Official Title: Weight Management in Rural Communities

NCT Number: 02932748

Approval Date: August 5, 2020

Document: Study Protocol with Statistical Analysis Plan

Introduction

The 2010 Census indicates that 19.3% of the U.S. population, or approximately 60 million people, reside in rural areas (1). Obesity prevalence in both children (2-4) and adults is significantly higher in rural compared with urban residents (5-8), and approaches 40% in rural adults (6, 7). Rural residents are less physically active (5, 6, 8), consume less healthy diets (5, 9), and have higher rates of obesity associated health problems (10-13), and all-cause mortality (6) compared with their urban counterparts. The Rural Healthy People 2020 survey of 1,214 rural health stakeholders indicated that nutrition and weight status ranked second behind access to health care as important rural health priorities (14).

Barriers to weight management for rural residents include limited availability of programs/professionals trained in weight management (6, 15, 16), and travel distance/expense to attend on-site programs (17) in areas with limited or non-existent public transportation (18). Healthy foods are less available and affordable in rural areas (19-21) requiring travel to urban areas where fresh produce, and less expensive foods are available (22, 23). Roads designed for higher speed traffic (24, 25), few sidewalks (26, 27) and limited availability of fitness facilities or parks (21, 28, 29) make rural areas less conducive to physical activity (PA).

Rural health clinics offer a potential venue for delivery of weight management to rural residents. However, traditional, on-site individual or group-based programs (30) require travel to a clinic for weekly face-to-face meetings, and are therefore impractical and/or inconvenient for rural residents. Rural clinics are unlikely to employ staff with the requisite expertise to provide effective weight management. Thus, weight management in rural clinics is generally limited to brief physician counseling and/or referral to a registered dietitian to assist patients with complying to an energy reduced diet and increased PA; an approach which is minimally effective (30-32).

Our research team has demonstrated the effectiveness of weight management delivered by university-based health educators via group conference (6 mos. =-10.3%, 18 mos. = - 7.4%) (33, 34), or individual phone (IP) calls (6 mos. = -10.5%) (35) to both urban and rural adults. Weight loss with the group phone (GP) intervention was equivalent to an identical intervention delivered in a traditional on-site group meeting format (34). Telephone delivery eliminates the need for travel to on-site meetings (17). Group phone delivery allows participant interaction which has the potential to increase accountability, social support, and rapport, and has also been associated with reduced drop-out (36) and improved weight loss (37, 38). Group-based interventions may be especially desirable for rural residents who are often socially isolated (39), while the IP approach allows participant anonymity, that some may prefer.

Thus, effective weight management can be achieved when interventions are delivered by university-based health educators using GP or IP approaches. However, the comparative effectiveness of GP and IP interventions, when delivered by rural clinic associated personnel, e.g., nurses, nurse practitioners, physician assistants, or community health professionals trained by our research team, has not been evaluated, and will be the focus of this trial.

Methods and Materials

Study Overview

Health care providers at five primary care clinics, or community health professionals serving individuals in rural Kansas, will be trained to deliver the GP and IP interventions and an

enhanced version of usual care to compare weight loss (0-6 mos.), weight maintenance (7-18 mos.), and weight change during a 6 mo. period of no contract (19-24 mos.) between interventions. The GP and IP interventions will be identical with the exception of the format (group vs. individual) and duration of contact, i.e., GP (~45 min/session) vs. IP (~15 min/session). Usual care, which is generally limited to brief counseling (5-7 min.) during a routine physician visit and/or referral to a registered dietitian (40), will be enhanced by increased contact with the health care providers and provision of information regarding community assets for increased PA and improved nutrition. We considered using an established weight management intervention such as the Diabetes Prevention Program or Look AHEAD protocols (41-43) as a comparison group. Although efficacious in some settings, the delivery of these interventions is expensive and burdensome for both participants and providers, and are unlikely to be tolerated by rural clinics. Following considerable discussion, we decided to compare our GP and IP interventions to an enhanced version of weight management as currently practiced in rural primary care clinics (40), i.e., enhanced usual care (EUC). Two hundred overweight/obese adults will be randomized in a 2:2:1 allocation to the GP (n=80), IP (n=80), or EUC (n=40) arms. Outcomes will be assessed by the research team at baseline (0 mos.), following weight loss (6 mos.), during weight maintenance (12 and 18 mos.) and after a 6 mo. no-contact period (24 mos.). The primary aim is to compare weight change at 6 mos. between the 3 interventions arms; GP, IP, and EUC, analyzed using intention-to treat principles. Secondarily, we will compare the following across the three interventions groups: 1) weight at 12, 18 and 24 mos. 2) metabolic syndrome risk factors (waist circumference, triglycerides, HDL-cholesterol, blood pressure, fasting glucose) at 6, 12 and 18 mos. Cost, cost effectiveness, and contingent valuation analysis and extensive process evaluation will also be completed. Approval for this study has been obtained from the Human Subjects Committee at the University of Kansas-Lawrence.

Clinic recruitment

At least five clinics, located in rural areas, and/or serving primarily rural residents, with a census of ~4,000 to 8,000 patients will be asked to participate. A universally recognized classification scheme or definition for urban/rural areas does not exist (44-46). For this project we will use the U.S. Census Bureau definition which states: ""Rural is defined as all population, housing, and territory not included within an urbanized area or urban cluster" (47). An urbanized area is defined as a population of 50,000 or more, and urban clusters are areas with populations of at least 2,500, but less than 50,000. Each clinic will be asked to assist with recruitment of 40 participants, deliver the interventions and provide space for both outcome assessments and delivery of the EUC intervention arm.

Participant eligibility

To enhance generalizability of the results, individuals with chronic medical conditions, or common risk factors such as hypertension, tobacco use, hyperlipidemia, diabetes mellitus, etc., who receive clearance from their primary care physician, will be allowed to participate. These individuals are representative of those typically seeking weight management, and that have participated in our previous trials demonstrating the effectiveness of both the GP and IP interventions (34, 48). Medical conditions and medication use may be considered potential confounders; however, randomization should ensure that health status will be similar across study groups. In addition to requiring primary care physical approval, additional inclusion and exclusion criteria (Table 1), and a comprehensive medical management plan have been developed to protect the participants in this trial. Weight loss in high risk participants, i.e., those with chronic conditions or using prescription medications, will be monitored by both the health educators and the study physician. Participants will be asked to report changes in medications

and/or adverse events to the health educators, via toll-free phone call, fax, or email, as they occur.

Recruitment/randomization

In addition to recruitment by rural clinic personnel, we will also recruit using flyers posted in rural communities and media advertising including print, radio and Facebook®. We will recruit at least 50% females and minorities to reflect or exceed minority representation in rural Kansas (16.7%) (49). Potential participants will be asked to contact study staff via phone, email or our laboratory web site. Interested individuals will be directed to complete a brief web-based screener on our laboratory website, or will be interviewed by phone, to assess self-reported height and weight (BMI), medication use, presence of chronic disease, smoking habits, previous attempts at weight loss, and current level of PA. Those satisfying the initial eligibility criteria will be scheduled to attend an in-person meeting with study staff at the participant's respective clinic. At this session staff will describe the project, answer questions, obtain consent, complete eligibility screening surveys, and measure height and weight to determine preliminary eligibility based on BMI. Screening surveys including health history, depression, eating behavior and binge eating will be administered using web-based software (Research Electronic Data Capture software (REDCap), Vanderbilt University, Nashville, TN) (50). These surveys will be completed during the in-person meeting or at home, depending on the availability of home internet access. Project staff will then send a form (fax/email) to the potential participant's primary care physician describing the study and requesting clearance for participation. Final eligibility based on BMI will be confirmed at baseline testing, using height and fasting weight assessed with participants wearing hospital gowns. Participants in each clinic will be randomized, stratified by sex, to one of the three study arms. The randomization sequence will be generated by an independent statistician, sent to the project coordinator and concealed until intervention groups are assigned.

Community assessments-Physical activity/healthy eating

Prior to initiating the intervention we will evaluate environmental facilitators/barriers to both PA and healthy eating in the area surrounding each participating clinic. The Rural Active Living Assessment tools which include The Street Segment Assessment, Town-wide Assessment, and The Town Program and Policy Assessment (51) will be used to assess the built environment, town characteristics, community programs, and policies and resources that can influence PA. Facilitators/barriers to healthy eating will be based on surveys with both clinic health professionals and patients. Food availability will be assessed using a validated survey developed for the Multi-Ethnic Study of Atherosclerosis to measure perceived availability of healthy food options and access to food shopping in an individual's neighborhood (52, 53). Information gathered related to the PA or healthy eating environment will be used to tailor our intervention to each participating clinic.

INTERVENTION

Health educator selection/training. Our research team, in collaboration with clinic/health system management, will select a staff member with an interest in delivering weight management, e.g., nurse, nurse practitioner, physician's assistant, registered dietician, exercise physiologist, or a qualified professional from the local community, e.g. registered dietician, certified diabetes or health educator, to serve as health educator. Participating clinics, or community professionals will be compensated for time devoted to this project. The selected health educator in each clinic will deliver all three interventions, i.e., GP and IP, and EUC, to minimize the potential for health educator effects. Health educators will be provided with a detailed intervention notebook which outlines the topics for each session, provides answers to common participant questions, and strategies for engaging participants in the intervention.

Health educators will be trained by our research team during an initial one-day, on-site session at each clinic, and four one-hour sessions conducted via FaceTime® prior to initiating the intervention. On-site training will provide an overview of the intervention notebook, discuss the biologic/medical impacts of weight loss and strategies for effective intervention delivery via GP or IP calls, or face-to-face that will be utilized in the EUC arm. Audio recordings from GP sessions from our completed NIH trial which compared GP and face-to-face delivery of weight management (34) will be utilized to demonstrate effective leadership and facilitation techniques in the GP setting. Strategies for conducting IP and face-to-face interventions will be demonstrated by role playing with a member of our research team with the health educator and clinic staff as participants. The four follow-up training sessions will be used to reinforce strategies taught during on-site training and to further model teaching strategies used in GP, IP and face-to-face sessions. Prior to initiating the intervention all health educators will be required to successfully conduct three simulated sessions of each of the three intervention arms, i.e. GP, IP, and EUC in which members of the research team will serve as participants. A standardized checklist, including the important skills/strategies taught during training, will be used to assure all health educators demonstrate mastery of these skills. The research team will be available for consultation with health educators to address issues that may arise during the interventions.

Theoretical model. The intervention will be grounded in Social Cognitive Theory, a triadic, dynamic model that indicates an individual's behavior is uniquely determined by the reciprocal interaction of personal, behavioral, and environmental factors, to effect change in energy intake (EI) and PA (54, 55). We will focus on social cognitive techniques which have been shown to be most effective for changing EI and PA including intention formation, goal setting, self-monitoring (diet, PA, weight), and participant feedback relative to intervention compliance (56). These techniques will be enhanced by employing behavior shaping (gradually modifying diet and PA), social support, and stimulus control (strategies to decrease cues for less desirable and increase cues for more desirable diet and PA behaviors). Additionally, cognitive strategies will be used to increase self-efficacy and to deal with social relationships affected by weight, such as identifying/confronting self-sabotage attempts, responding to stress with non-food techniques, relapse prevention strategies to teach participants to recognize precursors and consequences of lapses, and develop plans for addressing high risk situations. The intervention is also informed by both social ecologic (57) and social network theories (58) as content will be tailored to both the physical and social environment of participants.

General Description. All intervention arms will complete weight loss (6 mos.) and weight maintenance (12 mos.). Weight will also be evaluated following a 6 mos. no contact follow-up. A comparison of contact format and intervention session frequency and duration between intervention arms is shown in Table 2. The protocols for reducing EI, increasing PA, content presented during behavioral sessions, and self-monitoring diet, weight, and PA will be identical in the GP and IP arms. Participants in both the GP and IP arms will receive identical notebooks that will include detailed instructions for the weight loss and weight maintenance diets including recipes, instructions for PA, self-monitoring diet and PA, and the schedule for behavioral sessions. The notebooks will be organized by behavioral session and contain handouts, worksheets, and assignments specific to each session.

Group and individual phone arms.

Diet-Weight loss (0-6 mos.). Energy intake will be prescribed at 1,200-1,500 kcal/d for women and 1,500-1,800 kcal/d for men as recommended by current weight management guidelines from the American Heart Association/American College of Cardiology/The Obesity Society (30). Participants will be asked to consume a minimum daily total of two portion controlled entrées (~200 to 300 kcal each, saturated fat ≤ 3g, sodium ≤ 600 mg), two low calorie shakes (~100 kcal

each), at least five one-cup servings of fruits/vegetables, and ad libitum non-caloric beverages to achieve their energy reduction goals. Participants will be asked to purchase entrées from a list maintained by the study dietician that satisfies these caloric/fat/sodium requirements, as well as fruits/vegetables, and non-caloric beverages. Two low calorie shakes per day (Profile by Sanford Health, Sioux Falls, SD) will be provided to participants during weight loss (0-6 mos.). Participants will order shakes, which are available in a variety of flavors, either on-line or by telephone. Shakes will be delivered by the United Parcel Service to participant's residence. The study will provide the shakes and shipping during weight loss (0-6 mos.) The list of available frozen and shelf stable entrées currently contains over 180 entrées from numerous manufacturers, e.g., Healthy Choice™, Smart Ones ™, Michelina's ™ etc., which meet the caloric, saturated fat and sodium requirements. This list will be updated by the study dietician as new products become available. The recommended entrées are affordable and available at most grocery stores at a cost of $2-$4 each, which may be an important consideration for individuals in rural areas where household income is often low (6). The Academy of Nutrition and Dietetics Evidence Analysis Library indicates strong, consistent, supportive evidence (Grade I) that a portion controlled entrée approach results in significantly greater weight loss and maintenance compared with meal plan diets, and are especially useful for individuals who have difficulty with food selection and portion control (59). This approach simplifies food shopping and preparation, and can be incorporated as part of a long-term dietary plan. The nutritional information on the product labels (calories, fat, protein, etc.) simplifies adherence to specific energy and nutrient recommendations. The use of portion controlled entrées and shakes for weight loss has been criticized for inadequately preparing participants to deal with meal planning and portion control required for successful weight loss maintenance. However, this approach requires decision making regarding shopping and preparation of fruit/vegetables, beverages and also provides participants with an understanding of appropriate portion size. Numerous trials by our group (34, 48, 60) and others (61-63) have reported excellent maintenance of weight initially lost using portion controlled entrées and low calorie shakes. The study dietician will assure that all diets are both energy and nutritionally adequate based on current dietary guidelines (64). Participants for whom additional weight loss would be contraindicated, e.g., BMI of ≤ 22 kg/m^2 will be placed on a weight maintenance diet at any time during the 18 mo. intervention. Those who continue to lose weight will be referred to appropriate health professionals/agencies, and may be dismissed from the trial.

Diet- Weight maintenance and no-contact follow-up (7-24 mos.). Participants will be encouraged to consume a diet with an energy level designed to maintain weight loss. Recommended EI will be based on the resting metabolic rate (RMR) equation of Mifflin-St Jeor (65) adjusted for activities of daily living (RMR x 1.4-1.6) as participants will have a routine PA program. Participants will be encouraged to continue using commercially available portion controlled entrées, low calorie shakes, or transition to a meal plan or combination portion controlled entrée/meal plan diet. A meal plan diet, based on the United States Department of Agriculture's MyPlate guidelines (66) will prescribe amounts of grains, proteins, fruits, vegetables, dairy, and fats to achieve the desired level of EI. Participants experiencing weight gain will be counseled to improve compliance with the diet and PA protocols.

Physical activity (0- 24 mos.). We will prescribe a progressive moderate intensity PA program, e.g., brisk walking, jogging, biking, etc., as recommended in the "2009 ACSM Position Stand on Physical Activity Interventions for Weight Loss and Prevention of Weight Regain in Adults" (67). The prescribed activities can be completed in rural communities that frequently lack public or commercial exercise facilities. Prescribed PA will progress from 45 min/wk. during week 1 to 225 min/wk. at 4 mos. and remain at 225 min/wk. for the duration of the 18 mo. intervention and 6 mo. no contact follow-up. As the intervention progresses, participants will be

encouraged to try new activities and/or target an event such as a 5 or 10K race, charity walks, etc., to provide variety and motivation. Pedometers will be provided as a motivational tool and to track steps across the 18 mo. active intervention.

Self-monitoring. Participants will be ask to self-monitor diet, i.e., the number of portion controlled entrées, shakes and servings of fruits and vegetables/day, PA, i.e., pedometer steps, self-report minutes of activity, and body weight across the 6 mo. weight loss and 12 mo. weight maintenance interventions. Participants will report this data twice each week using a web-based form on our laboratory website or by phone calls to health educators for those without internet access. This information will summarized by research staff and made available to clinic health educators for use during behavioral counseling sessions.

Group phone intervention: Delivery/session content. The GP intervention will be delivered to 12-15 participants during a 45 minute call weekly from 0-6 mos. and biweekly from 7-18 mos. using the MaestroConference® software platform (Oakland, CA) that allows group audio conferences to be accessed by phone. Approximately five minutes prior to scheduled meetings, typically late afternoon or early evening, participants will call a toll-free line and enter a unique code number to join the meeting. Participants will be required to remain on the call for the duration of each session to be considered as having attended the session. Call duration for each participant is monitored by the Maestro software. Each meeting will include a check-in question to generate discussion regarding diet and PA, a review of participants self-monitored diet, weight and PA data reported since the previous meeting, a lesson on a weight management topic, and an experiential learning assignment requiring problem solving, or the practice of behavioral strategies, to be completed prior to the next meeting. Sample topics include: energy density (increase volume, not calories), obtaining fruits and vegetables in rural communities, exercising in rural communities, eating/exercising on the go, etc. Several sessions at the end of the weight loss phase (mo. 6) will include discussions regarding complying with a conventional diet, i.e., meal planning, food shopping, meal preparation, portion control, etc. During weight maintenance (7-18 mos.) group sessions will focus on planning and following a meal plan diet with or without incorporation of portion controlled entrées/shakes, and cardinal behaviors for successful weight maintenance such as self-monitoring, regular PA, eating on weekends/vacations, and controlling EI on special occasions and holidays, etc.

Individual phone intervention: Delivery/session content. The IP intervention will be delivered via brief, i.e., ~15 min. scheduled phone calls weekly from 0-6 mos. and biweekly from 7-18 mos.. Prior to each call participants will be asked to read a lesson in the study notebook. Lesson topics will parallel those in the GP intervention and focus on weight loss over mos. 0-6 and weight maintenance during mos. 7-18. During each call, health educators will highlight the major points of the lesson, review self- monitoring data relative to weight, diet and PA, and problem solve, if necessary. Thus, the IP intervention is predominately self-directed with minimal education and support from the health educator. In contrast, the GP intervention includes health educator directed, 45 min educational/behavioral sessions, and provides both health educator and group support.

Enhanced usual care

Delivery/session content. Health educators will conduct individual face-to-face meetings (~45 min) at the clinic site, four times across 18 mos. These sessions will be held in conjunction with outcome assessments to minimize participant travel. Participants will receive printed materials from public health organizations such as the Weight-Control Information Network (68) and NIH Aim for a Healthy Weight (69) that include topics such as healthy eating, portion size, and MyPlate recommendations, (i.e.being physically active, self-monitoring, and problem-solving) (66). Pedometers and forms to self-monitor weight, diet and PA will also be provided; however,

self-monitoring will not be required and will be shared with health educators only if desired. During each session health educators will discuss participant's progress towards their weight loss goals, review salient points from the written materials, assist participants with developing strategies to overcome any compliance barriers they may experience, and answer questions.

Diet-Weight loss (0-6 mos.). Energy intake will be prescribed at 1,200-1,500 kcal/d for women and 1,500-1,800 kcal/d for men using a high volume, lower fat diet (20-30% EI) meal plan diet as recommended by the Academy of Nutrition and Dietetics (70) and the USDA's MyPlate approach (66). Participants will be provided examples of meal plans consisting of suggested servings of proteins, grains, fruits and vegetables, dairy, and fats based on their energy needs, and will be counseled on appropriate portion sizes.

Diet- Weight maintenance and no-contact follow-up (7-24 mos.). Participants will be encouraged to continue with a meal plan diet with an energy level designed to maintain weight loss. Recommended EI will be based on the RMR equation of Mifflin-St Jeor (65) adjusted for activities of daily living (RMR x 1.4-1.6) as participants will have a routine PA program. Meal plans with suggested servings of protein, grains, fruits and vegetables, dairy, and fats to achieve specific energy requirements will be provided. Similar to the GP and IP arms, a participant for whom additional weight loss would be contraindicated, e.g., BMI of ≤ 22 kg/m^2 will be placed on a weight maintenance diet at any time during the 18 mo. intervention. Those who continue to lose weight will be referred to appropriate health professionals/agencies, and may be dismissed from the trial.

Physical activity (0- 24 mos.). Participants will be asked to complete moderate intensity PA, e.g., walking, jogging, biking etc., that will progress gradually from 45 min/wk. at baseline to 150 min/wk. at mo. 4 and remain at 150 min/wk. for the duration of the 24 mo. trial. The 150 min/wk. is based on the current U.S. Department of Health and Human Services PA guidelines of 150 min/wk. of moderate-intensity PA for overall health (71). We recognize that this recommendation differs from the 225min/wk. recommended for the GP and IP arms. Based on our observations of both rural and urban health clinics, physicians and staff rarely recommend greater than 150 min/wk. of PA for their patients. Thus, we chose 150 min/wk. to represent "real world" clinical practice.

Participant retention strategies.

Participants will complete a "contact form" including basic information, i.e., name, address, phone number, email. Participants in the GP or IP arms who miss > three consecutive behavioral sessions will be contacted by phone, text or email (maximum of three attempts). A maximum of three attempts will also be made to contact participants in the EUC arm who do not attend a scheduled session.

Outcome assessments.

Outcomes will be obtained at each participating clinic. As outlined in Table 3, most outcomes will be assessed at 0, 6, 12, and 18 months. Physical measures, i.e., height, weight, waist circumference, and blood pressure, will be obtained between 7-11 a.m., following a minimum 12-hour fast, by trained research assistants blinded to condition. Research assistants will receive refresher training and complete reliability assessments for physical measures two to three times each year.

Anthropometric measures. Weight will be measured with a digital scale accurate to ± 0.1 kg (Befour Inc. #PS6600, Saukville, WI) with participants in a hospital gown. Height will be measured with a stadiometer (Model #IP0955, Invicta Plastics Limited, Leicester, UK). The average of two measures within 0.25 cm will be recorded. Body mass index (BMI) will be

calculated as weight (kg) divided by height (m^2). Waist circumference will be measured with an anthropometric tape using the procedures described by Lohman et. al. (72). Three measurements will be obtained with the outcome recorded as the average of the closest 2 measures.

Blood chemistry/ blood pressure. Fasting blood samples will be obtained by a clinic phlebotomist. Analysis of HDL and LDL cholesterol, triglycerides, glucose, and HbA1c (diabetics) will be completed by the commercial laboratories that are contracted by each participating clinic. Blood pressure will be obtained in duplicate, with an automated sphygmomanometer (DinaMap ProCare 100, General Electric Healthcare, Chicago, IL) using the National Health and Nutrition Examination Survey (NHANES) blood pressure protocol (73).

Compliance with diet recommendations. Energy and macronutrient intake will be assessed using the self-administered, web-based VioScreen Graphical Food Frequency System (Viocare Technologies, Inc., Princeton, NJ). Participants will complete the survey at a computer in a private room during the clinic assessment visit, or at home on a tablet or personal computer within one or two days following the clinic visit. Participants who fail to complete the survey within that time frame will receive email and telephone reminders. Assessment of nutrient intake using VioScreen is correlated with assessments obtained from a traditional paper and pencil food frequency questionnaire: total fat = 0.82, saturated fat = 0.84, protein = 0.67, carbohydrate = 0.79, alcohol = 0.90 (74).

Compliance with physical activity recommendations. Participants will wear an ActiGraph Model GT3X+ (ActiGraph LLC, Pensacola, FL) portable tri-axial accelerometer on a belt over the non-dominant hip, at the anterior axillary line, during waking hours for seven consecutive days, with the exception of bathing, swimming and contact sports. The ActiGraph accelerometer has been shown to provide valid and reliable assessments of PA in adults (75-77). A 7-day monitoring period provides a reliable estimate of moderate-to-vigorous PA (78-80). ActiGraphs will be initialized and downloaded using ActiLife Software version 6.13.3 or higher and set to collect in the raw data mode at 60 Hz. ActiGraph data will be processed using the protocol used for adults in the 2003-2004 and 2005-2006 cycles of NHANES (81, 82). Data will be aggregated over 60-sec epochs. The following intensity cut-points will be used: sedentary (< 1.0 METs; ≤ 100 counts/min), light (1.1-2.99 METs; 101-2019 counts/min.), moderate (3.0-5.99 METs; 2020-5998 counts/min) and vigorous ≥ 6 METs; ≥ 5999 counts/min) (81, 82). Non-wear time will be defined as at least 60 consecutive minutes of zero counts, with allowance for 1-2 min. of counts between 0 and 100. Counts ≥ 20,000/min will be considered spurious and will be deleted (83). We have a custom SAS program to complete these analyses. ActiGraphs, with instructions on their use, will be distributed to participants at their scheduled assessment visit clinic. Participants will be asked to wear the ActiGraph for seven consecutive days, beginning the day following the clinic visit, and return the ActiGraph to the research team using a postage pre-paid padded envelope provided.

Questionnaires. The following instruments will be used to assess behavioral factors that may impact weight management: Health Related Quality of life (HRQOL) will be assessed using the Short Form 36 (SF36) (84). Daily stress associated with eating, i.e., planning/preparing, monitoring nutrients, concerns about eating correctly, will be assessed with the Nutrition Hassles Questionnaire (85). Finally, the implementation of Social Cognitive Theory will be assessed by measuring the “active” ingredient, self-efficacy, using the Weight Efficacy Lifestyle Scale (WELS) (86), Barriers Self Efficacy (BARSE) (87), and the Exercise Self-Efficacy Scale (EXSE) (88). Acceptable construct validity and internal consistency of these instruments have been established (84, 85, 87-90). Questionnaires will be completed online using REDCap

software during the clinic visit by participants with no home internet access or at home within one or two days following the clinic visit for participants with home internet access.

Process evaluation

As described below, process evaluation will monitor the fidelity of intervention delivery, the extent to which the intervention was implemented and received, and the extent to which participants actively engaged in the intervention across time.

Intervention fidelity. To assure quality control and standardization of intervention delivery, all GP, IP, and EUC sessions will be audio recorded. Research staff will randomly review one session each month in the GP and IP arms, and 25% of sessions in the EUC arm for each health educator. Recordings will be compared with a standardized checklist of specific content and time scheduled for delivery of that content. Health educators who fail to deliver at least 80% of scheduled content for the scheduled duration will be required to receive additional training from the research team that will be delivered remotely via FaceTime®. Health educators who fail to satisfy the intervention delivery criteria after receiving additional training will be replaced by another clinic staff member or a qualified community professional. A member of the research team will be available to substitute for health educators who are unable to deliver a session, or while a new health educator is trained in the event a health educator is dismissed or leaves the clinic. Health educator absences and turnover will be tracked and the effect on weight change will be evaluated in the analysis.

Implementation. The extent to which the intervention was implemented and received will be assessed using records of participant attendance at scheduled sessions that will be maintained by health educators.

Engagement. In addition to attendance, which will be tracked by health educators in all three intervention arms, participant engagement in the GP and IP arms will be estimated by participant compliance with the self-monitoring protocol, i.e., the frequency of reporting body weight, diet (portion controlled entrées, low calorie shakes, fruits and vegetables) and PA (pedometer steps, activity minutes).

Structured interviews. A convenience sample of 20% of participants, stratified by intervention arm, and a sample of clinic staff, e.g., health educators, physicians etc., will be invited to participate in structured interviews at both 6 and 18 months. Interviews will be conducted by phone and will be designed to gather information that might be useful in improving the interventions, and/or implementing the interventions in rural clinics. Topics will include, preference for intervention format, length, difficulties in complying with intervention components, suggestions for improving the intervention, overall satisfaction with the intervention, including the diet and PA recommendations, behavior session frequency, duration and content, and health educator performance. Information regarding resource use associated with participating and delivering the intervention for inclusion in the cost analysis will also be collected.

Cost considerations

A potential advantage of remote delivery of weight management, e.g., GP or IP calls may be lower fixed and variable costs for both participants and providers. Fixed costs are independent of the number of participants while variable costs are directly associated with the number of participants enrolled (91). A process flow chart will be created and validated by consensus of the research team to assure a complete accounting of resources used in all intervention groups (92). Cost, cost effectiveness, and contingent valuation analyses will be completed at both 6 and 18 mos. as these costs may differ between the weight loss and weight maintenance phases of the interventions. The cost perspective for all analyses will be societal which includes the

value of participant time, as this time cannot be used for work or leisure. Both provider and participant costs will be collected prospectively.

Provider costs. The cost of space to conduct sessions with participants in the EUC arm, and to deliver both the GP and IP arms, will be estimated by multiplying the local market values for office per square foot by the amount of space utilized. Monthly billing statements will provide an estimate of utility costs including heat, electric, computer and internet services. The cost of provider time, i.e. wages and benefits, will be estimated as the number of hours worked obtained from provider maintained logs, multiplied by the provider's wage. Cost associated with purchase and shipping of the low calorie shakes provided to participants in both the GP and IP arms will also be tracked with billing and expense records.

Participant costs. The cost of participant time required to attend GP or IP sessions, or travel to and attend in-person sessions required in the EUC arm, will be estimated from self-reports of time spent in these activities multiplied by the median wage in the region. Transportation costs will be estimated from self-reported driving mileage multiplied by the federal mileage reimbursement rate.

Cost analysis. Differences in total costs and cost effectiveness; i.e., cost/kg weight loss between intervention arms will be evaluated using a one-way analysis of variance (ANOVA). We will also make qualitative comparison between the cost effectiveness of our interventions and others reported in the literature, such as the Diabetes Prevention Program (93). Weight loss represents only one potential benefit associated with participation in a weight management program. Other potential benefits included improved health, enhanced attractiveness, increased vitality and productivity etc. We will use contingent evaluation analysis where participants express preferences for hypothetical programs with different attributes such as costs, time, delivery method, and magnitude of weight loss to determine how differences in these affect preferences for the GP, IP and enhanced usual weight management strategies. Contingent valuation data will be analyzed using conditional logit analysis, with adjustments for clustering of observations within clinics.

Statistical power and analysis

Statistical power. Differences in weight loss at six mos. between participants randomized to the IP or EUC, and GP or IP are of primary interest. We hypothesize that six month weight loss will average 2 kg, 8 kg, and 12 kg in the EUC, IP, and GP arms, respectively, with a common standard deviation for weight change of 7 kg (34) (35). Statistical power was determined assuming a type 1 error rate of 2.5% for each of our two primary comparisons. Based on these assumptions, randomization of 200 participants with a 2:2:1 allocation; GP (n=80), IP (n=80), EUC (n=40) will provide 98% power to detect significantly greater weight loss in IP versus EUC, and 91% power to detect significantly greater weight loss in GP versus IP. The global F-test for a one-way ANOVA provides greater than 99% power under these assumptions. The primary analysis will be intent-to-treat with imputation of missing data using multiple imputation techniques. However, a completers only analysis, with a 20% loss to follow-up, will still provide 95% power for the IP-EUC, and 83% power for the GP-IP comparisons.

Analysis plan. A global one-way ANOVA will be followed with two pairwise t-tests on the two comparisons of interest, IP versus EUC, and GP versus IP. Statistical significance for each pairwise comparisons will be $p \leq 0.025$; however, all other analyses will be conducted at $p < 0.05$. These primary analyses will be intent-to-treat utilizing multiple imputation for missing data and to determine corresponding *p*-values. In addition to the intent-to-treat analysis, a completers only analysis will be performed, i.e., participants with weight at 6 months. Secondarily, we will compare weight between the three study arms across 24 months using a mixed linear model,

assuming an autoregressive correlation structure of weight over time, controlling for baseline weight, treatment group and time as covariates. The global comparison across the three arms will be followed by two pairwise comparisons of interest, i.e., IP versus EUC, and GP versus IP. Independent comparisons of change in each chronic disease risk factor, i.e., waist circumference, triglycerides, HDL cholesterol, blood pressure, and fasting glucose at 6, 12, and 18 mos., across the 3 intervention arms will be completed using a mixed linear model, assuming an autoregressive correlations structure. We will also compare Quality of life (SF-36), daily stress associated with eating (Nutrition Hassles Questionnaire), self-efficacy for weight change (WELS), self-efficacy for exercise (EXES), and self-efficacy for overcoming barriers to exercise (BARSE) among the three intervention arms across 24 months using a using a mixed linear model assuming an autoregressive correlation structure both unadjusted and adjusted for covariates. A variety of exploratory analyses, as deemed appropriate by the principal investigator and the project biostatistician, e.g., assessment of the impact of health educator absences and turnover, community environment for healthy eating and PA etc. on weight loss outcomes, will be performed. Analyses will be completed using SAS version 9.4 or higher.

Missing data. We will determine if the proportion of participants lost to follow-up differs by intervention arm and/or sex, and compare demographic characteristics between those lost to follow-up and completers. If there are differences across treatment groups, we will examine demographic characteristics, i.e., sex, age, magnitude of weight loss, between completers and those lost to follow-up, to determine if there are significant differences ($p < 0.05$) in those characteristics. If missing data are related to intervention group and/or demographic characteristics, we will use model based multiple imputation; otherwise, traditional multiple imputation will be used.

REFERENCES

1. Bureau USC. Urban, Urbanized are, Urban Cluster, and Rural Population, 2010 and 2000. Washington, DC: U.S. Census Bureau; 2010.

2. Kenney MK, Wang J, Iannotti R. Residency and racial/ethnic differences in weight status and lifestyle behaviors among US youth. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2014;30(1):89-100. Epub 2014/01/05. doi: 10.1111/jrh.12034. PubMed PMID: 24383488; PMCID: PMC4696387.

3. Johnson JA, 3rd, Johnson AM. Urban-rural differences in childhood and adolescent obesity in the United States: a systematic review and meta-analysis. Childhood obesity (Print). 2015;11(3):233-41. Epub 2015/05/01. doi: 10.1089/chi.2014.0085. PubMed PMID: 25928227.

4. Liu JH, Jones SJ, Sun H, Probst JC, Merchant AT, Cavicchia P. Diet, physical activity, and sedentary behaviors as risk factors for childhood obesity: an urban and rural comparison. Childhood obesity (Print). 2012;8(5):440-8. Epub 2012/10/16. doi: 10.1089/chi.2012.0090. PubMed PMID: 23061499.

5. Trivedi T, Liu J, Probst J, Merchant A, Jhones S, Martin AB. Obesity and obesity-related behaviors among rural and urban adults in the USA. Rural and remote health. 2015;15(4):3267. Epub 2015/10/16. PubMed PMID: 26458564.

6. Meit M, Kundson A, Gilbert T, Txy-Chiy Yu A, Tanenbaum E, Ormson E, TenBroeck S, Bayne A, Popat S. The 2014 Update of the Rural-Urban Chartbook: The Rural Health Reform Policy Research Center; 2014 [cited 2017 May 31]. Available from: http://www.ruralhealthresearch.ogr/.

7. Befort CA, Nazir N, Perri MG. Prevalence of obesity among adults from rural and urban areas of the United States: findings from NHANES (2005-2008). The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2012;28(4):392-7. Epub 2012/10/23. doi: 10.1111/j.1748-0361.2012.00411.x. PubMed PMID: 23083085; PMCID: PMC3481194.

8. Matthews KA, Croft JB, Liu Y, Lu H, Kanny D, Wheaton AG, Cunningham TJ, Khan LK, Caraballo RS, Holt JB, Eke PI, Giles WH. Health-Related Behaviors by Urban-Rural County Classification - United States, 2013. Morbidity and mortality weekly report Surveillance summaries (Washington, DC : 2002). 2017;66(5):1-8. Epub 2017/02/06. doi: 10.15585/mmwr.ss6605a1. PubMed PMID: 28151923.

9. Lutfiyya MN, Chang LF, Lipsky MS. A cross-sectional study of US rural adults' consumption of fruits and vegetables: do they consume at least five servings daily? BMC public health. 2012;12:280. Epub 2012/04/12. doi: 10.1186/1471-2458-12-280. PubMed PMID: 22490063; PMCID: PMC3365871.

10. O'Connor A, Wellenius G. Rural-urban disparities in the prevalence of diabetes and coronary heart disease. Public health. 2012;126(10):813-20. Epub 2012/08/28. doi: 10.1016/j.puhe.2012.05.029. PubMed PMID: 22922043.

11. Krishna S, Gillespie KN, McBride TM. Diabetes burden and access to preventive care in the rural United States. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2010;26(1):3-11. Epub 2010/01/29. doi: 10.1111/j.1748-0361.2009.00259.x. PubMed PMID: 20105262.

12. Trivedi T, Liu J, Probst JC, Martin AB. The metabolic syndrome: are rural residents at increased risk? The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2013;29(2):188-97. Epub 2013/04/05. doi: 10.1111/j.1748-0361.2012.00422.x. PubMed PMID: 23551649.

13. Kulshreshtha A, Goyal A, Dabhadkar K, Veledar E, Vaccarino V. Urban-rural differences in coronary heart disease mortality in the United States: 1999-2009. Public health reports (Washington, DC : 1974). 2014;129(1):19-29. Epub 2014/01/02. doi: 10.1177/003335491412900105. PubMed PMID: 24381356; PMCID: PMC3863000.

14. Bolin JN, Bellamy GR, Ferdinand AO, Vuong AM, Kash BA, Schulze A, Helduser JW. Rural Healthy People 2020: New Decade, Same Challenges. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2015;31(3):326-33. Epub 2015/05/09. doi: 10.1111/jrh.12116. PubMed PMID: 25953431.

15. Boehmer TK, Lovegreen SL, Haire-Joshu D, Brownson RC. What constitutes an obesogenic environment in rural communities? American journal of health promotion : AJHP. 2006;20(6):411-21. Epub 2006/07/29. PubMed PMID: 16871821.

16. Tai-Seale T, Chandler C. Nutrition and Overweight Concerns in Rural Areas: A Literature Review. Rural Health People 2010: A companion document to Healthy People 2010.

College Station, TX: The Texas A&M University System Health Science Center, Schools of Rural Public Health, Southwest Rural Health Research Center; 2003. p. 115-30.

17. Klitzman P, Armstrong B, Janicke DM. Distance as a predictor of treatment attendance in a family based pediatric weight management program in rural areas. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2015;31(1):19-26. Epub 2014/07/22. doi: 10.1111/jrh.12078. PubMed PMID: 25040534.

18. Service ER. Rural America at a Glance: 2016 Edition. In: Agriculture USDo, editor. Washington, DC2016.

19. Cafer AM, Kaiser ML. An analysis of differences in predictors of food affordability between rural and urban counties. Journal of Poverty. 2016;20(1):34-55.

20. Hardin-Fanning F, Rayens MK. Food cost disparities in rural communities. Health promotion practice. 2015;16(3):383-91. Epub 2014/10/12. doi: 10.1177/1524839914554454. PubMed PMID: 25305093; PMCID: PMC4393346.

21. Seguin R, Connor L, Nelson M, LaCroix A, Eldridge G. Understanding barriers and facilitators to healthy eating and active living in rural communities. Journal of nutrition and metabolism. 2014;2014:146502. Epub 2015/01/13. doi: 10.1155/2014/146502. PubMed PMID: 25574386; PMCID: PMC4276670.

22. Buro B, Gold A, Contreras D, Keim AL, Mobley AR, Oscarson R, Peters P, Procter S, Smathers C. An Ecological Approach to Exploring Rural Food Access and Active Living for Families With Preschoolers. Journal of nutrition education and behavior. 2015;47(6):548-54.e1. Epub 2015/11/14. doi: 10.1016/j.jneb.2015.08.020. PubMed PMID: 26566097.

23. Lenardson JD, Hansen AY, Hartley D. Rural and Remote Food Environments and Obesity. Current obesity reports. 2015;4(1):46-53. Epub 2015/12/03. doi: 10.1007/s13679-014-0136-5. PubMed PMID: 26627089.

24. Seguin RA, Morgan EH, Connor LM, Garner JA, King AC, Sheats JL, Winter SJ, Buman MP. Rural Food and Physical Activity Assessment Using an Electronic Tablet-Based Application, New York, 2013-2014. Preventing chronic disease. 2015;12:E102. Epub 2015/07/03. doi: 10.5888/pcd12.150147. PubMed PMID: 26133645; PMCID: PMC4492214.

25. Hansen AY, Umstattd Meyer MR, Lenardson JD, Hartley D. Built Environments and Active Living in Rural and Remote Areas: a Review of the Literature. Current obesity reports. 2015;4(4):484-93. Epub 2015/09/14. doi: 10.1007/s13679-015-0180-9. PubMed PMID: 26364307.

26. Robinson JC, Carson TL, Johnson ER, Hardy CM, Shikany JM, Green E, Willis LM, Marron JV, Jr., Li Y, Lee CH, Baskin ML. Assessing environmental support for better health: active living opportunity audits in rural communities in the southern United States. Prev Med. 2014;66:28-33. Epub 2014/06/24. doi: 10.1016/j.ypmed.2014.05.021. PubMed PMID: 24954744; PMCID: PMC4138048.

27. King KE, Clarke PJ. A disadvantaged advantage in walkability: findings from socioeconomic and geographical analysis of national built environment data in the United States. American journal of epidemiology. 2015;181(1):17-25. Epub 2014/11/22. doi: 10.1093/aje/kwu310. PubMed PMID: 25414159; PMCID: PMC4334827.

28. Pitts SB, Vu MB, Garcia BA, McGuirt JT, Braxton D, Hengel CE, Huff JV, Keyserling TC, Ammerman AS. A community assessment to inform a multilevel intervention to reduce cardiovascular disease risk and risk disparities in a rural community. Family & community health. 2013;36(2):135-46. Epub 2013/03/05. doi: 10.1097/FCH.0b013e31828212be. PubMed PMID: 23455684; PMCID: PMC4155752.

29. Cai Y, Richards EA. Systematic Review of Physical Activity Outcomes of Rural Lifestyle Interventions. Western journal of nursing research. 2016;38(7):909-27. Epub 2016/01/06. doi: 10.1177/0193945915625922. PubMed PMID: 26728043.

30. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Journal of the American College of Cardiology. 2014;63(25 Pt B):2985-3023. Epub 2013/11/19. doi: 10.1016/j.jacc.2013.11.004. PubMed PMID: 24239920.

31. Leblanc ES, O'Connor E, Whitlock EP, Patnode CD, Kapka T. Effectiveness of primary care-relevant treatments for obesity in adults: a systematic evidence review for the U.S. Preventive Services Task Force. Annals of internal medicine. 2011;155(7):434-47. Epub 2011/10/05. doi: 10.7326/0003-4819-155-7-201110040-00006. PubMed PMID: 21969342.

32. Booth HP, Prevost TA, Wright AJ, Gulliford MC. Effectiveness of behavioural weight loss interventions delivered in a primary care setting: a systematic review and meta-analysis. Fam Pract. 2014. Epub 2014/10/10. doi: 10.1093/fampra/cmu064. PubMed PMID: 25298510.

33. Lambourne K, Washburn RA, Gibson C, Sullivan DK, Goetz J, Lee R, Smith BK, Mayo MS, Donnelly JE. Weight management by phone conference call: a comparison with a traditional face-to-face clinic. Rationale and design for a randomized equivalence trial. Contemporary clinical trials. 2012;33(5):1044-55. Epub 2012/06/06. doi: 10.1016/j.cct.2012.05.014. PubMed PMID: 22664647; PMCID: Pmc3408567.

34. Donnelly JE, Goetz J, Gibson C, Sullivan DK, Lee R, Smith BK, Lambourne K, Mayo MS, Hunt S, Lee JH, Honas JJ, Washburn RA. Equivalent weight loss for weight management programs delivered by phone and clinic. Obesity (Silver Spring, Md). 2013;21(10):1951-9. Epub 2013/02/15. doi: 10.1002/oby.20334. PubMed PMID: 23408579; PMCID: Pmc4442605.

35. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. Eating behaviors. 2010;11(1):11-7.

36. Minniti A, Bissoli L, Di Francesco V, Fantin F, Mandragona R, Olivieri M, Fontana G, Rinaldi C, Bosello O, Zamboni M. Individual versus group therapy for obesity: comparison of dropout rate and treatment outcome. Eat Weight Disord. 2007;12(4):161-7. Epub 2008/01/30. PubMed PMID: 18227637.

37. Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD. Individual versus group therapy for obesity: effects of matching participants to their treatment preferences. J Consult Clin Psychol. 2001;69(4):717-21. Epub 2001/09/12. PubMed PMID: 11550739.

38. Cresci B, Tesi F, La Ferlita T, Ricca V, Ravaldi C, Rotella CM, Mannucci E. Group versus individual cognitive-behavioral treatment for obesity: results after 36 months. Eat Weight Disord. 2007;12(4):147-53. Epub 2008/01/30. PubMed PMID: 18227635.

39. Baernholdt M, Yan G, Hinton I, Rose K, Mattos M. Quality of life in rural and urban adults 65 years and older: findings from the National Health and Nutrition Examination survey. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2012;28(4):339-47. Epub 2012/10/23. doi: 10.1111/j.1748-0361.2011.00403.x. PubMed PMID: 23083080; PMCID: PMC3615459.

40. Wadden TA, Volger S, Sarwer DB, Vetter ML, Tsai AG, Berkowitz RI, Kumanyika S, Schmitz KH, Diewald LK, Barg R, Chittams J, Moore RH. A two-year randomized trial of obesity treatment in primary care practice. The New England journal of medicine. 2011;365(21):1969-79. Epub 2011/11/16. doi: 10.1056/NEJMoa1109220. PubMed PMID: 22082239; PMCID: Pmc3282598.

41. Wadden TA, West DS, Delahanty L, Jakicic J, Rejeski J, Williamson D, Berkowitz RI, Kelley DE, Tomchee C, Hill JO, Kumanyika S. The Look AHEAD study: a description of the lifestyle intervention and the evidence supporting it. Obesity (Silver Spring, Md). 2006;14(5):737-52. Epub 2006/07/21. doi: 10.1038/oby.2006.84. PubMed PMID: 16855180; PMCID: Pmc2613279.

42. Wadden TA, West DS, Neiberg RH, Wing RR, Ryan DH, Johnson KC, Foreyt JP, Hill JO, Trence DL, Vitolins MZ. One-year weight losses in the Look AHEAD study. Factors associated with success. Obesity. 2009;17(4):713-22.

43. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. The New England journal of medicine. 2002;346(6):393-403. Epub 2002/02/08. doi: 10.1056/NEJMoa012512. PubMed PMID: 11832527; PMCID: Pmc1370926.

44. Hall SA, Kaufman JS, Ricketts TC. Defining urban and rural areas in U.S. epidemiologic studies. Journal of urban health : bulletin of the New York Academy of Medicine. 2006;83(2):162-75. Epub 2006/06/01. doi: 10.1007/s11524-005-9016-3. PubMed PMID: 16736366; PMCID: PMC2527174.

45. Ingram DD, Franco SJ. 2013 NCHS Urban-Rural Classification Scheme for Counties. Vital and health statistics Series 2, Data evaluation and methods research. 2014(166):1-73. Epub 2014/04/30. PubMed PMID: 24776070.

46. Inagami S, Gao S, Karimi H, Shendge MM, Probst JC, Stone RA. Adapting the Index of Relative Rurality (IRR) to Estimate Rurality at the ZIP Code Level: A Rural Classification System in Health Services Research. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2016;32(2):219-27. Epub 2015/09/24. doi: 10.1111/jrh.12148. PubMed PMID: 26397170.

47. Ratcliffe M, Burd C, Holder K, Fields A. Defining Rural at the U.S. Census Bureau. Washington, D.C.: U.S. Census Bureau 2016.

48. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. Eating behaviors. 2010;11(1):11-7. Epub 2009/12/08. doi: 10.1016/j.eatbeh.2009.08.002. PubMed PMID: 19962115; PMCID: PMC2823259.

49. Council HA. Race and Ethnicity in Rural America

Rural Research Briefs. 2012:1-11.

50. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377-81. Epub 2008/10/22. doi: 10.1016/j.jbi.2008.08.010. PubMed PMID: 18929686; PMCID: Pmc2700030.

51. Hartley D, A. H. Rural Active Living Assessment (RALA) Tookit: Codebook and Assessment tools 2010 2010 [cited 2914 October 20]. Available from: http://www.activelivingresearh.org/node/11947.

52. Ma X, Barnes TL, Freedman DA, Bell BA, Colabianchi N, Liese AD. Test-retest reliability of a questionnaire measuring perceptions of neighborhood food environment. Health & place. 2013;21:65-9. Epub 2013/02/26. doi: 10.1016/j.healthplace.2013.01.008. PubMed PMID: 23434497; PMCID: PMC3634345.

53. Moore LV, Diez Roux AV, Nettleton JA, Jacobs DR, Jr. Associations of the local food environment with diet quality--a comparison of assessments based on surveys and geographic information systems: the multi-ethnic study of atherosclerosis. American journal of epidemiology. 2008;167(8):917-24. Epub 2008/02/29. doi: 10.1093/aje/kwm394. PubMed PMID: 18304960; PMCID: PMC2587217.

54. Bandura A. Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, New Jersey: Prentice-Hall; 1986.

55. Bandura A. Social cognitive theory. Six theories of child development: Revised formulations and current issues. Greenwich, CT: JAI Press; 1989.

56. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. Health psychology : official journal of the Division of Health Psychology, American Psychological Association. 2009;28(6):690-701. Epub 2009/11/18. doi: 10.1037/a0016136. PubMed PMID: 19916637.

57. Golden SD, Earp JA. Social ecological approaches to individuals and their contexts: twenty years of health education & behavior health promotion interventions. Health education & behavior : the official publication of the Society for Public Health Education. 2012;39(3):364-72. Epub 2012/01/24. doi: 10.1177/1090198111418634. PubMed PMID: 22267868.

58. Kadushin C. Understanding Social Networks: Theories, Concepts and Findings. New York, NY: Oxford University Press; 2012.

59. Nutrition AAoDa. How effective (in terms of client adherence and weight loss and maintenance) are meal replacements (liguid meals, meal bars, frozen prepackaged means)? 2011.

60. LeCheminant JD, Jacobsen DJ, Hall MA, Donnelly JE. A comparison of meal replacements and medication in weight maintenance after weight loss. Journal of the American College of Nutrition. 2005;24:347-53.

61. Ditschuneit HH, Flechtner-Mors M. Value of structured meals for weight management: risk factors and long-term weight maintenance. Obes Res. 2001;9 Suppl 4:284s-9s. Epub 2001/11/15. doi: 10.1038/oby.2001.132. PubMed PMID: 11707555.

62. Befort CA, Klemp JR, Austin HL, Perri MG, Schmitz KH, Sullivan DK, Fabian CJ. Outcomes of a weight loss intervention among rural breast cancer survivors. Breast cancer research and treatment. 2012;132(2):631-9. Epub 2011/12/27. doi: 10.1007/s10549-011-1922-3. PubMed PMID: 22198470; PMCID: PMC3314288.

63. Befort CA, Klemp JR, Sullivan DK, Shireman T, Diaz FJ, Schmitz K, Perri MG, Fabian C. Weight loss maintenance strategies among rural breast cancer survivors: The rural women connecting for better health trial. Obesity (Silver Spring, Md). 2016;24(10):2070-7. Epub 2016/09/02. doi: 10.1002/oby.21625. PubMed PMID: 27581328; PMCID: PMC5039073.

64. Agriculture USDoHaHSaUSDo. Dietary Guidelines for Americans 2015-2020, 8th Edition. Washington, D.C.2015.

65. Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. American Journal of Clinical Nutrition. 1990;51:241-7.

66. Agriculture USDo. Choose MyPlate. In: USDA, editor. Washington, DC2013.

67. Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK. Appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. Medicine & Science in Sports & Exercise. 2009;41(2):459-71.

68. The Weight-Control Information Network: A Project of the National Insititues of Diabetesand Digestive and Kidney Diseases of the National Institutes of Health. Nutrition Reviews. 1995;53(8):232-3.

69. Institute NHLaB. Aim for a Health Weight [cited 2014 October 10]. Available from: https://www.nhlbi.nih.gov/health/educational/lose_wt/index.htm.

70. Raynor HA, Champagne CM. Position of the Academy of Nutrition and Dietetics: Interventions for the Treatment of Overweight and Obesity in Adults. Journal of the Academy of Nutrition and Dietetics. 2016;116(1):129-47. Epub 2016/01/01. doi: 10.1016/j.jand.2015.10.031. PubMed PMID: 26718656.

71. Committee PAGA. Physical activity guidelines advisory committee report, 2008. Washington, DC: U.S. Department of Health and Human Services; 2008.

72. Lohman TG, Roche AF, Martorell R. Anthropometric standardization reference manual. Champaign,Ill: Human Kinetics Books; 1988.

73. Centers fDCa, Prevention. National Health and Nutrition Survey (NHANES):Health Tech/Blood Pressure Procedures Manual. Atlanta, GA: Center for Disease Control and Prevention; 2009.

74. Kristal AR, Kolar AS, Fisher JL, Plascak JJ, Stumbo PJ, Weiss R, Paskett ED. Evaluation of web-based, self-administered, graphical food frequency questionnaire. Journal of the Academy of Nutrition and Dietetics. 2014;114(4):613-21. Epub 2014/01/28. doi: 10.1016/j.jand.2013.11.017. PubMed PMID: 24462267; PMCID: PMC3966309.

75. Butte NF, Ekelund U, Westerterp KR. Assessing physical activity using wearable monitors: measures of physical activity. Medicine and science in sports and exercise. 2012;44(1 Suppl 1):S5-12. Epub 2011/12/23. doi: 10.1249/MSS.0b013e3182399c0e. PubMed PMID: 22157774.

76. Trost SG, McIver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. Medicine and science in sports and exercise. 2005;37(11 Suppl):S531-43. Epub 2005/11/19. PubMed PMID: 16294116.

77. Hendelman D, Miller K, Baggett C, Debold E, Freedson P. Validity of accelerometry for the asssesment of moderate intensity physical activity in the field. Medicine and science in sports and exercise. 2000;32 (Suppl):S442-S9.

78. Ward DS, Evenson KR, Vaughn A, Rodgers AB, Troiano RP. Accelerometer use in physical activity: best practices and research recommendations. Medicine and science in sports and exercise. 2005;37(11 Suppl):S582-8. Epub 2005/11/19. PubMed PMID: 16294121.

79. Kang M, Bjornson K, Barreira TV, Ragan BG, Song K. The minimum number of days required to establish reliable physical activity estimates in children aged 2-15 years. Physiological measurement. 2014;35(11):2229-37. Epub 2014/10/24. doi: 10.1088/0967-3334/35/11/2229. PubMed PMID: 25340374.

80. Cain KL, Sallis JF, Conway TL, Van Dyck D, Calhoon L. Using accelerometers in youth physical activity studies: a review of methods. Journal of physical activity & health. 2013;10(3):437-50. Epub 2013/04/27. PubMed PMID: 23620392.

81. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Medicine and science in sports and exercise. 2008;40(1):181-8. Epub 2007/12/20. doi: 10.1249/mss.0b013e31815a51b3. PubMed PMID: 18091006.

82. Matthews CE, Chen KY, Freedson PS, Buchowski MS, Beech BM, Pate RR, Troiano RP. Amount of time spent in sedentary behaviors in the United States, 2003-2004. American journal of epidemiology. 2008;167

(7):875-81.

83. Masse LC, Fuemmeler BF, Anderson CB, Matthews CE, Trost SG, Catellier DJ, Treuth MS. Accelerometer data reduction: A comparison of four reduction algorithms on select outcome variables. Medicine & Science in Sports & Exercise. 2005;37(11 (Suppl)):S544-S54.

84. Hennessy CH, Moriarty DG, Zack MM, Scherr PA, Brackbill R. Measuring health-related quality of life for public health surveillance. Public health reports (Washington, DC : 1974). 1994;109(5):665-72. Epub 1994/09/01. PubMed PMID: 7938388; PMCID: PMC1403555.

85. Hatton DC, Haynes RB, Oparil S, Kris-Etherton P, Pi-Sunyer FX, Resnick LM, Stern JS, Clark S, McMahon M, Morris C, Metz J, Ward A, Holcomb S, McCarron DA. Improved quality of life in patients with generalized cardiovascular metabolic disease on a prepared diet. The American journal of clinical nutrition. 1996;64(6):935-43. Epub 1996/12/01. PubMed PMID: 8942420.

86. Clark M, Abrams DB, Niaura RS. Self-efficacy in weight management. Journal of Consulting and Clinical Psychology. 1991;59:739-44.

87. McAuley E. Self-efficacy and the maintenance of exercise participation in older adults. Journal of behavioral medicine. 1993;16(1):103-13. Epub 1993/02/01. PubMed PMID: 8433355.

88. McAuley E. The role of efficacy cognitions in the prediction of exercise behavior in middle-aged adults. Journal of behavioral medicine. 1992;15(1):65-88. Epub 1992/02/01. PubMed PMID: 1583674.

89. Grandy S, Hashemi M, Langkilde AM, Parikh S, Sjostrom CD. Changes in weight loss-related quality of life among type 2 diabetes mellitus patients treated with dapagliflozin. Diabetes, obesity & metabolism. 2014;16(7):645-50. Epub 2014/01/22. doi: 10.1111/dom.12263. PubMed PMID: 24443876.

90. Fontaine KR, Cheskin LJ. Self-efficacy, attendance, and weight loss in obesity treatment. Addict Behav. 1997;22(4):567-70. Epub 1997/07/01. PubMed PMID: 9290865.

91. McLean RA. Financial Management in Healthcare Organizations. Albany, N.Y. : Delmar Publishers; 1997.

92. Dranove D. Measuring Costs. In: Sloan FA, editor. Valuing health care: costs, benefits, and effectiveness of pharmaceuticals and other medical technologies. New York, N.Y.: Cambridge University Press; 1996. p. 61-80.

93. Krukowski RA, Pope RA, Love S, Lensing S, Felix HC, Prewitt TE, West D. Examination of costs for a lay health educator-delivered translation of the Diabetes Prevention Program in senior centers. Prev Med. 2013;57(4):400-2. Epub 2013/07/09. doi: 10.1016/j.ypmed.2013.06.027. PubMed PMID: 23831492.