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# Weight management in rural health clinics: Results from the randomized midwest diet and exercise trial

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## Abstract

**Introduction:** Rural living adults have higher rates of obesity compared with their urban counterparts and less access to weight management programs. Previous research studies have demonstrated clinically relevant weight loss in rural living adults who complete weight management programs delivered by university affiliated interventionists. However, this approach limits the potential reach, adoption, implementation, and maintenance of weight management programs for rural residents. Weight management delivered through rural health clinics by non-physician clinic associated staff, for example, nurses, registered dieticians, allied health professionals, etc. has the potential to improve access to weight management for rural living adults. This trial compared the effectiveness of a 6-month multicomponent weight management intervention for rural living adults delivered using group phone calls (GP), individual phone calls (IP) or an enhanced usual care control (EUC) by rural clinic associated staff trained by our research team.

**Methods:** Rural living adults with overweight/obesity ($n$ = 187, age ~ 50 years 82% female, body mass index ~35 kg/m$^2$) were randomized (2:2:1) to 1 of 3 intervention arms: GP, which included weekly ~ 45 min sessions with 7–14 participants ($n$ = 71), IP, which included weekly ~ 15 min individual sessions ($n$ = 80), or EUC, which included one-45 min in-person session at baseline.

**Results:** Weight loss at 6 months was clinically relevant, that is, ≥5% in the GP (−11.4 kg, 11.7%) and the IP arms (−9.1 kg, 9.2%) but not in the EUC arm (−2.6%, −2.5% kg). Specifically, 6 month weight loss was significantly greater in the IP versus EUC arms (−6.5 kg. $p \leq 0.025$) but did not differ between the GP and IP arms (−2.4 kg, $p > 0.025$). The per participant cost per kg. weight loss for implementing the intervention was $93 and $60 for the IP and GP arms, respectively.

**Conclusions:** Weight management delivered by interventionists associated with rural health clinics using both group and IP calls results in clinically relevant

6 months weight loss in rural dwelling adults with overweight/obesity with the group format offering the most cost-effective strategy.
**Clinical trial registration:** ClinicalTrials.gov (NCT02932748).

**KEYWORDS**
cost effectiveness, group, individual, rural, telephone delivery, weight management

## 1 | INTRODUCTION

The American Heart Association/American College of Cardiology/Obesity Society (AHA/ACC/TOS) guidelines for the management of overweight and obesity in adults recommend that primary care practitioners evaluate and manage overweight and obesity in their patients.[1] Limited time available at office visits, lack of training in behavioral interventions and low reimbursement rates have at least partially contributed to the low level of adoption of weight management by primary care physicians.[2–8] Thus, the development and evaluation of strategies for weight management in primary care settings delivered by other clinic associated staff, for example, nurses, registered dieticians, allied health professionals, etc., has the potential to improve access to weight management in general, and specifically for underserved groups such as rural residents at high risk for obesity.

Approximately 60 million Americans or ~19% of the population live in rural areas.[9] The prevalence of obesity is higher in rural (~40%) compared with urban residents (~33%)[10,11] and the prevalence of obesity has increased more rapidly in rural compared with urban residents over the past 3 decades.[12,13] The prevalence of obesity-associated chronic conditions including type 2 diabetes,[14,15] metabolic syndrome[16] and coronary heart disease[17] is also higher in rural residents than in urban areas. However, the availability of weight management programs in rural areas is limited and typically consists of brief physician counseling, an approach which typically achieves minimal weight loss.[18]

Travel to attend in-person multi-component weight management programs (reduced energy diet, increased physical activity, self-monitoring, behavioral education) is inconvenient for many rural residents who may live a considerable distance from the clinic and have limited or no access to public transportation.[19] This report describes the results from an effectiveness trial in rural living adults with overweight/obesity randomized to a multicomponent weight management intervention conducted in accordance with AHA/ACC/TOS guidelines delivered using group phone (GP) or individual phone (IP) calls or an enhanced usual care control (EUC) by rural clinic associated staff trained by our research team.

## 2 | METHODS

### 2.1 | Study overview

A detailed description of the rationale, design, and methods for this trial has been previously published.[20] Briefly, we randomized 187 adults with overweight/obesity in a ~2:2:1 allocation to the GP ($n = 71$), IP ($n = 80$), or EUC ($n = 36$) arms. The trial was designed and powered to compare 6-month weight loss (kg) between the GP and IP arms and between the IP and EUC arms using intention-to-treat (ITT) principles. We hypothesized superior 6-month weight loss in the GP compared with the IP arm and in the IP compared with the EUC arm.

This project was approved by the Institutional Review Board for the Protection of Human Subjects at the University of Kansas-Lawrence and registered on ClinicalTrials.gov (NCT02932748). Participants provided informed consent prior to participation in any trial related activities. This trial was conducted between 2017 and 2021.

### 2.2 | Clinic recruitment

We contacted 27 primary care clinics in rural areas, that is, population less than 50,000,[21] and/or clinics serving primarily rural residents located within 100 miles of greater Kansas City, KS regarding participation in this trial. Clinics were asked to assist with the recruitment of ~20–40 participants, identify an interventionist to deliver the weight management intervention, and provide space for both outcome assessments and delivery of the EUC arm. Six of the 12 clinics that expressed interest agreed to participate (four Medicare-Designated Rural Health Clinics and two hospital-owned clinics).

### 2.3 | Interventionist selection/training

Our research team, in collaboration with rural clinic/health system management, selected a staff member (four clinics) or an associated qualified professional (two clinics) to deliver the weight management intervention. Interventionist backgrounds included two registered dietitians, two registered nurses and two allied health professionals (health teacher, kinesiologist). Each interventionist delivered all three intervention arms, that is, GP, IP and EUC for their respective sites to minimize the potential for interventionist effects.

Interventionists were 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. Interventionists were provided with a detailed intervention notebook which outlined the topics for each session, provided answers to common participant questions, and strategies for engaging participants in the intervention. On-site training provided an overview of the intervention notebook, discussed the biologic/medical impacts of weight loss and strategies for effective intervention delivery via GP or IP calls

or face-to-face that was utilized in the EUC arm. Audio recordings from GP sessions from our completed National Institutes of Health (NIH) trial, which compared GP and face-to-face delivery of weight management[22] were utilized to demonstrate effective leadership and facilitation techniques in the GP setting. Strategies for conducting IP and face-to-face interventions were demonstrated by role playing with a member of our research team with the interventionists and clinic staff as participants. The four follow-up training sessions were used to reinforce the strategies taught during on-site training and to further model the teaching strategies used in GP, IP and EUC sessions. Prior to initiating the intervention, all interventionists were required to successfully conduct three simulated sessions of each of the three intervention arms, that is, GP, IP, and EUC, in which members of the research team served as participants. A standardized checklist, including the important skills/strategies taught during training, was used to ensure that all interventionists demonstrated mastery of these skills. The research team was available for consultation with interventionists to address issues that arose during the interventions.

## 2.4 | Participant eligibility

To enhance generalizability of our results, individuals with chronic medical conditions or common risk factors such as hypertension, tobacco use, hyperlipidemia, diabetes mellitus, etc., who received clearance from their primary care physician, were allowed to participate in this trial. These individuals are representative of those typically seeking weight management and have participated in our previous trials demonstrating the effectiveness of both the GP and IP interventions delivered by university-based interventionists.[23,24] In addition to requiring primary care physician approval, additional inclusion criteria were age ≥21 years, and Body mass index (BMI) ≥25 kg/m$^2$ and ≤45 kg/m$^2$. Exclusion criteria were: participation in a structured weight loss or physical activity program within 6 months of enrollment, not weight stable (±4.6 kg) for 3 months prior to enrollment, specialized diet regimen, binge eating disorder, participation in >3, 30-min bouts of planned exercise/week, unable to participate in moderate intensity physical activity, serious medical risk such as active or recent cancer or recent cardiac event, that is, heart attack, stroke, angioplasty etc., as determined by the individual's primary care physician's clearance form, pregnant during the previous 6 months, lactating, or planned pregnancy in the following 18 months, current use of antipsychotics or untreated depression, unwilling to be randomized to 1 of 3 study arms, and planning to move out of the area prior to completion of the trial. Weight loss in high-risk participants, that is, those with chronic conditions or using prescription medications, was monitored by both interventionists and the study physician.

## 2.5 | Participant recruitment/randomization

Rural clinic personnel were asked to recruit ~20–40 participants through point of care referrals or selecting patients with a BMI ≥25 kg/m$^2$ from clinic electronic medical records. The study team also recruited participants using flyers posted in rural communities and media advertising including print, radio, and Facebook®. Potential participants were asked to contact the study staff via phone, email, or our laboratory web site. Interested individuals completed a brief web-based screener on our laboratory website or were 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 physical activity. Those satisfying the initial eligibility criteria were scheduled to attend an in-person meeting with study staff at the participant's respective clinics. Participants in each clinic were stratified by sex and randomized to one of three study arms in a 2:2:1 ratio (GP, IP, and EUC), respectively. The randomization sequences were generated by the project statistician, sent to the project coordinator, and concealed until intervention arms were assigned at baseline testing.

## 2.6 | Intervention description

### 2.6.1 | Group and individual phone arms

Participants received a study notebook of printed materials that included the schedule and content for behavioral sessions. Identical dietary, physical activity, and self-monitoring recommendations were prescribed for both the GP and IP arms as follows:

*Diet-weight loss (0–6 months)*

Energy intake was prescribed at 1200–1500 kcal/d for women and 1500–1800 kcal/d for men as recommended by current weight management guidelines from the American Heart Association/American College of Cardiology/The Obesity Society.[1] Participants were asked to consume a minimum daily total of two commercially available portion-controlled entrées (~200–300 kcal each, saturated fat ≤3 g, sodium ≤600 mg), two low calorie shakes (~100 kcal each), one serving of non-fat dairy (~100 kcal), at least five one-cup servings of fruits/vegetables, and ad libitum non-caloric beverages. Two low calorie shakes per day (Profile by Sanford Health, Sioux Falls, SD) were provided to participants during weight loss.

*Diet-weight maintenance and no-contact follow-up (7–24 months)*

Participants were asked to consume a diet with energy intake to maintain weight loss based on the resting metabolic rate (RMR) equation of Mifflin-St Jeor[25] adjusted for activities of daily living (RMR × 1.4 – 1.6). Participants were encouraged to continue using commercially available portion-controlled entrées, low calorie shakes, or transition to a meal plan or combination of these options.

*Physical activity (0–24 months)*

Participants were asked to complete a progressive moderate-to-vigorous physical activity program, for example, brisk walking, jogging, biking, etc., that progressed from 45 min/wk. during week 1–

225 min/wk. at 4 months and remained at 225 min/wk. for the duration of the intervention.

*Self-monitoring*

Participants were asked to self-monitor diet, that is, number of portion-controlled entrées, shakes, servings of fruits and vegetables/day, pedometer steps (Omron HJ-320 Tri-Axis Alvita), self-reported minutes of physical activity and body weight across the 6-month weight loss and 12-month weight maintenance interventions. Participants were asked to report self-monitoring data weekly using a web-based form or a phone call to interventionists for participants without Internet access ($n = 2$). Self-monitoring data was summarized by research staff and made available to interventionists for use in providing personalized feedback via midweek phone or email contact and during the weekly scheduled intervention calls.

*Group phone-intervention delivery/behavioral education session content*

The GP intervention was delivered to 7–14 participants during a 45-min call weekly from 0 to 6 month and every other week from 7 to 18 months using the Maestro Conference® software platform (Oakland, CA), which allows group audio conferences to be accessed by phone and automatically records each session. Each meeting included a check-in question to generate discussion regarding diet and physical activity, a review of participants self-monitored diet, weight and physical activity 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. Weight management lesson topics included energy density, obtaining fruits and vegetables in rural communities, exercising in rural communities, eating/exercising on the go, etc.

*Individual phone-intervention delivery/behavioral education session content*

The IP intervention was delivered during scheduled 15 min, weekly phone calls from 0 to 6 months and every other week from 7 to 18 months using the Maestro Conference® software platform (Oakland, CA) as previously described. Prior to the call, participants were directed to review the corresponding lesson. During each call, interventionists reviewed self-monitoring diet, weight, and physical activity data, discussed highlights of weight management lessons, and solved problems, if necessary.

### 2.6.2 | Enhanced usual care

Usual care for weight management in primary care clinics typically consists of a brief discussion (<15 min) and recommendations for weight loss conducted during a primary care clinic appointment. Enhanced usual care in this trial included individual in-person meetings (~45 min) with an interventionist at the rural clinic at baseline, 6, 12 and 18 months. Participants also received printed materials from the Weight-Control Information Network[26] and NIH Aim for a Healthy Weight[27] that included topics such as healthy eating, portion size, and MyPlate recommendations, that is, being physically active, self-monitoring, and problem-solving that were discussed during the meetings.[28] During each session interventionists discussed participant's progress toward their weight loss goals, reviewed salient points from the written materials, and assisted participants in developing strategies to overcome compliance barriers.

*Diet-weight loss (0–6 months)*

Energy intake was prescribed at 1200–1500 kcal/d for women and 1500–1800 kcal/d for men using a high volume, lower fat (20%–30% energy intake) meal plan as recommended by the Academy of Nutrition and Dietetics[29] and the USDA's MyPlate approach.[28] Participants were provided with sample meal plans consisting of suggested servings of proteins, grains, fruits, vegetables, dairy, and fats and counseled on appropriate portion sizes.

*Diet-weight maintenance and no-contact follow-up (7–24 months)*

Participants were asked to consume a diet with recommended energy intake based on the RMR equation of Mifflin-St Jeor[25] adjusted for activities of daily living (RMR $\times$ 1.4 – 1.6) to maintain weight loss.

*Physical activity (0–24 months)*

Participants were asked to complete moderate to vigorous physical activity, for example, walking, jogging, biking, etc., that progressed gradually from 45 min/wk. at baseline to 150 min/wk., that is, 30 min/day, 5 days/wk. at month 4 and continued at 150 min/wk. for the duration of the trial.[30]

*Self-monitoring*

Self-monitoring was not required in the EUC arm; however, participants were provided with a pedometer (Omron HJ-320 Tri-Axis Alvita) and paper forms to self-monitor weight, diet, and physical activity if they desired.

## 2.7 | Outcome assessments

### 2.7.1 | Anthropometrics

Weight, height, and waist circumference were assessed at baseline, 6, 12, 18 and 24 months at individual participating rural clinics between 7 and 11 AM, following a minimum 12-h fast by trained research staff blinded to intervention arm. Weight was measured, in duplicate, to the nearest 0.1 kg using a calibrated digital scale (Model #PS6600, Belfour, Saukville, WI) with participants wearing a hospital gown. Standing height was measured in duplicate using a portable stadiometer (Model #IP0955, Invicta Plastics Limited). BMI was calculated as weight (kg) divided by height ($m^2$). Waist circumference was measured using the procedures described by Lohman et al.[31] Rural clinics received $1000 as compensation for

the use of clinic space to conduct outcome assessments. Fasted body weight during COVID-19 restrictions on in-person contact was collected as follows. The calibrated Befour digital scale and a hospital gown were delivered to participant's homes in a sanitized box. Staff phoned participants and directed them to retrieve and set-up the scale on a firm, non-carpeted surface in their home. Participants were asked to change into the hospital gown, step on the scale, and take a cell-phone photo of the digital display and text the photo to the research staff. We were unable to develop no-contact protocols for the assessment of height or waist circumference. Therefore, these outcomes are unavailable for participants who did not allow in-person contact. Note: Weight, height, and waist circumference were assessed at participating rural clinics by trained research staff for all participants completing the 6-month weight loss intervention.

### 2.7.2 | Process outcomes

*Intervention fidelity* was assessed by comparing audio recordings of a random sample of 20% of education/behavioral counseling sessions in each of the three intervention arms (GP, IP and EUC) with a check list of content that was scheduled to be delivered during each session. *Attendance* at behavioral sessions was obtained from interventionist records and expressed as the percentage of the scheduled sessions attended. *Self-monitoring* of diet, physical activity, and body weight (GP & IP only) was assessed from participant records and expressed as the percentage of weeks that data was tracked. *Energy intake* (kcal/day) was estimated within one week before or after each assessment visit (baseline, 6, 12, and 18 months) using the self-administered web-based VioScreen Graphical Food Frequency System (Viocare Technologies, Inc., Princeton, NJ).[32] *Moderate-to-vigorous physical activity* (minutes/day) was assessed over 7 consecutive days at baseline, 6, 12, and 18 months with an ActiGraph Model GT3X+ (ActiGraph Limited Liability Company) worn at the waist using the moderate intensity cut-point used in National Health and Nutrition Examination Survey.[33,34]

### 2.7.3 | Cost of intervention delivery

The cost of delivering the 6-month weight loss intervention, including supplies and intervention implementation, was estimated in 2019 U. S. dollars. Supply costs, that is, pedometers, participant notebooks, providing and shipping low-calorie shakes and printed materials for the GP and IP arms, and pedometers and printed materials for the EUC arm were obtained from purchase receipts. Implementation costs, that is, time devoted to interventionist training, preparation and delivery of behavioral sessions and email contacts with participants were estimated as the time spent in these activities obtained from interventionist time sheets multiplied by interventionists hourly wage, which was based on an annual salary of $70,000 including benefits. The cost/kg weight loss was calculated as the average total cost per participant divided by the average per participant weight loss. Cost effectiveness for the GP and IP interventions compared with EUC was evaluated using the incremental cost effectiveness ratio, that is, differences in cost divided by the differences in 6-month weight loss.

## 2.8 | Statistical methods

### 2.8.1 | Power

Statistical power was determined assuming a type 1 error rate of 2.5% for each of our two primary comparisons, that is, GP versus IP and IP versus EUC. Power calculations assumed a mean 6-month weight loss of 12 kg, 8 kg, and 2 kg in the GP, IP and EUC arms, respectively, with a common standard deviation of 7 kg.[23,24] Based on these assumptions, randomization of 187 participants with a 2:2:1 allocation provided >99% power for the global *F*-test in a one-way analysis of variance (ANOVA) and over 90% power for the two pairwise comparisons. Statistical power was calculated using nQuery 9.3 (Statistical Solutions, Inc.).

### 2.8.2 | Analysis

Our primary analysis compared the difference in weight change across 6 months (GP vs. IP and IP vs. EUC) using a global one-way ANOVA followed by two pairwise *t*-tests evaluated at $p \leq 0.025$ based on intention-to-treat principles using data from completers only. To evaluate the potential impact of participant attrition, we compared the results for our primary analysis using data from completers only with results of the same analysis using a data set created using SAS Proc MI ($k = 10$) to impute missing 6-months data.[22] Missing data were not related to treatment or demographic characteristics; therefore, traditional multiple imputation was used. Analysis of our secondary aims, that is, between arm differences (GP vs. IP and IP vs. EUC) for change in BMI, energy intake and physical activity across 6 months for completers used a global one-way ANOVA followed by two pairwise *t*-tests with a type I error rate of 0.05. Differences between the GP and IP arms for behavioral session attendance and frequency of self-monitoring were evaluated using Chi-squared test. We originally proposed to compare changes in body weight and BMI between intervention arms across 12, 18, 24 months. The COVID-19 pandemic, which was in place during ~19 months of this trial, had a deleterious impact on participant retention (12 months = 51%, 18 months = 48%, 24 months = 39%) and thus statistical power. Therefore, results for mean weight change for participants who completed assessments at 12, 18, and 24 months are presented for descriptive purposes only. All analysis were conducted with SAS 9.4 (SAS Institute).

## 3 | RESULTS

### 3.1 | Participants

One hundred and eighty-seven participant characteristics are presented in Table 1. Participants were ~50 years old, 82% female, 13% minority, with a mean BMI of ~35 kg/m$^2$. Participant retention at the 6 month was similar in the GP (66%), IP (75%) and EUC arms (78%) ($p = 0.34$) (Figure 1). There were no differential effects of gender on participant retention ($p = 0.14$). One serious adverse event that was not related to participation in this trial was reported.

### 3.2 | Primary/secondary aims

Results from a global one-way ANOVA revealed significant differences in weight loss across 6 months between intervention arms: GP = −11.4 ± 6.7 kg, IP = −9.1 ± 6.8 kg, EUC = −2.6 ± 4.8 kg, $p < 0.001$ (Table 2, Figure 2). Results from both and imputed and completers-only analyses indicated significantly greater 6-month weight loss in the IP compared with the EUC arm (imputed = −5.1 kg, 97.5% CI (−8.2, −1.9); completers = −6.5 kg, 97.5% CI (−9.8, −3.2); $p \leq 0.025$) and no significant differences in 6-month weight loss between the GP and IP arms (imputed = −2.0 kg, 97.5% CI (−4.5, 0.56); completers = −2.4 kg, 97.5% CI (−5.2, 0.5); $p > 0.025$). Results from pairwise *t*-tests indicated a significantly greater reduction in BMI in the GP (−4.1 ± 2.2 kg/m$^2$) compared with the IP arm (−3.2 ± 2.3 kg/m$^2$) 95% CI (−1.8, −0.1), $p \leq 0.05$). Clinically relevant 6-month weight loss (≥5%) was observed in 87%, 72% and 25% of participants in the GP, IP, and EUC arms, respectively (Table 3). Mean weight change across 12, 18 and 24 months by intervention arm is presented in Table 4.

### 3.3 | Process data

Attendance at scheduled behavioral sessions across 6 months was 62% in the GP and 73% in the IP intervention arms ($p = 0.05$). Reductions in energy intake across 6 months were similar in the GP (−934 ± 921 kcal/day) compared with the IP arm (−841 ± 518 kcal/day), 95% CI (−452, +265) and significantly greater in the IP compared with the EUC arm (−358 ± 545 kcal/day), 95% CI (−891, −75) ($p < 0.05$). Moderate-to-vigorous physical activity was low at baseline (GP = 13 ± 12 min/day, IP = 16 ± 18 min/day, EUC = 10 ± 8 min/day) and increased modestly to 20 ± 17, 24 ± 23, and 16 ± 15 min/day in the GP, IP and EUC arms at 6 months, respectively. Between arm changes in moderate-to-vigorous physical activity across 6 months were not statistically significant. Although adherence to the study recommendations for physical activity (GP and IP = 225 min/wk, EUC = 150 min/wk.) the weekly physical activity at 6 month in both the GP and IP arms (~150 min/wk.) meets the minimal recommendations associated with improved health.[30] Self-monitoring was completed by 72% and 78% of participants in the GP and IP arms, respectively $p = 0.24$. Intervention fidelity across 6 months was excellent, that is, ≥80% of the scheduled lesson topics were delivered 99% of the time.

### 3.4 | Cost and cost effectiveness

The per participant costs associated with implementing the 6-month weight loss intervention (Table 5) suggest that both the cost per kilogram weight loss (GP = $60, IP = $93) and the incremental cost per kilogram weight loss in comparison with EUC (GP = $70, IP = $120) suggest that intervention delivery using GP is more cost-effective than IP.

**TABLE 1** Baseline characteristics of adults with overweight/obesity randomized to a group phone, individual phone, or enhanced usual care weight management intervention.

| | Intervention arms | | |
|---|---|---|---|
| **Variable** | **Group phone (*n* = 71)** | **Individual phone (*n* = 80)** | **Enhanced usual care (*n* = 36)** |
| Age (yrs.)[a] | 50.4 ± 14.2 | 49.4 ± 11.2 | 50.4 ± 13.8 |
| Weight (kg) | 99.1 ± 17.8 | 97.4 ± 18.3 | 99.5 ± 19.3 |
| BMI (kg/m$^2$) | 35.6 ± 4.7 | 34.6 ± 4.5 | 35.2 ± 4.5 |
| Female | 59 (83.1%) | 66 (82.5%) | 28 (77.8%) |
| Minority[b] | 10 (14.1%) | 12 (15%) | 4 (11.1%) |
| Rural resident | 55 (77.5%) | 65 (81.3%) | 28 (77.8%) |
| Education | | | |
| ≤ High school graduate | 11 (15.7%) | 13 (16.5%) | 10 (27.8%) |
| Some college or bachelor degree | 41 (57.7%) | 49 (61.3%) | 18 (50.0%) |
| Graduate degree | 18 (25.7%) | 17 (21.5%) | 8 (22.2%) |

[a]Values are mean ± standard deviation or sample size (*n*) and percentage.

[b]Race/ethnicity other than non-Hispanic white.

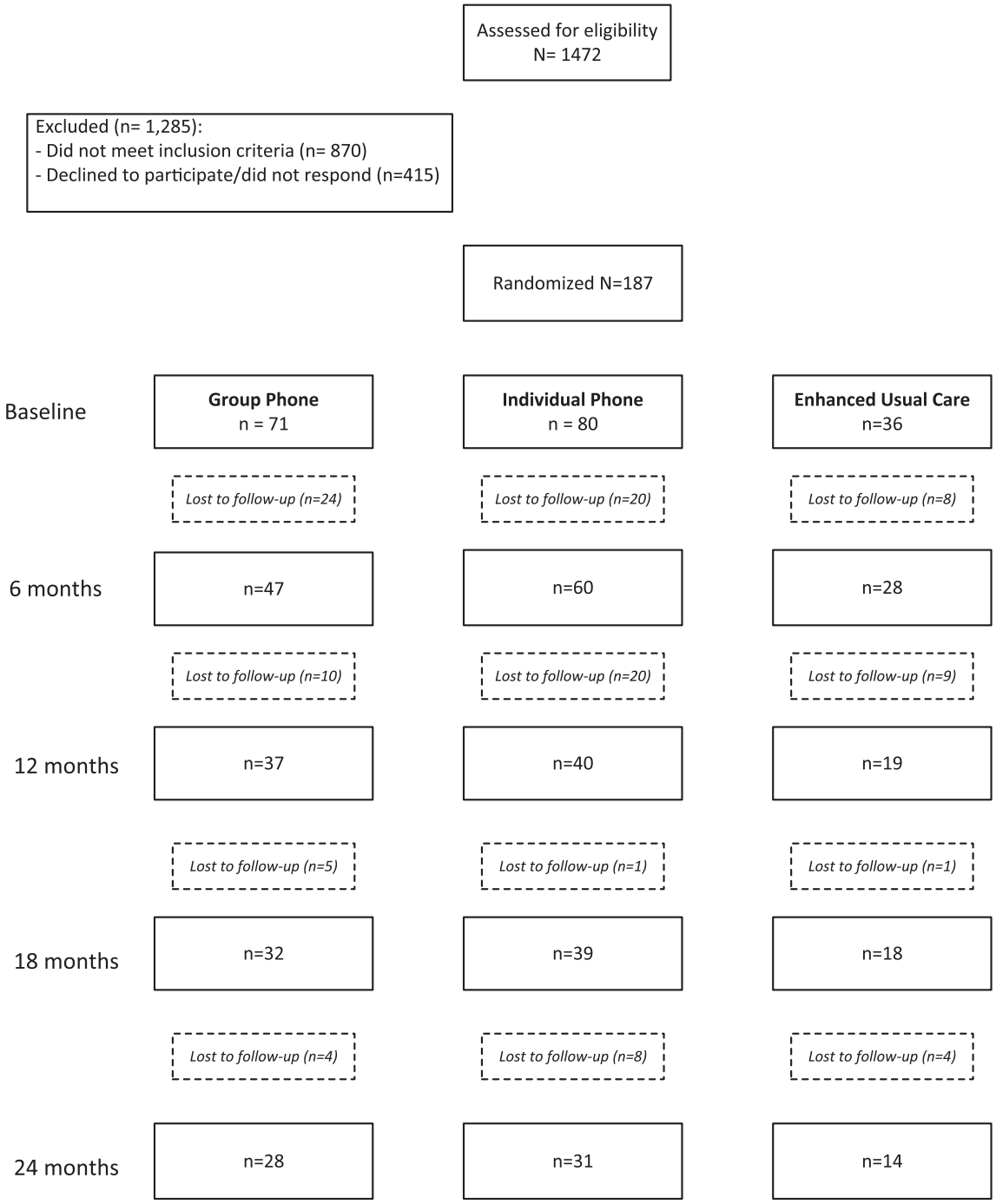


**FIGURE 1** Participant enrollment and retention across the 24-month trial.

## 4 | DISCUSSION

The primary aim of this trial was to compare the effectiveness of a 6-month multicomponent weight management intervention in rural living adults with overweight/obesity when delivered by rural clinic staff or clinic associated qualified professionals using GP or IP with an EUC. Weight loss in the GP (−11.4 kg, 87% ≥ 5%) and IP arms (−9.1 kg, 72% ≥ 5%) did not differ significantly; however, weight loss using both GP and IP was significantly greater than the minimal weight loss observed in the EUC arm (−2.6 kg, 25% ≥ 5%). The minimal, but statistically significant differences in 6-month changes in percent weight loss and BMI between the GP (−11.7% −4.1 kg/m$^2$) and IP arms (−9.2% −3.2 kg/m$^2$), were a function of using a type 1 error rate of 0.05 for evaluation of these secondary outcomes compared with a 0.025 type 1 error rate used for evaluating our primary outcome, that is, weight change in kilograms.

We are unaware of previous trials in rural living adults that have compared the effectiveness of weight management interventions using individual or GP when the interventions were delivered by rural care clinic staff trained by university-based weight management

**TABLE 2** Changes in weight (kg, %), BMI and waist circumference across 6 months in adults with overweight/obesity randomized to a group phone, individual phone, or enhanced usual care weight management intervention.

| | Group phone (GP) ($n$ = 47) | Individual phone (IP) ($n$ = 60) | Enhanced usual care (EUC) ($n$ = 28) | Overall model $p$ value | Difference GP-IP | Difference IP-EUC |
|---|---|---|---|---|---|---|
| Weight (kg) | −11.4 ± 6.7 | −9.1 ± 6.8 | −2.6 ± 4.8 | <0.001 | −2.4 (−5.2, 0.5) | −6.5 (−9.8, −3.2)[b] |
| Imputed weight (kg) | −10.9 ± 7.7 | −8.9 ± 6.9 | −3.9 ± 5.4 | <0.0001 | −2.0 (−4.6, 0.6) | −5.1 (−8.2, −1.9)[b] |
| Weight (%) | −11.7 ± 6.6 | −9.2 ± 6.8 | −2.5 ± 4.2 | <0.001 | −2.5 (−4.9, −0.1)[a] | −6.7 (−9.5, −3.8)[a] |
| BMI (kg/m$^2$) | −4.1 ± 2.2 | −3.2 ± 2.3 | −0.9 ± 1.6 | <0.001 | −0.9 (−1.8, −0.1)[a] | −2.2 (−3.3, −1.3)[a] |
| Waist circumference (cm) | −7.2 ± 6.1 | −6.1 ± 5.8 | −2.1 ± 4.5 | 0.001 | −1.1 (−3.3, 1.1) | −3.9 (−6.5, −1.4)[a] |

[a]Significantly different at $p \leq 0.05$.

[b]Significantly different at $p \leq 0.025$.

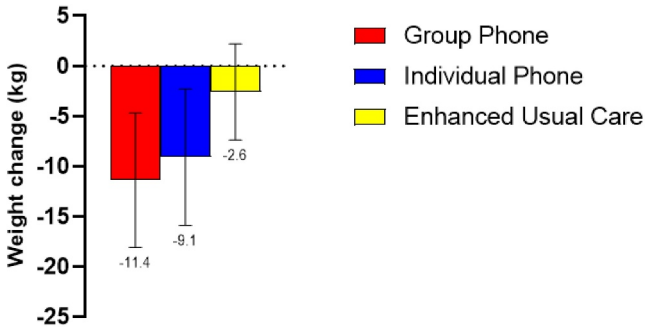


**FIGURE 2** Changes in weight (kg) across 6 months in adults with overweight/obesity randomized to a group phone, individual phone, or enhanced usual care weight management intervention.

**TABLE 3** Categories of weight change across 6 months in adults with overweight/obesity randomized to a group phone, individual phone, or enhanced usual care weight management intervention.

| | Group phone | | Individual phone | | Enhanced usual care | |
|---|---|---|---|---|---|---|
| | $n$ | % | $n$ | % | $n$ | % |
| Weight loss | | | | | | |
| <5% | 6 | 12.8 | 16 | 28.1 | 13 | 46.4 |
| ≥5% | 41 | 87.2 | 41 | 71.9 | 7 | 25.0 |
| Weight gain | 0 | 0 | 3 | 5.0 | 8 | 28.6 |

professionals. However, a previous pilot trial by our group in a small sample of rural living women ($n$ = 34) using a weight loss intervention similar to the current trial delivered by university-based professionals found significantly greater 6-month weight loss using GP (−14.9 kg) compared with IP (−9.5 kg, $p < 0.01$).[24] The magnitude of 6-month weight loss observed in rural living adults in the GP arm in the current trial (−11.4 kg) with intervention delivered by rural clinic staff is similar to that observed in trials in rural residents using a similar multicomponent intervention delivered by university-based weight management professionals. For example, two trials in rural female breast cancer survivors where the interventions were delivered using GP reported 6-month weight loss of −12.5 kg ($n$ = 31)[22] and −12.2 kg ($n$ = 78).[35] A recent trial by Befort et al[36] compared weight loss/maintenance in a large sample of rural living adults with overweight/obesity (75% female) delivered at rural health clinics by clinic staff (nurse, registered dietician, advanced practice provider, physician) trained by the research team either in group in-clinic ($n$ = 468) or individual in-clinic formats ($n$ = 473) or by university-based professionals with masters degrees or doctorates in nutrition, psychology, exercise science or public health using GP ($n$ = 466). Mean 6-month weight loss in the GP arm (−7.7 kg) was significantly greater than that in the individual in-clinic arm (−5.7 kg, $p$ = 0.002). However, 6-month weight loss in the GP and in-person group arm (−8.3 kg) did not differ significantly ($p$ = 0.30). In the current trial, we observed clinically relevant 6-month weight loss in both the GP and IP arms with an intervention delivered by a combination of nurses ($n$ = 2), registered dietitians ($n$ = 2) and allied health professionals ($n$ = 2) in a rural health care setting. The current trial was not designed or powered to assess the impact of interventionist background on the effectiveness of the weight loss intervention. However, results from a recent meta-analysis of 27 randomized trials indicated that 12-month weight loss in non-rural living adults delivered in the primary care setting was significantly greater when interventions were delivered by non-medical professionals, that is, health coach, non-clinical staff (−2.0 kg) or other health practitioners,

**TABLE 4** Changes in weight across 12, 18 and 24 months in adults with overweight/obesity randomized to a group phone, individual phone or enhanced usual care weight management intervention.

| | Group phone | | Individual phone | | Enhanced usual care | |
|---|---|---|---|---|---|---|
| Time point | *n* | Weight change (kg) | *n* | Weight change (kg) | *n* | Weight change (kg) |
| 12 months | 37 | −9.3 ± 7.2 | 40 | −8.5 ± 7.8 | 19 | −2.2 ± 5.7 |
| 18 months | 32 | −7.9 ± 7.6 | 39 | −6.2 ± 7.4 | 18 | −2.4 ± 5.5 |
| 24 months | 28 | −5.4 ± 7.9 | 31 | −3.4 ± 7.3 | 14 | +0.1 ± 5.0 |

**TABLE 5** Estimated per participant cost and cost-effectiveness for delivery of a 6-month weight loss intervention to adults with overweight/obesity randomized to group phone, individual phone or enhanced usual care from the payer perspective.

| Costs | Group phone | Individual phone | Enhanced usual care |
|---|---|---|---|
| Supplies[a] | $535 | $535 | $25 |
| Intervention implementation | $144 | $314 | $36 |
| Total cost | $679 | $849 | $61 |
| Weight loss (kg) | −11.4 | −9.1 | −2.6 |
| Cost per kg weight loss | $60 | $93 | - |
| Incremental total cost compared to EUC | $618 | $788 | - |
| Incremental weight change (kg) compared to EUC | −8.8 | −6.5 | - |
| Incremental cost per kg weight loss compared to EUC | $70 | $120 | - |

[a]Includes the cost of providing and shipping low-calorie shakes to participants in the group and individual phone arms.

that is, dietitian, combination of practitioners (−2.3 kg) compared with interventions delivered by general practice physicians (−1.1 kg) or nurses (−0.5 kg, $p = 0.005$).[37] Thus, the results of the current trial and the limited available literature suggest that with appropriate training, staff associated with rural health care clinics can deliver weight management interventions that achieve clinically relevant short-term weight loss (6-month) in rural residents that are similar in magnitude to 6-month weight loss achieved in rural residents with interventions delivered by university-based weight management professionals.

Six-month weight loss in the current trial was similar when the intervention was delivered using either group (−11.4 kg) or IP (−9.1 kg), suggesting that rural clinics have two options for remote delivery of weight management to their patients. Interventions delivered by phone may be more widely accessible to rural residents, in contrast to the Internet, where access to phone service is generally universal. Group-based interventions have the potential to promote participant interaction, which may be desirable in residents who are frequently socially isolated[38] and have also been associated with reduced participant attrition[39] and improved weight loss compared with interventions delivered individually.[40] However, individual delivery, which has also been shown to achieve clinically relevant weight loss, provides participant anonymity that some may prefer. As expected, our results indicated that group delivery resulted in a lower per participant cost per kilogram weight loss and a lower incremental per participant cost per kilogram weight loss compared with EUC than that observed in the IP arm. Thus, GP would provide the most cost-effective option for rural clinics interested in providing weight management for their patients.

As described previously, the COVID-19 pandemic had a deleterious impact on participant retention after 6 months; thus, statistical analysis for weight change at 12, 18 and 24 months was not conducted. However, the observed 24-month weight change in both the GP (−5.4 kg) and IP arms (−3.4 kg) in the current trial was similar to long-term weight loss reported in other trials conducted in rural living adults delivered by rural health clinic staff[36] or by U.S. Cooperative Extension System (CES) family and consumer sciences extension agents or individuals with a bachelor's or master's degree in nutrition, exercise science, or psychology.[41] For example, 24-month weight loss in the Befort et al. trial, described previously,[36] ranged from −2.6 to −4.4 kg across the three intervention arms. Perri et al[41] reported weight loss following completion of a 22-month trial (4 months in-person weight loss, 12 months maintenance via GP or IP, 6-month no contact follow-up) in rural living adults delivered by CES agents of −5.9 kg and −6.1 kg using P and IP, respectively. Taken together, these results suggest the potential for the use of both group and IP delivery for long-term weight in rural dwelling adults. Additional powered trials to evaluate the impact of weight management interventions delivered through rural health clinics by non-physician clinic associated staff, for example, nurses, registered dieticians, allied health professionals etc. on long-term weight loss in rural dwelling adults are warranted.

Strengths of this trial include the use of a randomized design, intervention delivery of all three intervention arms by the same interventionist to reduce the potential of interventionist effects, a high level of fidelity for intervention delivery, and reasonable participant compliance with the dietary and self-monitoring components of the intervention. The COVID-19 pandemic, which

resulted in participant retention of <51% at 12, 18 and 24 months, is the primary weakness of this trial and eliminated our ability to conduct a statistical comparison of weight change between intervention arms following both a weight maintenance intervention and a 6-months no-contact follow-up as proposed.[20] This trial provided no-cost, low-calorie shakes (2/day) across the 6-month weight loss intervention, which may have impacted the adherence with dietary recommendations and the magnitude of weight loss observed in this trial. However, low-calorie shakes similar to those used in this trial are widely available at grocery stores and on-line at a cost of ~$1.25 each, which should not impose an unrealistic financial burden for rural living adults seeking weight management. Finally, the results of this trial are specific to rural living adults with overweight/obesity in the midwestern U.S. and may not be generalizable to rural residents in other geographic regions of the U.S. or other countries.

## 5 | CONCLUSIONS

Weight management interventions delivered by personnel associated with rural health clinics via group or individual phone calls provide effective treatment options for short-term (6-month) weight loss in rural living adults with overweight and obesity. Additional work is required to develop strategies for the implementation and dissemination of this approach through rural health clinics and to develop and evaluate interventions for long-term weight management in rural living adults. The evaluation of the impact of interventionist background on intervention components including session attendance, self-monitoring, and adherence to diet and physical activity recommendations and both short- and long-term weight loss delivered through rural health care clinics is warranted.

### AUTHOR CONTRIBUTIONS

**Anna M. Gorczyca**: Study design, data management, interpretation of data, writing-original draft. **Richard A. Washburn**: Study design and concept, interpretation of data, writing-original draft, critical revision of manuscript. **Lauren T. Ptomey**: Study design, data management, interpretation of data, critical revision of manuscript. **Matthew S. Mayo**: Study design, statistical analysis, interpretation of data, critical revision of manuscript. **Ron Krebill**: Data management, statistical analysis, interpretation of data, critical revision of manuscript. **Debra K. Sullivan**: Interpretation of data and critical revision of manuscript. **Cheryl A. Gibson**: Interpretation of data and critical revision of manuscript. **Sarah Stolte**: Interpretation of data and critical revision of manuscript. **Joseph E. Donnelly**: Study design and concept, interpretation of data, critical revision of manuscript.

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### CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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