PROTOCOL TITLE:
New Ulm at HOME (NU-HOME)

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VERSION NUMBER/DATE:
Version 12 (4/22/19) Water park pass for wearing the actigraph enough.

VERSION HISTORY:

Revision #	Version Date	Summary of Changes	Consent Change?
1	9/21/2015	Original application submitted to IRB	
2	10/25/2015	Response to stipulations	Y
3	10/12/2016	Added a consent form for Action Team members	Y
4	3/27/2017	Final recruitment materials	N
5	4/26/2017	Final consent and assent forms and phone screener	Y
6	6/6/2017	Revisions to parent survey	N
7	2/8/2018	validation for migration to ETHOS	N
8	3/28/18	Cohort 2 recruitment materials	N
9	9/7/18	Recruitment trinkets and in person screening	N
10	9/13/18	Current participants send flyers to friends	N
11	2/5/19	Measurement at school and gift cards for interim child height and weight	N
12	4/22/19	Water park pass	N

Study Summary

Study Title	New Ulm at HOME (NU-HOME)
Study Design	Randomized Controlled Trail
Primary Objectives	**Primary aim:** To test the effectiveness of the NU-HOME program, a family-based health promotion intervention to prevent excess weight gain among 7-10 year old children. The main hypothesis is that children in the intervention group will have significantly lower body mass index z-scores (BMIz), relative to children in the control group at post-intervention (7 months), after adjustment for baseline values.
Secondary Objectives	**Secondary aims:** To examine intervention effects on the following family- and child-level outcomes: 1) Home availability of healthful foods and beverages and quality of those served at family meals and snacks. 2) Children's dietary intake (e.g., calories, fruits and vegetables, sugar-sweetened beverages). 3) Children's minutes of moderate-to-vigorous physical activity and sedentary behavior per week, particularly screen time.

Primary Study Intervention or Interaction	The 7-month NU-HOME program is based on Social Cognitive Theory and a socio-ecological framework to prevent childhood obesity by addressing home environments and family and individual health behaviors through promotion of healthful family meals, snacks and beverage consumption, and the promotion of physical activity through collaboration with community partners.
Study Population	Action Team = Community leaders who were defined by NIH as research participants as part of Community Based Participatory Research (CBPR) Main Trial = Children ages 7-10 and the parent/guardian in their family who prepares most of the meals
Sample Size	Action Team = 14-20 Main Trial = 120 Parent child dyads or 240 people total
Study Duration for Individual Participants	Action Team members = 5 years Main Trial participants = 1.5 years

1.0 Objectives

1.1 Purpose

Primary aim: To test the effectiveness of the NU-HOME program, a family-based health promotion intervention to prevent excess weight gain among 7-10 year old children. The main hypothesis is that children in the intervention group will have significantly lower body mass index z-scores (BMIz), relative to children in the control group at post-intervention (7 months), after adjustment for baseline values.

Secondary aims: To examine intervention effects on the following family- and child-level outcomes:
1) Home availability of healthful foods and beverages and quality of those served at family meals and snacks.
2) Children's dietary intake (e.g., calories, fruits and vegetables, sugar-sweetened beverages).
3) Children's minutes of moderate-to-vigorous physical activity and sedentary behavior per week, particularly screen time.

2.0 Background

2.1 Significance of Research Question/Purpose

New Ulm at HOME (NU-HOME) is a unique research collaboration between leaders in a rural community and academic obesity researchers. The proposed partnerships include the University of Minnesota (UMN), New Ulm local health care system (Allina Health), Minneapolis Heart Institute Foundation (MHIF), Brown County Public Health, local elementary schools, UMN extension service, local colleges and several existing community stakeholder groups. Our long-term goal is to establish a sustainable, effective intervention to prevent excess weight gain in children in rural communities. The objective of the proposed research is to test the effectiveness of the NU-HOME program, a family meals-focused health promotion intervention to prevent excess weight gain among 7-10 year old children (n=120) in the New Ulm rural community.

2.2 Preliminary Data

Our research team has completed extensive preliminary studies to support the proposed research, including a pilot randomized controlled trial (RCT) (NIH R21-DK0072997), a full-scale urban RCT (NIH R01-DK084000), a survey of rural parents and several adult-focused rural health promotion programs (HONU).

Healthy Home Offerings via the Mealtime Environment (HOME) pilot. The HOME pilot study consisted of formative research (Fulkerson et al., 2011) and a two-arm RCT to prevent childhood obesity (Fulkerson et al., 2010). We successfully met feasibility and acceptability aims for recruitment (n=44), retention (100%) and implementation (5-sessions). The intervention included interactive family nutrition education activities, child cooking skills development, taste-testing, parent groups (meal planning and preparation support), and hands-on meal preparation with the entire family. Satisfaction and attendance were high; 86% of families attended at least four of five sessions. Significant intervention effects were found at post-intervention for increased child food preparation skills (M=17.5 vs. 15.2, p<.01) and parental report of children helping to make dinner (M=1.9 vs. 1.6, p<.01). Intervention versus control homes showed trends of higher fruit and vegetable availability (M=23.7 vs. 21.7, p=.12) and lower availability of quick, high-fat microwaveable foods (M=2.3 vs. 3.0, p=.11). Trends of higher intakes of fruits and vegetables (M=3.5 vs. 2.6 servings, p=.08) and lower intakes of sweetened beverages (M=0.4 vs. 0.7 servings, p=.09) among intervention compared to control children were also apparent. As expected in this pilot study, we did not see significant BMI change differences by treatment group at post-intervention.

HOME Plus full-scale trial. The recently completed full-scale HOME Plus study RCT (intervention and attention-only control) with 160 families (8-12 year-old child and parent/guardian) was conducted in urban communities using a staggered cohort design (two cohorts) (Fulkerson et al., 2014). Eligibility included child BMI>50th percentile; English literacy; no plans to move within 6 months; and no severe medical conditions prohibiting study participation. Recruitment and baseline assessments occurred in summers of 2011 (Cohort 1) and 2012 (Cohort 2), followed by randomization (n=81 intervention families, n=79 control families). Participants were representative of the larger county; 71% white (child), 44% overweight/obese (child), 35% household received economic assistance, with full representation of the economic range; however, HOME Plus parents were more likely to have a college degree (61%). Data collection was very successful with 100% compliance at baseline, 93% retention at post-intervention and 89% at follow-up (21-months post randomization). Each assessment included psychosocial surveys and anthropometry (parent and child), puberty assessment (child), three 24-hour dietary recalls (child), home food inventory (parent), and a family meal inventory of 7 dinners (parent).
Families randomized to the intervention attended 10 monthly sessions delivered by trained interventionists to multiple family groups (approximately 5-10 families) in community settings. Other family members also attended sessions or childcare (75% of families brought additional family members). The intervention focused on experiential activities and included parent discussion groups, hands-on nutrition activities, taste-testing, and family meal preparation. Participation was high with 68% of families attending at least 7 of 10 in-person sessions and 84% completing at least 4 of 5 goal-setting calls which used motivational interviewing techniques. Families randomized to the control group received monthly newsletters with healthful eating tips. The intervention had a promising reduction in excess weight gain when treatment groups were compared for the entire sample. Moreover, given the influence of puberty on weight gain, post-hoc stratification analyses were conducted to assess effects on BMI-z-scores by pubertal onset; findings indicated a statistically significant pubertal onset-by-treatment group interaction at both post-

intervention (p=0.01) and follow-up (p=0.02). Sub-group analyses indicated a main effect of treatment among prepubescent children only, at both post-intervention (p=0.03) and follow-up (p=0.001). These findings suggest family meals-focused programming may be efficacious to prevent children's excess weight gain prior to pubertal onset. Thus, the proposed study is justified in using BMI-z-score as the primary outcome and recruiting 7-10 year old children.

Surveys of parents living in rural communities. Since the previous grant submission, we conducted a survey at the Minnesota State Fair in August 2014 to gather information from rural parents (n=174) about their family meal behaviors and interest in attending a program, such as the one proposed. Parents were eligible if 1) s/he was the family's primary meal preparer; 2) had a child between the ages of 8-12 who lived with them at least 50% of the time; and 3) had a rural zip code. Rural was defined using ZIP Rural-Urban Commuting Area Codes (RUCA) (unpublished data). Using RUCA codes allowed rural participants to be divided into groups from isolated, small rural, and large rural communities. Results indicated 80% of rural families eat family meals 4 or more days per week, comparable to the national (78.4%) rate (http://mchb.hrsa.gov/nsch/2011-12/health/index.html). Nearly three quarters of participants (73%) said they would be interested in attending in-person community-based family sessions focused on cooking and healthy eating. Of those interested, the majority (70%) was also interested in an online component; most parents (91%) reported ready access to the internet. Families reported driving long distances for everyday routine activities (e.g., traveling an average of 11-15 miles to work, for healthcare or to purchase groceries) and were willing to travel an average of 16 miles to attend a family meals-focused program.

Existing New Ulm health promotion programs. The HONU Project, launched in 2009, is a 10-year community demonstration project aimed at reducing adult myocardial infarctions and modifiable heart disease risk factors in the rural community of New Ulm (Boucher 2008) (VanWormer et al., 2012). New Ulm is located about 100 miles southwest of the Twin Cities metropolitan area in an agricultural region of the state. Healthcare is provided primarily by one system (Allina Health) that operates in New Ulm as New Ulm Medical Center (NUMC), the only clinic and hospital (35 beds) located in the community. The HONU Project is a collaborative partnership of Allina, the Minneapolis Heart Institute Foundation (MHIF), NUMC and the community. The MHIF leads design and implementation of the project through partnership with NUMC and the community. The project has primarily been funded through grants to MHIF from Allina, CDC, USDA and foundations. The community is represented by a 12-member steering committee that includes representation from NUMC, New Ulm city officials, Chamber of Commerce, school district and local colleges, Brown County Public Health, community organizations and the general public (including parents). The committee provides input on strategies to ensure interventions are tailored to New Ulm community audiences and helps promote community engagement. Research and evaluation work is coordinated by staff at the Division of Applied Research at Allina. For evaluation purposes, the target population of HONU interventions is adults ages 40-79 residing in the 56073 zip code (13,290 adults; includes New Ulm). Baseline assessments (2009) of dietary intake and obesity showed only 17% of New Ulm adults ate 5+ servings/day of fruits and vegetables, well below guidelines, and 35% of adults were overweight and 41% were obese (Van Wormer et al., 2012). These health indicators along with lower median household income indicate these adults are at risk for continued poor health. Building on lessons learned, HONU approaches improving population health through adult- focused interventions integrated into healthcare, worksites, and the larger community by modifying the environment. A recent evaluation found

participation in any two component HONU Project programs was associated with significantly higher odds of blood pressure control two years later among those with uncontrolled blood pressure at baseline (Sillah et al., 2014). With national trends for hypertension remaining stable for the last decade, this decrease is exciting. In 2011-2012, approximately 500 residents registered for a holiday weight management program. Seventy percent of those retained (280-300), either maintained (18%) or lost (52%) weight, with mean weight loss of 4.2 lbs. Thus, HONU interventions appear to be making a difference in the health of adults in the community but there is a need, and a community desire, for family-focused programs. To date, HONU nutrition interventions have primarily focused on environmental reengineering to increase availability of healthful options in restaurants, grocery stores and convenience stores (Pereira et al., 2014); community-wide health marketing campaigns; adult nutrition education and weight management; and school-based initiatives to improve food at concessions.

2.3 Existing Literature

Childhood obesity is a serious public health problem (Ogden et al., 2014; NIH, 2011). Although previous environmental approaches to obesity prevention show some promise, few studies significantly engage parents or focus on the home environment, which is essential to promote healthful behaviors at home. Parents are primary role models for healthful eating (Draxten et al., 2014) and activity (Trost et al., 2011) and gatekeepers for food and beverage availability and degree of inactivity at home. Moreover, for children, the home setting is where most calories and energy dense foods are consumed (Briefel et al., 2009) and where most sedentary behavior occurs, particularly screen time (Rideout et al., 2010) (e.g., television). Children in rural communities are particularly vulnerable regarding increased risk for obesity and diabetes (USDHHS, 2011; Singh et al., 2010; Lutfiyya et al., 2007; Rockeymoore et al., 2014; NAC on Rural Health, 2011); owing in part to poverty (Lutifiyya et al., 2007) and lower access to healthful foods and physical activity opportunities (Yousefian et al., 2011; Seguin et al., 2014). Thus, effective programs that engage families in rural communities to prevent excess weight gain among children are critically needed.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoints/Events/Outcomes

Primary aim: To test the effectiveness of the NU-HOME program, a family-based health promotion intervention to prevent excess weight gain among 7-10 year old children. The main hypothesis is that children in the intervention group will have significantly lower body mass index z-scores (BMIz), relative to children in the control group at post-intervention (7 months), after adjustment for baseline values.

3.2 Secondary Endpoints/Events/Outcomes

Secondary aims: To examine intervention effects on the following family- and child-level outcomes:

1) Home availability of healthful foods and beverages and quality of those served at family meals and snacks.
2) Children's dietary intake (e.g., calories, fruits and vegetables, sugar-sweetened beverages).
3) Children's minutes of moderate-to-vigorous physical activity and sedentary behavior per week, particularly screen time.

4.0 Study Interventions/Interactions

4.1 Description

The research design includes qualitative research and a randomized controlled trial. We will be conducting the research in several stages.

Stage 1: Planning and adaptation (months 1-12). Stage 1 will focus on establishing a Steering Committee (larger community group) and an Action Team (specific team of community partners to put decisions into action). These groups will use a Community-Based Participatory Research (CBPR) approach to adapt the HOME Plus program (shown to be effective in an urban community) for a rural community. Members of the Action Team will meet monthly for the first year to determine how to adapt the HOME Plus program for rural families. During committee meetings, community assets will be mapped to facilitate buy-in and ensure inclusion of necessary partners, and assess and finalize our strategies. A logic model of the relationships between program resources, activities, outputs and outcomes will be created using a graphical depiction to address needs of the rural communities and facilitate implementation and uptake.

An ongoing evaluation of the extent to which CBPR principles are followed will be conducted. Thus, we will develop guidelines to describe the academic/community partnership and how decisions were made. Committee members will complete a CBPR survey that assesses decision-making processes for: 1) participant involvement, 2) shaping the purpose/scope of research, 3) research implementation and context, and 4) nature of research outcomes. (Change in protocol to submit survey items and Action Team Consent Form approved 10/12/16.) Committees will also use a RE-AIM framework to assess Reach, Effectiveness, Adoption, Implementation, and Maintenance to address real world contexts of research translation.

Stage 2: Randomized controlled trial (Years 2-5). Planning will be followed by a randomized controlled trial (RCT) in rural New Ulm. Participants will include 120 7-10 year-old children and their primary meal-preparing parent/guardian.

Study participants will be recruited using multiple methods. Recruitment will be conducted by UMN staff and community partners, including area schools, Allina Health, New Ulm Medical Center physicians, UMN Extension Service, Brown County Public Health and community organizations. We will use direct mailing, flyers, presentations and other public announcement delivery channels. At some events, families will be given a small trinket to increase interest in learning about the program. Trinkets will be of minimal monetary value ($1.00 or less) and will include items such as fruit and vegetable stress balls, pens, note pads, jump ropes and indoor Frisbees. Current study participants will also be contacted and asked to share approved study flyers with any friends who they think might be interested in the study. All recruitment materials will direct interested families to contact the Evaluation Director by phone for eligibility screening. Study staff will also be available to screen interested families in person at recruitment events. An open access website page will house study information for potential participants and control group families to facilitate recruitment for the RCT. As part of our recruitment strategy, we will use personal health records available to a study Co-Investigator (Dr. Abbey Sidebottom, a community partner from Allina Health who was awarded a subcontract) to identify potentially eligible participants for a recruitment mailing. The UMN academic researchers on the team will not have access to PHI. Dr. Abbey Sidebottom will access medical records at the New Ulm Medical Center to identify parent names and addresses of children who are eligible to

participate in the NU-HOME study (i.e., they will be 7-10 years old). This information will only be used to send an introduction letter (from Allina Health) about the study and invite the parent to participate. Dr. Sidebottom will not send PHI to the UMN researchers and it will not be retained as research data.

Participants will complete measurements at three time points: baseline (before randomization), at post intervention (8-10 months after randomization) and at follow-up (14-16 months post randomization). At baseline, adult participants will provide written consent for participation and children will provide written assent. Data collection will be conducted in a quasi-group format (individual families working with individual staff) in convenient community locations, simultaneously. Based on our previous work, baseline assessments should take 1.5-2 hours, with shorter subsequent assessments. Trained study-staff will measure the height and weight of the adult and child participants. Online surveys will be completed on an electronic device (laptop, ipad, phone) by the adult participant to assess household level data (e.g., home food availability, family meal frequency and environment, nutritional quality of foods served at meals and snacks) and individual-level data (physical activity, usual fruit and vegetables intake). The parent and child will also participate in two interviews about the food the child ate in the past 24-hours. (Change in protocol from child interview to parent and child interview and from three to two interviews was approved 4/24/17.) The child will also wear an accelerometer to assess their physical activity. The child participant will also complete surveys to assess individual level data (e.g., fruit and vegetable preferences). Children will also complete two additional midpoint measurements.

During the two additional short data collection visits, child participant's height and weight will be measured and they will answer questions about physical activity, particularly at school, and healthy eating. (Change in protocol for additional child measurement was approved 4/24/17.) Children will be measured after school, removed briefly from class during school or measured at their home. Principals have provided support for measuring students at school and parents will be notified in advance of the measurements by text, email, or letter (depending on their preferred method of communication).

Following baseline data collection, families will be randomized to the intervention program (NU-HOME; n=60 families) or a delayed intervention (n=60 families) in a staggered cohort design (two cohorts). The 7-month NU-HOME program aims to prevent childhood obesity by actively engaging children and parents/guardians to prepare regular, nutritionally-sound and appropriately-portioned snacks and meals eaten together and by reducing sedentary behavior, particularly screen time. The NU-HOME intervention program will promote physical activity through the existing programs of our community partners and resources in the community as well as through the study website. The 7-month intervention will be delivered to multiple family groups in convenient community settings. Intervention families will participate in seven monthly, two-hour sessions. All household members will be invited to participate in the sessions, as the inclusion of the entire family will facilitate comprehensive support for increasing the healthfulness of the home environment. Sessions will include an introduction and food preparation with all family members, separate adult and child sessions, and end with concluding statements, home activity assignments and enjoyment of a large group "family meal." The Research Team will develop a website for intervention participants. (Change in protocol to provide UMN accounts for intervention participants on secure UMN website developed specifically for the NU-HOME study was approved 10/2/17.) Intervention families will be allowed access with a secure, password

protected login. They will have access to sessions that will be augmented online and will cover session content, video demonstrations and session materials (e.g., recipes) for both parents and children. The Research Team will coordinate with Heart of New Ulm (HONU) webmasters to link the NU-HOME website to the HONU main webpage after the research is complete. Intervention staff will establish and maintain rapport with families in sessions and will support families by phone four times during the intervention. Calls will use established protocols to employ motivational interviewing techniques such as reflective listening, agenda setting, and eliciting change talk to set goals and support behavior change and self-monitoring. All data collected as part of these calls will be entered in a secure REDCap database.

Stage 3 (Year 5): Delayed intervention. Our program design includes a wait-list control group and a “train the trainers” model to facilitate good will, stakeholder satisfaction and sustainability. Wait-list control group families will be able to receive the NU-HOME program after follow-up data collection.

Stage 4 (Year 5): Dissemination. The dissemination phase will begin with meetings between the Steering Committee, Action Team and Research Team to decide on timing of and venues for dissemination. We expect venues will include traditional academic journals, research conferences, technical and lay reports (to parents, health care professionals, stakeholders), local non-research conferences at schools, community events, and media.

5.0 Procedures Involved

5.1 Study Design

The research design includes both a Community-Based Participatory Research design in the initial phases to adapt the existing program for use in a rural community as well as a Randomized Controlled Trial (RCT) to test the modified program with 120 7-10 year old children and the primary meal preparer in the family. In the RCT, 60 families will be randomized to receive the NU-HOME program while the other 60 families will receive a delayed program after they have completed data collection.

5.2 Study Procedures

During the initial planning stage, Action Team members will meet monthly and use CBPR principles to adapt the existing program for use with rural families. During committee meetings, community assets will be mapped to facilitate buy-in and ensure inclusion of necessary partners, and assess and finalize our strategies. A logic model of the relationships between program resources, activities, outputs and outcomes will be created using a graphical depiction to address needs of the rural communities and facilitate implementation and uptake. An ongoing evaluation of the extent to which CBPR principles are followed will be conducted through CBPR surveys. (Change in protocol to submit survey items and Action Team Consent Form was approved 10/12/16.)

During the RCT, 120 7-10 year-old children and their primary meal-preparing parent/guardian will complete measurements at three time points: baseline (before randomization), at post intervention (8-10 months after randomization) and at follow-up (14-16 months post randomization). At the baseline visit, adult participants will provide written consent for participation and children will provide written assent. Trained study-staff will measure the height and weight of the adult and child participants. Online surveys will be

completed on an electronic device (laptop, ipad, phone) by the adult participant to assess household level data (e.g., home food availability, family meal frequency and environment, nutritional quality of foods served at meals and snacks) and individual-level data (physical activity, usual fruit and vegetables intake). The parent and child will also participate in two interviews about the food the child had to eat in the past 24-hours. (Change in protocol for child interview to parent and child interview and from three to two interviews approved 4/24/17.) The child will also wear an accelerometer to assess their physical activity. The child participant will also complete surveys to assess individual level data (e.g., fruit and vegetable preferences).

5.3 Follow-Up

Data will be collected at post intervention (8-10 months post randomization) and at Follow-up (14-16 months post randomization)

5.4 Individually Identifiable Health Information

In our initial application, we completed appendix H and were awarded a waiver of HIPAA authorization requirement. As part of our recruitment strategy, we proposed using personal health records available to a study Co-Investigator (Dr. Abbey Sidebottom, a community partner from Allina Health who was awarded a subcontract) to identify potentially eligible participants for a recruitment mailing. The UMN academic researchers on the team will not have access to PHI. Dr. Abbey Sidebottom will access medical records at the New Ulm Medical Center to identify parent names and addresses of children who are eligible to participate in the NU-HOME study (i.e., they will be 7-10 years old). This information will only be used to send an introduction letter (from Allina Health) about the study and invite the parent to participate. Dr. Sidebottom will not send PHI to the UMN researchers and it will not be retained as research data. As enrollment begins, Dr. Sidebottom will compare names of enrolled parents to her list of those included in the mailing so we can assess the effectiveness of this recruitment method; she will only share the aggregate information.

As part of the research, the NU-HOME team will be collecting personal identifiable information including full names, birthdays, telephone numbers, email addresses, and mailing addresses of enrolled participants. Direct identifiers will be maintained so we can contact participants (by mail, email, or telephone) to schedule their data collection visits, inform them of their randomization status, remind them of intervention session dates and conduct goal-setting phone calls. We will contact families to inform them if they are in the intervention or the delayed intervention group. We will also ask both child and adult participants a separate question on the consent form asking for permission to take their photographs. Photos will be taken at intervention sessions to share with families and in presentations but will not be used as data. Participants are free to say YES or NO to the item on photographs while continuing to participate in other research activities with the study. In all cases, the privacy of measurements for each child and parent will be maintained, and all measurements will be carried out in a sensitive, nonjudgmental and positive atmosphere.

6.0 Data Banking

6.1 Storage and Access

Participating families will be assigned a unique study ID number. The ID number will be linked to the identifying information and stored on a secure REDcap server accessible only by study staff with approved access. Participant height and weight and the Home Food Inventory data are collected on paper and entered into a secure REDCap server. The hard copies are deidentified and are stored in a locked file cabinet in the School of Nursing. All

other data are collected via an online REDCap survey and stored on a secure REDCap server. Data are downloaded on a regular basis and saved to Box in a folder that is only accessible to the Principal Investigator and Project Manager. When the data have been cleaned and prepared for analysis, deidentified datasets are uploaded to a folder that is shared with the analyst at Allina Health.

6.2 Data

Deidentified data that may be used for future use include all survey data, dietary recall data, physical activity data, height and weight data and all process data related to intervention attendance and participation. In addition, identifiable data such as name, address, phone number and email which we used to contact participants and will be maintained for seven years after the end of the study.

6.3 Release/Sharing

After data entry, cleaning and linkage, a de-identified data set will be created which, along with associated documentation, will be made available to users after analyses related to the major aims of the study have been reported and only under a data-sharing agreement as suggested by the NIH that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. Any request for data will be evaluated by the study Principal Investigator.

7.0 Sharing of Results with Participants

7.1 Describe Whether Results Will Be Shared and How

As part of the CBPR work with the Action Team in stage 4 (Year 5), decisions will be made as a group about when to share data with participants and the community, what data to share and how the data will be shared. Expected venues for sharing study results will include traditional academic journals, research conferences, technical and lay reports (to parents, health care professionals, and stakeholders), local non-research conferences at schools, community events, and media. The Research Team has experience writing about main study findings in lay reports and disseminating to participants.

8.0 Study Duration

8.1 Describe

Action Team members will be involved in all five years of the study. In the first year of the study, they will work to adapt the existing HOME Plus program for rural families and later will work to solidify plans for the delayed intervention and be involved in deciding how to disseminate study findings. Mail trial participants will be involved in the study for approximately 1.5 years from baseline data collection through follow-up data collection. The study is funded for five years and includes planning, implementation of the RCT, a delayed intervention and dissemination of findings.

9.0 Study Population

9.1 Inclusion Criteria

Child participants must be between 7 and 10 years old and live with the adult participant at least 50% of the time. The adult participants must be the primary-meal preparing parent/guardian.

9.2 Exclusion Criteria

Participants must not be planning on moving away from the area in the next year and be free from medical conditions contraindicating study participation.

9.3 Screening

For Cohort 1, interested individuals will call the Evaluation Director to be screened for eligibility. She will describe the study, answer any questions, and ask additional questions to determine eligibility based on inclusion and exclusion criteria. For Cohort 2, attempts are being made to increase the diversity of the study sample. Flyers will be distributed in both English and Spanish. The flyers in Spanish will direct interested families to a bilingual staff member who will screen them for eligibility. For Cohort 2, study staff will also be available at community events to screen interested families in person. Families will be offered small trinkets to increase interest in learning about the research study. Trinkets will be of minimal monetary value ($1.00 or less) and will include items such as fruit and vegetable stress balls, pens, note pads, jump ropes and indoor Frisbees.

10.0 Vulnerable Populations

10.1 Identify

Child between the ages of 7-10 years are included in the study. One parent is required to provide consent for their participation and the children are required to provide assent to enroll.

Pregnant women may be included as being pregnant is not an exclusion criterion. Healthful eating would benefit a pregnant woman and neither the intervention or the measurement pose more than minimal risk to the pregnant woman or her fetus.

10.2 Adults Lacking Capacity to Consent

N/A

10.3 Additional Safeguards

See 10.1

11.0 Number of Participants

11.1 Number of Participants to be Consented

For the CBPR planning phase, we anticipate approximately 15 community members will be consented as members of the Action Team. (Change in protocol to add an Action Team Consent Form was approved 10/12/16.)

For the main trial, 120 parent/child dyads will be enrolled (total = 240 individuals).

12.0 Recruitment Methods

12.1 Recruitment Process

Recruitment will be conducted by UMN staff and community partners, including area schools, Allina Health, New Ulm Medical Center physicians, UMN Extension Service, Brown County Public Health and community organizations. We will use direct mailing, flyers, presentations and other public announcement delivery channels. Current study participants will also be contacted and asked to share approved study flyers with any friends who they think might be interested in the study. All recruitment materials will direct interested families to contact the Evaluation Director by phone for eligibility screening (or a bilingual staff member for families calling from the Spanish flyer). Stud staff will also be available to screen interested families in person at community events and families will be offered small trinkets to increase interest in learning about the research study. Trinkets will

be of minimal monetary value ($1.00 or less) and will include items such as fruit and vegetable stress balls, pens, note pads, jump ropes and indoor Frisbees.

12.2 Sources of Participants

We will use community recruitment so participants will be any members of the New Ulm and surrounding communities who meet eligibility requirements. In addition, Dr. Sidebottom, the Allina Health Co-Investigator, will identify eligible children (based on age) in the New Ulm Medical Center records and send their family a letter of invitation.

12.3 Identification of Potential Participants

In some cases, individuals will self-identify as a possible participant based on flyers in the community. In others cases, we will target potentially eligible families. For example, we will send flyers home from school with students in grades that correspond to the 7-10 year old age range. In addition, Dr. Sidebottom, the Allina Health Co-Investigator, will identify eligible children (based on age) in the New Ulm Medical Center records and send their family a letter of invitation. Dr. Sidebottom will make initial contact with potential subjects within this method of recruitment. The PI and other UMN researchers will not have access to the medical records. Interested families will be directed to call the Evaluation Director for eligibility screening (or a bilingual staff member for families calling from the Spanish flyer). Current study participants will also be contacted and asked to share approved study flyers with any friends who they think might be interested in the study.

12.4 Recruitment Materials

We will use direct mailing, flyers, presentations and other public announcement delivery channels. Current study participants will also be contacted and asked to share approved study flyers with any friends who they think might be interested in the study. (Change in protocol in which we submitted final recruitment materials was approved 3/27/17.) (Change in protocol submitted 3/20/2018 for recruitment materials for Cohort 2 with names of both major towns included in Cohort 2 as well as a Spanish version of the flyer). Families will be offered small trinkets to increase interest in learning about the research study. Trinkets will be of minimal monetary value ($1.00 or less) and will include items such as fruit and vegetable stress balls, pens, note pads, jump ropes and indoor Frisbees.

12.5 Payment

At each data collection visit, families will receive a $25 gift card for height and weight measurement and for completing surveys that day. Over the following two weeks, they will receive an additional $25 gift card for completing one additional phone interview about the food the child ate the previous day and returning the physical activity tracker the child wore for 7 days. The family will receive a third $25 gift card for completing the snack and evening meal screener surveys. Thus, if a family completes all of the planned data collection at each data collection period, they will receive $75 each time (total of $225 in gift cards per family if they complete all data collection at each of the 3 data collection time points). (Change in protocol to break up the $75 payment into three separate $25 allotments was approved 4/26/17.) Cohort 2 families who complete the interim child height and weight measurement will receive a $15 gift card. At post-intervention data collection, Cohort 2 families who wear their actigraph long enough will be entered to win a pack of 10 passes to the Sleepy Eye waterpark. On each day a child participant wears their actigraph for at least 12 hours, their name will be entered into the drawing. The drawing will take place this summer. Families will not receive direct compensation for attendance at intervention sessions (primary or delayed intervention); however, as attendance at each session is logged, participating families will receive a $10 gift card to compensate them for gas while

attending intervention sessions since this study is being conducted in a rural area and participants may drive quite far to participate. In addition, at each in-person session, families may receive take-home groceries of the featured monthly fruit/vegetable. Families may also add their names for drawings for door prizes (e.g., kitchen equipment, pass to local physical activity facility) and a chance to win the opportunity to have a home visit by a chef. Participants will be notified that this is a drawing and not everyone will receive this incentive.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances

We do not anticipate situations where a participant would be withdrawn without their consent.

13.2 Withdrawal Procedures

13.3 Termination Procedures

As we do not anticipate terminating participants, if this situation arises, we will submit a change in protocol and receive approval before doing so.

14.0 Risk to Participants

14.1 Foreseeable Risks

The study has minimal risks. Participants may feel uncomfortable answering questions about their own or their family's eating habits but they are told they can skip any survey questions they do not wish to answer. Participants may also feel uncomfortable completing measurements as part of data collection in a group setting; however, we provide partitions for privacy when measuring height and weight, do not indicate their height or weight verbally and provide separate tables between families for completion of surveys. Participants may have some conflict about changing the food offerings or television limits in their home; however, families will choose from several behavioral goals provided.

14.2 Reproduction Risks

N/A

14.3 Risks to Others

N/A

15.0 Incomplete Discloser or Deception

15.1 Incomplete Disclosure or Deception

N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits

There are no direct benefits to participation; however participants are taught to make healthful food choices and may improve their health if they make dietary changes or improve the heathfulness of the foods in their home food environment.

17.0 Data Management

17.1 Data Analysis Plan

Analysis plan. The analysis plan integrates our theoretical framework for behavior change and our temporal design. The analysis plan includes descriptive analyses, assessment of

primary and secondary outcomes, and testing of potential moderation and mediation effects using an intent-to-treat methodology.

Descriptive analyses. Baseline participant characteristics will be reported using means and standard deviations or median for continuous measures and frequencies for categorical measures. To examine group comparability at baseline, differences between intervention and wait-list controls will be assessed using chi-square tests for categorical data or two-sample t-tests for comparisons of continuous data. Descriptive statistics of all outcome measures will be calculated at each assessment period. Inter-item correlations and internal consistency measures (i.e., Cronbach's alpha) will also be calculated.

Primary outcome analyses. For the analysis of the primary outcome of child BMI, a two-step approach will be used. First, two-sample t-tests will be used to assess potential changes in age- and gender-adjusted child BMI z-scores from baseline to post-intervention (i.e., immediate change). Second, baseline-adjusted analysis of covariance while adjusting for child age, gender, race and economic assistance will be performed. Analyses of associations with overweight status will be conducted with multivariate logistic regression while adjusting for baseline BMI z-scores or BMI z-squared to allow for curvature. Sustained program effects will be assessed using a similar approach with follow-up BMI z-scores.

Intent-to-treat principle. All comparisons will be performed under the intent-to-treat principle (i.e., all randomized participants will be included and analyzed according to group assignment, regardless of compliance). A 5% two-sided type I error rate will be used to determine statistical significance. SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA) will be used for statistical analyses. Because the intervention is delivered in multiple family groups, we anticipate group facilitation effects (i.e., participants have greater benefits than if the intervention were delivered individually). Thus, we will investigate intraclass correlations (ICCs) in the test for intervention effectiveness.

Secondary outcome analyses. Secondary outcomes will be analyzed using the same approach as with the primary outcome. In addition, to compare study groups over time, linear mixed models with baseline measures, group, and time (baseline, post-intervention and follow-up) as fixed covariates will be fitted. Group by time interactions will also be introduced. Transformation will be considered to ensure data normality. Other potential covariates (i.e., gender, age, education level, rural code) will be entered in models, if necessary. These models will assess between-group effects following randomization, within-group changes, and whether changes in the outcomes from baseline to post-intervention or to follow-up differed between the groups (group x time interaction). Based on preliminary studies, we expect that intervention families will have changes in food availability and intake, physical activity and sedentary behaviors after receipt of the NU-HOME program that will remain consistent at follow-up.

17.2 Power Analysis

Power calculations are based on two assessment time points, correlation over time, and variability of age- and gender-adjusted BMI z-scores. We propose to recruit 120 families (one eligible child and one parent per family) to allow for a 15% attrition rate with a final effective sample of about 100 families in the study by the end of follow-up. Using child (<11 years old) data from the HOME Plus trial, we estimated a within-child correlation (ρ) between the primary outcome measurements over time of 0.9. Utilizing a baseline-adjusted analysis approach, with a sample size of 96 (48 per group), we will be able to detect an

effect size (ES) of 0.25 for age- and gender-adjusted BMI z-scores at 80% power. This effect size corresponds to approximately 1.4 kg decrease in average weight gain between intervention and control groups. This corresponding decrease was estimated using BMIi=M(1+LSzi)1/L formula with age-and gender-specific L,M,S parameters and average weight and height values for 8-10 year old boys and girls [at 50th or higher percentile for weight].

17.3 Data Integrity

Participating families will be assigned a unique study ID number. The ID number will be linked to the identifying information and will be stored electronically on a secure REDcap database within the School of Nursing. Identifing information will be accessible only to research staff who have been supplied with access rights using their University of Minnesota password. Paper data will be locked in a file cabinet in a secure, locked room in the School of Nursing. All electronic data will be stored in REDcap files. In addition, REDcap will allow identifiable data to be hidden from staff who have access to the file but do not need use the identifing information to perform their duties (for example data entry). All datasets are also regularly uploaded to Box with access only by the PI and Project Manager.

18.0 Confidentiality

18.1 Data Security

Participating families will be assigned a unique study ID number. The ID number will be linked to the identifying information only on a secure REDcap server accessible only by study staff with approved access. All electronic data will be stored in REDcap files. REDcap is a secure site used by researchers at the Univerity of Minnesota. Staff must be granted access to open the REDcap files and opening the files requires the use of a password. In addition, REDcap will allow identifiable data to be hidden from staff who have access to the file but do not need use the identifing information to perform their duties (for example data entry). All research staff will be have completed the required IRB Social and Behavioral and HIPAA trainings. A copy of the consent forms will not be placed in the participants medical, educational or employment records.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

19.1 Date Safety Monitoring

The intervention and measurement protocols pose minimal risk to participants. Because of this low risk status, the Data Safety Monitoring Plan (DSMP) for this trial focuses on close monitoring by the principal investigator (PI) in conjunction with a safety officer (Dr. Renee Sieving, a Professor with the School of Nursing at the University of Minnesota, Director of the Center for Adolescent Nursing, and Director of the Healthy Youth Development-Prevention Research Center). Safety reports will be sent to the PI, and the safety officer. The Evaluation Director will be responsible for assembling the data and producing these reports, as well as assuring that all parties obtain copies of these reports. We plan to collect injury data from the treatment and control (wait-list) group monthly during the 7-month intervention. We do not expect many injuries as a result of participating in the proposed intervention program. However, there is a possibility of injuries (e.g., minor burns, cuts) during the cooking component of the intervention. It is anticipated that most injuries related to cooking activities in a healthy child/parent population would be mild in nature and allow a complete return to the same activities after a brief recovery period. If necessary, alternative meal preparation activities (e.g., mixing, washing) will be substituted during the brief

recovery period. An Adverse Event Form will be used by the study staff to report injuries or other adverse events that occur as a result of the intervention, particularly the cooking component. The safety officer will review, collate, and evaluate adverse events in real-time. Any serious adverse events reported to the University of Minnesota IRB will also be reported to the NIH funding institute. All adverse events will be evaluated by the Safety Officer and the principal investigator within 72 hours and reported to the UMN IRB; serious adverse events within 24 hours. Any study-related serious adverse event will be reported to the NIH funding institute within 2 weeks; all others will be included in the annual report to NIH funding institute. The frequency of data review for this study differs according to the type of data and can be summarized in the following table:

Data type	Frequency of review
• Subject accrual rate (adherence to protocol regarding demographics, inclusion/exclusion) and retention rate	• Bi-monthly during the trial recruitment period for cohorts 1 and 2 • At the completion of each of the three measurement periods for cohorts 1 and 2
• Adverse event rates (injuries)	• 24-72 hours
• Compliance with intervention program	• At completion of sessions 3, 6, and 10 of the intervention program
• Safety report	• Every 6 months

20.0 Provisions to Protect the Privacy Interest of Participants

20.1 Protecting Privacy

For the Community Based Participatory Research portion of the study, each member of the Action Team will provide written consent in a private area.

For the main trials, participants will contact the Evaluation Director if interested in the study, she will describe the study and mail them consent and assent forms to review. She will then schedule a time for a baseline measurement. At the baseline measurement, several families will be completing data collection at the same time but consent and assent will occur in a private area with the Evaluation Director, PI, Dr. Linde (Co-I), Intervention Director or other data collection staff lead with IRB approval to do so. In all cases, the privacy of measurements for each child and parent will be maintained, and all measurements will be carried out in a sensitive, nonjudgmental and positive atmosphere. Children and parents will be told that they can stop the activity at any time or not answer specific questions. They will also be assured of the confidentiality of their responses and that their names will not be kept with any data they provide. All parent/guardian and child participants will be informed they are free to withdraw from the study at any time without penalty. While several families may be at one location at the same time for measurements, the room will be arranged so each family has their own area with as much privacy as possible. All height and weight measurements will be taken behind a privacy screen and staff members will not verbally announce the values.

20.2 Access to Participants

After a participant enrolls in the study, the research team does not have permission to access any of their medical, student, or private records.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury

N/A due to the fact that the study involved no greater than Minimal Risk

21.2 Contract Language

N/A

22.0 Consent Process

22.1 Consent Process

Dr. Jayne Fulkerson (PI), Dr. Jennifer Linde (Co-I), Ms. Friend (MPH, P&A staff) and Ms. Flattum (MS, P&A staff) and Ms. Lori Rathburn (data collection staff lead) will be obtaining all consents and assents for Cohort 1. One of the five will be present during all data collection. All have extensive experience consenting participants for previous NIH-funded research studies, have completed CITI training and have been trained in HIPAA. Ms. Rathburn and Ms. Friend will work closely with Drs. Fulkerson and Linde to develop the procedures for consenting participants. For Cohort 2, attempts are being made to recruit more diverse families by offering a flyer about the study in Spanish. Those families who speak Spanish will be directed to a bilingual staff member for screening. During screening, Spanish speaking families will be asked if they prefer to participate in the data collection and intervention in English or Spanish. If there are families who wish to enroll in the study who prefer to speak in Spanish, we will translate the consent form into Spanish and train bilingual staff to obtain consent in Spanish. Similarly, we will revise our data collection materials accordingly (and submit to the IRB for approval) but, at this time, we do not know if these changes will be needed.

All interested parents will be mailed a consent form (for themselves) and assent form (for their child) prior to the baseline data collection visit where consent/assent is obtained in writing from both adults and child participants. This allows them time to read the forms in advance and formulate questions. Drs. Fulkerson and Linde, Ms. Friend and Ms. Rathburn will answer all questions that potential participants have regarding the study and will inquire whether the potential participant would like to participate in the study. If the potential participant would like more time to think about it or is uninterested in participating, s/he will be allowed to keep the materials describing the study in case s/he changes his/her mind. All potential participants will be reminded that their decision regarding participation will not affect their relationships with the University of Minnesota or community partners.

22.2 Waiver or Alteration of Consent Process

N/A

22.3 Non-English Speaking Participants

For Cohort 1, we anticipate all participants will be literate in English and will complete the consent procedures in English. For Cohort 2, attempts are being made to recruit more diverse families by offering a flyer about the study in Spanish. Those families who speak Spanish will be directed to a bilingual staff member for screening. During screening, Spanish speaking families will be asked if they prefer to participate in the data collection and intervention in English or Spanish. If there are families who wish to enroll in the study who prefer to speak in Spanish, we will translate the consent form, data collection and intervention materials into Spanish and train bilingual staff to obtain consent in Spanish.

22.4 Participant Who are Not Yet Adults

All child participants (7-10 years old) will be asked to provide written assent. One parent or legal guardian will also be asked to provide written consent for the child to participate in the study.

22.5 Cognitively Impaired Adults, or Adults with Fluctuating or Diminished Capacity to Consent

N/A

22.6 Adults Unable to Consent

N/A

23.0 Setting

23.1 International Research

N/A

23.2 Community Based Participatory Research

Allina Health and the Minneapolis Heart Foundation currently partner together to deliver a program for New Ulm adults to reduce myocardial infarctions; Hearts Beat Back The Heart of New Ulm Project (HONU). The current NU-HOME project retains that partnership but extends it to include the University of Minnesota with an additional focus on child and family health in the New Ulm community. HONU has an existing Executive Committee whose members will be invited to join the NU-HOME Steering Committee and Action Team. Additionally, other community partners will be invited to joing the NU-HOME Steering Committee including New Ulm Medical Center physicians, UMN Extension Service, Brown County Public Health and other community organizations.

The PI, research team and community partners will meet regularly through the Steering Committee and Action Team to reduce potential risks and maximize benefits for research participants and the community. The NU-HOME study will use CBPR strategies with the Action Team as we adapt the materials during year 1 and conduct recruitment during years 2 and 3. We will use CBPR methodology to engage stakeholders in each phase of the research, listen to concerns and develop protocols to reduce risk. We will only use methods deemed acceptable by stakeholders. In regards to sharing results, our research plan for study dissemination of findings includes providing information to all participants and the community in addition to scientific audiences. We will consult with the Steering Committee and Action Team on appropriate outlets for lay audiences.

Community members participating in the Action Team will sign consent forms to complete CBPR surveys and be allowed to withdraw their participation at any time. (Change in protocol to submit survey items and Action Team Consent Form approved 10/12/16.)

23.3 Research Sites

Sites where research will potentially be conducted include elementary school, community centers, churches, and online. School space may be used to collect data and to deliver the program in the evenings if the Action Team deems it the most logical and appropriate place for intervention delivery. Intervention delivery would only occur after the school day is over. We may also use the schools to recruit participants (such as sending home a flyer about

the program) if the community partners deems it logical and appropriate. Teachers will not have a role in the research project unless they are a member of the Steering Committee or Action Team. Other sites such as churches and community centers may be used for data collection, program delivery or recruitment as the Steering Committee and/or Action Team deems appropriate. Data will be collected from online surveys using electronic devices such as laptops, iPads and phones.

24.0 Multi-Site Research

N/A

25.0 Resources Available

The study is not being conducted by a student researcher.

We feel we have the ability to recruit the target number of participants and have plans in place to expand our target area if necessary. Our team's evaluation of MN Department of Education data of the New Ulm 56073 zip code indicates there are approximately 725 7-10 year old children. Thus, we would need to recruit about 16% of children in New Ulm to meet our goal of 120. Although we do not anticipate difficulty with recruitment given the high participation rate of adults in HONU programs (70% of targeted adults), if it appears that recruitment will be difficult, we will also recruit from the neighboring community of Springfield with whom our community partners have an established relationship. Extending our reach beyond New Ulm to include Springfield will increase our pool of eligible children.

As outlined below, the study is funded for 5 years with time allocated to adapting the program (year 1), recruiting participants (year 2 for cohort 1 and 3 for cohort 2), competing baseline, post intervention (8-10 months after randomization) and follow-up (14-16 months after randomization) data collection (years 2-4), delivering the seven month intervention program (year 2 for cohort 1 and year 3 for cohort 4), delivering the delayed intervention, and dissemination the findings.

Study Timeline																				
	Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
Steering Committee Meetings																				
Stage 1 (CBPR adapt program)																				
Stage 2 (RCT) Hire and train																				
Cohort 1																				
Cohort 2																				
Stage 3 (Delayed intervention)																				
Stage 4 (Dissemination)																				

Facilities will include those at the University of Minnesota, Allina Health, Minneapolis Heart Institute Foundation and those in the New Ulm, Sleepy Eye and surrounding communities where the study will be conducted. Allina Health will commit personnel for recruitment of NUMC patients, and statistical analysis of electronic health record data and NU-HOME study data. Minneapolis Heart Institute Foundation will commit personnel to assist in facilitating committee meetings; adaptating/refining materials, protocols and programming; subject and volunteer recruitment; day-to-day operations in New Ulm and Sleepy Eye; and oversight of staff who will deliver the NU-HOME intervention program in community settings. Sites where research will be potentially be conducted include elementary schools, community centers, churches, and online through the study website.

To ensure all persons assisting with the research have been adequately trained, we will ask everyone working with participants to complete the CITI Social and Behavioral training and the University of Minnesota HIPAA training and they will be added to the University of Minnesota's IRB. Research team members who will be obtaining consent from study participants include Dr. Jayne Fulkerson (PI), Dr. Jennifer Linde (Co-I), Ms. Friend (MPH, P&A staff), Ms. Rathburn (civil service staff) and a bilingual staff member if families state they prefer to participate in Spanish during the screening process. All have extensive experience consenting participants for previous NIH-funded research studies, have completed CITI training and have been trained in HIPAA. Ms. Rathburn and Ms. Friend will work closely with Drs. Fulkerson and Linde to develop the procedures for consenting participants. Dr. Fulkerson will also complete all IRB required by Allina Health.

26.0 References

Boucher JL, Pereira RF, Graham KJ, Pettingill RR, Toscano JV, Henry TD. The Heart of New Ulm: A vision for the future. *J Cardiovasc Transl Res.* 2008 Dec; 1(4): 310-316.

Briefel RR, Wilson A, Gleason PM. Consumption of low-nutrient, energy-dense foods and beverages at school, home, and other locations among school lunch participants and nonparticipants. *J Am Diet Assoc.* 2009 Feb; 109(2 Suppl): S79-90.

Draxten M, Fulkerson JA, Friend S, Flattum CF, Schow R. Parental role modeling of fruits and vegetables at meals and snacks is associated with children's adequate consumption. *Appetite.* 2014 Jul; 78: 1-7. PMCID:PMC4034448.

Fulkerson JA, Rydell S, Kubik MY, Lytle L, Boutelle K, Story M, Neumark-Sztainer D, Dudovitz B, Garwick A. Healthy Home Offerings via the Mealtime Environment (HOME): Feasibility, acceptability, and outcomes of a pilot study. *Obesity (Silver Spring).* 2010 Feb; 18 Suppl 1: S69-74.

Fulkerson JA, Kubik MY, Rydell S, Boutelle KN, Garwick A, Story M, Neumark-Sztainer D, Dudovitz B. Focus groups with working parents of school-aged children: What's needed to improve family meals? *J Nutr Educ Behav.* 2011 May-Jun; 43(3): 189-193. PMCID: PMC3217335.

Fulkerson JA, Neumark-Sztainer D, Story M, Gurvich O, Kubik MY, Garwick A, Dudovitz B. The Healthy Home Offerings via the Mealtime Environment (HOME) Plus study: Design and methods. *Contemp Clin Trials.* 2014 May; 38(1): 59-68. PMCID: PMC4075328.

Lutfiyya MN, Lipsky MS, Wisdom-Behounek J, Inpanbutr-Martinkus M. Is rural residency a risk factor for overweight and obesity for U.S. children? *Obesity (Silver Spring).* 2007 Sep; 15(9): 2348-2356.

The National Advisory Committee on Rural Health and Human Services. The 2011 Report to the Secretary:Rural Health and Human Services Issues. NACRHHS; 2011.

NIH Obesity Research Task Force. Strategic plan for NIH obesity research: U.S. Department of Health and Human Services, National Institutes of Health. 2011. Report No.: NIH 11-5493.

Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* 2014 Feb 26; 311(8): 806-814.

Pereira RF, Sidebottom AC, Boucher JL, Lindberg R, Werner R. Assessing the food environment of a rural community: baseline findings from the Heart of New Ulm project, Minnesota, 2010-2011. *Prev Chronic Dis.* 2014 Mar 6; 11: E36. PMCID: PMC3944948.

Rideout VJ, Foehr UG, Roberts DF. Generation M2: Media in the lives of 8-18-year-olds. Menlo Park, California: Henry J. Kaiser Family Foundation; 2010.

Rockeymoore M, Moscetti C, Fountain A. Rural childhood obesity prevention toolkit. Robert Wood Johnson Foundation; 2014.

Seguin R, Connor L, Nelson M, LaCroix A, Eldridge G. Understanding barriers and facilitators to healthy eating and active living in rural communities. *J Nutr Metab.* 2014; 2014: 146502. PMCID: PMC4276670.

Sillah A, Sidebottom AC, Boucher JL, Pereira R, VanWormer JJ. Program participation and blood pressure improvement in the Heart of New Ulm Project, Minnesota, 2009-2011. *Prev Chronic Dis.* 2014 Mar 27; 11: E48. PMCID: PMC3970769.

Singh GK, Siahpush M, Kogan MD. Rising social inequalities in US childhood obesity, 2003-2007. *Ann Epidemiol.* 2010 Jan; 20(1): 40-52.

Trost SG, Loprinzi PD. Parental influences on physical activity behavior in children and adolescents: A brief review. *American Journal of Lifestyle Medicine.* 2011; 5(2): 171-181.

U.S. Department of Health and Human Services, Maternal and Child Health Bureau. The health and wellbeing of children in rural areas: A portrait of the nation 2007. Rockville, Maryland: U.S. Department of Health and Human Services; 2011.

VanWormer JJ, Johnson PJ, Pereira RF, Boucher JL, Britt HR, Stephens CW, Thygeson NM, Graham KJ. The Heart of New Ulm Project: Using community-based cardiometabolic risk factor screenings in a rural population health improvement initiative. *Popul Health Manag.* 2012 Jun; 15(3): 135-143.

Yousefian A, Leighton A, Fox K, Hartley D. Understanding the rural food environment--perspectives of low income parents. *Rural Remote Health.* 2011; 11: 1631.