



Weight management in rural health clinics: The Midwest diet and exercise trial

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ABSTRACT

Obesity prevalence is higher in rural compared to urban residents. Rural health clinics offer a potential venue for delivery of weight management. However, traditional programs require travel to attend on-site meetings which is impractical or inconvenient for rural residents. Clinic staff in most rural settings are unlikely to be trained to provide effective weight management. Remote delivery using group phone conferences (GP) or individual phone calls (IP), by staff associated with rural clinics eliminates the need for travel to attend on-site meetings. The effectiveness of these approaches will be the focus of this trial. Staff at five primary care clinics, serving primarily rural residents, will be trained to deliver GP and IP interventions and an enhanced usual care (EUC), (i.e., individual face-to-face meetings (~45 min) at clinic site, four times across 18 mos.). Two hundred overweight/obese adults (BMI \geq 25.0–45.0 kg/m², age \geq 21 yrs.) will be recruited through each clinic and randomized to GP (n = 80), IP (n = 80), or EUC (n = 40) to compare weight loss (0–6 mos.), weight maintenance (7–18 mos.), and weight change during a 6 mo. no contact follow-up (19–24 mos.) between intervention arms. The GP and IP interventions will be identical in lesson plan content, diet, and physical activity. The only difference between groups will be the delivery format (group vs. individual) and session duration (GP ~45 min/session; IP ~15 min/session). Primary (body weight) and secondary outcomes (waist circumference, energy/macronutrient intake, physical activity) will be assessed at baseline, 6, 12, 18 and 24 mos. Cost and contingent valuation analyses will also be completed.

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1. 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 1214 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

Abbreviations: EI, Energy intake; EUC, Enhanced usual care; GP, Group phone; IP, Individual phone; PA, Physical activity

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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 dropout [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.

2. Methods and materials

2.1. 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 contact (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. Secondly, 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.

2.2. Clinic recruitment

At least five clinics, located in rural areas, and/or serving primarily rural residents, with a census of ~4000 to 8000 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 2500, but < 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.

2.3. 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.

2.4. 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

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