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Effect of Behavioral Therapy With In-Clinic or Telephone Group Visits vs In-Clinic Individual Visits on Weight Loss Among Patients With Obesity in Rural Clinical Practice

A Randomized Clinical Trial

Christie A. Befort, PhD; Jeffrey J. VanWormer, PhD; Cyrus Desouza, MD; Edward F. Ellerbeck, MD; Byron Gajewski, PhD; Kim S. Kimminau, PhD; K. Allen Greiner, MD; Michael G. Perri, PhD; Alexandra R. Brown, MS; Ram D. Pathak, MD; Terry T.-K. Huang, PhD; Leslie Eiland, MD; Andjela Drincic, MD

IMPORTANCE Rural populations have a higher prevalence of obesity and poor access to weight loss programs. Effective models for treating obesity in rural clinical practice are needed.

OBJECTIVE To compare the Medicare Intensive Behavioral Therapy for Obesity fee-for-service model with 2 alternatives: in-clinic group visits based on a patient-centered medical home model and telephone-based group visits based on a disease management model.

DESIGN, SETTING, AND PARTICIPANTS Cluster randomized trial conducted in 36 primary care practices in the rural Midwestern US. Inclusion criteria included age 20 to 75 years and body mass index of 30 to 45. Participants were enrolled from February 2016 to October 2017. Final follow-up occurred in December 2019.

INTERVENTIONS All participants received a lifestyle intervention focused on diet, physical activity, and behavior change strategies. In the fee-for-service intervention (n = 473), practice-employed clinicians provided 15-minute in-clinic individual visits at a frequency similar to that reimbursed by Medicare (weekly for 1 month, biweekly for 5 months, and monthly thereafter). In the in-clinic group intervention (n = 468), practice-employed clinicians delivered group visits that were weekly for 3 months, biweekly for 3 months, and monthly thereafter. In the telephone group intervention (n = 466), patients received the same intervention as the in-clinic group intervention, but sessions were delivered remotely via conference calls by centralized staff.

MAIN OUTCOMES AND MEASURES The primary outcome was weight change at 24 months. A minimum clinically important difference was defined as 2.75 kg.

RESULTS Among 1407 participants (mean age, 54.7 [SD, 11.8] years; baseline body mass index, 36.7 [SD, 4.0]; 1081 [77%] women), 1220 (87%) completed the trial. Mean weight loss at 24 months was −4.4 kg (95% CI, −5.5 to −3.4 kg) in the in-clinic group intervention, −3.9 kg (95% CI, −5.0 to −2.9 kg) in the telephone group intervention, and −2.6 kg (95% CI, −3.6 to −1.5 kg) in the in-clinic individual intervention. Compared with the in-clinic individual intervention, the mean difference in weight change was −1.9 kg (97.5% CI, −3.5 to −0.2 kg; $P = .01$) for the in-clinic group intervention and −1.4 kg (97.5% CI, −3.0 to 0.3 kg; $P = .06$) for the telephone group intervention.

CONCLUSIONS AND RELEVANCE Among patients with obesity in rural primary care clinics, in-clinic group visits but not telephone-based group visits, compared with in-clinic individual visits, resulted in statistically significantly greater weight loss at 24 months. However, the differences were small in magnitude and of uncertain clinical importance.

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Visual Abstract

Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Christie A. Befort, PhD, University of Kansas Medical Center, 3901 Rainbow Blvd, MS 1008, Kansas City, KS 66160 (cbefort@kumc.edu).

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Obesity affects 42% of adults in the US.[1] The prevalence of obesity is even higher in rural communities,[2,3] but patients with obesity in rural communities have less access to evidence-based weight management programs than patients in nonrural communities.[4,5]

In 2011, the Centers for Medicare & Medicaid Services elected to cover intensive behavioral therapy for obesity with up to 22 individual 15-minute face-to-face visits over a 12-month period.[6] However, less than 1% of eligible beneficiaries used the service, and those who used the benefit had on average only 2 visits per year.[7]

Group visits for behavior change have been shown to be an effective alternative to individual in-person office visits[8-10] and preserve the benefits of a face-to-face encounter and coordination with the health care team, consistent with patient-centered medical home principles,[11] while also providing unique opportunities for peer support. Group visits for obesity can also be delivered by telephone[12,13] and integrated into call centers that provide a high volume of telephone-based care, such as those offered by disease management programs.

Given the absence of direct evidence for the effectiveness of the Medicare Intensive Behavioral Therapy benefit and the continued need for alternative care delivery models suited for rural practices, the objective of this cluster randomized trial was to compare the effect of fee-for-service individual visit model with 2 alternatives, in-clinic group visits and telephone-based group visits, on weight change among adults with obesity.

Key Points

Question Does behavioral obesity treatment delivered in rural primary care settings via in-clinic group visits or telephone group visits improve weight loss compared with the fee-for-service model with in-clinic individual visits?

Findings In this cluster randomized trial that included 1407 participants, in-clinic group visits, compared with in-clinic individual visits, resulted in significantly greater mean weight loss at 24 months (−4.4 kg vs −2.6 kg, respectively), and the difference between telephone-based group visits and in-clinic individual visits was not significantly different (−3.9 kg vs −2.6 kg).

Meaning In rural primary care practices, behavioral weight loss therapy delivered via in-clinic group visits resulted in statistically significantly greater weight loss than in-clinic individual visits, although the difference was small and of uncertain clinical importance.

Methods

The Rural Engagement in Primary Care for Optimizing Weight Reduction (REPOWER) trial was approved by institutional review boards at the University of Kansas Medical Center and the VA Nebraska-Western Iowa Health Care System. All participants provided written informed consent. The trial was designed to be pragmatic.[14] Thirty-six primary care practices that predominantly or exclusively served rural residents in the Midwestern US were randomly assigned by the study statistician using a computer-generated random number to 1 of 3 study groups in equal numbers, with randomization stratified by academic institutional affiliations (each primary care practice was affiliated with 1 of 3 different academic institutions). Randomization occurred after practices committed to the study. Three practices (2 randomized to in-clinic individual visits and 1 randomized to in-clinic group visits) declined participation after randomization but prior to patient enrollment for reasons unrelated to randomized assignment (study physician resigned for health reasons, staffing changes, and changes in data security requirements) and were subsequently replaced. Study data were collected and managed using REDCap (Research Electronic Data Capture) tools hosted at the University of Kansas Medical Center. The trial protocol and statistical analysis plan are available in Supplement 1.

Participants

Patients were eligible if they were 20 to 75 years old, had a body mass index of 30 to 45 (calculated as weight in kilograms divided by height in meters squared), resided in a rural location,[15] and had at least 1 clinic visit within the prior 18 months. Exclusion criteria included a history of bariatric surgery and pregnancy, myocardial infarction, stroke, or new cancer diagnosis in the last 6 months. There were no exclusion criteria for recent weight loss or medications that affect weight. Because obesity disproportionally affects racial/ethnic minorities in rural communities,[2] race and ethnicity information was collected based on participant report using fixed categories with an open-ended option.

Recruitment strategies included in-clinic referrals and direct mailings from clinic registries. Detailed recruitment methods have been previously described.[16]

Interventions

Diet, physical activity, and behavioral recommendations were the same across all study groups and were based on the Look AHEAD lifestyle intervention.[17] Participants received a calorie goal (1200-1500 kcal/d if weight was <114 kg; 1500-1800 kcal/d if weight was ≥114 kg) and were instructed to consume a balanced diet with 5 or more fruit and vegetable servings per day. Portion control and optional use of protein shakes and frozen entrees were encouraged, but no food or scales were provided. Participants were instructed to increase planned physical activity up to 225 minutes per week, to set weekly diet and physical activity goals, and to self-monitor daily with a physical activity monitor and commercial app or written log. Clinicians delivering the interventions were instructed to provide feedback to participants on logs. Intervention materials addressed problem-solving for overcoming barriers, including those common to rural environments.

The 3 delivery models were designed to represent how they may be typically delivered in clinical practice, including the selection and training of counselors. A summary of visit, counselor, and training characteristics of the 3 models is shown in eTable 1 in Supplement 2.

In-Clinic Individual Visits (Modified Medicare Intensive Behavioral Therapy Model)

In this group, practice-employed clinicians provided 15-minute face-to-face individual counseling visits following the

frequency reimbursed by Medicare: weekly for 1 month, biweekly for months 2 to 6, and monthly thereafter. Two modifications were made to the Medicare provision: (1) participants were not required to lose 3 kg or more by 6 months to receive additional visits and (2) visits remained monthly during year 2 rather than weekly to biweekly during months 13 to 18 as in the yearly benefit covered by Medicare. Each practice selected 1 to 2 counselors, most commonly nurses, who conducted visits according to Medicare billing requirements, in which coverage is allowed if the primary care clinician is physically present in the setting when counseling is delivered.[18] Only 1 physician was selected to serve as a counselor. Counselors received a 1-time 3-hour training focused on diet and physical activity guidelines, behavioral strategies, and motivational interviewing. Each practice received an intervention tool kit including example sessions and patient handouts.

In-Clinic Group Visits

In this group, practice-employed clinicians delivered group visits at the practice, with a median of 14 patients per group. Visits were 60 minutes and were weekly for the first 3 months, every other week for months 4 to 6, and monthly thereafter. This frequency was based on group-based interventions and experience from the Rural LITE trial comparing 3 doses of group visits.[19] The first 14 sessions were delivered face-to-face. For subsequent sessions, practices had the option to switch to group telephone conference calls; however, all but 1 practice opted to continue face-to-face visits. Between 1 and 3 counselors were selected locally, predominantly nurses, and included only 1 physician. Counselors received the same 1-time training plus a group treatment manual with accompanying patient manuals, a 1-day in-person workshop focused on group facilitation, and optional biweekly to monthly telementoring sessions. Fidelity monitoring was limited following a pragmatic approach. Study personnel observed counselors once, and counselors completed a checklist for each visit documenting attendance and completion of core components. Counselors were encouraged to incorporate community resources.

Telephone Group Visits

Patients at practices randomized to telephone group visits received the same group-based lifestyle intervention, but sessions were delivered remotely via audio-only telephone conference calls by centralized study staff with graduate degrees in relevant fields (eg, nutrition, exercise science, psychology). The treatment manual, session frequency, session length, and group size were the same as for the in-clinic group intervention (median group size of 14 patients per group). Training included shadowing an experienced counselor, weekly to monthly staff meetings, and fidelity monitoring through review of recorded sessions; counselors also completed the same intervention session checklist as those conducting in-clinic group intervention sessions.

Role of Primary Care Clinicians

The role of the local primary care physicians (and advanced practice clinicians who served as the primary study clinicians at 5 practices) across all groups was to refer patients to the study and support patients during routine medical visits. Clinicians received a 1-time training on obesity treatment guidelines. At practices randomized to in-clinic individual and in-clinic group visits, documentation of intervention sessions occurred in the electronic medical record according to local processes. For telephone group visits, remote counselors sent 5 progress reports to participants' clinicians documenting weight change to date, known barriers and motivators, and concise recommendations for clinician action (eg, praise weight loss; discuss plans to maintain tracking and exercise).

Outcomes

Weight was measured at baseline and at 6, 18, and 24 months by trained staff at each practice using a calibrated study scale (MX-115; Befour Inc) with the patient in light clothing or a gown. There were 2 primary comparisons: change in weight at month 24 between the in-clinic group intervention vs the in-clinic individual visit intervention and between the telephone group intervention vs the in-clinic individual visit intervention. Secondary outcomes included percentage weight loss at each follow-up visit, the proportion of participants achieving 5% and 10% weight loss at 6- and 24-month follow-up, and comparisons between in-clinic group visits and telephone group visits. Interim time points leading up to 24 months (6 and 18 months) were not explicitly prespecified in the protocol for absolute change in weight. A weight change of 2.75 kg is consistent with a minimum clinically important difference,[20] although this is not stated in the protocol. The proportions achieving weight loss thresholds of 5% and 10% at 6- and 24-month follow-up were added as secondary outcomes near the end of the trial prior to data review. (In the protocol [Supplement 1], the analytical plan for all weight-related outcomes, both primary and secondary, are described under a heading indicating primary aims only.) Additional secondary outcomes not reported in this article include heterogeneity of treatment effects by participant characteristics (race, education, income, employment status, travel time, history of weight loss), change in blood pressure, fasting glucose and lipids, patient-reported quality of life, sleep, and stress, and exploratory process measures to evaluate patient reach and practice-level sustainability of the interventions.

Statistical Analysis

Analyses used linear mixed-effects multilevel models, which included random cluster (clinic) effects, to examine absolute change in weight and percentage weight loss over time. An unstructured covariance matrix was used. Participants were analyzed according to randomized group, models included participants with baseline weight data, and missing weight data were treated as missing at random and addressed using maximum likelihood methods. Generalized linear mixed models were used to compare the percentage of participants achieving 5% and 10% thresholds. Models included randomization strata based on affiliated academic institution. Prespecified sensitivity analysis adjusted for covariates that showed imbalance between groups based on a standardized difference greater than 0.20 for the following variables: sex, race/ethnicity, education, diabetes, cardiovascular disease, and

travel time to the clinic. The threshold of standardized difference of greater than 0.20 for defining imbalanced covariates was defined post hoc. Three additional post hoc sensitivity analyses were conducted: adjusting for baseline weight, imputing baseline weight for missing 24-month weight data, and excluding the single Veterans Administration (VA) clinic (the only practice randomized to in-clinic group visits that switched to telephone group visits after 14 sessions [4 months] as allowed per protocol). With 36 clinics, approximately 40 patients per practice, and an intraclass correlation coefficient of 0.05, the trial had at least 80% power to detect a net treatment effect of 2.75 kg at 24 months (determined from effects observed in prior trials[21,22] and consistent with a minimum clinically important difference).[20] For the 2 primary comparisons (in-clinic group visits vs in-clinic individual visits, and telephone group visits vs in-clinic individual visits), a 2-sided significance level was set at .025 with Bonferroni correction. For secondary outcomes and comparisons, α was set at .05. Because of the potential for type I error due to multiple comparisons, findings for secondary end points and analyses should be interpreted as exploratory. Analyses were conducted with SAS version 9.4 (SAS Institute Inc).

Results

Of the 36 included practices, 10 were rural health clinics and 12 were federally qualified health centers. Twenty-two practices were located in isolated or small rural areas. eTable 2 in Supplement 2 shows practice characteristics.

A total of 1931 patients were screened and 1432 were enrolled (**Figure 1**). Participants had a mean age of 54.7 (SD, 11.8) years and a mean body mass index of 36.7 (SD, 4.0); 76.8% were female, 96.2% were White non-Hispanic, and 46.8% were from an isolated rural area[15] (**Table 1**). Participants removed from the study (n = 25; for pregnancy [n = 9], bariatric surgery [n = 4], major medical contraindications [n = 9], or death [n = 3]) were excluded from analyses a priori. Among the remaining 1407 participants, 86.7% completed testing at 24-month follow-up (86.7% in the in-clinic individual, 87.6% in the in-clinic group, and 85.8% in the telephone group interventions).

Primary Outcomes

At 24 months, mean weight loss was -4.4 kg (95% CI, -5.5 to -3.4 kg) for in-clinic group visits, -3.9 kg (95% CI, -5.0 to -2.9 kg) for telephone group visits, and -2.6 kg (95% CI, -3.6 to -1.5 kg) for in-clinic individual visits (**Figure 2** and **Table 2**). Compared with in-clinic individual visits, the difference in mean weight change was -1.9 kg (97.5% CI, -3.5 to -0.2 kg; $P = .01$) for in-clinic group visits and -1.4 kg (97.5% CI, -3.0 to 0.3 kg; $P = .06$) for telephone group visits.

Secondary Outcomes

At 6-month follow-up, mean weight loss was -8.3 kg (95% CI, -9.2 to -7.4 kg) for in-clinic group visits, -7.7 kg (95% CI, -8.6 to -6.8 kg) for telephone group visits, and -5.7 kg (95% CI, -6.7 to -4.8 kg) for in-clinic individual visits. Compared with in-clinic individual visits, the difference in mean weight change was -2.6 kg (95% CI, -3.8 to -1.4 kg; $P < .001$) for in-clinic group visits and -2.0 kg (95% CI, -3.2 to -0.8 kg; $P = .002$) for telephone group visits (eTable 3 in Supplement 2). There were no significant differences between in-clinic group and telephone group visits with regard to mean weight loss at any time point. Prespecified sensitivity analysis with adjustment for baseline characteristics, as well as post hoc sensitivity analyses with adjustment for baseline weight, imputation of baseline weight for missing weight data, and excluding the single VA site, all showed similar findings (eTable 4 in Supplement 2).

At 24 months, there was no significant difference in the proportion of participants who achieved clinically meaningful weight loss greater than 5% between in-clinic group visits (44.1% [95% CI, 35.2%-47.8%]) and in-clinic individual visits (36.0% [95% CI, 30.2%-42.3%]; odds ratio [OR], 1.4 [95% CI, 1.0-2.0]; $P = .07$) or between telephone group visits (41.4% [95% CI, 37.9%-50.6%]) and in-clinic individual visits (OR, 1.3 [95% CI, 0.9-1.8]; $P = .22$). At 24 months, there was no significant difference in the proportion who achieved greater than 10% weight loss between in-clinic group visits (22.6% [95% CI, 18.1%-27.9%]) and in-clinic individual visits (17.1% [95% CI, 13.3%-21.8%]; OR, 1.4 [95% CI, 0.9-2.1]; $P = .09$) or between telephone group visits (22.3% [95% CI, 17.9%-27.6%]) and in-clinic individual visits (OR, 1.4 [95% CI, 0.9-2.1]; $P = .11$). Percentage weight loss and proportions who achieved greater than 5% and greater than 10% weight loss at 6 and 18 months are shown in eTable 5 in Supplement 2. Comparisons of those who achieved greater than 5% and greater than 10% weight loss at 18 months were post hoc.

Session Attendance

Mean attendance rates for in-clinic individual visits, in-clinic group visits, and telephone group visits were 12.1 of 14 visits (86.4%), 12.7 of 18 visits (71.6%), and 11.7 of 18 visits (66.2%) from 0 to 6 months and 10.6 of 18 visits (58.9%), 7.4 of 18 visits (40.9%), and 6.6 of 18 visits (35.9%) from 6 to 24 months (**Table 3**).

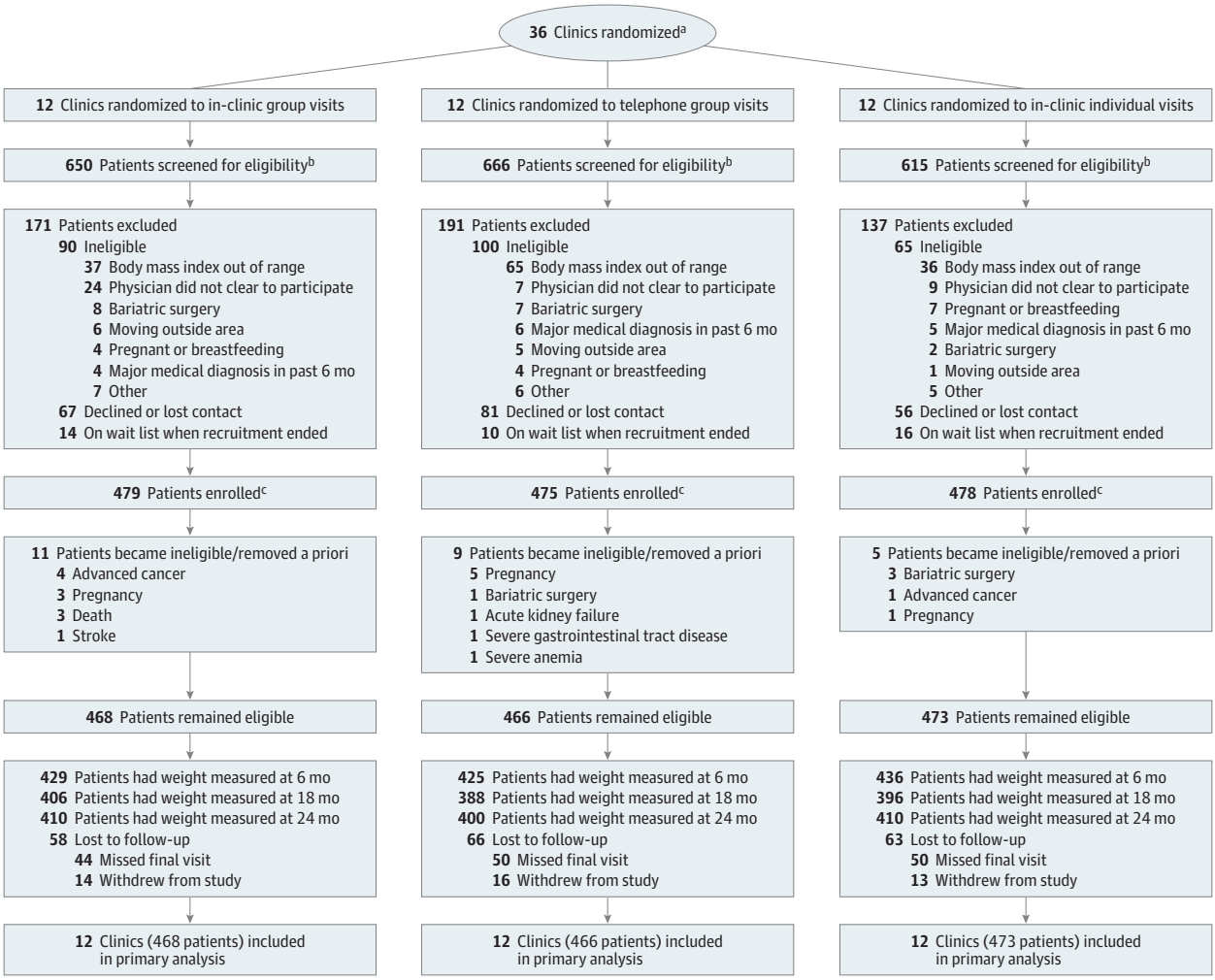
Adverse Events

Three unrelated deaths and 261 hospitalizations were reported, including 94 for the in-clinic individual intervention, 88 for the in-clinic group intervention, and 82 for the telephone group intervention. Only 3 events were determined to be possibly study related (2 joint replacements and 1 cholecystectomy), and 1 probably related (recurrent syncope) (eTable 6 in Supplement 2).

Discussion

In this trial, in-clinic group visits, but not telephone group visits, resulted in statistically significant greater weight loss at 24 months compared with a modified Medicare Intensive Behavioral Therapy model with traditional in-clinic individual visits. Results also demonstrated no significant difference in the proportion of participants attaining weight loss greater than 5%, a clinically important change, at 24 months for any of the between-group comparisons. Therefore, although the 24-month mean difference between in-clinic group and in-clinic individual

Figure 1. Participant Flow Through the Rural Engagement in Primary Care for Optimizing Weight Reduction Trial



[a] One practice in the in-clinic group intervention randomized in cohort 1 declined prior to enrolling patients, and the replacement practice was randomized in cohort 2. One practice in the in-clinic group intervention and 1 practice in the in-clinic individual intervention randomized in cohort 3 declined, after randomization but prior to enrolling patients, and were subsequently replaced with the next recruited practices.

[b] Median number of patients screened per clinic: for in-clinic group visits, 54 (interquartile range [IQR], 49-58); for telephone group visits, 55 (IQR, 51-59); and for in-clinic individual visits, 51 (IQR, 47-57).

[c] Median number of patients enrolled per clinic: for in-clinic group visits, 40 (IQR, 39-42); for telephone group visits, 40 (IQR, 38-42); and for in-clinic individual visits, 40 (IQR, 39-41).

visits was statistically significant, the absolute difference in weight loss of -1.9 kg was small in magnitude and may not represent a clinically important difference.

In-clinic individual visits had a higher proportion of attendance, particularly at later time points, compared with both in-clinic group visits and telephone group visits, although this intervention did not result in greater weight loss. Attendance was not due to payment incentives. Participants were not paid, and practice staff were paid per visit similarly across intervention groups. In addition, travel time to clinics was similar across groups. The flexible scheduling of individual visits, and perhaps the greater attention to individual needs with one-on-one interaction, may have led to greater attendance. In both group interventions, participants chose from approximately 3 to 4 meeting time options, mostly before- or after-hours; however, changes in participants' schedules may have hindered attendance over 2 years. Thus, the benefits of group visits (eg, peer support and accountability) may be most pronounced during initial treatment as supported by the larger between-group weight losses observed at 6 months, as is typically true of weight loss interventions. Data presented here suggest that peer interaction in group visits may not lead to greater attendance compared with individual visits.

The travel time to clinics was relatively low (median, 8-11 minutes) compared with a primary care–based weight loss trial in an urban setting (25 minutes)[23] and with self-reported travel time for medical/dental care in a national sample (22 minutes).[24] The low travel time reflects accessibility of many of the practices,

Table 1. Baseline Participant Characteristics

Characteristics	In-clinic group visits (n = 468)	Telephone group visits (n = 466)	In-clinic individual visits (n = 473)
Age, mean (SD), y	55.7 (12.0)	54.1 (11.9)	54.1 (11.5)
Weight, mean (SD), kg	102.9 (15.5)	102.7 (15.6)	103.1 (15.4)
Body mass index, mean (SD)[a]	36.7 (3.9)	36.6 (3.9)	36.9 (4.0)
Sex, No. (%)			
Female	343 (73.3)	361 (77.5)	377 (79.7)
Male	125 (26.7)	105 (22.5)	96 (20.3)
Rurality, No. (%)[b]			
Isolated rural	203 (43.4)	212 (45.5)	244 (51.6)
Small rural core	83 (17.7)	89 (19.1)	78 (16.5)
Large rural core	182 (38.9)	165 (35.4)	151 (31.9)
Race/ethnicity, No. (%)[c]			
White non-Hispanic	442 (94.4)	448 (96.1)	463 (97.9)
Hispanic or Latino	14 (3.0)	13 (2.8)	6 (1.3)
Black or African American non-Hispanic	5 (1.1)	2 (0.4)	0
American Indian or Alaskan Native non-Hispanic	2 (0.4)	2 (0.4)	2 (0.4)
Multiracial/not specified	5 (1.1)	1 (0.2)	2 (0.4)
Married, No. (%)	366 (78.2)	366 (78.5)	366 (77.4)
Household income, No. (%)	n = 457	n = 448	n = 456
<$35 000	110 (24.1)	109 (24.3)	113 (24.8)
$35 000-$74 999	209 (45.7)	183 (40.8)	201 (44.1)
≥$75 000	138 (30.2)	156 (34.8)	142 (31.1)
Education, No. (%)			
High school graduate or less	99 (21.2)	84 (18.0)	113 (23.9)
Some college	232 (49.6)	218 (46.8)	242 (51.2)
Bachelor's degree	86 (18.4)	96 (20.6)	80 (16.9)
Graduate or professional degree	51 (10.9)	68 (14.6)	38 (8.0)
Employment status, No. (%)[d]			
Employed			
Full time	255 (54.5)	255 (54.7)	271 (57.3)
Part time	64 (13.7)	66 (14.2)	80 (16.9)
Retired	113 (24.1)	101 (21.7)	85 (18.0)
Homemaker/volunteer	27 (5.8)	34 (7.3)	31 (6.6)
Unemployed/looking for work	9 (1.9)	10 (2.2)	6 (1.3)
Health insurance, No. (%)[e]			
Private/other	329 (70.3)	322 (69.1)	346 (73.2)
Medicare	108 (23.1)	105 (22.5)	84 (17.8)
Any Medicaid	23 (4.9)	27 (5.8)	31 (6.6)
Uninsured	8 (1.7)	12 (2.6)	12 (2.5)
Medical conditions, No. (%)[f]			
Hypertension	215 (45.9)	200 (42.9)	228 (48.2)
Hypercholesterolemia	204 (43.6)	164 (35.2)	199 (42.1)
Depression/other mental health	186 (39.7)	182 (39.1)	183 (38.7)
Arthritis	164 (35.0)	152 (32.6)	156 (33.0)
Diabetes	128 (27.4)	114 (24.5)	95 (20.1)
Joint replacement history	52 (11.1)	54 (11.6)	57 (12.1)
Cancer history	48 (10.3)	53 (11.4)	46 (9.7)
Cardiovascular disease	39 (8.3)	26 (5.6)	27 (5.7)
No prior assistance with weight loss, No. (%)	160 (34.3) (n = 467)	146 (31.5) (n = 464)	166 (35.2) (n = 472)
Travel time to clinic, median (interquartile range), min	10.5 (2.8-29.6)	11.0 (2.6-27.1)	8.2 (2.2-21.9)

Conversion: To convert weight to pounds, divide by 0.45.

[a] Calculated as weight in kilograms divided by height in meters squared.

[b] Rurality was defined by Rural-Urban Commuting Area Codes[15]; isolated rural indicates the primary flow is to a tract outside any urban area or cluster; small rural core, the primary flow is within an urban cluster of 2500 to 9999; large rural core, the primary flow is within an urban cluster of 10 000 to 49 999.

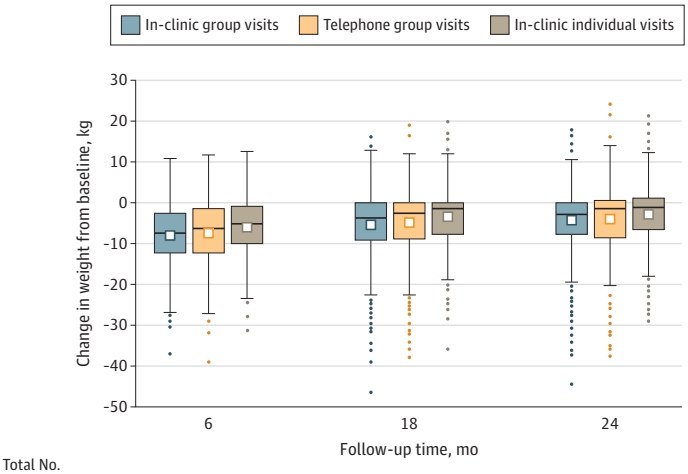
[c] Race/ethnicity was defined by participant self-report.

[d] Full-time employment was defined as 35 hours per week or more.

[e] Health insurance categories are mutually exclusive and defined as any Medicaid coverage, followed by any Medicare coverage, private/other insurance only, and no insurance.

[f] Medical conditions were assessed by participant self-report.

Figure 2. Observed Weight Change by Treatment Group Including Primary Outcome at 24 Months



Total No.			
In-clinic group visits	429	406	410
Telephone group visits	425	388	400
In-clinic individual visits	436	396	410

In the box plots, the middle lines represent median observed change in weight (calculated as baseline weight subtracted from observed follow-up weight), open squares represent mean observed change, box tops and bottoms represent interquartile range, whiskers extend to the most extreme observed values with 1.5 times the interquartile range of the nearer quartile, and dots represent observed values outside that range. More negative values indicate greater weight loss. Mean weights at baseline were 102.9 (SD, 15.5) kg for the in-clinic group intervention, 102.7 (SD, 15.6) kg for the telephone group intervention, and 103.1 (SD, 15.4) kg for the in-clinic individual intervention. Analyses used linear mixed-effects multilevel models, which included random cluster (clinic) effects, and adjusted for randomized strata (affiliated academic medical center) to examine the primary outcome of group comparison of absolute change in weight at 24 months. An unstructured covariance matrix was used, and missing weights were treated as missing at random and addressed using maximum likelihood methods. The primary outcome, the difference in mean weight change at 24 months compared with in-clinic individual visits was −1.9 kg (97.5% CI, −3.5 to −0.2 kg; $P = .01$) for in-clinic group visits and −1.4 kg (97.5% CI, −3.0 to 0.3 kg; $P = .06$) for telephone group visits. There were no significant differences between in-clinic group visits and telephone group visits.

of which 60% were located in isolated or small rural areas. Except at the single VA clinic, patients and clinicians in the in-clinic group intervention preferred to continue meeting in person rather than switch to telephone group calls after 14 visits. Further research is warranted on the actual and perceived travel burden of rural residents, particularly in light of the potential benefits of attending visits in a health care setting with a clinician who has expertise in the local community.

Wadden et al[25] recently evaluated the intensive behavioral therapy provision among 50 adults in an academic setting outside of primary care and found that a similar proportion achieved greater than 5% weight loss after 12 months (44%). Other studies of primary care–based interventions with individual telephone visits observed weight loss ranging from −4.0 kg to −4.6 kg at 12 to 24 months.[21,26,27] The Look AHEAD intervention, which took place in academic-based settings, reported a 6.5% mean weight loss at 24 months.[28] Some of the Look AHEAD intervention components, such as more frequent visits, offering a combination of group and individual visits, or providing meal replacement shakes, may improve the weight loss observed across the 3 delivery strategies. In addition, remote delivery through home-based telemedicine/televideo may offer advantages over audio-only conference calls, and the scalability of this approach is relevant to both rural and urban settings. The Medicare Intensive Behavioral Therapy benefit could be adapted to support group visits, telemedicine visits, or some combination of visit types.

This trial was designed to have a high degree of pragmatic elements to enhance the likelihood that the findings would be generalizable to clinical practice. Practices represented a diverse mix of practice types across a wide geographic region. In addition, patients were recruited through clinic registries and referrals rather than by research staff, and there were few exclusion criteria and a high eligibility rate (87% of those screened).[16] Practice-employed staff delivered the intervention even though few had prior experience in weight loss counseling. Also, the training was designed to represent the amount of time a practitioner might take off from clinical care, and fidelity monitoring was limited to the centralized telephone group model. To our knowledge, this was the first pragmatic trial comparing the Medicare reimbursable model with in-clinic group and telephone group visits. To our knowledge, this trial was the largest trial implementing behavioral weight loss interventions within local practices.

Limitations

This study has several limitations. First, the sample was predominantly White non-Hispanic and mostly female. However, the proportion of men was similar to other weight loss trials,[29] and the race/ethnicity of the sample represents the population within the participating rural practices.[16] Second, the study did not have a control group that did not receive a weight loss intervention. Third, the study was designed to compare current care delivery models under pragmatic conditions and thus

Table 2. Weight Loss, Percentage Weight Loss, and Percentage of Patients Losing Greater Than 5% and Greater Than 10% at 24 Months[a]

Outcomes	In-clinic group visits (n = 468)	Telephone group visits (n = 466)	In-clinic individual visits (n = 473)	Mean difference or odds ratio (95% CI)	*P* value
Weight, mean (SD), kg					
Baseline	102.9 (15.5)	102.7 (15.6)	103.1 (15.4)		
24 mo	97.4 (17.3)	97.6 (17.7)	99.7 (17.1)		
Primary outcome					
Weight loss at 24 mo, mean (95% CI), kg[b]	-4.4 (-5.5 to -3.4)	-3.9 (-5.0 to -2.9)	-2.6 (-3.6 to -1.5)		
In-clinic group vs in-clinic individual visits				-1.9 (-3.5 to -0.2)[c,d]	.01
Telephone group vs in-clinic individual visits				-1.4 (-3.0 to 0.3)[c,d]	.06
In-clinic group vs telephone group visits				-0.5 (-1.9 to 0.9)[c]	.48
Secondary outcomes					
Weight loss at 24 mo, mean % (95% CI)[b]	-4.3 (-5.3 to -3.3)	-3.8 (-4.9 to -2.8)	-2.5 (-3.5 to -1.4)		
In-clinic group vs in-clinic individual visits				-1.8 (-3.2 to -0.4)[c]	.01
Telephone group vs in-clinic individual visits				-1.3 (-2.8 to 0.1)[c]	.06
In-clinic group vs telephone group visits				-0.5 (-1.9 to 0.9)[c]	.51
>5% Weight loss at 24 mo, % (95% CI)[e]	44.1 (35.2 to 47.8)	41.4 (37.9 to 50.6)	36.0 (30.2 to 42.3)		
In-clinic group vs in-clinic individual visits				1.4 (1.0 to 2.0)[f]	.07
Telephone group vs in-clinic individual visits				1.3 (0.9 to 1.8)[f]	.22
In-clinic group vs telephone group visits				1.1 (0.8 to 1.6)[f]	.54
>10% Weight loss at 24 mo, % (95% CI)[e]	22.6 (18.1 to 27.9)	22.3 (17.9 to 27.6)	17.1 (13.3 to 21.8)		
In-clinic group vs in-clinic individual visits				1.4 (0.9 to 2.1)[f]	.09
Telephone group vs in-clinic individual visits				1.4 (0.9 to 2.1)[f]	.11
In-clinic group vs telephone group visits				1.0 (0.7 to 1.5)[f]	.93

[a] All models were adjusted for randomization strata based on academic medical center affiliation and included random cluster (clinic) effects. See eTables 3 and 5 in Supplement 2 for intermediate end points at 6 and 18 months.

[b] Analyses used linear mixed-effects multilevel models to examine the outcomes of group comparison of absolute weight loss and percentage weight loss at 24 months. An unstructured covariance matrix was used, and missing weights were treated as missing at random and addressed using maximum likelihood methods.

[c] Mean difference.

[d] Variability data are 97.5% confidence intervals.

[e] Generalized linear mixed models were used to compare the percentages of participants achieving 5% and 10% weight loss thresholds.

[f] Odds ratio.

Table 3. Sessions Attended

	In-clinic group visits (n = 468)	Telephone group visits (n = 466)	In-clinic individual visits (n = 473)
0 to 6 mo			
Maximum No. of sessions	18	18	14
Mean No. attended (95% CI)	12.7 (11.9-13.5)	11.7 (10.9-12.5)	12.1 (11.2-12.9)
Mean % attended (95% CI)[a]	71.6 (66.2-77.0)	66.2 (60.8-71.7)	86.4 (80.8-92.0)
6 to 24 mo			
Maximum No. of sessions	18	18	18
Mean No. attended (95% CI)	7.4 (6.2-8.6)	6.6 (5.4-7.8)	10.6 (9.4-11.8)
Mean % attended (95% CI)[b]	40.9 (34.3-47.6)	35.9 (29.2-42.5)	58.9 (52.1-65.8)

[a] From 0 to 6 months, the mean percentage of sessions attended within each practice ranged from 62% to 83% for in-clinic group visits, from 52% to 75% for telephone group visits, and from 49% to 98% for in-clinic individual visits.

[b] From 6 to 24 months, the mean percentage of sessions attended within each practice ranged from 27% to 50% for in-clinic group visits, from 21% to 49% for telephone group visits, and from 19% to 87% for in-clinic individual visits.

did not control for different professional backgrounds or training of the interventionists. Enhanced training for clinicians delivering individual in-clinic visits may improve outcomes for this model.[30] Fourth, the study was not limited to older adults covered by Medicare and did not require a greater than 3-kg weight loss for continued sessions; thus, replication of the intensive behavioral therapy provision is needed in a Medicare population.

Conclusions

Among patients with obesity in rural primary care clinics, in-clinic group visits but not telephone-based group visits, compared with in-clinic individual visits, resulted in statistically significantly greater weight loss at 24 months. However, the differences were small in magnitude and of uncertain clinical importance.

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Author Affiliations: Department of Population Health, University of Kansas Medical Center, Kansas City (Befort, Ellerbeck); Center for Clinical Epidemiology and Population Health, Marshfield Clinic Research Institute, Marshfield, Wisconsin (VanWormer); Division of Endocrinology, University of Nebraska Medical Center, Omaha (Desouza, Eiland, Drincic); Department of Biostatistics, University of Kansas Medical Center, Kansas City (Gajewski, Brown); Department of Family Medicine and Community Health, University of Kansas Medical Center, Kansas City (Kimminau, Greiner); College of Public Health and Health Professions, University of Florida, Gainesville (Perri); Department of Endocrinology, Marshfield Clinic Health System, Marshfield, Wisconsin (Pathak); School of Public Health and Health Policy, Center for Systems and Community Design, City University of New York, New York, New York (Huang).

Author Contributions: Drs Befort and Gajewski had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Befort, VanWormer, Ellerbeck, Gajewski, Kimminau, Greiner, Perri, Pathak, Huang, Eiland.
Acquisition, analysis, or interpretation of data: Befort, VanWormer, Desouza, Ellerbeck, Gajewski, Kimminau, Greiner, Perri, Brown, Pathak, Huang, Drincic.
Drafting of the manuscript: Befort, Desouza, Gajewski, Kimminau, Pathak.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Befort, Gajewski, Brown.
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Supervision: Befort, VanWormer, Desouza, Pathak, Drincic.

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REFERENCES

1. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity and severe obesity among adults: United States, 2017-2018. *NCHS Data Brief*. 2020;(360):1-8.

2. 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). *J Rural Health*. 2012;28(4):392-397. doi:10.1111/j.1748-0361.2012.00411.x

3. Hales CM, Fryar CD, Carroll MD, Freedman DS, Aoki Y, Ogden CL. Differences in obesity prevalence by demographic characteristics and urbanization level among adults in the United States, 2013-2016. *JAMA*. 2018;319(23):2419-2429. doi:10.1001/jama.2018.7270

4. Ariel-Donges AH, Gordon EL, Dixon BN, et al. Rural/urban disparities in access to the National Diabetes Prevention Program. *Transl Behav Med*. 2019;ibz098. doi:10.1093/tbm/ibz098

5. Bolin JN, Bellamy GR, Ferdinand AO, et al. Rural Healthy People 2020: new decade, same challenges. *J Rural Health*. 2015;31(3):326-333. doi:10.1111/jrh.12116

6. Centers for Medicare & Medicaid Services. *Decision Memo for Intensive Behavioral Therapy for Obesity*. Published November 29, 2011. Accessed February 7, 2020. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&bc=ACAAAAAAIAAA&NCAId=253&

7. Batsis JA, Bynum JP. Uptake of the Centers for Medicare and Medicaid obesity benefit: 2012-2013. *Obesity (Silver Spring)*. 2016;24(9):1983-1988. doi:10.1002/oby.21578

8. Borek AJ, Abraham C, Greaves CJ, Tarrant M. Group-based diet and physical activity weight-loss interventions: a systematic review and meta-analysis of randomised controlled trials. *Appl Psychol Health Well Being*. 2018;10(1):62-86. doi:10.1111/aphw.12121

9. Paul-Ebhohimhen V, Avenell A. A systematic review of the effectiveness of group versus individual treatments for adult obesity. *Obes Facts*. 2009;2(1):17-24. doi:10.1159/000186144

10. 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):717-721. doi:10.1037/0022-006X.69.4.717

11. Jackson GL, Powers BJ, Chatterjee R, et al. The patient centered medical home: a systematic review. *Ann Intern Med*. 2013;158(3):169-178. doi:10.7326/0003-4819-158-3-201302050-00579

12. Donnelly JE, Goetz J, Gibson C, et al. Equivalent weight loss for weight management programs delivered by phone and clinic. *Obesity (Silver Spring)*. 2013;21(10):1951-1959. doi:10.1002/oby.20334

13. Befort CA, Klemp JR, Sullivan DK, et al. Weight loss maintenance strategies among rural breast cancer survivors: the rural women connecting for better health trial. *Obesity (Silver Spring)*. 2016;24(10):2070-2077. doi:10.1002/oby.21625

14. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool:

designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147. doi:10.1136/bmj.h2147

15. US Department of Agriculture Economic Research Service. Rural-Urban Commuting Area Codes (RUCAs). Accessed September 11, 2019. https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx

16. Befort CA, Kurz D, VanWormer JJ, Ellerbeck EF. Recruitment and reach in a pragmatic behavioral weight loss randomized controlled trial: implications for real-world primary care practice. *BMC Fam Pract*. 2020;21(1):47. doi:10.1186/s12875-020-01117-w

17. Wadden TA, West DS, Delahanty L, et al; Look AHEAD Research Group. The Look AHEAD study: a description of the lifestyle intervention and the evidence supporting it. *Obesity (Silver Spring)*. 2006;14(5):737-752. doi:10.1038/oby.2006.84

18. Centers for Medicare & Medicaid Services Medical Learning Network. *Intensive Behavior Therapy for Obesity*. Updated March 9, 2012. Accessed March 3, 2014. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7641.pdf

19. Perri MG, Limacher MC, von Castel-Roberts K, et al. Comparative effectiveness of three doses of weight-loss counseling: two-year findings from the Rural LITE trial. *Obesity (Silver Spring)*. 2014;22 (11):2293-2300. doi:10.1002/oby.20832

20. Jensen MD, Ryan DH, Apovian CM, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; Obesity Society. 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. *J Am Coll Cardiol*. 2014;63(25 pt B):2985-3023. doi:10.1016/j.jacc.2013.11.004

21. Appel LJ, Clark JM, Yeh HC, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med*. 2011;365(21):1959-1968. doi:10.1056/NEJMoa1108660

22. Tronieri JS, Wadden TA, Chao AM, Tsai AG. Primary care interventions for obesity: review of the evidence. *Curr Obes Rep*. 2019;8(2):128-136. doi:10.1007/s13679-019-00341-5

23. Fabricatore AN, Wadden TA, Moore RH, Butryn ML, Heymsfield SB, Nguyen AM. Predictors of attrition and weight loss success: results from a randomized controlled trial. *Behav Res Ther*. 2009; 47(8):685-691. doi:10.1016/j.brat.2009.05.004

24. Probst JC, Laditka SB, Wang JY, Johnson AO. Effects of residence and race on burden of travel for care: cross sectional analysis of the 2001 US National Household Travel Survey. *BMC Health Serv Res*. 2007;7:40. doi:10.1186/1472-6963-7-40

25. Wadden TA, Walsh OA, Berkowitz RI, et al. Intensive behavioral therapy for obesity combined with liraglutide 3.0 mg: a randomized controlled trial. *Obesity (Silver Spring)*. 2019;27(1):75-86. doi:10.1002/oby.22359

26. Eaton CB, Hartman SJ, Perzanowski E, et al. A randomized clinical trial of a tailored lifestyle intervention for obese, sedentary, primary care patients. *Ann Fam Med*. 2016;14(4):311-319. doi:10.1370/afm.1952

27. Bennett GG, Steinberg D, Askew S, et al. Effectiveness of an app and provider counseling for obesity treatment in primary care. *Am J Prev Med*. 2018;55(6):777-786. doi:10.1016/j.amepre.2018.07.005

28. Wadden TA, Neiberg RH, Wing RR, et al; Look AHEAD Research Group. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. *Obesity (Silver Spring)*. 2011;19 (10):1987-1998. doi:10.1038/oby.2011.230

29. Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. *Obesity (Silver Spring)*. 2012;20(6): 1234-1239. doi:10.1038/oby.2011.140

30. Wadden TA, Tsai AG, Tronieri JS. A protocol to deliver intensive behavioral therapy (IBT) for obesity in primary care settings: the MODEL-IBT program. *Obesity (Silver Spring)*. 2019;27(10):1562-1566. doi:10.1002/oby.22594