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Protocol for the Rural Engagement in Primary Care for Optimizing Weight Reduction (RE-POWER) Trial: Comparing three obesity treatment models in rural primary care

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ABSTRACT

Obesity disproportionately affects rural residents in the United States, and primary care has the potential to fill a major gap in the provision of weight management services for rural communities. The objective of this cluster-randomized pragmatic trial is to evaluate the comparative effectiveness of three obesity treatment models in rural primary care: the Intensive Behavior Therapy fee-for-service (FFS) model reimbursed by Medicare, a team-based model that recognizes the patient-centered medical home (PCMH) as a preferred delivery approach, and the centralized disease management (DM) model, in which phone-based counseling is provided outside of the primary care practice. We hypothesize that the PCMH and DM treatments will be more effective than FFS in reducing weight at 24 months. Thirty-six practices from the rural Midwestern U.S. are randomized to deliver one of the three interventions to 40 patients (N = 1440) age 20 to 75 with a BMI 30–45 kg/m^2. In the FFS arm, primary care providers and their personnel counsel patients to follow evidence-based weight loss guidelines using the Medicare-designated treatment schedule. In the PCMH arm, patients receive a comprehensive weight management intervention delivered locally by practice personnel using a combination of in-person and phone-based group sessions. In the DM arm, the same intervention is delivered remotely by obesity treatment specialists via group conference calls. The primary outcome is weight loss at 24 months. Additional measures include fasting glucose, lipids, quality of life indicators, and implementation process measures. Findings will illuminate effective obesity treatment intervention(s) in rural primary care.

1. Introduction

Rural residents in the United States are disproportionately affected by obesity [1] and obesity-related illnesses, including diabetes and heart disease [2–4]. This higher obesity prevalence is accompanied by a 32% higher age-adjusted death rate compared to urban residents outside of inner cities [5,6]. Nearly 20% of the U.S. population lives in rural communities, constituting one of the largest medically underserved populations in the nation [3,7]. As such, decreasing rural health disparities is a high national priority as outlined in the agendas of Health and Human Services [8], the Surgeon General [9], and the Center for Disease Control and Prevention [10].

Rural residents encounter multiple barriers to maintaining a healthy lifestyle, including a lack of built environmental features that facilitate

Abbreviations: FFS, fee-for-service; PCMH, patient-centered medical home; DM, disease management; PCP, primary care provider; CMS, Centers for Medicare and Medicaid Services; FQHC, federally qualified health center; PAB, Patient Advisory Board; RE-AIM, Reach, Adoption, Implementation, Maintenance; RHC, Rural Health Clinic; CFIR, Consolidated Framework for Implementation Research.

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physical activity [11,12], and limited access to healthy food outlets [13] and evidence-based commercial weight control programs [14]. However, most rural residents have a primary care provider [15] (PCP) and routinely look to their physician to guide them toward healthy lifestyles [14]. Thus, rural primary care has the potential to fill a major gap in the provision of weight management services.

The U.S. Preventive Services Task Force recommends PCPs screen for obesity and offer or refer patients to intensive behavioral obesity treatment [16]. However, PCPs often fail to diagnose obesity and offer weight loss counseling to only 20–40% of obese patients [17,18]. When brief counseling is provided, it typically falls short of the intensity needed for meaningful weight change [19]. Systematic reviews have concluded that low-intensity (e.g. quarterly) PCP counseling is insufficient to achieve clinically meaningful weight loss [19,20].

The Centers for Medicare and Medicaid Services (CMS) approved fee-for-service reimbursement for PCP-delivered Intensive Behavioral Therapy (IBT) for Obesity [21] in 2011, delivered in the format of 15-minute counseling sessions provided weekly for one month and every other week for five months. Patients who lose ≥3 kg by six months are eligible for additional monthly sessions. However, the effectiveness of this approach remains unknown and the uptake of this provision appears to be slow [22]. Barriers to uptake may include inadequate session length, low reimbursement rates, patient travel burden, and the requirement that patients attend separate visits during regular clinic hours [23].

Given the limited impact of the fee-for-service (FFS) system in managing chronic illness [24], two alternative care models have emerged in the U.S.: the patient-centered medical home (PCMH) [25] and centralized disease management (DM) [26]. Both approaches offer coordinated care delivery, either within (PCMH) or external to a given practice (DM), and provide more intensive treatment than FFS. These models are the most prominent alternatives to chronic disease care, yet no studies have directly compared these approaches to the CMS FFS approach.

In February 2014, the Patient-Centered Outcomes Research Institute (PCORI) issued a request for applications (RFA) for trials comparing alternatives to FFS in underserved primary care settings [27]. This 5-year cluster randomized pragmatic trial was funded to compare the effectiveness of a team-based approach modeled after PCMH, and DM to the FFS model in primary care practices throughout the rural Midwestern U.S. We hypothesize that PCMH and DM treatments will be more effective than FFS in reducing weight at 24 months.

2. Methods

2.1. Overview

In this study, 36 primary care practices in Kansas, Nebraska, Wisconsin, and Iowa are randomized to deliver obesity treatment to eligible patients following one of the FFS, PCMH, and DM models. The FFS arm includes PCP-delivered obesity counseling sessions following the schedule reimbursed by the Medicare IBT provision [21]. Both the PCMH and DM arms include a common evidence-based comprehensive lifestyle intervention, but the delivery mechanisms differ. In the PCMH arm, the intervention is delivered by auxiliary health professionals within the primary care practice using in-person group office visits followed by group phone visits via conference calls. PCMH practices receive intensive and on-going training to build their capacity for delivering this care. In the DM arm, the intervention is delivered centrally by obesity treatment specialists using group phone visits via conference calls, and patient progress is routinely communicated back to the PCPs. The primary outcome is weight loss from baseline to 24 months. Fig. 1 presents the study flow diagram.

The design of this trial was influenced by the specifications of the PCORI RFA under which it is funded [27]. The comparison arm(s) to be tested against the FFS approach were required to be modeled after the U.S. Preventive Services Task Force recommendations for obesity treatment, which specify a comprehensive lifestyle intervention that includes at least 14 in-person sessions in the first 6 months [16]. We viewed the in-person session requirement as a potential barrier for the rural setting, particularly in frontier areas where patients travel long distances to receive care. Thus, we consulted with providers from rural practices interested in participating in the trial about acceptability of after-hours in-person group visits (PCMH) versus referral to phone-based programs. We concluded that both approaches were acceptable, and that we could frame the in-person group visit approach after anticipated future payment structures to further enhance its acceptability. Therefore, we proposed two comparison arms to be tested against the FFS model, one with the required minimum 14 in-person sessions followed by additional group phone visits (PCMH) and one with group sessions entirely remote by phone (DM). This decision was approved by PCORI as consistent with the RFA.

This study has been approved by the University of Kansas Medical Center Institution Review Board (IRB), which is serving as a central IRB for this study under the PCORnet-funded Greater Plains Collaborative, a Clinical Data Research Network.

2.2. Aims

The primary aim of the study is to test the hypotheses that both the PCMH model and DM model are more effective than the current CMS-based FFS model in reducing weight at 24 months. The secondary aims of the study are: [1] test the hypothesis that the DM is more effective than the PCMH model in reducing weight at 24 months, [2] to compare the effects of the three arms on blood pressure, waist circumference, fasting glucose and lipids, quality of life, sleep, and stress, [3] to assess the heterogeneity of treatment effects across sociodemographic subgroups (i.e. education level, income level, employment status, and distance traveled to receive care), and [4] to evaluate reach, adoption, implementation, and maintenance of the treatment models in each arm using the RE-AIM framework [28].

2.3. Primary care practice types

Primary care practices that predominantly or exclusively serve rural residents are enrolled. Practice types are diverse and include Rural Health Clinics, Federally Qualified Health Centers (FQHC), hospital-owned, stand-alone, and integrated healthcare system practices, and Veterans Administration (VA) Community Based Outpatient Clinics. The diversity of sites is consistent with PCORI's emphasis on including heterogeneity in practice and patient recruitment. We made the decision to include VA sites in part to assist with recruiting rural men.

A total of 36 practices, randomized in three cohorts of 12 practices each, will participate. Twenty practices are recruited by the University of Kansas Medical Center, 10 by Marshfield Clinic, and 6 by the University of Nebraska Medical Center. Practices are recruited through outreach and continuing education efforts of their respective institutional sites. Practices are selected to participate based on a lead physician's interest in improving patient care for obesity treatment, their capacity to develop a patient registry with sufficient patient numbers (300 to 400 who meet age and BMI criteria) to recruit 40 patients, their interest and capacity to deliver the interventions in FFS and PCMH arms, and their readiness to start according to the study timeline. Practices must demonstrate capacity to implement all 3 arms and sign a Practice Agreement detailing their responsibilities and commitment across all 3 arms. To account for the possibility that a practice may decide not to participate after randomization, one to two additional practices are recruited and randomized in cohorts 1 and 2. As of the

time of this report, 14 practices have been randomized in cohort one, all 14 practices accepted their randomization, and all but 1 viewed randomization as favorable. One practice in cohort one left the study prior to patient enrollment because the lead physician resigned due to health problems.

2.4. Cluster randomization

Practices are randomly allocated in equal proportions to each of the three arms (FFS, PCMH, DM). Randomization is stratified by institutional affiliation (University of Kansas Medical Center, University of Nebraska Medical Center, Marshfield Clinic). Twelve practices are enrolled in each arm.

2.5. Patient inclusion criteria

Patients are eligible for this study if they are between the ages of 20 and 75 years, have a BMI between 30.0 and 45.0 kg/m^2, reside in a rural location as defined by Rural–Urban Commuting Area Codes [7], Urban Influence Codes [29], amount of agricultural income, or individual commuting patterns. Patients must be willing to attend counseling visits, have access to a telephone, and speak English. One individual per household is permitted to enroll in the study. Patients must have medical clearance from their PCP to participate.

2.6. Patient exclusion criteria

As a pragmatic trial, the exclusion criteria are kept minimal to maximize generalizability and reduce patient screening burden. Exclusions are necessary to minimize risks and to avoid major potential confounders, including: a history of bariatric surgery or planned bariatric surgery within two years, myocardial infarction in the last six months, stroke in the last six months, new cancer diagnosis in the last six months, pregnancy in the last six months or planned within the next two years, currently lactating, or severe medical condition where weight loss is contraindicated (determined by the patient's PCP). Patients who plan to relocate outside of their provider's service area or who plan to leave their primary care clinic in the next two years are also excluded.

2.7. Patient recruitment

Each participating primary care practice develops a registry of potentially eligible patients with a BMI between 30.0 and 45.5 kg/m^2. PCPs have the option to review the registry and identify patients who may be inappropriate for the study based on other severe medical conditions (e.g. terminal cancer) before recruitment letters are sent. Study recruitment letters are mailed to registry patients, along with a study brochure, and a pre-stamped, opt-in postcard. Interested patients contact the central study team by phone, via the project's website, or returning the postcard. Recruitment also occurs through in-clinic referrals. Study brochures are distributed in the clinics, and providers refer patients during routine medical visits and instruct interested patients to contact the central RE-POWER study team.

Providers may elect to prioritize some patients in their registries to receive the mailed recruitment letters first. Any provider selection bias in prioritizing the mailings, e.g., based on perception of patient motivation, may be similar to selection bias when deciding which patients to refer during routine clinical care. The method by which providers develop their registries, prioritize patients to receive the recruitment letters, and how they distribute brochures and make referrals in the clinic is documented in detail and will be considered when comparing patient reach across sites (see Section 2.10).

2.8. Screening and informed consent

The central RE-POWER study team initially screens patients for eligibility by phone. Following screening, patients are sent baseline surveys either by mail or they are provided an online link. Patients are required to complete these before attending an in-person enrollment appointment at their primary care practice. Once a patient has completed the baseline surveys, the primary care practice team schedules an in-clinic enrollment visit. During this visit, practice personnel verify BMI eligibility, obtain written informed consent, and collect baseline anthropomorphic and lab measures.

2.9. Intervention descriptions

Table 1 provides an overview of provider roles, counseling session frequency and type, and training by treatment arm.

2.9.1. Training for all arms

Participating PCPs, nurses, and auxiliary health professionals in all treatment arms attend a half day central training in behavioral obesity treatment, followed by a half day training in study protocols. This training is sufficient to enable PCPs to implement the FFS counseling or provide support to patients in either the PCMH or DM arms. The training covers evidence-based guidelines for diet and physical activity, behavioral strategies, and effective communication for encouraging and empathizing with patients. Study protocol-specific training includes human subjects' protection, scheduling protocols, retention strategies, anthropomorphic measurement protocols, and use of REDCap (Research Electronic Data Capture) to enter study data. Provider knowledge and understanding of training content is assessed at the completion of the central training. Additional training specific to each arm is described below.

2.9.2. Fee-for-service arm (FFS)

The FFS comparison condition reflects the current CMS reimbursement model for IBT. PCPs conduct face-to-face 15-minute office visits counseling sessions following the session schedule reimbursed by the CMS IBT provision: weekly sessions for one month, followed by every other week through month six, and monthly thereafter through 24 months. To maximize study retention, we chose not to implement the IBT requirement that individuals lose ≥3 kg by six months in order to receive additional counseling sessions. Practices in this arm choose a variety of different approaches to deliver this care, including having RNs or other health professionals at the practice deliver the sessions with the PCP immediately available for consultation, in accordance with the CMS incident-to billing provisions [21]. Practices receive a toolkit to facilitate delivery of IBT including example session objectives based on the 5A's Model (Assess, Advise, Agree, Assist, Arrange), case studies, and patient hand-outs that follow the 2013 Guidelines for the Management of Overweight and Obesity in Adults for diet, physical activity, and behavior modification strategies (e.g., self-monitoring, goal setting) [30].

2.9.3. Patient centered medical home (PCMH).

Practices randomized to the PCMH arm deliver a comprehensive lifestyle intervention. This arm requires fewer in-person office visits than the FFS arm, allows for intervention delivery by a non-PCP within the clinic (combined with PCP care coordination), offers opportunities for interactions with other patients with group visits, and takes advantage of after-hours and telephone visits. Counseling sessions are delivered by practice personnel designated as a care coordinator who may be a nurse, registered dietitian, or behavioral counselor. Care coordinators are intended to be existing practice personnel, however a practice may elect to hire a new staff person to fill this role in combination with other practice needs. Patients attend 12 weekly in-person group visits in the first 3 months, followed by every other week in-person

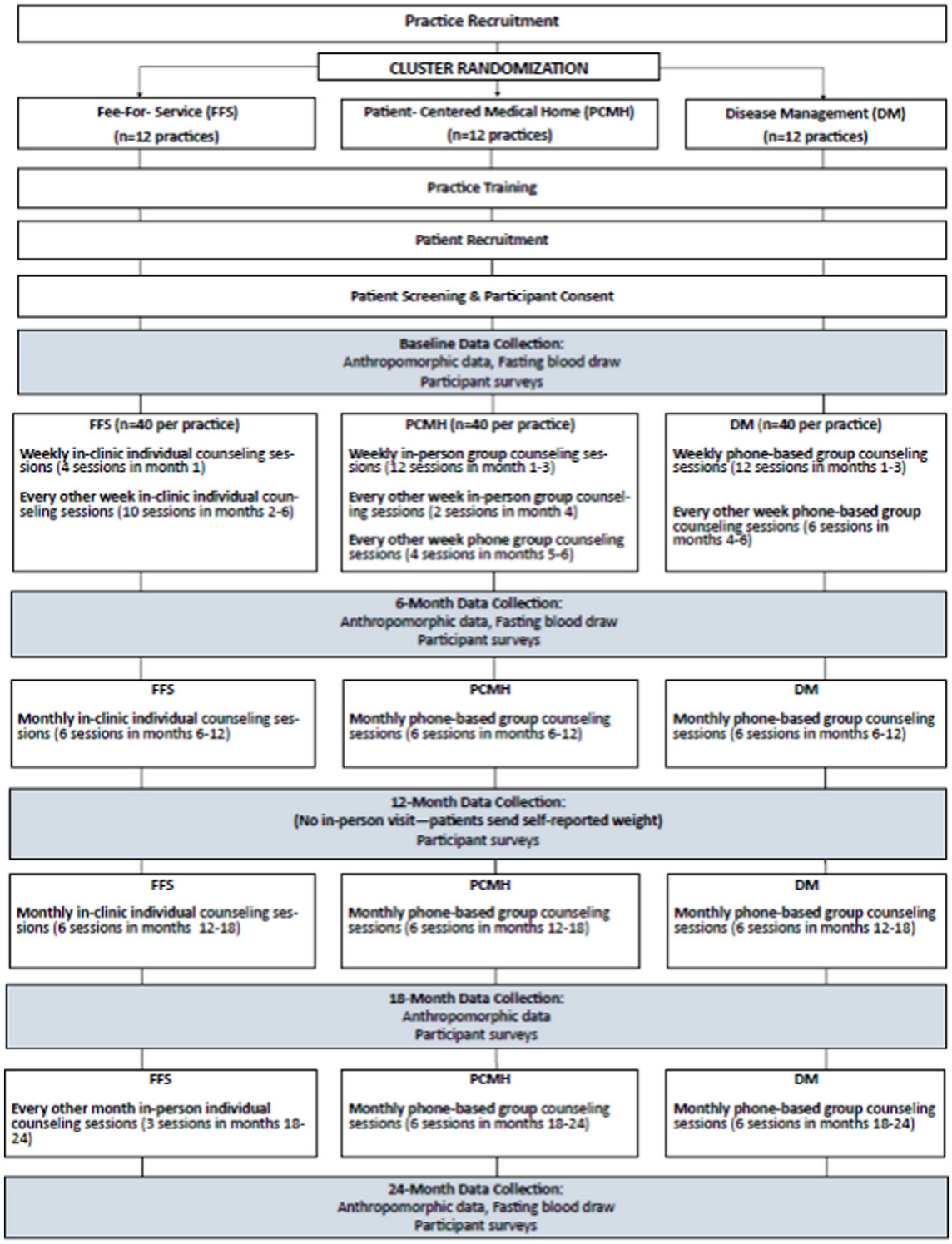

Fig. 1. Study flow diagram.

group visits in month 4, every other week group phone visits in months 5–6, and monthly group phone visits through 24 months. Group in-person and phone visits last 60 min and are comprised solely of patients from the practice. The care coordinator documents patients' progress in the medical record and flags this documentation to the attention of the patient's PCP according to practice-specific workflow processes. Practices can tailor the intervention delivery to their specific practice, community, and patients. For example, they may include community

Table 1
Practice roles, training, and office support by condition.

	Fee-for-service	PCMH	Disease management
Obesity counselor	PCP or clinic-employed RN or auxiliary health professional under PCP supervision	Care coordinator (nurse, registered dietitian, or behavioral counselor)	Remote obesity treatment specialist (masters or doctorate in nutrition, psychology, or exercise science)
Session type and frequency	Individual in-person, 15 min • Weekly for mo 1 • Every other week for mo 2–6 • Monthly for mo 7–24	Group visits in-person, 60 min • Weekly for mos. 1–3 • Every other week for mo. 4 Group visits by phone, 60 min • Every other week for mos. 5–6 • Monthly for mos. 7–24	Group visits by phone, 60 min • Weekly for mos. 1–3 • Every other week for mos. 4–6 • Monthly for mos. 7–24
PCP role	Provide sessions or supervise and be immediately available during the counseling visits	Follow-up and provide encouragement in routine medical visits	Follow-up and provide encouragement in routine medical visits
Patient care coordination	Limited to face-to-face visit only	• Group visits to enhance peer social support • Care coordinator summarizes and shares patient's progress with PCP	• Group phone visits to enhance peer social support • PCP receives individual patient reports from remote provider
Project- provided PCP and counselor training	• Half-day training on assessing and treating obesity • IBT toolkit including session guide and patient hand-outs modeled after 5 A's approach, instructions for dietary assessment and feedback, and web-based resources	• Half-day training on assessing and treating obesity • For care coordinators: o Full-day workshop on group visits o Every other week telementoring o Standardized session-by-session treatment manual	• For obesity treatment specialists: o Relevant graduate degree and experience with weight loss counseling o Weekly training/quality control o Fidelity monitoring of audio-recorded sessions o Standardized session-by-session treatment manual

resources, guest speakers, or replace phone visits with in-person visits, depending on their patients' preferences. The central RE-POWER study team will learn about and monitor such modifications through regularly scheduled check-in visits with the lead physician and/or practice liaison.

2.9.3.1. Training for care coordinators in PCMH arm. The additional training in this arm is designed to replicate a real-world example based on of the amount of time a practitioner is likely to be taken away from routine clinical care. In addition to the study-wide central training, care coordinators attend a full day in-person central training workshop on the delivery of the comprehensive lifestyle intervention program. The workshop is interactive and focuses primarily on group facilitation skills, counseling skills that are informed by motivational interviewing principles [31], and health behavior change principles and strategies. Care coordinators receive a detailed standardized treatment manual that includes session-by-session instructions and patient hand-outs, modeled after the Look AHEAD Lifestyle Intervention Counselor's Manual [32]. Upon completion of the central training, care coordinators complete a competency assessment in the basic elements of the intervention. Following the workshop, care coordinators receive ongoing information and support through the session-by-session standardized treatment manual and bi-weekly group telementoring training sessions held with all the practices assigned to the PCMH arm using secure video-conference technology. Care coordinators present de-identified cases to the team, and brief didactic presentations to reinforce core issues or address solutions to problems encountered. This model of training has been applied to build capacity for PCPs in rural and underserved areas to effectively treat a number of chronic conditions [33,34] and is used here to build capacity for delivering a comprehensive lifestyle intervention by providing ongoing training and quality control. To further augment training, a member of the central RE-POWER study team will observe program delivery at least once in each practice during one of the early group visits and provide additional on-site guidance. We chose this limited amount of on-site observation to maintain a real world training approach in keeping with the pragmatic nature of the trial. In fact, the lesser attention to treatment fidelity in the PCMH arm compared to the DM arm underlies our secondary aim hypothesis that the DM arm will result in better outcomes.

2.9.4. Disease management (DM)

The DM model offers the same comprehensive lifestyle intervention as in the PCMH arm, but is delivered by obesity treatment specialists from a central research team based at KUMC. Counselors on this team have advanced degrees in nutrition, exercise science, public health or psychology who complete a standardized training program described below. For the DM arm, groups of 12–16 patients are formed across multiple practices and phone-based sessions are held via conference calls. Sessions are the same duration and frequency as the PCMH arm. We have found the phone-based delivery approach to be ideal for rural residents because it eliminates travel burden and provides social support while preserving a level of anonymity [35,36]. Counselors use a REDCap management tool that allows for capture of session duration, attendance, adherence to session protocols, and patient-level note taking.

To enhance integration with primary care, obesity treatment specialists send quarterly progress reports to the patients' PCPs. To maximize the chance that PCPs will act on these reports, they are kept brief and follow a structured format that includes patient's self-reported progress to date for weight loss, diet, and physical activity, patient-reported barriers and motivators, as well as concise recommendations for PCP action (e.g., 'Please provide patient with positive feedback on weight loss to date'). These patient progress reports are made available in medical records according to workflow processes unique to each practice.

2.9.4.1. Training and quality control in DM arm. Obesity treatment specialists in the DM arm participate in a year-long training program that included didactics, reading evidence-based literature, listening to recordings of treatment sessions, motivational interviewing training, and shadowing an experienced counselor. DM counselors follow the same standardized treatment manual as the PCMH Care Coordinators. They also participate in ongoing training and quality monitoring, including weekly staff meetings where recorded sessions are reviewed,

upcoming lessons are discussed, and problems regarding patient adherence, retention, and group facilitation. In addition, counselors follow a standardized checklist of the content to be covered for each session. Fidelity to the intervention is reviewed for at least 10% of recorded sessions. If a counselor falls below an 80% threshold of fidelity to covering the session components, additional review and training are required.

2.9.5. Comprehensive lifestyle intervention to be delivered in PCMH and DM arms

The lifestyle intervention for PCMH and DM incorporates strategies from the Look AHEAD Lifestyle Intervention (e.g., group visits, portion control strategies) [37] and is guided by a social-cognitive framework [38]. The session frequency (weekly for 3 months, bi-weekly for 3 months, and monthly thereafter) was selected based on recent findings and experience of our investigative team from the Rural LITE trial comparing three doses of weight loss counseling [39]. The primary objective is to decrease caloric intake and increase physical activity to produce gradual weight loss, with an individual goal of 10% weight loss at 6 months followed by maintenance of diet and physical activity to sustain a 5 to 10% weight reduction through 24 months. Each patient receives a treatment handbook with session-by-session content and program information (session schedule, conference call information, self-monitoring instructions). Intervention components are summarized in Table 2.

The intervention is tailored to the rural setting. Values and culture in rural communities are influenced by access difficulties, lack of privacy, isolation, greater poverty, and older populations [40]. These aspects of rural life influence rural values, including those related to health, which include conservatism, self-reliance, and orientation toward work, family, and religion [40]. However, traditions and customs vary across rural gradients, from town to town, and from farm to town. Thus, the intervention highlights the shared identity among rural residents while at the same time recognizing differences in values that may exist. Intervention components targeted to the rural setting include simplified educational materials and self-monitoring forms to address lower education levels, problem solving sessions focused on barriers to accessing physical activity facilities and healthy foods, recipes for low fat versions of traditional "country" dishes, and alternative home-based physical activity options (e.g., exercise DVDs) for when walking outside is hampered by the extreme weather conditions.

2.9.5.1. Diet. During weight loss, patients receive instructions to follow a reduced-calorie diet that includes a calorie goal and ≥5 fruit and vegetable (FV) servings per day. Emphasis is placed on portion control and consuming low calorie, high volume foods (Volumetrics) with high amounts of FVs, fiber, and water [41]. To facilitate adherence, pre-portioned meals and shakes are recommended, consistent with the Diabetes Prevention Program and Look AHEAD dietary interventions. Pre-portioned meals are purchased by participants and may include frozen entrees (< 350 kcal each) that are widely available (even in small grocery stores), canned soup, or other portion-controlled meals. Pre-portioned meals are affordable and have consistently shown greater weight loss, long-term weight loss maintenance, and greater increases in FVs and fiber compared to relying completely on individuals preparing all their own meals [42–44]. During weight loss maintenance, patients are given a new personalized calorie goal calculated from the Harris-Benedict equation and rounded down by approximately 200 kcal to the nearest even kcal/day level [45].

2.9.5.2. Physical activity. Physical activity is increased through a guided home-based program. Home-based programs have been shown to produce greater long-term adherence compared to on-site programs [46,47] and appear to be generally preferred by rural residents [12,48]. Patients are advised to gradually increase their physical activity over the first 12 weeks to 225 min/week of moderate intensity activity, consistent with national guidelines for weight loss maintenance [49]. Information about community physical activity resources and facilities are provided by the practice staff when available.

2.9.5.3. Behavioral strategies. Self-monitoring and goal-setting are the core behavioral strategies reinforced throughout the intervention. To facilitate self-monitoring and counselor feedback, patients are encouraged to use the highly ranked commercial smart phone application, Lose It® [50]. Group counselors have direct access to patient self-monitoring data captured through Lose It® and are instructed to provide feedback through the App weekly during the first 3 months and every other week after that. Patients without access to a smart phone are provided a calorie counter book and instructed to keep written logs. Patients set specific, measureable, and realistic diet and physical activity goals during every session and check-in with their goal progress during subsequent sessions. Other behavioral strategies taught and reinforced throughout the intervention include stimulus control and problem-solving.

2.9.5.4. Weight loss maintenance. During the maintenance period, key elements of the intervention are continued support, accountability,

Table 2
Lifestyle intervention goals and self-monitoring strategies.

	Weight loss phase	Weight loss maintenance phase
Weight loss goal	10% weight loss	Maintain within 2%
Diet goals	1200 kcal/day if <250 lbs. 1500 kcal/day if ≥250 lbs	Calorie goal personalized to maintenance needs
	Portion control, recommended 2 prepackaged meals and 2 shakes/day	Portion control, recommended 2 prepackaged meals/shakes and 1 home prepared healthy meal/day
	≥5 1-cup fresh or frozen fruit and vegetable servings/day	Same
	≤25% calories from fat	Same
	Reduced sodium	Same
	High fiber	Same
Physical activity goals	Work up to 225 min/week of moderate intensity activity in bouts ≥10 min 10,000 steps/day	Maintain 225 min/week; increase up to 300 min/week if achieve 225 min/week 10,000 steps/day
Frequency of self-weighing	At least weekly	At least weekly, daily recommended
Self-monitoring diet		
Frequency and content	Daily food log and counting calories and fruit and vegetable servings	Same
Method	Lose It® App or paper tracking	Same
Self-monitoring physical activity		
Frequency and content	Daily minutes and steps	Same
Method	Pedometer	Same

and help with addressing routine problems or lapses. The maintenance intervention incorporates a social cognitive approach to relapse prevention [51] using a successful 5-step problem-solving model [52]. Counseling strategies are used following principles of motivational interviewing [31] to help patients resolve ambivalence about continuing to exercise and/or eat healthy once weight loss plateaus or regain is experienced. The maintenance intervention represents a change from the more didactic approach of initial treatment and focuses on support and problem-solving for enhanced motivation and long-term coping skills.

2.10. Measures

Anthropomorphic and lab measures are collected at baseline, 6, 18, and 24 months in-person at the practice sites. Practice personnel collect the measures and enter them into REDCap. Self-report questionnaires are administered via online REDCap surveys sent by the central RE-POWER study team via email or mail hard copy, depending on patient preference. Patients are asked to complete questionnaires at five time points (baseline, 6, 12, 18, and 24 months).

2.10.1. Anthropomorphic measures

Body weight, waist circumference, and blood pressure are directly measured and recorded at baseline, 6, 18, and 24 months during in-clinic assessment visits. Patients are weighed in light clothing (shorts and t-shirt) in a fasting state using a calibrated digital scale accurate to 0.1 kg (Befour MX-115, Inc). Height is measured at baseline with a stadiometer, and BMI is calculated by dividing weight (kg) by height (m) squared. To estimate central adiposity, waist circumference is obtained with 2 measurements within 2 cm using standardized procedures [53]. Blood pressure is measured by clinic staff after the patient rests in a seated position for 5 min. Two blood pressure measures are collected concurrently and, if either the systolic or diastolic measurements are greater than 5 mm Hg apart, a third measurement is taken after a one-minute break.

2.10.2. Fasting glucose and lipids

A clinic phlebotomist collects blood draws at baseline, 6, and 24 months during in-clinic assessment visits. The collection, processing, analysis and storage of samples differs slightly depending on the site. Practices with in-house labs process serum or plasma onsite. Practices with off-site labs send whole blood samples to their preferred local lab to process serum or plasma. Lab technicians measure fasting glucose and lipids (i.e. low-density lipoprotein, high-density lipoprotein, triglycerides, and total cholesterol). Lab results are sent to the practice per their routine workflow, and practice personnel then enter lab results directly into the study's central data collection system. Data are also uploaded to patients' electronic health record per routine practice protocol.

2.10.3. Questionnaires

2.10.3.1. Demographic information. Information collected at baseline consists of date of birth, race/ethnicity, household and personal income, marital status, level of education for patient and spouse/partner, employment status for patient and spouse/partner, physical address, health insurance status and type, and years lived in rural setting. Updates occur at 12 and 24 months.

2.10.3.2. Medical history. Self-reported medical history is collected at baseline. Changes in medical history are assessed at each subsequent assessment time point. Smoking history and alcohol use [54] are also assessed at baseline and at each follow-up assessment.

2.10.3.3. Medication information. Baseline medications are collected by the central RE-POWER study team through a phone interview. Patients report changes in medications on each follow-up survey.

SF-12v2, a shortened version of the original SF-36, is a widely used measure of physical and mental health-related quality of life [55,56]. The SF-12 differentiates quality of life among obese versus normal weight individuals [57].

Impact of Weight on Quality of Life-Lite (*IWQOL-L*) is a 31-item measure of weight-related quality of life, including physical function, self-esteem, sexual life, public distress, and work [58]. The IWQOL-L has demonstrated internal consistency reliability and construct validity when compared to other quality of life measures, detects quality of life changes in response to weight loss during an intervention, and distinguishes differences in quality of life based on BMI [58–60].

Pittsburg Sleep Quality Index (*PSQI*) [61] is a 10-item measure that assesses sleep timing and disturbances over the past month and is reliable and valid in a variety of populations. The PSQI distinguishes between sleep quality in individuals with obesity/metabolic syndrome and those who are of normal weight [62], and has been shown to predict the magnitude of weight loss during an intervention [63].

Perceived Stress Scale (*PSS*) is a widely-used 10-item measure of perceived stress [64]. The PSS has established internal consistency reliability, factorial validity, and construct validity in a variety of samples, including obese adults [65].

Table 3
RE-AIM measures.

Measure type	Measure
	% of patients in registries who respond to recruitment mailings
Reach	% of patients in clinic registries who enroll
(Representativeness of patients)	Comparison of characteristics between enrolled patients and patients who are screened but do not enroll
Effectiveness	Measured with primary and secondary outcomes
(Impact at patient level)	
	Comparison between participating and non-participating practices within our networks on:
	Practice type (e.g., FQHC, RHC, hospital-owned, stand-alone)
	Practice size
	PCMH readiness practices and systems to address counseling for diet, physical activity, and weight management.
Adoption	Practice size
(Representativeness of practices)	Presence of registered dietitians or behavioral counselors
	Degree of rurality as this corresponds to access to other community resources
	Distance to a large hospital as this is associated with scope of practice in the rural setting
	Counseling session attendance
Implementation	Provider completion of trainings
(Process by which interventions are delivered)	Provider self-assessed competencies
	Provider-reported facilitators and barriers to implementation (qualitative interviews)
	% of participating practices that begin billing Medicare
Maintenance	% of practices that use obese patient registries after recruitment ends
(Translation at the practice level)	% of practices that continue intensive behavioral treatment of obesity

Patient Health Questionnaire-9 (*PHQ-9*) is a 9-item, reliable, valid criteria-based measure of depressive symptoms and severity [66].

Modifiable Activity Questionnaire (*MAQ*) measures the duration and frequency of 38 leisure time physical activities over the last 7 days [67]. The MAQ has evidence of validity when compared to accelerometer measurements of activity [67,68].

National Cancer Institute's Energy Screener is a 17-item survey designed to estimate an individual's percentage calorie intake from fat in the past 12 months. This measure has demonstrated validity among obese individuals when compared to the Food Frequency Questionnaire [69] and 24-hour dietary recall [70].

Frequency of fast food and sugar sweetened beverage consumption is assessed with three items from the Behavioral Risk Factors Surveillance System (BRFSS) [71]. A fourth item assesses frequency of eating out at non-fast food restaurants.

Fruit and Vegetable Screener is a brief low burden, 2-item questionnaire assessing the number of cups of fruits and vegetables consumed daily. It has good 2-week test–retest reliability and moderate validity when compared to 24-hour recall values [72].

2.10.3.4. Patient experience of care and program satisfaction. Experience of care is assessed with 10 items adapted from integrated care performance measure recommendations [73]. Satisfaction with program components is assessed with eight items adapted from similar previous trials [39,74,75] plus two items assessing group cohesion for the PCMH and DM arms [75].

2.10.4. Implementation process measures

We use the RE-AIM framework to evaluate Reach (at the patient level), Adoption (at the practice level), Implementation (at patient and practice level), and Maintenance (at the practice level) [76]. Table 3 describes quantitative RE-AIM measures.

To inform and augment these quantitative measures, we will conduct structured interviews with participating providers, practice staff, and study patients. Interviews with providers and practice staff last approximately 60 min and occur at 6, 12, and 24 months for all participating practices. The structured interview guide focuses on barriers and facilitators to implementing the intervention at the practice level using a set of questions modeled after domains in the Consolidated Framework for Implementation Research (CFIR) [77]. Domains assessed include perceptions about the complexity, evidence strength, and relative advantage of the intervention itself, the priority and compatibility of a focus on obesity treatment within the local practice climate, and the process of implementing the intervention and engaging local opinion leaders.

Interviews with study patients last approximately 30 min and occur after they have completed the final follow-up visit, with 20 patients randomly selected from each of the three arms and data collection continuing until saturation is reached. Patient sampling for interviews is stratified by level of participation (session attendance high vs low), level of weight loss (< 5%, 5–10%, >10%), and sex. Interviews focus on facilitators and barriers to uptake and adherence. We ask about satisfaction with intervention components, including session type, location, and time, helpfulness of counselors and PCPs, and usefulness of intervention components. We pay particular attention to barriers related to sociocultural and environmental constraints from living in a rural community.

2.11. Patient and stakeholder engagement

The trial design has been guided by patient and stakeholder input since its inception. The Patient Advisory Board (PAB) includes 10 men and women living with obesity in rural communities throughout Kansas, Nebraska, Wisconsin, and Iowa. Some PAB members have successfully lost weight and kept it off whereas others are considering making a weight loss attempt. Provider stakeholders are rural primary care physicians with a vested interest in improving the treatment of obesity in their practices and in care quality improvement. To launch our study engagement and enhance working relationships, we held a day-long kick off meeting in Kansas City where approximately 35 PAB members, provider stakeholders, investigators, and project staff shared personal and practice-level stories and experiences, discussed intervention preferences across the three arms, and brainstormed potential barriers and solutions to practice and patient recruitment and retention. Continued input from the PAB and provider stakeholders occurs during monthly conference calls and regular phone and email communication. Provider stakeholders helped develop the practice reimbursement strategies, while PAB input helped to select the patient-reported outcome measures, targeted components of the intervention and training materials, and the study name and logo. The PAB developed the recruitment brochures and designed elements of the survey data collection process. Ongoing input from the PAB and provider stakeholders helps guide recruitment and retention strategies, process evaluations, interpretation of findings, and dissemination plans, particularly for reaching a broader, non-academic audience.

2.12. Data management and statistical analysis

2.12.1. Sample Size

Treatment effects for PCP counseling alone with varying levels of intervention intensity have ranged from 0.1 to 1.7 kg at 12 to 24 months follow-up with the majority falling below 1 kg [19]. To determine sample size, we set the type I error at 0.025 (overall type I error rate of 0.05 for first two aims), intraclass correlation coefficient at 0.05, and 40 patients per practice. With 36 practices, the trial will have 80% power to detect a net treatment effect of 2.75 kg (SD = 8). This effect size is supported by the available literature [78,79], and our previous work using a DM approach [36].

2.12.2. Missing data

Based on our prior history using a similar retention plan in the rural setting, we expect to retain a minimum of 80% of patients at 24 months across all three treatment arms. For patients who fail to attend in-clinic study assessment visits, we will use weight abstracted from medical charts if within 3 months of the target date at 6 and 18 months or 4 months of the target date at 24-months. All primary analyses will be conducted using intent-to-treat and will assume that individuals who discontinue participation in the study prior to month 24 with unavailable chart weight, on average, regain weight at a rate of 0.3 kg per month up to their baseline weight. This conservative approach has been employed by several others [80–82], and is consistent with published reviews of weight regain following lifestyle treatment for obesity [83].

2.12.2.1. Statistical analysis for primary aims: Weight loss at 24 months. Weight loss at 24 months will be compared between PCMH vs FFS and DM vs FFS, as well as DM vs PCMH. Hierarchical linear mixed models will be used to examine the group differences, accounting for the correlation between patients from the same clinic.

2.12.2.2. Secondary analyses for patient-centered outcomes. Each secondary outcome at 24 months will be compared across all treatment arms using separate hierarchical linear mixed models.

2.12.2.3. Secondary analysis to assess heterogeneity of treatment effects across patients. We anticipate treatment effects will vary among patients based on characteristics identified by the literature and by our PAB as important for service utilization. Specifically, we will explore whether DM and PCMH show larger effects over FFS for racial/ethnic minorities (African Americans and Latinos), those with lower education, and those with lower income. The more intensive and accessible treatment in DM and PCMH may be especially important for subgroups who have

fewer resources and face greater life stress [84,85]. We also expect that DM and PCMH will show larger effects over FFS for patients who travel longer distances to receive care or who are employed full-time because the traditional face-to-face office visit during regular clinic hours may limit their uptake of treatment. We will also explore interactions between treatment conditions and weight loss history [86] as patients with prior knowledge and skills for successful weight loss may benefit more from the brief counseling provided in FFS. Using separate hierarchical linear mixed models predicting weight loss at 24 months, we will examine interactions between each of the five patient factor and treatment arms using omnibus interaction F-statistic from SAS Proc Mixed. To assure the overall Type I error is fixed at .05, we will continue to test specific group differences only if the omnibus p-value $< 0.05/5 = 0.01$.

2.12.2.4. Analyses to evaluate the reach and sustainability of the interventions with the RE-AIM framework. Each RE-AIM measure will be compared across treatment arms using descriptive statistics. After aggregating to the practice level, the patient-level factors (session attendance, ratings of care) will be tested and compared across arms using separate analysis of variance (ANOVA) models.

3. Discussion

Primary care has great potential to fill a major gap in access to evidence-based weight control programs, particularly in rural communities. Findings from this pragmatic trial will inform effective treatment models for delivering behavioral obesity treatment in rural primary care. While both PCMH [78,87–89] and DM [35,78,90] treatment models have emerged as promising obesity treatment models that are congruent with primary care clinical settings, our study is unique in that our findings will determine the comparative effectiveness of these treatment models with the current CMS-reimbursed standard of IBT for Obesity. Although Medicare established the FFS obesity treatment model in late 2011, it has not yet been rigorously evaluated for effectiveness [19]. Among the concerns with the approach is the brief 15-minute visit duration, which may not be enough to produce meaningful weight loss [23].

This trial is being conducted simultaneously as the Promoting Weight Loss in Primary Care in Louisiana (PROPEL) Trial by Katzmarzyk and colleagues at Pennington Biomedical Research Center, funded under the same PCORI RFA [91]. In the PROPEL trial, practices in the active arm recruit low income, predominantly African American patients to receive an intensive lifestyle intervention delivered by a trained external health coach, while practices randomized to usual care receive a one-time webinar on the current CMS IBT approach to reimbursing for obesity treatment. The two trials have common eligibility criteria and a primary endpoint focused on weight loss at 24 months. Combined evidence from the RE-POWER and PROPEL trials will help optimize models for treating obesity in primary care for underserved populations.

Results from the current study will also provide valuable information regarding the dissemination potential of these treatment models. While the RE-AIM framework has been frequently used to assess obesity treatment implementation in worksites, schools, and geographically linked communities [92,93], few studies have systematically examined the implementation process in primary care. Two ongoing hybrid effectiveness-implementation mixed methods studies are underway in specific primary care settings. Campbell-Scherer and colleagues are examining the effect of an obesity treatment learning collaborative among Canadian primary care teams. Their primary endpoint is adoption at the provider level as measured by the number of weight management visits conducted per provider, and secondary endpoints include patient BMI, quality of life, and satisfaction with care [94]. Damschroder and colleagues are examining the implementation of the VA Diabetes Prevention Program compared to the VA MOVE!® program [75]. Their primary aim is to evaluate the implementation strategy through fidelity checklists and structured interviews with clinic staff guided by the Consolidated Framework for Implementation Research (CFIR) model and the RE-AIM model. The secondary aim is to evaluate the effectiveness of implementation on patient outcomes including weight, hemoglobin A1c, and session attendance. No previous studies to our knowledge have examined the implementation of CMS-reimbursed IBT for Obesity or a PCMH or DM model of care for obesity treatment. Based on the findings from our RE-AIM measures and CFIR-guided structured interviews, this study will provide valuable information on patient and provider-level uptake and key systems factors that contribute to successful implementation in practices, e.g. factors that facilitate clinic management, patient flow, and maximize intervention reach.

The current study is among the first large scale, pragmatic effectiveness trials of obesity treatment conducted in rural America to date. Previous trials in underserved populations have targeted African Americans, Hispanics, and individuals of low socioeconomic status [95–97], and another current trial is focused on rural community health centers in North Carolina. [98] Rural residents face many of the same barriers as other underserved populations such as lack of access and environmental support [11,12]. Rural families traditionally consume high-fat, high-calorie diets that, in the past, were largely offset by the physical demands of vigorous physical labor such as farming [99]. However, cultural eating patterns (e.g., "country cooking") [14,100] as well as less access to healthful foods many have maintained these dietary patterns [101]. In addition, in rural communities cultural norms seldom encourage leisure time physical activity and one is less likely to encounter other people exercising [11], a key determinant of physical activity adoption [11]. The comprehensive lifestyle intervention delivered in this study is tailored to rural residents, both in content and delivery method. The emphasis on phone-based sessions addresses the travel barrier faced by many rural residents.

Finally, this trial is grounded in a patient-centered approach in which the feedback and preferences of both rural primary care patients and providers is incorporated into all aspects of the study. The typical and substantial delay in disseminating new research innovations into clinical care has resulted in part from focusing on interventions and outcomes that lack relevance or access for patients or providers or are not widely generalizable to real-world healthcare settings [102]. In response to these issues, a national patient-centered research focus, with support by PCORI, has emerged in an effort to enhance the impact of clinical research and ultimately lead to improved population health outcomes [103]. In addition to large-scale patient-centered comparative effectiveness trials such as this one, the National Patient-Centered Clinical Research Network (PCORnet) has been launched to integrate and leverage big data and bring together health research, healthcare delivery, and the patient voice to advance healthcare knowledge [104]. Thus, patient and stakeholder engagement in this trial is representative of a shift in clinical research, highlighting the importance of working closer with patients and providers in order to enhance study quality, relevance, and priority, and ultimately population-level patient outcomes.

4. Summary

Primary care is the backbone of the U.S. healthcare system, but it has been underutilized for obesity treatment, particularly in rural settings where access to evidence-based weight management programs is lacking [17,18]. The fee-for-service approach to obesity treatment embodied in CMS-reimbursed IBT for Obesity is not being widely utilized, and the effectiveness of this model remains unknown. PCMH and DM models of care are two viable approaches being adopted nationally for other chronic diseases, yet no studies have directly compared these two approaches to the FFS model for obesity. The findings from this study may contribute to a new standard of primary care for obesity treatment in the rural U.S.

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