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Title of Research Protocol: Buen Provecho!: A Virtual Family-Based Intervention to Promote Health

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ABSTRACT

Title: Buen Provecho!: A Virtual Family-Based Intervention to Promote Health

Short Title: Buen Provecho Virtual Intervention

Rationale: Obesity rates are significantly higher among Hispanic youth in the United States, disproportionately putting these children at an increased risk for obesity-related diseases such as hypertension, dyslipidemia, and impaired glucose tolerance. While virtual programming offers an innovative option for pediatric weight management, limited data exists on the efficacy of virtual interventions for this population and their guardians (parents / caregivers).

Objectives: The purpose of this pilot study is to compare the effectiveness of an expanded virtual educational program (expanded –Inova Healthy Plate Club, x-IHPC) at modifying knowledge, self-efficacy, and behaviors when compared to traditional in-office counseling for guardians of children who are obese or overweight.

Study Design: In order to test the effectiveness of the x-IHPC intervention, outcomes from participants in this pilot study will be compared with outcomes from a comparison group of similar participants who receive standard nutrition counseling during their regularly scheduled check-ups. The team will enroll 25 children in the x-IHPC intervention and the same number in the comparison group (n=50). Both groups will receive standard in-office counseling, but the intervention group will also receive the x-IHPC.

Study Methodology: The comparison group receives standard, in-office counseling at visits 1, 3-months and 6-months. The intervention group receives standard in-office counseling at the same intervals, and also participates in a 12-week x-IHPC developed by a dietitian curriculum specialist. In addition, a key pillar of this study is identifying and training Community Health Workers (CHWs) to be Spanish-speaking facilitators of the x-IHPC and utilizing community engagement strategies. Training these CHWs and including them in designing the x-IHPC curriculum, will ensure that the programming is culturally appropriate; includes local features that relate directly to the community's needs; and enables study facilitators to respond effectively to the questions and learning needs of the parents and children involved in the program.

Statistical Methodology:

To examine the research question, a longitudinal analysis using generalized estimating equations (GEE) will be conducted to assess if mean differences exist on dietary measures, screen time, physical activity and guardian self-efficacy and confidence between the intervention and comparison groups while accounting for the correlation among the repeated measurements and controlling for covariates.

1. INTRODUCTION

1.1. Specific Aims

Obesity rates are significantly higher among Hispanic youth in the United States, disproportionately putting these children at an increased risk for obesity-related diseases such as hypertension, dyslipidemia, and impaired glucose tolerance. Despite this disparity, there is a lack of literature pertaining to culturally relevant and family-centered interventions for Hispanic youth and their families. While virtual programming offers an innovative option for pediatric weight management, limited data exists on the efficacy of telehealth /virtual interventions for this population and their guardians.

The purpose of this community-engaged quasi-experimental study is to determine whether a family-based, culturally tailored, virtual intervention enables guardians to shape the weight-related aspects of their home environments and the lifestyle behavioral practices (diet, exercise, screen behaviors) to be more supportive of their family's optimal health and weight, compared to standard in-office counseling alone. Specifically, the study intends to compare the effectiveness of an expanded virtual educational program (x-IHPC) at modifying knowledge, self-efficacy, and behaviors when compared to traditional in-office counseling for guardians of children who are obese or overweight.

1.2. Hypothesis

Research Question: Among guardians of children ages 6-12 years who are obese or overweight, does a family-based, culturally-tailored, virtual intervention change knowledge, self-efficacy, and behaviors about modifiable lifestyle practices to promote healthy eating when compared to standard in-office counseling?

Ho: A family-based, culturally-tailored, virtual intervention does not significantly change knowledge, self-efficacy, and behaviors about modifiable lifestyle practices when compared to standard in-office counseling.

Ha: A family-based, culturally-tailored, virtual intervention does significantly change knowledge, self-efficacy, and behaviors about modifiable lifestyle practices when compared to standard in-office counseling.

1.3. Background and Significance

Childhood obesity has been an epidemic in the United States for a generation. The national childhood obesity rate has been rising for decades putting millions of children at greater risk for Type 2 diabetes, high blood pressure, asthma, and other serious conditions.^{1,2} Recent data show that 15.5% of youth ages 10 to 17 have obesity. More importantly, the data exposes persistent racial and ethnic disparities with rates significantly higher among Hispanic youth than among White or Asian youth.³ The high prevalence of obesity among Hispanic children contributes to disparities in obesity-related disease risk factors including hypertension, dyslipidemia, and impaired glucose tolerance. It also puts them at risk for chronic comorbidities in adulthood.

Centers for Disease Control and Prevention (CDC) Growth Charts are used to measure the size and growth patterns of children and teens in the United States, with BMI-for-age weight status categories and corresponding percentiles. In children, BMI percentile cutoffs for obesity are intended to reliably define a level above which a child is more likely to have or be at risk of developing obesity-associated adverse health outcomes or diseases. Children are considered overweight at the 85th to less than the 95th percentile. Children are considered obese at the 95th percentile or greater.⁴

¹ QuickStats: Prevalence of Obesity and Severe Obesity Among Persons Aged 2–19 Years — National Health and Nutrition Examination Survey, 1999–2000 through 2017–2018. *MMWR Morb Mortal Wkly Rep* 2020;69:390. DOI: <http://dx.doi.org/10.15585/mmwr.mm6913a6>

² Mohanan S, Tapp H, McWilliams A, Dulin M. Obesity and asthma: pathophysiology and implications for diagnosis and management in primary care. *Exp Biol Med* (Maywood). 2014;239(11):1531–40.

³ HRSA. (2019). National Survey of Children's Health (NSCH). Accessed August, 2021. <https://mchb.hrsa.gov/data/national-surveys>

⁴ CDC. (2020). <https://www.cdc.gov/obesity/childhood/defining.html>.

Recent research is exposing the connection between obesity and COVID-19.⁵ The CDC includes obesity as one of the underlying conditions that increases risk of severe illness from COVID-19.⁶ People with obesity tend to become sicker, are more likely to be hospitalized, and are even more likely to die with COVID-19 infection.⁷ COVID-19 has also disproportionately impacted people of color and impoverished communities. Hispanic people have higher rates of infection and are more than three times as likely to die from COVID-19 as are White people. Risks of severe illness are also worse for children; Black and Hispanic children are much more likely than their White peers to be hospitalized because of COVID-19.⁸

Given this high prevalence of childhood obesity and persistent racial/ethnic and socioeconomic disparities, there is an urgent need to find solutions to provide intensive, family-based pediatric weight management. Without such interventions, the chronic pandemic of obesity will continue to be exacerbated, particularly among disproportionately burdened populations.⁹ Ensuring populations affected disproportionately by obesity benefit from preventive strategies remains one of the most pressing unmet challenges in community health policy and practice.¹⁰

While obesity is a function of biology and genetics, the role of social, environmental, and economic factors in the epidemic are equally important. Experts suggest offering virtual obesity-prevention programming as a needed solution for the complex management of childhood obesity.¹¹ Providing culturally-tailored, targeted virtual programming allows children and families to have access to high quality obesity-reduction programming in their homes in a convenient and an accessible way to increase health equity. However, there is a lack of literature pertaining to culturally relevant, family-centered interventions for Hispanic youth and their families.¹² While evidence supports the use of telehealth or mobile health interventions as adjuncts to pediatric weight management as being feasible and cost-effective, limited data exists on the efficacy or effectiveness of exclusive telehealth for pediatric weight management.^{9, 11} Therefore, the purpose of this project is to test a virtual program targeting modifiable weight-related lifestyle factors for Hispanic children and their families in Loudoun County, Virginia through a community-engaged partnership between HealthWorks for Northern Virginia (HWNV) and Inova.

This project builds on the success of an existing community-focused program called the Inova Healthy Plate Club (IHPC). Within the Inova Division of Population Health, the IHPC, aims to reduce obesity among

⁵ Lange SJ, Kompaniyets L, Freedman DS, et al. Longitudinal trends in body mass index before and during the covid-19 pandemic among persons aged 2-19 years—United States, 2018-2020. CDC Morbidity and Mortality Weekly Report. 17 September 2021. www.cdc.gov/mmwr/volumes/70/wr/mm7037a3.htm

⁶ CDC. (2020). Obesity, Race/Ethnicity, and COVID-19. <https://www.cdc.gov/obesity/data/obesity-and-covid-19.html>

⁷ Popkin, B. M., Du, S., Green, W. D., Beck, M. A., Algaith, T., Herbst, C. H., Alsukait, R. F., Alluhidan, M., Alazemi, N., & Shekar, M. (2020). Individuals with obesity and COVID-19: A global perspective on the epidemiology and biological relationships. *Obesity Reviews*; *Obes Rev*, 21(11), e13128-n/a. <https://doi.org/10.1111/obr.13128>

⁸ Kim, L., Whitaker, M., O'Halloran, A., Kambhampati, A., Chai, S. J., Reingold, A., Armistead, I., Kawasaki, B., Meek, J., Yousey-Hindes, K., Anderson, E. J., Openo, K. P., Weigel, A., Ryan, P., Monroe, M. L., Fox, K., Kim, S., Lynfield, R., Bye, E., . . . Garg, S. (2020). Hospitalization Rates and Characteristics of Children Aged <18 Years Hospitalized with Laboratory-Confirmed COVID-19 - COVID-NET, 14 States, March 1-July 25, 2020. *MMWR.Morbidity and Mortality Weekly Report*; *MMWR Morb Mortal Wkly Rep*, 69(32), 1081-1088. <https://doi.org/10.15585/mmwr.mm6932e3>

⁹ Woo Baidal, J. A., Chang, J., Hulse, E., Turetsky, R., Parkinson, K., & Rausch, J. C. (2020). Zooming Toward a Telehealth Solution for Vulnerable Children with Obesity During Coronavirus Disease 2019. *Obesity (Silver Spring, Md.)*, 28(7), 1184–1186. <https://doi.org/10.1002/oby.22860>

¹⁰ Kumanyika, S. K. (2019). A Framework for Increasing Equity Impact in Obesity Prevention. *American Journal of Public Health* (1971); *Am J Public Health*, 109(10), 1350-1357. <https://doi.org/10.2105/AJPH.2019.305221>

¹¹ Taveras, E. M., Marshall, R., Sharifi, M., Avalon, E., Fiechtner, L., Horan, C., Gerber, M. W., Orav, E. J., Price, S. N., Sequist, T., & Slater, D. (2017). Comparative Effectiveness of Clinical-Community Childhood Obesity Interventions: A Randomized Clinical Trial. *JAMA pediatrics*, 171(8), e171325. <https://doi.org/10.1001/jamapediatrics.2017.1325>

¹² Tamayo MC, Dobbs PD, Pincu Y. Family-Centered Interventions for Treatment and Prevention of Childhood Obesity in Hispanic Families: A Systematic Review. *J Community Health*. 2021 Jun;46(3):635-643. doi: 10.1007/s10900-020-00897-7. PMID: 32734580.

low-income children and prevent the future occurrence of heart disease/stroke, Type 2 Diabetes, and other related diseases. To date, IHPC has engaged more than 1,200 children in Northern Virginia in healthy-eating interventions. Two decades of research shows that family-based interventions work better than individual interventions at reducing childhood obesity.^{13 14} Therefore, the proposed study will examine the effectiveness of an expanded IHPC (x-IHPC), which will be virtual, family-based, and specifically designed for low-income Hispanic families in our community; all of which are evidence-based strategies for enhancing healthy eating interventions.

1.4. Preliminary Studies

None

2. STUDY DESIGN AND SUBJECT SELECTION

2.1. Study Type

Quasi Experimental: Behavioral Intervention with convenience sampling. In order to test the effectiveness of the x-IHPC intervention, outcomes from participants in this pilot study will be compared with outcomes from a comparison group of similar families who receive standard nutrition counseling during their regularly scheduled check-ups at HWNV. The team will enroll 25 children in the x-IHPC intervention and the same number in the comparison group (n=50). Both groups of children and guardians will receive standard in-office counseling, but the intervention group will additionally receive the x-IHPC (See study flowchart, Appendix A).

2.2. Setting/Location

Standard health counseling will take place during regularly scheduled office visits at the HWNV offices. The x-IHPC intervention is virtual and participants will engage in the intervention from their homes via virtual sessions.

2.3. Duration of Study

Participants will be part of the study for 6 months. This includes study recruitment, consenting, initial and subsequent in-office counseling, and x-IHPC for families enrolled in the intervention.

2.4. Number of Subjects

The team will enroll 25 children in the x-IHPC intervention and the same number in the comparison group (n=50).

2.5. Study Population

2.5.1. Gender of Subjects

There are no restrictions on the gender of the participants for this program.

2.5.2. Age of Subjects

The primary parent /guardian participating in the study is required to be over the age of 18 years.

2.5.3. Racial and Ethnic Origin

The x-HPC program is designed to address the cultural needs of self-identified Hispanic families in our community related to the family features that impact health. Any family is eligible to participate who identifies as Hispanic and Spanish is one of the primary languages spoken in the home.

2.5.4. Vulnerable Populations

¹³ Berge, J. M., & Everts, J. C. (2011). Family-Based Interventions Targeting Childhood Obesity: A Meta-Analysis. *Childhood Obesity; Child Obes*, 7(2), 11-121. <https://doi.org/10.1089/chi.2011.07.02.1004.berge>

¹⁴ Yavuz, H. M., van Ijzendoorn, M., H., Mesman, J., & van der Veek, S. (2015). Interventions aimed at reducing obesity in early childhood: a meta-analysis of programs that involve parents. *Journal of Child Psychology and Psychiatry; J Child Psychol Psychiatr*, 56(6), 677-692. <https://doi.org/10.1111/jcpp.12330>

This study intervention is designed for Hispanic families in our community. The primary guardian of children between 6-12 years who screen eligible to be part of the intervention will be the individuals giving consent for their family to be part of the intervention as well as the individual providing data for the study through surveys about family and child behaviors. It is possible that some of these guardians may be pregnant at the time of consent or become pregnant during the study. Because the focus of the study is healthy eating and modifying lifestyle behaviors to improve health, the study intervention (surveys, healthy eating activities, and counseling) pose no more than minimal risk to this vulnerable group. Although children are also considered a vulnerable group, the study activities pose minimal or no risk to the children involved in the intervention.

2.6. Recruitment

The study employs convenience sampling. Recruitment will take place through email to families who receive care at HWNV in English and Spanish as well as posters advertising the program placed in community spaces where children and families who are clients at HWNV spend time (updated recruitment flyer, Appendix B). If guardians are interested in being part of the program, there will be a contact person listed on the advertisement who will screen for eligibility. If a family is screened as eligible to be part of the x-IHPC intervention, a member of the study team will meet with the family virtually or in person and consent the guardian to be part of the study. This consent process will take place with a trained interpreter. The consent will be emailed to program participants prior to the consent conversation when possible. Whether consent occurs virtually or in person, a hard copy of the consent will be printed and stored by the Inova PI. A copy of the consent will be given to the guardian.

Participants will also be screened for eligibility during their well-child clinic visit at HWNV by the physician study PI. If guardian meets the study inclusion criteria, the PI will introduce the study to the guardian and ask if they would like more information.

Families will decide if they have the capacity to participate in the x-HPC intervention. They will be offered both groups, but can choose which group works for their family. We realize that this introduces selection bias into the study (families who self select to be part of the intervention are families who are interested in health and have the time and ability to attend). However, the intervention takes a lot of time and families need to choose the arm that works for their schedule.

2.7. Inclusion Criteria

Inclusion criteria include:

1. Child and Parent are clients at HealthWorks for Northern Virginia
2. Child between the ages 6-12 years
3. Child has a BMI percentage greater than 85%
4. Primary parent or guardian is > 18 years of age
5. Family identifies as Hispanic and Spanish is one of the primary languages spoken in the home
6. Children will be living with the primary guardian or parent for the duration of the program
7. Access to the internet
8. Parent or guardian is willing to commit to engaging in the 12 week program

2.8. Exclusion Criteria

Exclusion criteria include:

1. Family plans to change location within the year
2. During initial screening for the study, the study PI determines that the intervention may exacerbate existing medical conditions of the child or the family.

3. STUDY METHODS AND PROCEDURES

3.1. Study Treatment/Intervention

The purpose of this community-engaged quasi-experimental study is to determine whether family-based, culturally tailored, virtual intervention enables and motivates parents and children (experimental group) to shape the weight-related aspects of their home environments and lifestyle behavioral practices (diet, exercise, screen behaviors) to be more supportive of their family's optimal health and weight, compared to standard in-office counseling (comparison group).

Intervention: This project builds on the success of an existing community-focused program called the IHPC. Within the Inova Division of Population Health the IHPC aims to reduce obesity among low-income children and prevent the future occurrence of heart disease/stroke, Type 2 Diabetes, and other related diseases. To date, IHPC has engaged more than 1,200 children in Northern Virginia in healthy-eating interventions. Currently, this popular program is delivered in English, for 5-8 weeks, to children grades K - 8 in an afterschool setting.

The proposed study will examine the effectiveness of an expanded IHPC (x-IHPC), which will be virtual, family-based, and specifically designed for low income Hispanic families in our community; all of which are evidence-based strategies for enhancing healthy eating interventions. Family-based interventions are not a novel approach to obesity reduction. Two decades of research shows that family-based interventions work better than individual interventions at reducing childhood obesity.^{13,14} When the IHPC moved to a virtual format due to COVID-19 in 2020, facilitators required parental home involvement. The anecdotal success of that family involvement has fueled the desire of IHPC to expand their programming to include more education and activities for parents.

The x-IHPC will include 4 extra modules, (= 4 additional weeks of programming) that will be developed by a dietician curriculum specialist. The expanded IHPC will also include programming just for parents to increase their involvement. A key pillar of this study is identifying and training CHWs from HWNV to be Spanish-language facilitators of x-IHPC. Training these CHWs and including them in designing the x-IHPC curriculum will ensure that the programming is culturally appropriate; includes local features that relate directly to the community's needs; and enables facilitators to respond effectively to the questions and learning needs of the parents and children involved in the program.

IHPC provides produce boxes, nutrition and meal-preparation, education, and supportive counseling to address barriers related to obtaining produce and food. The intervention provides participants with a bi-weekly produce box for 12 weeks (6 boxes total) and helps families identify sustainable ways to obtain vegetables once the produce boxes end. Providing produce boxes exposes families to new, unfamiliar vegetables that are not common in their home countries, and allows families to experiment with new recipes on a limited income. The CHW will support families by coaching them on how to prepare these unfamiliar vegetables, give tips on finding sales at grocery stores, as well as by navigation to food assistance sites including food pantries, school meal sites and bus routes, and neighborhood food distributions. Parents will learn strategies to increase vegetable consumption by addressing perceived

barriers – such as the child doesn't like vegetables. Curriculum will also include topics such as how to increase physical activity and reduce screen time. Both the families in the x-HPC and families who receive the in-office counseling will be offered the 6 vegetable food boxes, delivered on a bi-weekly basis during their time in the study.

Families will decide if they have the capacity to participate in the x-HPC intervention. They will be offered both groups, but can choose which group works for their family. We realize that this introduces selection bias into the study (families who self select to be part of the intervention are families who are interested in health and have the time and ability to attend). However, the intervention takes a lot of time and families need to choose the arm that works for their schedule.

3.2. Comparison Group

A comparison group of similar families who receive standard nutrition, exercise, and weight-related lifestyle counseling during their regularly scheduled check-ups at HWNV will serve as the comparison group for this program. Both groups of children and guardians will receive standard in-office counseling, but the intervention group will also receive the x-IHPC intervention. Standard in-office counseling includes standard counseling related to diet, exercise, and screen behaviors. The comparison group will also get food boxes.

3.3. Randomization

None

3.4. Endpoints/Outcomes Measurements

3.4.1. Primary outcomes.

3.4.2.

Primary outcomes measured via a survey, which will include food frequency questionnaires, screen time estimates, physical activity questionnaires, estimated screen time reports, and guardian self-efficacy and confidence questions related to modifiable lifestyle behaviors.^{15 16 17} Survey data will be collected during phone calls from the PI or CHW at the outset of the study and then again at the conclusion of the study. An example survey has been included (Appendix C: Survey). The survey questions may be altered or deleted based on feedback from the study advisory board or the CHWs, as this study is based on community engagement and feedback. The final survey instrument will be submitted to this IRB for approval before the data collection begins.

3.4.3. Secondary outcomes

BMI percentile of children and guardians enrolled in the study. This will be measured at each office visit by a trained medical assistant or the physician.

3.5. Consent/Assent

Once a guardian has been screened as eligible for inclusion in the study, they will be approached by the physician PI and asked if they are interested in being part of the study. If they are interested, the PI will discuss whether they are interested in joining the comparison group or the intervention group. A member of the study team will meet with the family virtually or in person and consent the guardian to be part of the study (Appendix D: Consent). This consent process will take place with a trained interpreter. The consent will be provided in both English and Spanish. The consent will be emailed to program participants prior to the

¹⁵ Bryant, M. J., Ward, D. S., Hales, D., Vaughn, A., Tabak, R. G., & Stevens, J. (2008). Reliability and validity of the Healthy Home Survey: a tool to measure factors within homes hypothesized to relate to overweight in children. The international journal of behavioral nutrition and physical activity, 5, 23. <https://doi.org/10.1186/1479-5868-5-23>

¹⁶ Schrepft, S., van Jaarsveld, C. H., Fisher, A., & Wardle, J. (2015). The Obesogenic Quality of the Home Environment: Associations with Diet, Physical Activity, TV Viewing, and BMI in Preschool Children. PLoS one, 10(8), e0134490. <https://doi.org/10.1371/journal.pone.0134490>

¹⁷ Kininmonth, A. R., Schrepft, S., Smith, A., Dye, L., Lawton, C., Fisher, A., Llewellyn, C., & Fildes, A. (2021). The Home Environment Interview and associations with energy balance behaviours and body weight in school-aged children - a feasibility, reliability, and validity study. The international journal of behavioral nutrition and physical activity, 18(1), 167. <https://doi.org/10.1186/s12966-021-01235-3>

consent conversation when possible. Whether consent occurs virtually or in person, a hard copy of the consent will be printed and stored by the Inova PI. A copy of the consent will be given to the guardian.

3.6. Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study.

Study participants may leave the study at any time, without penalty. In some cases, the participant may be withdrawn if the HWNV physician PI determines that the study intervention is too burdensome for the participant or is adversely affecting the study participant's health. If any study participant leaves the study or is withdrawn from the study, their data will not be used in analysis.

4. STATISTICAL CONSIDERATIONS/DATA ANALYSIS

4.1. Sample Size

In order to test the effectiveness of the x-IHPC intervention, outcomes from participants in this pilot study will be compared with outcomes from a comparison group of similar families who receive standard nutrition counseling during their regularly scheduled check-ups at HWNV. The team will enroll 25 children in the x-IHPC intervention and the same number in the comparison group (n=50). Both groups of children and guardians will receive standard in-office counseling, but the intervention group will receive the x-IHPC.

4.2. Method of Data Analysis

Analyses will follow the intention-to-treat principle, which categorizes participants by their treatment assignments regardless of adherence to the intervention or incomplete follow-up, and includes them in all analyses. Descriptive statistics will be calculated and reported as mean, standard deviation and 95% confidence intervals for continuous variables and frequency and percentage for categorical variables. Characteristics of study participants will be compared at baseline between the intervention and control groups and tested for significance using the two-sample t-test for continuous variables and the Chi-square test for categorical variables. Comparisons that are significant at the $P < 0.10$ level will be considered for inclusion in multivariable models for primary and secondary analyses given that participants will not be randomized to their respective treatment groups.

Primary analyses will examine diet quality, screen time, physical activity, and guardian self-efficacy and confidence of those in the intervention and control groups while controlling for the correlated nature of the repeated measures within participants (i.e. baseline, post-intervention, and 6-month post-intervention). Secondary analyses will compare the BMI of guardians and BMI percentile of children at the three time points between the intervention and control groups. A longitudinal data analysis strategy will be employed with generalized estimating equations with robust CIs for both primary and secondary outcomes (Albert, 1999; Ma et al., 2012). A 2-sided p-value < 0.05 will be accepted to indicate statistical significance. Additional analyses will be conducted to determine if results were influenced by other covariates including demographics (age, gender, educational attainment of guardian, income, etc.). All analyses will be conducted in SAS version 9.2.

4.3. Data Storage

4.3.1. Data Management

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Privacy and confidentiality of all enrolled participants will be maintained.

The PI and co-PI at HWNV will have an electronic list of participants who are part of the study so they can provide the standard in-office counseling and data collection. The list will be accessed only by them on a password-protected document that is stored on password-protected computers at HWNV.

Survey data collected during the study will be uploaded directly into a secure online platform, RedCap, by the CHW collecting the data. Only the study PIs will have access to this platform to manage data.

4.3.2. Records Retention

Data will be stored electronically for six years in the secure online platform RedCap and on the password-protected computer of the PI Dr. Elyssa Wood. After three years the files will be permanently deleted.

5. HUMAN SUBJECTS PROTECTION (RISKS, BENEFITS, AND ALTERNATIVES)

5.1. Risks

This study poses minimal physical or psychological risk to the study participants. There is a risk that guardians will find the intervention time-consuming. If the burden of the intervention becomes too great, the participant can leave the study with no consequences.

Any adverse events related to the research study will be reported immediately to the IRB. Reportable events include any physical or psychological harm to any human that is related to the study intervention. Protocol deviations will also be reported to the IRB, including anything related to the study participants' safety, rights, or integrity of the study data.

5.2. Benefits

The benefits to participating in this study include improved knowledge about modifiable lifestyle behaviors that effect healthy eating and weight. A second benefit to participating in the study is that families will receive complimentary vegetable food boxes (6 boxes, delivered every other week) for the duration of their time in the study.

5.3. Alternatives

The alternative to participating in this research study is not to participate in the research study. There is no penalty to the eligible participants if they refuse to be part of the study or leave the study at any time.

5.4. Confidentiality

Every effort will take place to maintain the confidentiality of the study participants. Participants will be known to the physician study PI who is providing care during in-office clinic visits. Beside the PI and the co-PI at HWNV, no other HWNV staff member will have knowledge that the participant is part of the study. The PI and co-PI at HWNV will have an electronic list of participants who are part of the study, so they can provide the standard in-office counseling and data collection. The list will be accessed only by them on a password-protected document that is stored on password-protected computers at HWNV.

Survey data collected during the study will be uploaded directly into a secured online platform, RedCap, by the CHW collecting the data. Only the Inova and the HWNV PIs, will have access to this platform to manage data. Data will be de-identified before it is shared with the statistician for analysis. De-identification will occur by giving each participant a unique study ID. The document with participant names and unique study IDs will be kept on a password protected document on the Inova PI's password-protected computer.

6. SUBJECT COMPENSATION

6.1. Costs

There are no costs to being part of this study except for the usual and expected costs of attending a routine clinic visit.

6.2. Payment

There is no payment for taking part in this study. However, families will receive complimentary vegetable food boxes (6 boxes, delivered every other week) for the duration of their time in the study.

7. ADVERSE EVENT REPORTING

There is very low risk of adverse events in this study. Any adverse events (such as an abnormal physical exam finding that may be temporally related to the participant's involvement in the research) will be reported to the IRB immediately. Any unusual symptoms, actions, behaviors, or safety related events that occur during the study intervention activities will be reported immediately to the IRB. Any protocol deviations will be reported to the IRB immediately.

8. FUNDING

This study is supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR003015.

9. CONFLICTS OF INTEREST

There are no conflicts of interest from the PI or Co-PIs.

10. FACILITIES AND EQUIPMENT

In-office counseling will take place at the HWNV clinic building. The clinical building also supplies the computer equipment for the HWNV PI. The virtual platform (Zoom) and computer equipment for the x-IHPC comes from the Office of Community Engagement from the Inova health system. Storage for the boxes of x-IHPC supplies is also provided through this office. The office space and computer for PI Wood is provided through Inova Health System.

11. OUTSIDE CONSULTANTS/COLLABORATORS

The study statistician performing the data analysis is a consultant on this study. The statistician has a contract with the Inova Health System to provide statistical services.

12. CONTRACTURAL AGREEMENTS

The PI and co-PI from HWNV have a subrecipient agreement with Inova to partner on this research study.

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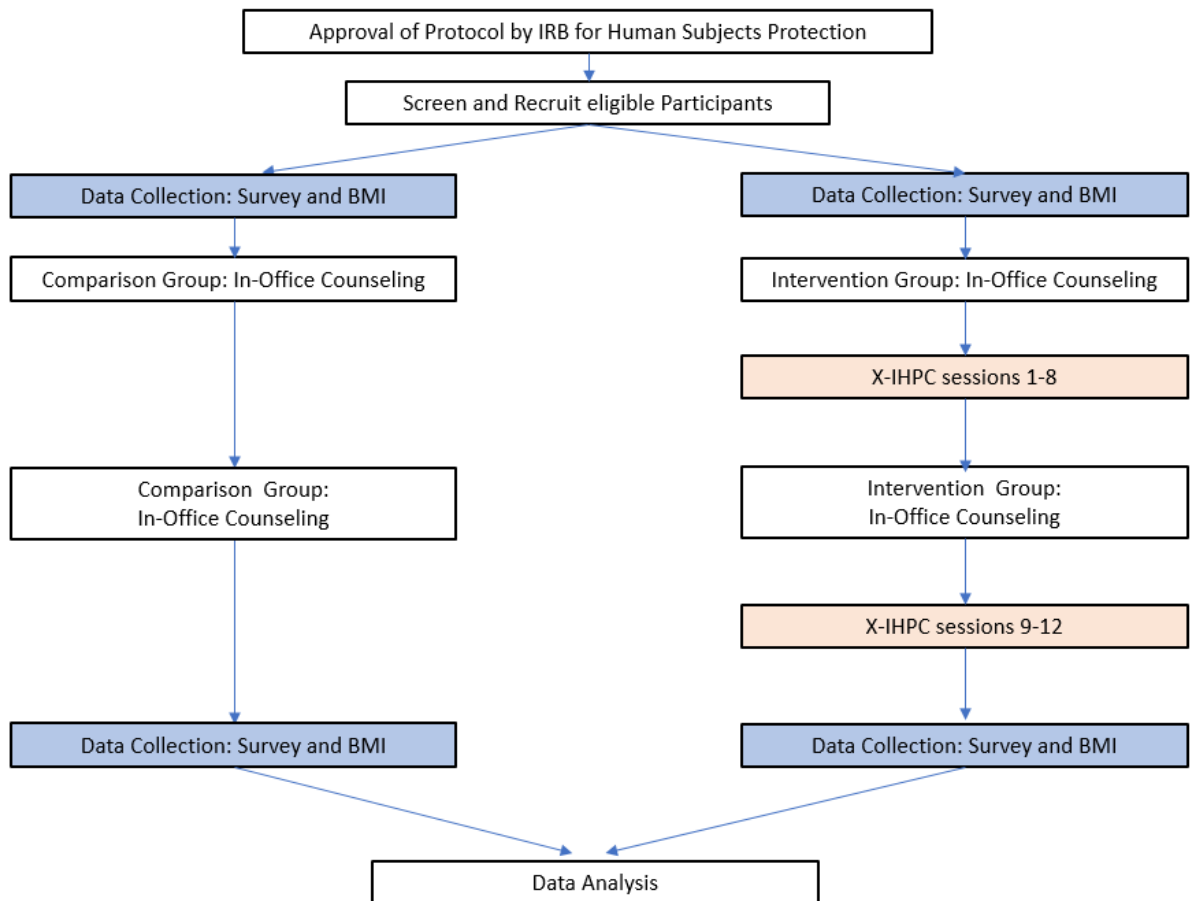
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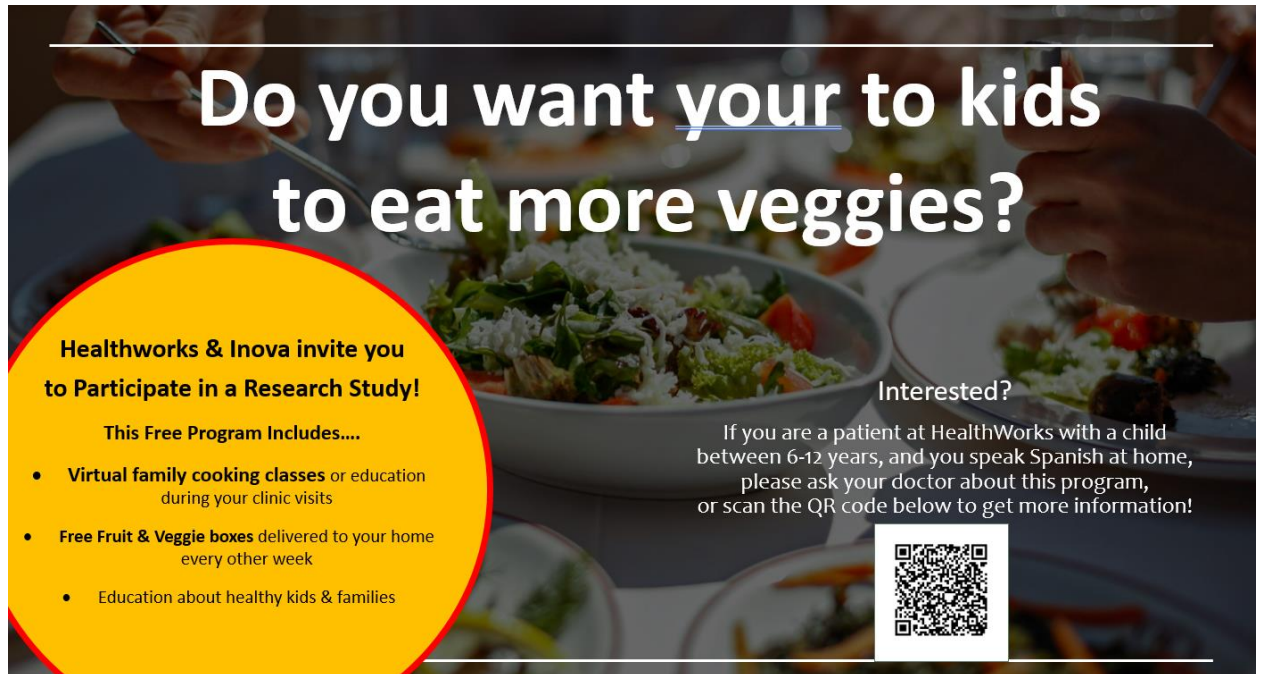
LIST OF ABBREVIATIONS

BMI	Body mass index
CDC	Centers for Disease Control and Prevention
CHW	Community Health Workers
co-PI	Co-Principal Investigator
COVID-19	Coronavirus disease
H0	Null hypothesis
HA	Alternative hypothesis
HIPAA	Health Insurance Portability and Accountability Act of 1996
HWNV	HealthWorks for Northern Virginia
IHPC	Inova Healthy Plate Club
IDPH	Inova Division of Population Health
Inova	Inova Health Services
IRB	Institutional Review Board
PI	Principal Investigator
PRN	Pro Re Nata position
SAB	Study Advisory Board
x-IHPC	expanded –Inova Healthy Plate Club

APPENDICES

Appendix A: Study Flow Chart





The flyer features a background image of hands serving food from a bowl. A large yellow circle on the left contains the main text and bullet points. A QR code is located in the bottom right corner.

Do you want your to kids to eat more veggies?


Healthworks & Inova invite you to Participate in a Research Study!

This Free Program Includes....

- **Virtual family cooking classes** or education during your clinic visits
- **Free Fruit & Veggie boxes** delivered to your home every other week
- Education about healthy kids & families

Interested?

If you are a patient at HealthWorks with a child between 6-12 years, and you speak Spanish at home, please ask your doctor about this program, or scan the QR code below to get more information!



Script and procedures for administration of the Buen Provecho! Study Survey

Adapted with permission from: Bryant, M. J., Ward, D. S., Hales, D., Vaughn, A., Tabak, R. G., & Stevens, J. (2008). Reliability and validity of the Healthy Home Survey: a tool to measure factors within homes hypothesized to relate to overweight in children. *The international journal of behavioral nutrition and physical activity*, 5, 23. <https://doi.org/10.1186/1479-5868-5-23>

The script

Administered By:

Date:

Start Time:

CALL PARTICIPANT

Good morning/evening. This is <your name>from <institute name>. Could I please speak to <participant name>?

Hello <participant name>. We have received the form that you mailed to us with consent to take part in our family home study. As we described in the consent form, the first part of the study involves a telephone interview which should take approximately 15 minutes. Is now a good time to conduct that interview with you?

If no No problem. I will try again using another time that you suggested might be alright on your availability form. Thank you. Goodbye.

If yes..... Okay. I'll begin with a few general questions and then move on to more specific questions about your family home environment. Please feel free to stop me at any point or ask me to clarify any questions that you don't understand. There are no right or wrong answers. Please answer honestly. You are not being judged on any of your responses.

What is your name?

* must provide value

What is your gender?

What is your ethnicity?

- ☐ Hispanic or Latino - a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- ☐ Not Hispanic or Latino

What is your race?

- ☐ American Indian
- ☐ Asian
- ☐ Hawaiian
- ☐ Black or African American
- ☐ White
- ☐ More than one race

What is your child's name?

* must provide value

What is your child's age?

* must provide value

What is your child's gender?

* must provide value

Are you the primary caregiver for < child's name> that you indicated as being suitable for this study?

* must provide value

- ☐ Yes
- ☐ No

reset

What is your relationship with < child's name>?

How many adults older than 17 years live in your home?

* must provide value

Only include people who live in your home all of the time.

How many children under the age of 18 years live in your home?

Only include people who live in your home all of the time.

Are there parks, walking trails or outdoor recreation areas within safe walking of your home?

Is it safe for your child to play outside where you live currently?

How often does your child play outside - alone or with other children?

Do you or anyone else in your home have any medical conditions that impact your diet or physical activities behaviors?

Please think of right now, today:

Do you have any fresh fruit in your home?

Please think of right now, today:

Do you have any fresh fruit in your home?

Do you have any fresh vegetables in your home now?

Where do you get most of your fresh vegetables?

How do you use your fresh vegetables?

Expand

Do you have any ready to eat fresh vegetables on a shelf in the refrigerator or on the kitchen counter now?

These include baby carrots, cherry tomatoes, or vegetables that you have sliced to make them ready to eat.

Do you have any canned or jarred vegetables in your home?

For canned vegetables: Where do you get them?

How do you use your canned vegetables?

Expand

Do you have any frozen vegetables in your home?

Can you tell me what frozen vegetables you have in your home?

How do you use your frozen vegetables?

Expand

ok to say "I don't use them"

Over the past 7 days, how often did your child eat vegetables?

Do you feel that you have enough money in your budget each week to buy fresh fruits or fresh vegetables?

Would it be possible for your child to get any salty snacks on their own, without your help?

- ☐ Yes
☐ No

reset

If we visited your home today, how many different salty snacks do you have in your home?
(examples: chips, nuts, crackers)

Do you feel that you have enough money in your budget each week to buy fresh fruits or fresh vegetables?	<input type="text" value=""/>	
Would it be possible for your child to get any salty snacks on their own, without your help?	<input type="radio"/> Yes <input type="radio"/> No	reset
If we visited your home today, how many different salty snacks do you have in your home? (examples: chips, nuts, crackers)	<input type="text" value=""/>	
Would it be possible for your child to and get sweet snacks on their own, without your help?	<input type="radio"/> Yes <input type="radio"/> No	reset
If we visited your home today, how many different sweet snacks do you have in your home?	<input type="text" value=""/>	
Would it be possible for your child to get soda on their own, without your help?	<input type="radio"/> Yes <input type="radio"/> No	reset
Over the last month, how often did you eat lettuce salad (with or without other vegetables)?	<input type="text" value=""/>	
Each time you ate lettuce salad, how much did you usually eat?	<input type="text" value=""/>	
Over the last month, how often did you eat French fries or fried potatoes?	<input type="text" value=""/>	
Each time you ate French fries or fried potatoes, how much did you usually eat?	<input type="text" value=""/>	
Over the last month, how often did you eat other white potatoes?	<input type="text" value=""/>	
Count baked, boiled, and mashed potatoes, potato salad, and white potatoes that were not fried.		
Each time you ate these potatoes, how much did you usually eat?	<input type="text" value=""/>	
Over the last month, how often did you eat cooked dried beans?	<input type="text" value=""/>	
Count baked beans, bean soup, refried beans, pork and beans and other bean dishes.		
Each time you ate these beans, how much did you usually eat?	<input type="text" value=""/>	
Think about all the foods you ate at your morning meal and morning snacks this past week. On how many days did you eat vegetables for your morning meal or morning snacks?	<input type="text" value=""/>	
When your child ate vegetables with breakfast, what is the total amount of vegetables they usually ate?	<input type="text" value=""/>	

When your child ate vegetables with breakfast, what is the total amount of vegetables they usually ate?	<input type="text"/>
Think about all the foods you ate at your lunch meal and lunch snacks in the past week. On how many days did you eat vegetables for your lunch meal?	<input type="text"/>
When your child ate vegetables with lunch, what is the total amount of vegetables they usually ate?	<input type="text"/>
Think about all the foods you ate at your dinner/supper meal and snacks in the past week. On how many days did you eat vegetables for your dinner meal?	<input type="text"/>
When your child ate vegetables with dinner, what is the total amount of vegetables they usually ate?	<input type="text"/>
Think about all the foods your child ate for snacks in the past week. How often did they eat vegetables as snacks?	<input type="text"/>
When your child ate vegetables as snacks, what is the total amount of vegetables they usually ate?	<input type="text"/>
Over the last month, how often did you eat mixtures that included vegetables?	<input type="text"/>
Count such foods as sandwiches, casseroles, stews, stir-fry, omelets, and tacos.	
Over the last month, how often did your child eat tomato sauce? Include tomato sauce on pasta or macaroni, rice, pizza and other dishes.	<input type="text"/>
Over the last week, how often did your child eat tomato sauce?	<input type="text"/>
(Include tomato sauce on pasta or macaroni, rice, pizza and other dishes)	
Over the last week, how often did you eat vegetable soups?	<input type="text"/>
Include tomato soup, gazpacho, chicken soup with vegetables	
When your child ate vegetable soup, how much did they usually eat?	<input type="text"/>
Where do you eat dinner?	<input type="checkbox"/> In the same place every night (example - a dining room or kitchen) <input type="checkbox"/> A different place most nights
I eat dinner with my children....	<input type="checkbox"/> Almost every week night <input type="checkbox"/> 2-4 times per week <input type="checkbox"/> 0-1 times per week nights

Do you have the following at home?	<input type="checkbox"/> Microwave <input type="checkbox"/> Blender <input type="checkbox"/> Measuring cups AND spoons <input type="checkbox"/> A pot <input type="checkbox"/> Frying Pan	
How do you usually heat your food?	<input type="checkbox"/> Oven / Stove <input type="checkbox"/> Microwave <input type="checkbox"/> Hot Plate <input type="checkbox"/> I do not have a place to heat food <input type="checkbox"/> Other	
Would you say that you have adequate space to prepare food in your kitchen?	<input type="radio"/> Yes <input type="radio"/> No	reset
Do you share a cooking space with individuals who are not in your family?	<input type="radio"/> Yes <input type="radio"/> No	reset
Do you and your children eat dinner together (all in one room at the same time) or apart (different rooms or different times)?	<div></div>	
What do you drink with your dinner?	<div></div>	
Is there anyone else who is responsible for feeding your children? (example: aunt, brother, sister, grandparent, or "other" family if parents live separately)	<div></div>	
If "yes", then who is responsible for feeding your child?	<div></div>	
What does your child drink with dinner?	<input type="checkbox"/> Nothing, they don't drink during meals <input type="checkbox"/> Water <input type="checkbox"/> Juice <input type="checkbox"/> Soda <input type="checkbox"/> Milk	
How many days a week does < child's name> eat breakfast?	<div></div>	
How many days a week does < child's name> eat breakfast at home?	<div></div>	
How many days a week do your family sit at a table to eat dinner together? This includes occasions when it is just < child's name> and yourself.	<div></div>	
How often does < child's name> eat breakfast in front of the TV each week?	<div></div>	
How often does < child's name> eat lunch in front of the TV each week?	<div></div>	
How often does < child's name> eat dinner in front of the TV each week?	<div></div>	
How often does < child's name> eat snacks in front of the TV each week?	<div></div>	

How often does < child's name> eat snacks in front of the TV each week?

How often does < child's name> eat dinner away from home each week?

How often does < child's name> eat fast food each week (example: McDonalds, Chik Fil A, taco bell, etc)

Do you ask < child's name> to eat everything on their plate at dinner;

Does your child have to eat all of their vegetables OR all of their dinner to get dessert?

Do you reward < child's name> with desserts, snacks or candy if they finish foods from their plate at dinner:

Do you allow < child's name> to have seconds if they finish foods from their plate at dinner;

Do you allow < child's name> to serve themselves at dinner:

Would you say that you serve the "same amount", "more" or "less" dinner to < child's name> compared to what you serve yourself?

Do you allow < child's name> to help themselves to snacks, including salty and sweet snacks, or candy when they are at home:

Does < child's name> help you shop for groceries at the store?

For example, you may get them to pick their own foods, or give them their own grocery list.

How many working TV's do you have in your home?

On an average school day, how many hours does your child watch TV?

How many tablets or ipads do you have in your home?

How many working computers or laptops do you have in your home?

How many working games consoles, such as Play Station or X-Box, do you have in your home?

On an average school day, how many hours does your child play video or computer games or use a computer for something that is not school work?

(Include activities such as Xbox, PlayStation, phone, tablet Nintendo DS, iPod touch, Facebook, and the Internet.)

Does your child have their own phone (not one they borrow from a parent)?

☐ Yes
☐ No

How often would you say that you restrict the amount of time < child's name> spends using a computer or laptop?

From the following options, how often would you say that you reward good behavior with extra screen time:

During the past month, other than your regular job, did you participate in any physical activities or exercises such as running, gardening or walking for exercise?

☐ Yes
☐ No

How often would you say that you are active in the presence of your child:

During the past 7 days, on how many days were you physically active for a total of at least 60 minutes per day?

(Add up all the time your child spent in any kind of physical activity that increased their heart rate and made them breathe hard some of the time.)

During the past 7 days, how many times did your child do a physical activity?

How much time does < child> usually spend doing physical activities on one of those days?
(can be hours or minutes)

During the last 7 days, on how many days did < child> do moderate physical activities like carrying light loads, bicycling, playing on the playground, or playing basketball? Do not include walking.

During the last 7 days, on how many days did < child> walk for at least 10 minutes at a time?

How much water does your child drink each day?

Do you feel that you need to change the amount of fruits and vegetables your child eats each week?

How confident do you feel that you can increase the number of vegetables your child eats each week?

How confident do you feel that you can obtain fresh fruit and vegetables for your family to eat during the week?

How confident do you feel that you can cook healthy meals for your family?

Do you feel that you need to change the amount of time your child spends using screens?

How confident do you feel that you can cook healthy meals for your family?	<input type="text"/>
Do you feel that you need to change the amount of time your child spends using screens?	<input type="text"/>
How confident do you feel that you can change the amount of time your child spends using screens?	<input type="text"/>
Do you feel that you need to change the amount of time your child spends doing physical activity?	<input type="text"/>
How confident do you feel that you can change the amount of time your child spends doing physical activity?	<input type="text"/>
When compared to other kids their age, I think my child:	<input type="text"/>
When compared to other kids their age, I think my child:	<input type="text"/>
When compared to other kids their age, I think my child:	<input type="text"/>

	My child Likes this	My child does not like this	I don't know if my child likes this	I don't know what that is	
Zucchini	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Kale	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Broccoli	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Cauliflower	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Spinach	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Green or Red Peppers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Radishes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Brussel Sprouts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Cabbage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Green Beans	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Asparagus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset