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ORIGINAL ARTICLE

# Weight loss in primary care: A pooled analysis of two pragmatic cluster-randomized trials

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## Abstract

**Objective:** The aim of this study was to report the results of five weight-loss interventions in primary care settings in underserved patients and to compare the level of pragmatism across the interventions using the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) tool.

**Methods:** Data from 54 primary care clinics (2,210 patients) were pooled from the Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) and Rural Engagement in Primary Care for Optimizing Weight Reduction (REPOWER) cluster-randomized trials. Clinics were randomized to one of five comparators: PROPEL usual care, PROPEL combination of in-clinic and telephone visits, REPOWER in-clinic individual visits, REPOWER in-clinic group visits, or REPOWER telephone group visits.

**Results:** At 24 months, weight loss (kilograms) was −0.50 (95% CI: −1.77 to 0.76), −3.05 (−4.10 to −2.01), −4.30 (−5.35 to −3.26), −4.79 (−5.83 to −3.75), and −4.80 (−5.96 to −3.64) in the PROPEL usual care, REPOWER in-clinic individual visits, REPOWER telephone group visits, REPOWER in-clinic group visits, and PROPEL in-clinic and telephone visits arms, respectively. At 24 months, percentage of weight loss was −0.360 (−1.60 to 0.88), −3.00 (−4.02 to −1.98), −4.23 (−5.25 to −3.20), −4.67 (−5.69 to −3.65), and −4.69 (−5.82 to −3.56), respectively, in the five arms. The REPOWER in-clinic individual visits intervention was the most pragmatic and reflects the current Centers for Medicare and Medicaid Services funding model, although this intervention produced the least weight loss.

**Conclusions:** Clinically significant weight loss over 6 months in primary care settings is achievable using a variety of lifestyle-based treatment approaches. Longer-term weight-loss maintenance is more difficult to achieve.

## INTRODUCTION

Obesity is a disease that affects 42% of American adults (1). Medically underserved populations such as those living in rural areas as well as those from minority populations experience an even higher prevalence of obesity (2,3). Obesity (BMI ≥ 30 kg/m$^2$) is associated with an increased risk of developing noncommunicable diseases such as type 2 diabetes, cardiovascular disease, and several cancers (4-6). More recently, research has indicated that obesity increases the risk of developing severe complications from COVID-19 (7), which compounds the public health impact of the observed racial disparities in COVID-19 infection and outcomes (8,9).

It is estimated that approximately 55% of physician office visits in the United States are conducted in primary care (10), and the US Preventive Services Task Force recommends that physicians offer intensive behavioral interventions to individuals with obesity (11). Therefore, it seems that primary care could be an important setting for the delivery of weight-loss treatment to large segments of the population. Weight-loss treatment delivered in primary care has resulted in limited success, demonstrating only 1 to 3 kg of weight loss over 6 to 24 months (12). This lack of significant weight loss can be attributed, in part, to the reliance on low-intensity interventions in this setting. However, there is evidence that higher-intensity (i.e., 12 or more sessions per year) interventions delivered by trained interventionists result in greater weight loss (13). Therefore, there is an urgent need to develop and test pragmatic treatment strategies in the primary care setting, especially those recommended in the *2013 AHA/ACC/TOS Guidelines for the Management of Overweight and Obesity in Adults*, in order to achieve clinically significant weight loss on the order of 3% to 5% (14,15). There is a gap between the current guidelines and what is currently implemented in clinical practice; in 2012 to 2013, less than 1% of beneficiaries availed themselves of the Centers for Medicare and Medicaid Services (CMS) reimbursement for intensive behavioral therapy for obesity (16). Therefore, comparative effectiveness studies are required to change the way that primary care practitioners approach the problem of obesity and engage and assist patients with obesity. This is particularly important for addressing health disparities in populations that have high rates of comorbid conditions and may have less access to evidence-based programs.

Two large, 2-year pragmatic cluster-randomized weight-loss trials conducted in underserved primary care settings were funded by the Patient-Centered Outcomes Research Institute (PCORI) in 2015 and were recently completed. The cluster design was used to minimize contamination between groups. These trials were the Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) trial (NCT02561221) (17) and the Rural Engagement in Primary Care for Optimizing Weight Reduction (REPOWER) trial (NCT02456636) (18). Efforts were made to harmonize the timeline, inclusion/exclusion criteria, and measurements between the two trials a priori. The purpose of this study was to report the results of five weight-loss interventions (2 from PROPEL and 3 from REPOWER) in primary care settings in underserved patients and to compare the level of pragmatism across the interventions using the Pragmatic Explanatory Continuum Indicator Summary (PRECIS)-2 tool (19).

### Study Importance

#### What is already known?

- Lifestyle interventions for obesity treatment delivered in academic health care or commercial settings result in clinically significant weight loss.
- The translation of evidence-based lifestyle interventions to primary care settings has not been successful, especially in underserved populations.

#### What does this study add?

- In this secondary analysis of data from two cluster-randomized trials conducted in primary care settings, significant weight loss was observed using several behavioral approaches; however, the degree of pragmatism varied across the study arms, which is an important consideration when balancing decisions about which approach to adopt into clinical practice.

#### How might these results change the focus of clinical practice?

- Clinically significant weight loss is achievable in primary care settings.
- The expansion of the primary care team to include the behavioral treatment of obesity may result in significant clinical and public health benefits.

## METHODS

The PROPEL trial was approved by the institutional review board of the Pennington Biomedical Research Center. The REPOWER trial was approved by the institutional review boards of the University of Kansas Medical Center and Veterans Affairs Nebraska-Western Iowa Health Care System. All patients provided written informed consent prior to participating in the study. PROPEL was conducted between April 2016 and September 2019 and REPOWER was conducted between February 2016 and December 2019; neither trial was impacted by the COVID-19 pandemic. Both trials are registered at ClinicalTrials.gov (NCT02561221; NCT02456636); each trial followed the recommendations in the Consolidated Standards of Reporting Trials (CONSORT) extension for cluster-randomized trials (20), and the trial-specific CONSORT diagrams are published with the original publications (17,18).

## Clinics

The PROPEL trial included 18 primary clinics from five health systems in Louisiana that served a large percentage of low-income, underserved patients; four systems of Federally Qualified Health Centers (FQHCs) and one large, nonprofit academic multispecialty health care-delivery system. The clinics were randomized to either an in-clinic/telephone (PROPEL-clinic/phone) group or a usual care (PROPEL-UC) group after stratification by health care system (21). The REPOWER trial included 36 primary care practices from the Midwestern US that predominantly or solely served rural patients; each clinic was affiliated with one of three academic institutions. The clinics were randomized to one of three groups (in-clinic individual visits [REPOWER-clinic-individual]; in-clinic group visits [REPOWER-clinic-group], or telephone group visits [REPOWER-phone-group]) after stratification by primary academic institutional affiliation (22).

## Participants

All participants were patients at the enrolled clinics. The primary inclusion criteria were broad and included an age of 20 to 75 years and a BMI (kilograms per meters squared) between 30 and 50 in PROPEL and between 30 and 45 in REPOWER. Full eligibility criteria for both trials have been previously published (21,22). A total of 803 patients from the PROPEL trial and 1,432 patients from the REPOWER trial were enrolled. The REPOWER trial excluded data from 25 patients who died ($n = 3$), became pregnant ($n = 9$), underwent bariatric surgery ($n = 4$), or developed a severe medical condition, e.g., advanced stage cancer ($n = 9$) from the analysis a priori. Data from such patients in the PROPEL trial ($n = 36$) were excluded only beyond the time of the event. Therefore, a total of 2,210 patients from the two trials contributed data to the analyses (PROPEL-clinic/phone = 9 clinics, 452 patients; PROPEL-UC = 9 clinics, 351 patients; REPOWER-clinic-group = 12 clinics, 468 patients; REPOWER-clinic-individual = 12 clinics, 473 patients; REPOWER-phone-group = 12 clinics, 466 patients; see Figure 1).

## Interventions

Patients received the intervention to which their clinic was assigned. The interventions have been described previously (21,22).

### Usual care (PROPEL-UC)

Patients in the PROPEL-UC group received routine care throughout the trial from their primary care team, whose training included a presentation and brochure on obesity treatment guidelines and CMS reimbursement. In addition, PROPEL-UC patients received six newsletters covering topics related to sitting and health, goal setting, staying safe in the heat, memory health, self-care, sleep hygiene, and smoking cessation.

### In-clinic/telephone visits (PROPEL-clinic/phone)

The PROPEL-clinic/phone group received weekly counseling sessions (16 in-person and 6 telephone) in the first 6 months, followed by monthly sessions (alternating in-person visits and telephone calls) for the remaining 18 months. Most sessions were conducted individually, whereas some sessions were conducted in small groups (2-3 patients), depending on patient preference. In-person individual sessions were 30 minutes, in-person group sessions were 1 hour, and phone sessions were 15 to 20 minutes in length. All sessions were delivered by study-employed health coaches embedded in the primary care clinics. The coaches had academic degrees related to nutrition, physical activity, or behavioral medicine and underwent an initial 1.5-day training session and yearly retraining. Weekly case-conferencing webinars attended by the coaches and the research team were held throughout the trial.

Patients in the PROPEL-clinic/phone group received counseling on how to set goals and develop individualized action plans for diet and physical activity that would achieve 10% weight loss within 6 months. Patients were provided with an electronic scale (BodyTrace) and were encouraged to weigh themselves daily. The daily weights were plotted onto a weight graph that compared their predicted weight loss to actual weight loss in real time. The weight graph was available to patients and their health coaches and allowed the coaches to monitor weight loss and adapt the intensity of the intervention.

The primary care physicians in the PROPEL-clinic/phone group had access to an online obesity science education program that provided education on obesity management, management of coexisting conditions such as type 2 diabetes and hypertension, minimization of bias and stigma related to obesity, and principles of health literacy.

### In-clinic individual visits (REPOWER-clinic-individual)

Patients in the REPOWER-clinic-individual group received 15-minute face-to-face individual counseling visits from practice-employed clinicians that occurred weekly for 1 month, every other week for months 2 to 6, and monthly thereafter. Each practice selected 1 to 2 counselors, most commonly clinic-employed nurses, who conducted the individual counseling sessions. The counselors participated in a single, 3-hour training session focused on dietary and physical activity recommendations, behavioral strategies, and motivational interviewing. Each counselor received an intervention tool kit including example sessions and patient handouts.

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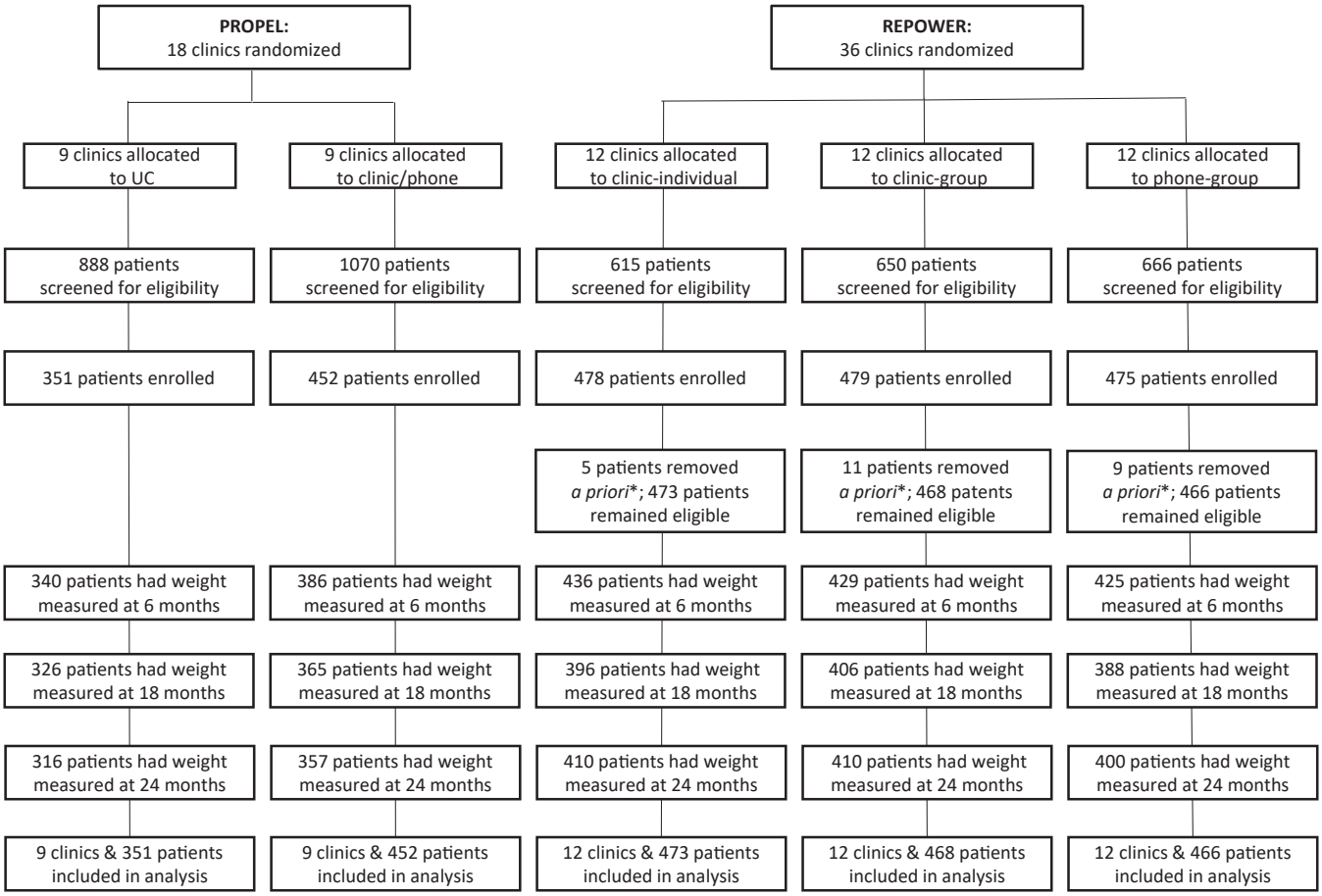


**FIGURE 1** Participant flow through the PROPEL and REPOWER trials. *Patients who became pregnant, had bariatric surgery, or developed a major illness and/or died were removed from the REPOWER trial a priori; patients who became pregnant, had bariatric surgery, or developed a major illness and/or died were retained in the PROPEL trial, and their data were removed beyond the time the event occurred. PROPEL, Promoting Successful Weight Loss in Primary Care in Louisiana trial; REPOWER, the Rural Engagement in Primary Care for Optimizing Weight Reduction trial

### In-clinic group visits (REPOWER-clinic-group)

Patients in the REPOWER-clinic-group arm participated in group counseling visits that were led by practice-employed clinicians. Visits were 60 minutes and occurred weekly for the first 3 months, every other week for months 4 to 6, and monthly thereafter. The first 14 sessions were delivered face-to-face, after which, practices had the option to switch to group telephone conference calls; however, all but one practice opted to continue face-to-face visits. Each clinic selected between one and three counselors (predominantly nurses) to deliver the intervention. The median in-clinic group size was 14 patients per group. Counselors in the REPOWER-clinic-group arm participated in the same 3-hour training as the REPOWER-clinic-individual arm and received a group treatment manual with accompanying patient manuals, a 1-day in-person workshop focused on group facilitation, and optional biweekly to monthly tele-mentoring sessions.

### Telephone group visits (REPOWER-phone-group)

Patients in the REPOWER-phone-group arm received the same group-based intervention as the REPOWER-clinic-group arm, but sessions were delivered via telephone conference calls by centralized study staff, employed by the research team, with graduate degrees in relevant fields (e.g., nutrition, exercise science, psychology). The treatment manual, session frequency, session length, and group size were the same as for the clinic-group arm. Training included shadowing an experienced counselor, weekly to monthly staff meetings, and fidelity monitoring through review of recorded sessions.

## Outcomes

Body weight was measured on a digital scale to the nearest 0.1 kg at baseline and at 6, 18, and 24 months of follow-up. The primary

outcome in the PROPEL trial was percentage of weight loss from baseline to 24 months, whereas the primary outcome in the REPOWER trial was absolute weight loss (kilograms) from baseline to 24 months (17,18). In the present study, we present results for both outcomes.

### Statistical analysis

The outcomes at 6, 18, and 24 months were analyzed in the context of repeated-measures linear mixed-effects multilevel models, which included random cluster (clinic) effects. Acknowledging the limitations associated with pooling data across two different trials, we do not report comparisons between arms, nor do we include covariates such as age, sex, and race in the model, given potential differences in the underlying distributions in the two populations. Intervention group, assessment time, and their interaction terms were included in the models without additional covariates. We performed intention-to-treat analyses, which included all patients (regardless of the number of assessments obtained) and used the restricted maximum likelihood method. The model assumed that missing values were missing at random, and all values presented in the tables and figure are model-based estimates. Weight loss (absolute and percentage) at each time point for each of the fives study arms was modelled. All analyses were conducted with the use of SAS software version 9.4 (SAS Institute).

## RESULTS

Patients had a mean BMI of 36.9 (4.2), a mean weight of 102.6 kg (15.9), and a mean age of 52.4 years (12.5); 79.6% were female individuals, and 71.6% were White individuals (Table 1). The mean body weights across groups ranged from 101.6 kg in PROPEL-clinic/phone to 103.1 kg in REPOWER-clinic-individual, and the proportion that was female ranged from 73.3% in REPOWER-clinic-group to 88.1% in PROPEL-clinic/phone. The racial breakdown of the sample varied considerably between the two trials: Black participants constituted 67.4% of the PROPEL sample and only 0.5% of the REPOWER sample. The proportion of the sample that was classified as rural also varied substantially between the two trials: based on clinic and home addresses, 35 out of 36 clinics (100% of patients) in REPOWER were rural, whereas 4 out of 18 clinics (9.2% of patients) in PROPEL were rural.

At 24 months, weight loss (kilograms) was −0.50 (95% CI: −1.77 to 0.76), −3.05 (−4.10 to −2.01), −4.30 (−5.35 to −3.26), −4.79 (−5.83 to −3.75), and −4.80 (−5.96 to −3.64), respectively, in the PROPEL-UC, REPOWER-clinic-individual, REPOWER-phone-group, REPOWER-clinic-group, and PROPEL-clinic/phone arms, respectively. At 24 months, percentage of weight loss (%) was −0.360 (−1.60 to 0.88), −3.00 (−4.02 to −1.98), −4.23 (−5.25 to −3.20), −4.67 (−5.69 to −3.65), and −4.69 (−5.82 to −3.56), respectively, in the PROPEL-UC, REPOWER-clinic-individual, REPOWER-phone-group, REPOWER-clinic-group, and PROPEL-clinic/phone arms, respectively.

Figure 2 presents the weight loss in each group at 6, 18, and 24 months. At 6 months, weight loss was similar in the REPOWER-clinic-group, REPOWER-phone-group, and PROPEL-clinic/phone groups; however, less weight loss was observed in the REPOWER-clinic-individual arm. At 24 months, the PROPEL-clinic/phone group maintained 66.8% of the initial weight loss (kilograms) achieved at 6 months, compared with 49.0% in REPOWER-clinic-individual, 55.1% in REPOWER-clinic-group, and 53.1% in the REPOWER-phone-group.

Table 2 provides a summary of design elements in the five comparator groups in the present study across the nine PRECIS-2 domains: eligibility criteria, recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis. The eligibility criteria were similar in the PROPEL and REPOWER trials: age 20 to 75 years, BMI between 30 to 50 in PROPEL and 30 to 45 in REPOWER, and being willing and able to participate in scheduled sessions, along with several additional exclusionary criteria (21,22). All recruitment for both trials was conducted in the primary care setting, although recruitment methods varied across clinics and relied to varying degrees on primary care physician referrals, electronic medical record-based approaches, and direct recruitment by study staff. The enrollment-to-screening rate ranged from 71.3% to 77.7% in REPOWER arms versus 39.5% to 42% in the PROPEL arms, reflecting differences in recruitment methods and study populations between the trials. In both trials, out-of-range BMI accounted for the greatest number of ineligible cases (37% in PROPEL and 54% in REPOWER). The setting was primary care clinics in all five comparator groups.

Organization refers to expertise and resources needed to deliver the intervention (19). Both the REPOWER-clinic-individual and REPOWER-clinic-group arms relied on existing clinic staff to deliver the intervention, whereas the PROPEL-clinic/phone and REPOWER-phone-group arms relied on research personnel to deliver the intervention. The training received by the counselors also differed across the active comparator groups, from 3 hours of baseline training only in the REPOWER-clinic-individual group to 13 hours of baseline training and 24 hours of follow-up training in the PROPEL-clinic/phone group. Furthermore, patient tools in the PROPEL-clinic/phone group included use of a scale for daily weighing, a weight-loss graph, and inclusion of portion-controlled foods in the meal plan (particularly in weeks 1-4), whereas patients in the REPOWER-clinic-individual, REPOWER-clinic-group, and REPOWER-phone-group arms were solely encouraged to use the Lose It! food diary app, in which the counselors could message the patients to provide feedback. Intervention delivery flexibility also varied across the five comparator groups. There was no intervention specified in the PROPEL-UC group. The number of contact hours in the interventions ranged from approximately 8 hours in the REPOWER-clinic-individual arm (32 15-minute sessions) to 18 hours in the PROPEL-clinic/phone (27 30-minute sessions and 16 15-to-20-minute sessions) and 36 hours in the REPOWER-clinic-group and REPOWER-phone-group arms (36 1-hour sessions). There was no fidelity monitoring in the PROPEL-UC and REPOWER-clinic-individual groups, whereas the degree of fidelity monitoring

**TABLE 1** Descriptive characteristics of patients in the PROPEL and REPOWER trials at baseline

| | PROPEL-UC[a] | PROPEL-clinic/phone[b] | REPOWER-clinic-individual[c] | REPOWER-clinic-group[d] | REPOWER-phone-group[e] | Total |
|---|---|---|---|---|---|---|
| *N* | 351 | 452 | 473 | 468 | 466 | 2,210 |
| Weight, mean (SD), kg | 102.7 (17.0) | 101.6 (16.4) | 103.1 (15.4) | 102.9 (15.5) | 102.7 (15.6) | 102.6 (15.9) |
| BMI, mean (SD), kg/m$^2$ | 37.2 (4.8) | 37.3 (4.6) | 36.9 (4.0) | 36.7 (3.9) | 36.6 (3.9) | 36.9 (4.2) |
| Age, mean (SD), y | 50.1 (13.6) | 48.8 (12.7) | 53.6 (11.5) | 55.2 (12.0) | 53.6 (11.9) | 52.4 (12.5) |
| Sex, no. *(%)* | | | | | | |
| Female | 280 (79.8) | 398 (88.1) | 377 (79.7) | 343 (73.3) | 361 (77.5) | 1,759 (79.6) |
| Male | 71 (20.2) | 54 (12.0) | 96 (20.3) | 125 (26.7) | 105 (22.5) | 451 (20.4) |
| Race, no. *(%)* | | | | | | |
| Black | 208 (59.3) | 332 (73.5) | 0 (0) | 5 (1.1) | 2 (0.4) | 547 (24.8) |
| White | 113 (32.2) | 95 (21.0) | 466 (98.5) | 450 (96.2) | 458 (98.3) | 1,582 (71.6) |
| Other | 30 (8.6) | 25 (5.5) | 7 (1.5) | 13 (2.8) | 6 (1.3) | 81 (3.7) |
| Rural, no. *(%)* | 7 (2.0) | 67 (14.8) | 473 (100) | 468 (100) | 466 (100) | 1,481 (67.0) |
| Education, no. *(%)* | | | | | | |
| High school or less | 94 (26.9) | 145 (32.1) | 113 (23.9) | 99 (21.2) | 84 (18.0) | 535 (24.2) |
| Some college/associate's degree | 155 (44.3) | 179 (39.6) | 242 (51.2) | 232 (49.6) | 218 (46.8) | 1,026 (46.5) |
| Bachelor's degree | 63 (18.0) | 71 (15.7) | 80 (16.9) | 86 (18.4) | 96 (20.6) | 396 (17.9) |
| Graduate degree | 38 (10.9) | 57 (12.6) | 38 (8.0) | 51 (10.9) | 68 (14.6) | 252 (11.4) |

[a]Usual care in PROPEL.

[b]In-clinic/telephone visits in PROPEL.

[c]In-clinic individual visits in REPOWER.

[d]In-clinic group visits in REPOWER.

[e]Telephone group visits in REPOWER.

Abbreviations: PROPEL, Promoting Successful Weight Loss in Primary Care in Louisiana trial; REPOWER, the Rural Engagement in Primary Care for Optimizing Weight Reduction trial; UC, usual care.

increased across the REPOWER-clinic-group, REPOWER-phone-group, and PROPEL-clinic/phone groups (Table 2). With respect to flexibility related to patient adherence to the intervention (defined here as attendance at counseling sessions), none of the comparator groups enforced attendance. However, all groups except for the PROPEL-UC group monitored adherence; between 50.8% and 74.2% of sessions were attended by participants across the four active intervention groups.

Follow-up of study participants occurred at predefined time points in both the PROPEL (6, 12, 18, and 24 months) and REPOWER trials (6, 18, and 24 months). The follow-up rates ranged from 81.1% to 87.7% across the five comparator groups. The primary outcome was weight loss in both the PROPEL (percentage of weight loss) and REPOWER (absolute weight loss) trials. Finally, the primary analysis in this study followed intent-to-treat principles, and individual participant-level data were pooled across the PROPEL and REPOWER trials.

## DISCUSSION

The results provide evidence that behavioral lifestyle interventions delivered in primary care settings produce clinically significant weight loss over 6 months; however, the maintenance of clinically significant weight loss at 24 months is more difficult to achieve. Results from the PROPEL trial were previously reported; the PROPEL-clinic/phone group produced clinically significant weight loss at 24 months compared with PROPEL-UC (17). Furthermore, results of the REPOWER study indicated that the REPOWER-clinic-group intervention produced significantly greater weight loss than the REPOWER-clinic-individual group, but results for the REPOWER-phone-group arm were not significantly different than the REPOWER-clinic-individual group (18). The results of the current investigation are consistent with the conclusions of a recent review that high-intensity behavioral counseling in primary care settings, when delivered in-person, by phone, or electronically, produce clinically significant weight loss (4-7 kg), whereas low- and moderate-intensity counseling produce only modest weight loss (1-2 kg) (13).

The CMS currently covers intensive behavioral counseling for obesity in Medicare beneficiaries. The coverage includes up to 22 individual 15-minute face-to-face visits in the first 12 months, and the benefit is limited to primary care practitioners and primary care settings (23). In the current study, the REPOWER-clinic-individual intervention was designed to be consistent with the CMS treatment approach and reimbursement strategy. Unfortunately, the REPOWER-clinic-individual group lost the least amount of weight

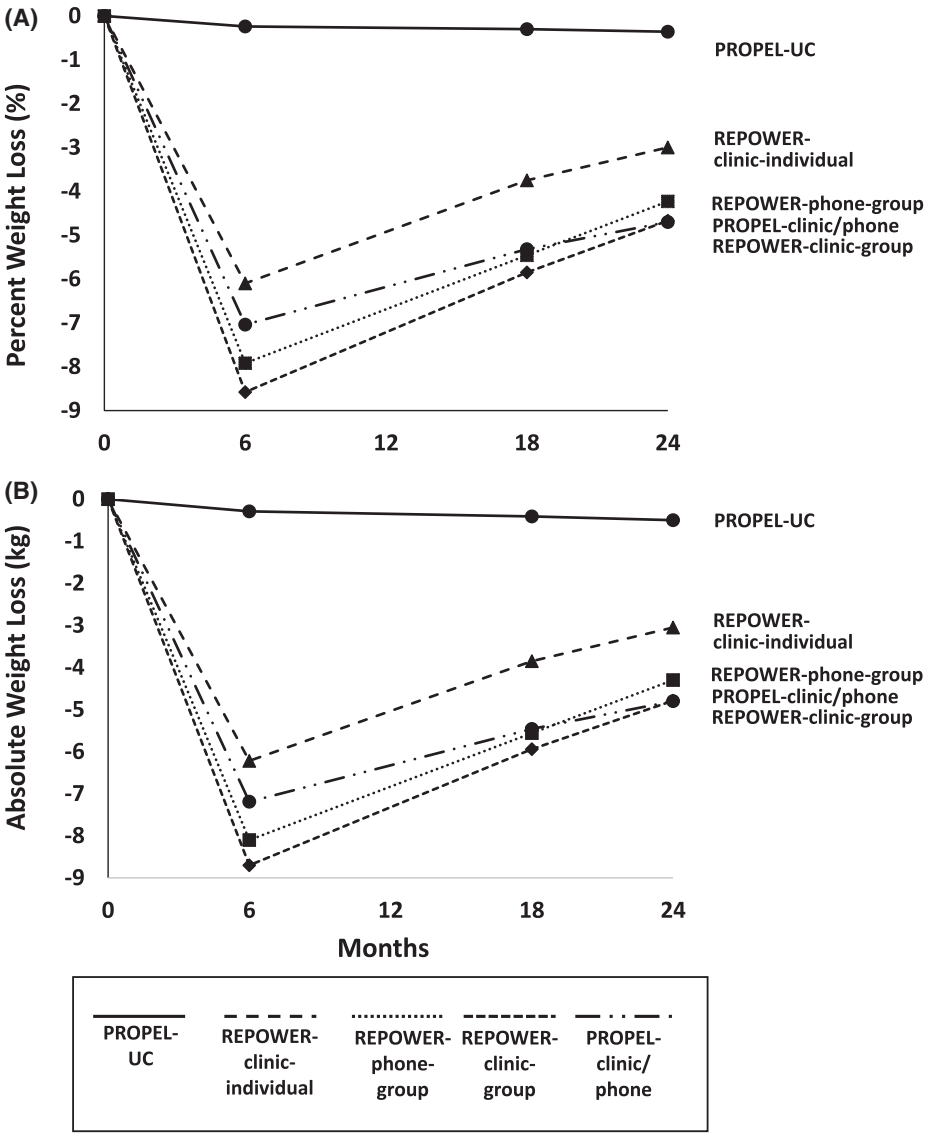


**FIGURE 2** Changes in (A) percent weight loss (percentage) and (B) absolute weight loss (kilograms) in the pooled analysis of data from the PROPEL and REPOWER trials. PROPEL, Promoting Successful Weight Loss in Primary Care in Louisiana trial; REPOWER, the Rural Engagement in Primary Care for Optimizing Weight Reduction trial; UC, usual care

over 24 months (−3.00 kg; 95% CI: −4.02 to −1.98). Consistent with evidence from other primary care weight-loss studies (13), it seems additional training of the providers/counselors and/or a more intensive intervention (more contact hours) may be required to sustain clinically significant weight loss, as recommended in the *2013 AHA/ACC/TOS Guidelines for the Management of Overweight and Obesity in Adults* (14,15). Our results provide support for expanding the current CMS reimbursement strategy to other members of a collaborative care team who can be trained in obesity treatment approaches such as those used in this study. Novel reimbursement schemes for weight loss are needed to support the implementation of higher-intensity, evidence-based therapies more broadly across health plans and care systems.

Weight-loss maintenance was higher in the PROPEL-clinic/phone group compared with other groups. The results for the PROPEL-clinic/phone group (maintenance of 66.8% of their initial 6-month weight loss at 24 months) were very similar to those of Wadden et al., in which patients enrolled in an enhanced brief lifestyle counseling program in primary care maintained 69.7% of their initial 6-month weight loss at 24 months (24). The Weight Loss Maintenance (WLM) trial was designed to study different weight-loss maintenance strategies after an initial 6-month weight-loss program. In that trial, at 30 months post initial weight loss, a personal-contact group maintained 52% of their initial weight loss, whereas an interactive internet-based intervention and self-directed (control) group maintained 40% and 35% of the initial weight loss, respectively (25). A recent review found that continuous monitoring and goal setting, sustained motivation and encouraging experiences, resistance to ever-present challenges, and enduring discouraging experiences are key factors in maintaining

**TABLE 2** Summary of intervention characteristics according to the PRECIS-2 tool across the randomized groups in PROPEL and REPOWER trials, and the mean weight loss observed in each group

| | PROPEL-UC[a] | PROPEL-clinic/phone[b] | REPOWER-clinic-individual[c] | REPOWER-clinic-group[d] | REPOWER-phone-group[e] |
|---|---|---|---|---|---|
| Eligibility | BMI 30-50 kg/m$^2$; age 20-75 y; able to participate in scheduled sessions; several exclusionary criteria[f] | BMI 30-50 kg/m$^2$; age 20-75 y; able to participate in scheduled sessions; several exclusionary criteria[f] | BMI 30-45 kg/m$^2$; age 20-75 y; willing to participate in scheduled sessions; several exclusionary criteria[g] | BMI 30-45 kg/m$^2$; age 20-75 y; willing to participate in scheduled sessions; several exclusionary criteria[g] | BMI 30-45 kg/m$^2$; age 20-75 y; willing to participate in scheduled sessions; several exclusionary criteria[g] |
| Recruitment | All recruitment conducted in the primary care setting[h]; 351 patients enrolled from 888 patients screened (39.5%) | All recruitment conducted in the primary care setting[h]; 452 patients enrolled from 1,070 patients screened (42%) | All recruitment conducted in the primary care setting[i]; 478 patients enrolled from 615 patients screened (77.7%) | All recruitment conducted in the primary care setting[i]; 479 patients enrolled from 650 patients screened (73.7%) | All recruitment conducted in the primary care setting[i]; 475 patients enrolled from 666 patients screened (71.3%) |
| Setting | 9 primary care clinics | 9 primary care clinics | 12 primary care clinics | 12 primary care clinics | 12 primary care clinics |
| Organization | No specified counselors; no counselor training; baseline PCP presentation (1 h) on CMS reimbursement and yearly brochure updates | Study-employed counselors; 13-h baseline counselor training and yearly counselor training (24 h total); PCP obesity science education program (3 h)<br>Patient tools: scale, weight graph, portion-controlled foods in meal plans particularly in weeks 1-4 | Clinic-employed counselors; 3-h baseline counselor training, intervention toolkit<br>Patient tools: encouraged to use Lose it! app | Clinic-employed counselors; 3-h baseline counselor training; group treatment manual; 8-h workshop; optional tele-mentoring<br>Patient tools: encouraged to use Lose it! app | Study-employed counselors; counselor shadowing; group treatment manual<br>Patient tools: encouraged to use Lose it! app |
| Flexibility (intervention delivery) | No intervention specified; no fidelity monitoring | 18 contact hours; 27 in-person/16 30-min telephone calls/15-20 min individual and small group (2-4 participants) sessions; additional sessions as needed (mean: 2.1)[j] sessions recorded and reviewed (median: 44 sessions/counselor), weekly staff meetings | 8 contact hours; 32 in-person, 15-min, individual sessions; no fidelity monitoring | 36 contact hours; 36 in-person, 1-h, group sessions; study personnel observed counselors once optional biweekly to monthly telemonitoring (55% median attendance) | 36 contact hours; 36 telephone calls; 1-h, group sessions; sessions recorded and reviewed (median 3.5 sessions/counselor), weekly to monthly staff meetings |
| Flexibility (patient adherence) | No measures to monitor or enforce adherence | Adherence monitored but not enforced; mean 74.2% of sessions attended; counselor follow-up for missed sessions | Adherence monitored but not enforced; mean 72.5% of sessions attended; no counselor follow-up for missed sessions | Adherence monitored but not enforced; mean 55.8% of sessions attended; no counselor follow-up for missed sessions | Adherence monitored but not enforced; mean 50.8% of sessions attended; minimal counselor follow-up for missed sessions |
| Follow-up | Follow-up occurred at 6, 12, 18, and 24 mo; visits conducted by study staff; 87.7% of patients measured at 24 mo | Follow-up occurred at 6, 12, 18, and 24 mo; visits conducted by study staff; 81.1% of patients measured at 24 mo | Follow-up occurred at 6, 18, and 24 mo; visits conducted by clinic staff; 85.8% of patients measured at 24 mo | Follow-up occurred at 6, 18, and 24 mo; visits conducted by clinic staff; 85.6% of patients measured at 24 mo | Follow-up occurred at 6, 18, and 24 mo; visits conducted by clinic staff; 84.2% of patients measured at 24 mo |

(Continues)

**TABLE 2** (Continued)

| | PROPEL-UC[a] | PROPEL-clinic/phone[b] | REPOWER-clinic-individual[c] | REPOWER-clinic-group[d] | REPOWER-phone-group[e] |
|---|---|---|---|---|---|
| Primary outcome | Weight loss (%) | Weight loss (%) | Weight loss (kg) | Weight loss (kg) | Weight loss (kg) |
| Primary analysis | Intent-to-treat[k] | Intent-to-treat[k] | Intent-to-treat[l] | Intent-to-treat[l] | Intent-to-treat[l] |
| 24-mo weight loss (kg)[m] | −0.50 (−1.77 to 0.76) | −4.80 (−5.96 to −3.64) | −3.05 (−4.10 to −2.01) | −4.79 (−5.83 to −3.75) | −4.30 (−5.35 to −3.26) |

[a]Usual care in PROPEL.

[b]In-clinic/telephone visits in PROPEL.

[c]In-clinic individual visits in REPOWER.

[d]In-clinic group visits in REPOWER.

[e]Telephone group visits in REPOWER.

[f]Exclusion criteria in PROPEL included a history of bariatric surgery or planned bariatric surgery within 2 years, stroke or heart attack in previous 6 months, active cancer (except prostate, skin, and thyroid if approved by physician), serious arrhythmias or cardiomyopathy, severe congestive heart failure, chronic inflammatory conditions, disease that is life threatening or that can interfere with or be aggravated by exercise or weight loss, giving birth within the past year, pregnancy or plans to become pregnant within 2 years, plans to move from the area within 2 years, currently participating in a weight-loss program or current use of weight-loss medication or recent weight loss (>10 lb in last 6 months), current major depression, history of suicidal behavior or diagnosed eating disorder (bulimia, anorexia), hospitalization for mental disorder or substance abuse in the previous year, and discretion of primary care physician or principal investigator.

[g]Exclusion criteria in REPOWER included a history of bariatric surgery or planned bariatric surgery within 2 years, myocardial infarction in the last 6 months, stroke in the last 6 months, new cancer diagnosis in the last 6 months, pregnancy in the last 6 months or planned within the next 2 years, currently lactating, severe medical condition in which weight loss is contraindicated (determined by the patient's PCP), plans to relocate outside of their provider's service area, or plans to leave their primary care clinic in the next 2 years.

[h]Recruitment methods in PROPEL included electronic health record queries, primary care practitioner referrals, communication with study staff, messages electronically sent through the electronic medical record portal to potentially eligible patents, and responses to recruitment materials posted throughout the clinics.

[i]Recruitment methods in REPOWER included sending recruitment letters to individuals in a registry of patients with BMI between 30.0 and 45.5 developed by primary care practice and also through in-clinic referrals whereby study brochures were distributed in the clinics and providers referred patients during routine medical visits and instructed interested patients to contact the central REPOWER study team.

[j]Additional intervention sessions were offered to in-clinic/telephone participants as needed. Overall, 222 (49.1%) of in-clinic/telephone participants had at least one additional in-person or phone session (mean: 2.1; median: 0).

[k]The intent-to-treat analysis in PROPEL included all randomized patients, regardless of number of visits completed. Patients who became pregnant, had bariatric surgery, or developed a major illness and/or died were retained in the PROPEL trial, and their data were removed beyond the time the event occurred.

[l]The intent-to-treat analysis in REPOWER included all randomized patients with the exception of 25 patients (1.7%) who became pregnant, had bariatric surgery, or developed a major illness and/or died, who were removed from the data set a priori.

[m]Model-based mean weight loss at 24 months in each group (analogous to Figure 2B).

Abbreviations: CMS, Centers for Medicare and Medicaid Services; PCP, primary care physician; PRECIS-2, Pragmatic Explanatory Continuum Indicator Summary; PROPEL, Promoting Successful Weight Loss in Primary Care in Louisiana trial; REPOWER, the Rural Engagement in Primary Care for Optimizing Weight Reduction trial.

substantial weight loss over time (26). Future research should focus on identifying inflection points for the transition from weight loss to weight maintenance and regain as well as developing optimal strategies for long-term weight loss in primary care settings.

Although this study presents an opportunity to compare results from five different weight-loss interventions delivered in primary care settings, there are limitations to combining data from two different trials. For example, this approach does not fully afford the independence of treatment assignment from the pre-randomization characteristics of the clusters/participants. Furthermore, each trial enrolled patients from the participating clinics after they had been randomized, which may have introduced bias.

Although an effort was made to harmonize the data collection schedule, measurements, and inclusion/exclusion criteria, some differences between the two trials should be noted. First, the upper inclusion limit for BMI was 50 in PROPEL, and it was 45 in REPOWER. This difference appeared to have only a minimal effect, as the mean BMI in PROPEL was 37.2, and the mean BMI in REPOWER was 36.7. Two inherent differences between the two trials were the degree of rurality and the racial distribution of the samples. PROPEL was conducted in urban (14 clinics) and rural (4 clinics) settings across Louisiana (21), and 67% of the sample consisted of Black participants. REPOWER was conducted in the rural Midwestern US, and the participating clinics predominantly or exclusively served rural residents (22); the sample consisted primarily of White participants (0.5% Black participants). In addition, unmeasured regional differences in the environments between the two study sites may have also existed (weather, built environment, etc.). The degree to which

the differences in demographic and environmental characteristics between the two trials affected the results is unknown; however, in the PROPEL trial, Black participants lost approximately 1 kg less body weight in the clinic/phone group compared with PROPEL-UC than other (primarily White) participants at 24 months (17). There was also heterogeneity in the types of counselors (and their backgrounds) across the study arms, with some being hired for the study, whereas others were clinic employees, which may have introduced some heterogeneity in intervention delivery.

PROPEL and REPOWER were designed as large pragmatic trials. As opposed to explanatory trials (i.e., efficacy or effectiveness), pragmatic trials purport to test whether an intervention actually works in "real life" (27). Pragmatic trials typically have large sample sizes, simple designs, fewer inclusion/exclusion criteria, and high external validity compared with explanatory trials (28). Explanatory trials usually exercise strict control over design elements such as inclusion/exclusion criteria, gold-standard measurement of study outcomes, and the maintenance of high intervention fidelity. Compromises are made on these design elements, to some extent, for increased external validity and generalizability in pragmatic trials. There is a range of pragmatism across all trials, and the degree of pragmatism also varied between PROPEL and REPOWER. Based on the results reported in Table 2, the REPOWER-clinic-individual intervention mirrored the current CMS approach to obesity treatment and is arguably the most pragmatic. However, it also produced the least amount of sustained weight loss at 24 months. Although the other interventions produced greater weight loss, the level of pragmatism (based on the PRECIS-2 elements) decreased across the REPOWER-clinic-group, REPOWER-phone-group, and PROPEL-clinic/phone groups. Despite the PROPEL-clinic/phone group demonstrating the least pragmatism from a study design perspective, this does not mean that the PROPEL-clinic/phone intervention *per se* was not pragmatic. The use of portion-controlled foods, daily weighing, and a personalized weight chart are all very practical intervention components that can be embedded in primary care settings. This is especially true considering that the PROPEL-clinic/phone group relied on a server-based platform for facilitating intervention delivery and fidelity, and such a system can be integrated into electronic medical records.

Given that the degree of pragmatism varied across the interventions in PROPEL and REPOWER, these results should be viewed in this context. Through the lens of generalizability and scalability (cost, feasibility, etc.) to other health care settings, the greater weight loss observed in the PROPEL-clinic/phone, REPOWER-clinic-group, and REPOWER-phone-group arms should be balanced with the greater pragmatism of the REPOWER-clinic-individual intervention. Innovative strategies to implement this approach across different health care settings should be explored using implementation science frameworks (29). Furthermore, given the proliferation of electronic medical records, patient portals, electronic scales, virtual clinic visit options, and associated technologies in recent years, there is a need to better understand the effectiveness of transitioning intervention delivery to new primary care platforms.

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## CONFLICT OF INTEREST

PTK, JWA, CKM, RLN, and WDJ report donated supplies from Health and Nutrition Technology and Nutrisystem for the Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) trial. MGP reports additional grant funding from NIH and chairing the Data and Safety Monitoring Board (DSMB) for the PCORI-funded Treatment Efforts Addressing Child Weight Management by Unifying Patients, Parents & Providers (TEAM-UP) trial. CKM additionally reports payments to his university for projects funded by Westat, WW (formerly WeightWatchers), the Egg Board, the Academy of Nutrition and Dietetics, Eli Lilly and Company, American Society for Nutrition, Helmsley Trust, Richard King Mellon Foundation, Evidation Health, Individuals Dedicated to Excellence and Achievement (IDEA) Public Schools, LiftFund Louisiana, Elizabeth Blackwell Institute for Health Research, and Novartis International AG. CKM further reports that ABGIL has provided grants to his institution and he was an investigator on those grants. This work is related to interventions that utilize weight graphs to track dietary adherence. CKM reports having received royalties from his institution for the licensing of weight-management approaches and weight-graphing algorithms. CKM reports serving on an advisory board for Naturally Slim and EHE Health and serving as a consultant for Zafgen; Florida Hospital; Metagenics, Inc.; and Gila Therapeutics, Inc. CKM is a facilitator for continuing education events hosted by the Academy of Nutrition and Dietetics. CKM regularly gives talks, both paid and unpaid, primarily to academic centers, including Robert Wood Johnson Foundation, Association for the Study of Obesity, American Society for Metabolic and Bariatric Surgery (ASMBS), Institute of Electrical and Electronics Engineers (IEEE), and American Association of Clinical Endocrinologists. CKM reports having received reimbursement for travel expenses from the the Academy of Nutrition and Dietetics, Association for Community Affiliated Plans Health/Naturally Slim, EHE Health, Aaptiv, the Obesity Society/IEEE, and the American Association of Clinical Endocrinologists. CKM reports United States and European Patent applications titled "Body weight management and activity tracking system." The other authors declared no conflict of interest.

## CLINICAL TRIAL REGISTRATION

ClinicalTrials.gov identifiers NCT02561221 and NCT02456636.

## DATA AVAILABILITY STATEMENT

Individual, deidentified participant data and SAS analysis code will be made available upon reasonable request to the Principal Investigators of PROPEL (Peter Katzmarzyk; peter.katzmarzyk@pbrc.edu) and REPOWER (Christie Befort; cbefort@kumc.edu). The study protocols are currently available alongside the published primary outcomes papers for each trial.

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