotely. We will make laptops available in the TCHP Center if they do not have a way of accessing the survey remotely. The participating parents will be stratified into one of three groups to assess 5 play cards each with the instruction card so as to not overburden the participants. There are therefore three different versions of the on-line survey (each provided in English and Spanish) assessing 5 play cards each. All versions of the surveys are attached in the Section S as word documents and will be entered into Survey Gyzmo. The Survey Gyzmo allows us to collect the parent¿s responses on-line via an encrypted and secure system (https). The survey includes a video link to a brief overview of the Healthy Dads Healthy Kids program, for new parents to our panel or parents that want a refresher of the program. The follow up interviews will allow us to probe their responses in more detail and further assess their barriers and facilitators for participating in the program. The three versions (based on the play cards the parents viewed) of the interview script are attached in Section S. Interviews will be conducted in-person at the parent¿s child pediatric clinic at one of the TCHP Center locations, if at all possible. If the parent is unable to meet us in person for the interview, we will conduct the interview over the phone. The remainder of the interview procedures remain as already described in the procedures.

Contact three: For the fathers panel will be an additional interview to explore how much time he spends with his kids, his work schedule and his attitudes about his health and weight. A interview guide is attached in section S.

Contact three: For moms will be an additional interview to explore how they would prefer to get information during the

program while keeping the focus on the fathers and children. They interview guide is attached in section S.

All of the focus groups and interviews will be audio-recorded and coded for thematic content. The audio recordings will be transcribed by an outside company and translated into English, if needed.

A Child Focus Group portion will be added to Study 1 to obtain Latino children's input on several of the activities and components of the HDHK program. Parents who are part of our parent panel will be contacted to see if their 5-11 year old child would like to participate since we already have permission to recontact them about study one components. If we cannot recruit adequate number of children from the existing parent panel, we will recruit additional children from the TCHP Center for Children and Women Clinics. Focus groups will be stratified by child age for younger (5-9 year olds) and older children (7-11 year olds) and language preference of child (English or Spanish). We deliberately overlapped the age groups slightly to allow for some flexibility to find a group that meets the child's age and language requirements. Two to four focus groups will be conducted, depending on children's language preference (if all children prefer English, only two focus groups will be needed). A focus group guide is attached in Section S and will explore the children's opinions about what they like to do with their father, their understanding of an activity on sometimes and always foods, their opinions on the sports skills cards and one of the games presented on the sport skill card, and their opinion on a craft project for the program.

Study Two: A cross-sectional multi-ethnic/racial sample of fathers (n=600) will be recruited to complete an on-line study that includes a demographic survey, physical activity parenting practice survey, food parenting practice survey, the Co-parenting Alliance survey, and the Pew Research division of labor in the household survey. Fathers will complete surveys administered via a secure internet survey. The secure internet survey will have a cover letter of consent followed by survey questions. Fathers will be instructed to answer the items regarding what they do themselves to parent their child. If fathers do not have access to a computer or internet service at home, computers will be made available at the CNRC, TCHP Center clinics or community centers for them to use. Contact information will be requested to process payment and to re-contact a sub-sample of the Father in 2 weeks. Participants can opt out of providing contact information but will then not receive payment. The survey will have audio-links to listen to the cover letter or individual survey questions for those fathers with limited literacy levels. Ninety of the fathers will be asked to complete the surveys again 2 weeks later to assess the test-retest reliability of the instruments in 15% of the sample. The full survey and cover letter are attached in Section S.

Study Three: The procedures for Study 3 are Attached in Section S due to space limitations. Clinical Trials Registration: NCT03532048

Add-on Study to Study 3 (Feasibility of assessing arterial stiffness in future trials of Papas Saludables, Ninos Saludables): procedures are attached in Section S due to space limitations

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 1540 Worldwide: 1540

Please indicate why you chose the sample size proposed:

Study 1: We will recruit Latino fathers (n=25) and mothers (n=10) to serve on a Panel of Latino Parents as key informants to help advise on the cultural adaptation of HDHK. It is possible that some parents may drop out during the course of the study. If that occurs they will be replaced. We anticipate this may happen to up to 50% of the sample. We will recruit up to 30 children to participate in the child focus groups. TOTAL SAMPLE FOR STUDY 1 n=100.

Study 2: We will recruit 1200 fathers for the cross-sectional study in order to have 600 who qualify and complete the full survey. There are no exact sample size requirements for planned estimation procedures such as Confirmatory Factor Analysis (CFA), or Item Response Modeling (IRM), due to the complexity of issues involved in the determination of a sample that provides stable estimates. However, general guidelines based on the ratio of subjects to variables exist (e.g., at least 5-10:1). Others recommend at least 100 to 150 participants are needed to avoid non-convergence or improper solutions of models by CFA,77 or a simulation study reporting a wide range of sample size (from 30 up to 450) with rather small lower bound sample size as enough. For adequate samples for IRM analysis, samples of 100 were proposed when there are few model parameters and samples of 200-500 for IRM models with larger number of parameters. To conduct differential item function (DIF) analysis within IRM, by race/ethnic groups, samples of 100-200 per group will be required. Therefore, a sample of 600 fathers should afford adequate power for evaluation of a 25-40 item instrument via CFA,IRM and DIF analyses. TOTAL SAMPLE FOR STUDY 2, n=1200.

Study 3: We plan to recruit 40 families and enroll the father, their 5-11 year old child(ren) and the child's mother, to participate in the feasibility study. We anticipate needing to screen 2-3 times as many fathers to find those that meet inclusion criteria. We also anticipate that on average, each family will have 2 children participating. Therefore, TOTAL SAMPLE FOR STUDY 3, n=240 (120 fathers, 80 children, 40 mothers/partners). Given this is a feasibility study assessing the feasibility of recruitment, data collection, randomization and attendance to the program, we expect a starting sample of 40 families to be sufficient in this pilot.

Total sample size across all three studies is anticipated to be 1510.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Study 1: The analysis of the qualitative data will include reviewing the parent and child responses from the audiotaped interviews and focus groups and notes taken by staff during these sessions. The content will be transcribed and coded for themes.

Study 2- Distributional characteristics will be assessed and outliers checked for accuracy. Prior to inferential procedures, standard descriptive statistics will be calculated for demographics. Psychometric analysis of food and physical activity parenting practices: The fit of each item to the proposed subscales of the Food and PA parenting practice scales (proposed latent variable) will be evaluated using confirmatory factor analysis (CFA) and item response modeling (IRM). The fit of competing models will be tested (i.e., one-factor versus two-factor versus three-factor, etc.) using a combination of absolute and relative fit indices such as the chi-square statistic and ratio of chi-square to degrees of freedom, the root mean square error of approximation (RMSEA), incremental fit index (IFI) and comparative fit index (CFI) as recommended by Hoyle and Panter. Standardized residuals and modification indices will also be examined. Because the chi-square is sensitive on the sample size, assessing both absolute (i.e., RMSEA) and incremental (i.e., normed fit index, NFI and CFI 82) fit induces is recommended. The criteria of an acceptable model fit include: RMSEA less than, or equal to 0.08, and NFI and CFI greater than 0.90, while a good model fit is obtained when RMSEA less than, or equal to 0.05, and NFI and CFI greater than 0.95. Hu and Bentler¡¯s two-index presentation strategy will be used as an alternative criteria, if necessary. These and item content will be used to determine whether an item should be retained or removed from the model. Cronbach coefficient alpha reliabilities will be computed for each subscale of the final model, to assess the internal reliability. IRM analysis will be performed to (1) evaluate the response categories, (2) estimate the item and person difficulty parameters, (3) test item fit using infit and outfit criteria, (4) estimate the reliability across the full range of the scale, (5) produce a Wright map linking individual and item distributions, and (6) conduct Fifferential item functioning by fathers race/ethnicity and educational status. Intra-class correlation coefficients (ICCs) will be computed to establish the test-retest reliability of the Food and PA parenting practice subscales from the sub-sample, using absolute agreement in two-way random models. ICC values up to .20 denote poor reliability; .21-.40 fair reliability; .41-.60 moderate reliability; .61-.80 substantial level of reliability; and > .80 excellent reliability. Regression models will assess demographics, coparenting alliance, and division of labor in household as predictors of physical activity and food parenting practices. Cluster analysis will explore profiles of father's use of parenting practices.

Study 3- Exploratory Analysis: Distributional characteristics will be assessed and outliers checked for accuracy. Prior to inferential procedures, standard descriptive statistics will be calculated for demographics, anthropometric and behavioral data, and data assessed for non-normality and transformation applied where appropriate. Analysis of Covariance (ANCOVA) will assess the group difference of father¡¯s weight after controlling for father¡¯s weight at baseline and potential covariates (father¡¯s education, household income and child gender), and group membership will be treated as the between subjects factor. Prior to conducting the ANCOVA, the homogeneity of regression assumption will be tested. This approach will also be used to assess the effect on children¡¯s BMI z-scores, and the father¡¯s and children¡¯s behaviors. Correlations of the father's and child's carotenoid intake as measured by the food frequency questionnaire will be compared to the average of the dermal carotenoid assessments at baseline as well as the correlation of the change of the reported and dermal assessments from T0-T1.

Feasibility Criteria for Study 3: Retention of subjects in study assessments 1. Retain 80% of intervention and control participants for pre- and post-assessments 2. Recruit 40 Latino fathers and their families in ≤ 4 months 3. Maintain ≥70% attendance to program sessions 4. The participating Latino fathers will be satisfied with the program as measured by 80% ¿excellent¿-¿good¿ satisfaction from questionnaires and exit interviews with the Latino fathers and their co-parent (typically children¿s mother). 5. Ability to collect anthropometric, behavioral and parenting data on at least 75% of the Latino fathers and anthropometric, and behavioral data on their children (both groups) at baseline and follow up

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

In Study One, fathers, mothers and children in the Panel of Latino Parents and Children are asked to provide input and feedback in order to culturally adapt the HDHK curriculum for the Latino population. There is minimal if any risk to the father or mother. There is a possible risk of loss of confidentiality, but all possible measures will be taken to minimize these risks (see section K).

Study Two, fathers are asked to participate in a secure internet survey over PA and food parenting practices. There is a possible risk of loss of confidentiality, but all possible measures will be taken to minimize these risks (see section K).

Study Three: Fathers, mothers and their children will participate in a healthy lifestyle program to promote national

guidelines for eating, physical activity and screen media use. Both fathers and children will be asked to participate in fun physical activity sessions, similar to PE class and there is a risk for injury. Facilitators will be trained in basic first-aid. Taking part in the physical activity sessions and doing the active games at home is considered minimal risk, because fathers and children can choose themselves the level of intensity and whether they participate.

The risks associated with assessments; Assessments are non-invasive procedures, that include heights, weights, waist circumference, blood pressure and heart rate measurements, and survey completion. Fathers and their children will also be asked to wear accelerometers at baseline and follow up. There are no known health risks or problems associated with wearing the activity (Actigraph GT3X) monitors. This activity monitor is commonly used to measure step counts and physical activity; and a similar monitors can now be found in cell phones and Fitbits that are publically available. There may be some embarrassment associated with wearing the Actigraph during the 7-day study period at baseline and follow up, but these are minimal risks. There is a possible risk of loss of confidentiality, but all possible measures will be taken to minimize these risks (see section K).

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There will be no benefit to participate in study 1 or 2. Participants in study 3 may have benefit as the goal is to help them to increase their physical activity, improve their eating behaviors, and decrease their screen media to meet national guidelines. These behavior changes may improve their weight status. This program may also aid in targeting fathers to be more engaged, less permissive, and good role- models which can have a positive influence on children's lifestyle behaviors and weight status outcomes.

Describe potential benefit(s) to society of the planned work.

As HDHK had demonstrated significant, clinically relevant weight loss for participating fathers and significant behavior change for fathers and their children among Australian samples, we anticipate the potential for having similar clinically and significant outcomes for US Latino families. This would aid in reducing obesity- related medical conditions could benefit other Latinos in the future.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Given the potential impact on society in light of minimal risk to the participating parents and children, the benefits outweigh the risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A waiver of full written consent and authorization will be required for fathers in Study 2, the cross-sectional study. The participant will be provided a cover letter for the secure internet survey (attached in section S), and consent will be obtained by clicking 'Yes' they wish to participate in survey.

Another waiver of full written consent and authorization will be required for the screening step of Fathers for study 3. A verbal consent for screening will be obtained and marked on the screening form.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

Study 2: Parents will be reporting on their own use of parenting practices to support their child for healthy physical activity and eating behaviors, their co-parenting alliance and division of household labor. Demographics will be obtained to describe the study population and contact information to send the participants their compensation for participation, to verify

person is real to provide payment, and to re-contact a random sub-sample to take this survey again 2 weeks later.

Study 3: The father will self-report all the data so will be fully aware of the data we collect. The primary risk to screening is a loss of confidentiality, and we will follow procedures outlined in protocol to safe guard the data.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

Study 2: Only survey data is collected and each participant can determine if they wish to voluntarily participate.

Study 3:The screening procedure will be explained to fathers and he will be given the right to opt out of screening and participation in the study.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Study 2: Only survey data is collected and identifiers of participants are required for payment disbursement and to contact for the follow up study, therefore the risk is minimal but identifiable data is necessary.

Study 3:A waiver of consent is necessary because it will most frequently be done by phone. This means that getting a written consent would drastically limit the number of fathers screened because he would either need to provide written consent in person or by mail.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Study 2: The Electronic identifiable data will be stored on pass-word protected BCM servers which only the PI and study staff have access. The data for Study 2 will be collected by a secure version of Survey Gizmo. BCM has a business agreement with Survey Gizmo to keep data secure and delete the data after 12 months. Payment for study 2 will be issued via ClinCard following BCM standard procedures. No hardcopy identifiable data is anticipated for Study 2, other than reimbursement forms required by BCM for payment of participants. Copies of these will be kept in locked file cabinets behind locked doors in the CNRC.

Study 3: Screening will be done with the attached health screening form. Any identifiable data will only be on a) the screening form, which will be kept locked up in study file cabinets in the CNRC, a federal building with 24 hour security and access limited to key cars; or b) a study tracking database of enrolled participants stored on pass-word protected BCM servers which only the PI and study staff have access.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Study 2 and 3: Contact information of participants will be destroyed once the study is complete.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Study 2: The only health information collected in study 2 are self-reported weight and height. Identifiable self-reported behavior data will be collected and will only be shared as indicated in this protocol. Copies will be made available to NIH (our sponsor) if requested by them and participants will be notified of this in the survey cover letter.

Study 3: The screening data will only be used to assess inclusion/exclusion criteria for this study and report on the feasibility outcome of recruitment, screening and enrollment into the Feasibility Study. Any reports regarding the screening outcomes will be for summarized data (total numbers, lists of reasons for not qualifying, etc) and no identifiers will be reported in such reports.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

No

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
Yes, as described:
Self reported health information as per the ACSM health screener.

Will additional pertinent information be provided to subjects after participation?
Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.
Study 3: Fathers will be told if they failed the health screener and instructed to see a medical provider for medical clearance in order to assess if it is safe for them to participate in the program.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
No

J2. Consent Procedures

Who will recruit subjects for this study?
PI
Research subject (ex - recruitment of family member into genetic studies)
PI's staff
Third Party: TCHP Centers staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Recruitment strategies for studies 1 and 3 will include fliers, posters and presentations at the TCHP Centers for Women and Children (Southewest Center and Greenspoint Center), including their health fairs and back to school fairs. The TCHP Facebook Feed will also be use to recruit for Study 3. The video used in Study 1 to give an overview of the Healthy Dads Healthy Kids program (attached in Section S) will be shown in clinic to families who are interested in Study 3. In a previous qualitative study with Latino fathers, we found our first contact was often with the mother, who referred the father to the study. We will include in the flyers a fill in tab with the ability to get contact information from potential subjects. The TCPA clinic will have drop boxes set up at the receptionist's desk so that subjects interested in learning more about the study can leave their contact information to be called by one of the study staff. Boxes will be checked at least once a week. Recruitment fliers for study 3 will also be distributed at other community locals close to the TCHP clincis (e.g. YMCA, community centers and libraries) where families who use the clinic may also go.

Children for the child focus groups in Study 1 will be recruited by first inviting children whose parents are part of the Latino Parent Panel who have already provided consent to be recontacted. If we do not get adequate number of children to participate by these means, additional children will be recruited by posting and handout fliers at the TCHP Centers for Women and Children (Southewest Center and Greenspoint Center), including their health fairs and back to school fairs. The Fliers will allow families to provide us with their contact information to learn more about the study. The fliers for the Child Focus Groups have been attached in Section S.

Recruitment strategies for studies 2 will include fliers, posters and presentations at the TCHP Centers for Women and Children (Southewest Center and Greenspoint Center), local community centers, health fairs, back to school fairs, public libraries, Fatherhood organizations, and English as a Second Language (ESL) courses; posters and fliers posted or handed out at local pediatric clinics, community centers, local businesses, work-sites (such as construction sites, if approved by management company), child-care centers, schools and the Texas Medical Center; notices posted in community newsletters, the CNRC Newsletter (Nutrition and Your Child), and online father groups or communities; calling volunteers from the CNRC volunteer list; and word-of-mouth with enrolled participants distributing fliers to friends and families who are fathers with elementary school-aged children. Social media will be used to recruit through the Texas Children¿s Health Plan Facebook account and through other social media and online sources using IRB approved study blurb and/or fliers. Announcements will be posted in the BCM research volunteer website and the CNRC website.

Oral presentations of the IRB approved blurb may also be presented on local TV station programs, like Univision and Telemundo.

We will contact the Public Relations department at BCM to use their resources, such as press release of study blurb, to promote the study.

In a previous qualitative study with Latino fathers, we found our first contact was often with the mother, who referred the father to the study.

Consent for Study 3: If the participating father figure is the child's guardian, the same consent form will be used for the child and father. If the participating father figure is another important adult in that child's life (uncle, adult brother, step dad, etc), two separate consent forms will be obtained: one for the child signed by the child's legal guardian (e.g. mother) and another for the participating man. A separate consent will also be obtained on the mother.

Are foreign language consent forms required for this protocol?
Yes

Which of the following ways will you document informed consent in languages other than English?
A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?
No

J4. Children

Will children be enrolled in the research?
Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
No

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Other:
No

At what institution will the physical research data be kept?
Physical research data such as informed consent documents, questionnaires, etc. will be kept at the Children's Nutrition and Research Center.

How will such physical research data be secured?
The CNRC is a federal building with 24 hr security and access to rooms with data cabinets requires badge access only to appropriate staff members. The cabinets are also kept locked at all times.

At what institution will the electronic research data be kept?
All the data will be kept at BCM. Electronic research data such as databases, spreadsheets, etc. will be kept on BCM IT services behind the institutional firewall in folders specific to PI & staff that are password protected.

Study 2 internet based survey data will be collected and stored on an https encrypted survey software (Professional Survey Gizmo) that is password protected. Data will regularly be downloaded to BCM IT servers for further storage. BCM has a business agreement with Survey Gizmo for this project.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
A professional transcription service will transcribe the audio-recorded interviews for study 1 and the exit interviews of study 3. They follow HIPPA guidelines and offer secure FTP transfer of audiofiles and transcribed documents. The audiofiles will not containing any names, date of births or other identifiers, but since it does contain participant's voices it may be identifiable.

In addition, our team of collaborators at other institutions (see co-investigators in section A), will be provided access to deidentified data to assist us in adapting the program and analyzing the data. The data provided to them will be coded by the BCM team and only the immediate BCM team will have access to records to decode the data. Thus, the data will be de-identified for our collaborators. For example, Collaborators at University of British Columbia (Dr. Masse) will be provided coded data from study 2 to hep with data analysis.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
The audiofiles will be sent to BCM approved Transcription Service using FTP secure methods or secure/encrypted BMC email to ensure confidentiality of shared data files.

De-identified or coded data may be shared with our co-investigators at other institutions to help us with data analysis. Such de-identified or coded data will be sent via secure emails or via BMC Data sharing box for big files.

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.

In study 2, mothers who will be asked to participate will be notified that their spouse/partner (child's father) has already participated. Fathers will be made aware of this prior to providing their spouse/partner's email address.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There will be no cost to participants in this study.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

235

Distribution Plan:

Study One: Parents on the Panel of Latino fathers and mothers will be compensated $30 for each assessment completed. At the end of a max of 5 contacts over 3 years, participants may receive a total of $150. Children who participate in the focus groups will receive $20 cash for their time. Study Two: Fathers will be compensated $15 for completing the online surveys. 90 fathers will be asked to complete the same survey two weeks later and be compensated $15. Payment will be issued via BCM ClinCard system, or cash in special circumstances. Study Three: Latino families will be compensated $50-85 for completing the baseline (T0) assessments, depending on number of kids participating. Families will be compensated $70-110 for completing T1 assessment and $30 for completing the exit interview. Dads and kids who take part in arterial stiffness add-on study will be paid $5 for each assessment. A max of $235 for dads & kids combined.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

Device 1: NIHem Noninvasive Hemodynamic Data Acquisition and Analysis Workstation

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Internet

Exact language of Advertisement:

The Center for Women and Children newsletter, Facebook page: Long Version:

Study 3 VERSION A:

Researchers at the Children¿s Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine are inviting Hispanic Fathers with children ages 5-11 to participate in the Papás Saludables, Niños Saludables program with their child to promote physical activity and eating behaviors. The program meets at The Center for Children and Women. English and Spanish sessions are available. Compensation provided. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Program.

Study 3 VERSION B:

Researchers at the Children¿s Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine are inviting Hispanic Fathers with children ages 5-11 to participate in the Papás Saludables, Niños Saludables program with their child to promote physical activity and eating behaviors. The program meets at The Center for Children and Women. English and Spanish sessions are available. Compensation provided. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the Papás Saludables Niños Saludables Program.

Study 3 Short Version: The Children¿s Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine are inviting Hispanic Fathers with children ages 5-11 to participate in a program meant to promote healthy eating and exercising. Compensation provided. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Program.

Mode of Advertising: Internet

Exact language of Advertisement:

Study 2: Survey for Fathers ¿ about how they interact with their child to promote physical activity and eating behaviors.

CNRC, Medical Center Hospitals, businesses ¿ Volunteer websites-newsletter:

Fathers with children ages 5-11 are needed to answer a 30 minute online survey about what they do with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the link: www.healthydads.net

Long Version: Researchers at the Children¿s Nutrition Research Center, Baylor College of Medicine are looking for Fathers with children ages 5-11 to answer a 30 minute online survey about their interactions with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or click the link: www.healthydads.net

Short Version: Fathers with children ages 5-11 needed to answer a 30 minute online survey about what he does with his child to promote physical activity and eating behaviors. Children¿s Nutrition Research Center, Baylor College of Medicine. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the website: www.healthydads.net

Mode of Advertising: Internet

Exact language of Advertisement:

Study 2 Encuesta por internet para PADRES - acerca de cómo interactúan con su niño para promover la actividad física y alimentación.

CNRC, Hospitales del Centro Médico, negocios ¿ Páginas de voluntarios ¿boletín informativo:

Se invita a Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos acerca de lo que él hace con su niño(a) para para promover la actividad física y la alimentación. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O abra el link: www.healthydads.net

Long Versión: Investigadores del Centro de Investigación de Nutrición Infantil del Colegio de Medicina de Baylor están buscando a Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos acerca de sus interacciones con su niño(a) para promover la actividad física y la alimentación. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O abra el link: www.healthydads.net

Short Versión: Se invitan Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos de lo que él hace con su niño(a) para promover la actividad física y la alimentación. Centro de Investigación de Nutrición Infantil del Colegio de Medicina de Baylor. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O vaya a la página: www.healthydads.net

Mode of Advertising: Other: Social Media

Exact language of Advertisement:

The Center for Women and Children newsletter, Facebook page:

Study 3 VERSION A:

Hispanic Fathers with children ages 5-11 are invited to participate in the Papás Saludables, Niños Saludables program, meant to promote healthy eating and exercising. The program meets at the clinic. English and Spanish. Compensation provided. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Program. Study 3 VERSION B: Hispanic Fathers with children ages 5-11 are invited to participate in the Papás Saludables, Niños Saludables program, meant to promote healthy eating and exercising. The program meets at the clinic. English and Spanish. Compensation provided. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the Papás Saludables Niños Saludables Program.

Mode of Advertising: Other: Social Media-Spanish

Exact language of Advertisement:

Study 3 Papas Saludables, Niños Saludables - acerca de participar en un programa para Padres Hispanos que promueve la actividad física y alimentación.

The Center for Women and Children newsletter, Facebook page:

Padres Hispanos con niños de 5-11 años se les invita a participar en el programa Papás Saludables, Niños Saludables, con la intención de promover la actividad física y la alimentación. En Inglés y Español. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Long Versión: Investigadores del Centro de Investigación de Nutrición Infantil del Departamento de Pediatría del Colegio de Medicina de Baylor están invitando a Padres Hispanos con niños de 5-11 años a participar en el programa Papás Saludables, Niños con su niño para promover la actividad física y la alimentación. El programa se reunirá en The Center for Children and Women. Disponible en inglés y español. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Short Versión: El Centro de Investigación de Nutrición Infantil del Departamento de Pediatría del Colegio de Medicina de Baylor invita a Padres Hispanos con niños de 5-11 años a participar en un programa con la intención de promover la actividad física y la alimentación. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Mode of Advertising: Other: Social Media

Exact language of Advertisement:

Study 2 Encuesta por internet para PADRES - acerca de cómo interactúan con su niño para promover la actividad física y alimentación.

CNRC, Hospitales del Centro Médico, negocios ¿ Páginas de voluntarios ¿boletín informativo:

Se invita a Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos acerca de lo que él hace con su niño(a) para para promover la actividad física y la alimentación. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O abra el link: www.healthydads.net

Long Versión: Investigadores del Centro de Investigación de Nutrición Infantil del Colegio de Medicina de Baylor están buscando a Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos acerca de sus interacciones con su niño(a) para promover la actividad física y la alimentación. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O abra el link: www.healthydads.net

Short Versión: Se invitan Padres con niños de 5-11 años para contestar una encuesta por internet de 30 minutos de lo que él hace con su niño(a) para promover la actividad física y la alimentación. Centro de Investigación de Nutrición Infantil del Colegio de Medicina de Baylor. Recibirá $15 por contestar la encuesta. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Estudio de PADRES. O vaya a la página: www.healthydads.net

Mode of Advertising: Other: Social Media

Exact language of Advertisement:

Study 2 CNRC, Medical Center Hospitals, businesses ¿ Volunteer websites-newsletter:

Fathers with children ages 5-11 are needed to answer a 30 minute online survey about what they do with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the link: www.healthydads.net

Long Version: Researchers at the Children¿s Nutrition Research Center, Baylor College of Medicine are looking for Fathers with children ages 5-11 to answer a 30 minute online survey about their interactions with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or click the link: www.healthydads.net

Short Version: Fathers with children ages 5-11 needed to answer a 30 minute online survey about what he does with his child to promote physical activity and eating behaviors. Children¿s Nutrition Research Center, Baylor College of Medicine. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the website: www.healthydads.net

Mode of Advertising: Other: Social Media Spanish

Exact language of Advertisement:

Study 3 The Center for Women and Children newsletter, Facebook page:

Padres Hispanos con niños de 5-11 años se les invita a participar en el programa Papás Saludables, Niños Saludables, con la intención de promover la actividad física y la alimentación. En Inglés y Español. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Long Versión: Investigadores del Centro de Investigación de Nutrición Infantil del Departamento de Pediatría del Colegio de Medicina de Baylor están invitando a Padres Hispanos con niños de 5-11 años a participar en el programa Papás Saludables, Niños con su niño para promover la actividad física y la alimentación. El programa se reunirá en The Center for Children and Women. Disponible en inglés y español. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Short Versión: El Centro de Investigación de Nutrición Infantil del Departamento de Pediatría del Colegio de Medicina de Baylor invita a Padres Hispanos con niños de 5-11 años a participar en un programa con la intención de promover la actividad física y la alimentación. Se dará compensación. Si está interesado, llame a Alicia al 713-798-0503 o por correo electrónico a healthydads@bcm.edu acerca del Programa para PADRES.

Mode of Advertising: BCM Clinical Trials Website

Exact language of Advertisement:

Study 2 Fathers with children ages 5-11 are needed to answer a 30 minute online survey about what they do with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the link: www.healthydads.net

Long Version: Researchers at the Children¿s Nutrition Research Center, Baylor College of Medicine are looking for Fathers with children ages 5-11 to answer a 30 minute online survey about their interactions with their child to promote physical activity and eating behaviors. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or click the link: www.healthydads.net

Short Version: Fathers with children ages 5-11 needed to answer a 30 minute online survey about what he does with his child to promote physical activity and eating behaviors. Children¿s Nutrition Research Center, Baylor College of Medicine. Get $15 for completing the survey. If interested, call Alicia at 713-798-0503 or email healthydads@bcm.edu about the FATHERS Study. Or go to the website: www.healthydads.net

Section F.2 Study 3 Procedures Supplemental File

Study 3 Procedures

Study 3 is a feasibility study of a RCT of the culturally adapted Healhty Dads Helahty Kids program for Hispanic families. The culturally adapted program is called Papás Saludables, Niños Saludables. The control is waitlist control group who will receive the full program after T1 assessment. The goal is to enroll forty fathers, their 5-11 year old child(ren) and their co-parent (e.g. mother) as a family unit. Fathers and their child(ren) will be the primary target in the study, but mothers also participate, if available. Multiple children per family can enroll if they meet the inclusion/exclusion criteria, but families will be encouraged to limit the number of children who participate to no more than three. Fathers will be screened for their health to participate in the physical activity portion of the study and whether they meet inclusion/exclusion criteria. The health screening will follow the 2015 updated American College of Sport Medicine exercise pre-participation screening protocol (1). The Health and inclusion/exclusion criteria screening will be done via phone or in-person following the screening protocol attached in Section S. Men will be notified this is a screening to participate in the study and that the information they share will be kept to track recruitment, screening and enrollment successes and failures (feasibility outcome of study). A verbal agreement will be requested by the staff screening and recorded on the screening sheet. If not obtained, screening will stop. A waiver of consent for screening can be found in section J1. Fathers who do not pass the health screener will be provided a letter to be seen by their PCP to obtain clearance for exercise participation. If they do not have a PCP they will be instructed to contact their health insurance for a list of doctors and if they do not have health insurance, a list of clinics will be provided (attached in section S).

Once screened, consented and enrolled, baseline data will be collected. Data assessments include baseline (T0) and post intervention group receiving the program (T1). The data assessments include:

<u>Both Dads and Kids:</u>

1. Demographics
2. Height, weight, and waist circumference as measured twice and averaged by trained research staff. If difference between the two initial measures are outside standard error, a third measure will be obtained.
3. Physical activity and sleep (as measured by wearing accelerometers for 5-7 days). Actigraph GT3X accelerometers will be used. Fathers and oldest child will be asked to wear accelerometers. If enough monitors are available, participating siblings will also be invited to wear the monitors. Fathers and children will be instructed in wearing their accelerometer and told to wear it 24 hours/day for the next 7 days, only taking it off when there is potential for getting it wet (e.g. bathing, showering, swimming). Study staff will remind the father and child to wear their monitor by text, email or phone call (depending on family preference) several times during week. Accelerometers and wear logs can be returned at the clinic or by prepaid envelope provided by the study. Once received back, accelerometer data will be reviewed for completeness (minimum of 8 hours/day for 5 days including 1 weekend days). If accelerometer data is not complete, the father and/or child will be encouraged (optional) to wear the monitor for additional days to complete the data.
4. Screen media use by survey questions

5. Dietary intake by age-appropriate Block food frequency questionnaire (2) on father and oldest participating child.
6. Dermal Carotenoid Assessment to assess dietary carotenoid intake. Carotenoids are nutrients we get from various fruits and vegetables. The Veggie Meter (Longevity Link, Corp., UT) is a portable electronic device that uses a small beam of light to measure skin carotenoid levels. Pressure-mediated reflectance spectroscopy will measure dermal carotenoid intensity. Before use, the device is calibrated. The same index finger of the participant is cleaned with an alcohol wipe and placed on the device's lens for 10 s at each visit. Triplicate readings are recorded electronically. This device does not diagnose or treat a disease or condition, so does not require FDA Investigational Device Exemption.
7. Program Satisfaction Survey at the end of the program

Mothers, if available, will be asked to assist the child in completing their questionnaires. If the family consists of a single father, he will assist the child in completing their questionnaires.

<u>Only Dads</u>

1. Blood pressure and heart rate (after quietly sitting for 5 minutes) measured by trained research staff twice and averaged. If difference between the two initial measures are outside standard error, a third measure will be obtained.

Fathers identified during assessments with blood pressure readings in the hypertensive range (≥ 140/90) or heart rate outside expected normal range (HR range 55-100) for men 25-60 years old,will be referred to their PCP or Harris County Health Clinic for evaluation. The PI will review case-by-case if they can participate, based on their other screening history. If BP ≥ 180/120 Dads will be encouraged to be seen urgently and will require medical clearance prior to participating..

<u>For Dads and Moms:</u>

2. Demographics
3. Food and physical activity parenting practices survey
4. Co-parenting alliance survey
5. Acculturation (Bi-Acculturation Scale) survey
6. Respeto (Respect sub-scale from the Mexican-American Cultural Values scale) survey
7. Pan-American familism survey.
8. Program Satisfaction Survey at the end of the program

Data will be collected at the TCHP Center Clinic where the program will be delivered. All data collection tools, survey packets for Father, child and mother, and the accelerometer wear log for fathers and children are attached in Section S. Data will be collected and managed by RedCap (via the BCM institutional contract). If data needs to be collected on hardcopies, they will be manually entered by staff and verified by a second staff. Hardcopies will be stored in the participant's study file in the locked study cabinet, in the study manager's office that is a federal building with 24 hour security (CNRC). The food frequency questionnaire (FFQ) is not attached because is an online purchase assessment tool which can be find at: Block Dietary Data Systems: www.nutritionquest.com. Nutrition Quest will help process the nutrition data that is coded with the participant's study ID. Nutrition Quest will not have access to any HIPPA related

data, nor identifying information on the participants. The only modification to the FFQ is if the child or father state they consume “other fruit” or “other vegetables” more than 3 times a week, which other fruit and vegetables they consume will be probed to get a more accurate carotenoid intake value. If the father or child states they

After baseline data are collected, families will be stratified into preferred language of program (English or Spanish) and randomly assigned to receive the program immediately (Intervention Group) or after a 5-7 month waitlist period (Control group). The culturally adapted HDHK program, called Papás Saludables, Niños Saludables, is a 10 week program for fathers and their children that meets weekly. Each participating father and child will be given a Papás Saludables, Niños Saludables T-Shirt to wear to program sessions to promote group cohesion (collectivism).

Mothers and other siblings are invited to session 4. The family will receive a cookbook of healthy Hispanic recipes at this session (https://snaped.fns.usda.gov/materials/flavors-my-kitchen-latino-cookbook). Like the original program, each weekly session is 90 minutes long, with approximately 30 minute separate pull-out sessions for the fathers and children, followed by a 45 minute active play session. The father sessions will be facilitated by one trained group leader and will use power point slides (see attached slides in section S). The child’s session is facilitated by a different trained group leader using the child handbook (attached in Section S). Like the original HDHK program, fathers are encouraged to improve their eating and physical behaviors to lose weight and to be good Role Models for their child. Children are encourage to help their fathers change their eating and physical activity behaviors to help them lose weight and improve their health. Like the original HDHK program, each session focuses on a different topic (e.g. importance of positive father involvement in their children’s growth and development; the importance of fathers and children engaging in active play together, including rough-and-tumble play; the underlying concepts behind energy balance to lose or maintain weight; an authoritative approach to parenting to promote physical activity and healthful eating for the child; changes the family can make in their food environment, selections and preparations to promote healthful eating; co-participation in physical activities of fathers and his children; and ways the whole family can reduce the time they spend on screens (e.g. TV, computer, tablets)). The main difference in the culturally adapted Papás Saludables, Niños Saludables program and the original HDHK program is reordering the session numbers, simplifying the language and content due to lower literacy level of some Hispanic fathers, and addition of a booster session to review everything learned so far in the middle of the program. Most session now also address the concepts of *respeto* (respect for authority figures, e.g. parents), *familism* (family cohesion), *simpatia* (harmonious interpersonal relationships), generational change in the role of Hispanic fathers, and raising your child in a culture different from your own which our formative work have identified as important. Additionally, food and photos have been adapted for Hispanic families and all material changed to US food and physical activity guidelines. Note that the sessions may change slightly based on on-going feedback and weather (e.g. practical sessions may need to be modified if rain does not allow for outdoor play). Changes will be minor and will not impact core content. Professionally translated Spanish versions of the program material will be added to the protocol in a separate amendment.

During the week, between program sessions, fathers and their children are encouraged to complete Health Challenges together at home (found in attached program material) and to play active games at home by using the Game Cards (attached in Section S). Two pedometers will

be given to each family as a way to track their steps and set challenges for each other. A small bag of physical activity toys (cones, bean bags, kick ball, etc) will be given to each family at the beginning of the program to help them play the active games at home. Small incentives, such as cookbook, pedometers, and active toys will be given out for attending some sessions. Research staff will send reminder texts to participating fathers and mothers to complete the home Health Challenges together, and to attend the next session. Mothers will be provided a Papás Saludables, Niños Saludables Mom's Handbook (attached in Section S) and will be sent short videos every week covering the same topics that were covered with Fathers and children to make sure she is aware of what is delivered in the program and can help facilitate and co-parent with the father, while maintain the program focus on Fathers. The videos will be shared with mothers via a secret group Papás Saludables, Niños Saludables Facebook page, text or email, depending on her preference. Mothers will also be offered recipe links and short motivational messages during the program to make them feel engaged. Moms will also be sent a weekly short survey to assess her viewing and thoughts on the videos. The manual of procedures for Communicating with moms can be found attached in Section S and includes links to the videos and examples of messages that may be sent.

Based on feedback from Hispanic parents who took part in study 1, we will offer transportation via taxis, Uber or Lyft to families who need it to attend the assessments and the program sessions. This will be set up by research staff and paid directly to transportation service. This will be arranged on a case-by-case basis.

After the 10 session program is completed for the intervention group, post-assessment data (T1) will be collected on all 40 families (intervention and wait-list control group) in the same way as described for the baseline data collection. In addition, fathers and mothers who took part in the Papás Saludables, Niños Saludables program will be asked to complete a satisfaction survey. Families who were assigned to the control group will start the program after the second data collection.

Exit interviews of all participating fathers, - mothers, and one child/family each who took part in the Papás Saludables, Niños Saludables program will be conducted. The interviews will be audio-recorded and coded for themes. The interview guides in English and Spanish are ttached.

Process Evaluation: Attendance to the data collection sessions and Papás Saludables, Niños Saludables program sessions will be tracked by the program facilitators and research staff. Fidelity of program delivery will be assessed via research staff observation and use of a fidelity assessment tool (Attached in Section S for the Dads Facilitator and Kids Facilitator). This tool will also assess program content that worked well with Hispanic families and what did not go well, to allow us to continue to make improvements in the program. Families who stop attending the program will be contacted and asked for reasons/ barriers. If possible, staff will help trouble shoot to get them back in the program. Reasons for drop out or poor attendance will be recorded.

Families in the wait-list control will start the Papás Saludables, Niños Saludables program in the spring 2019. Exit interviews on these participants will be conducted at the end of the program. Father's and children's anthropometrics and father's HR and BP will be measured as per previous assessments. A voluntary non-paid invitation will be extended to these families to participate in short video interviews to create a promotional video.

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