Persistent challenges in diabetes prevention require innovations in primary care that engage and empower patients to adopt lifestyle changes and to proactively manage their health (1). Therefore, an important opportunity for diabetes prevention is the development and implementation of primary care approaches that promote self-management knowledge, skills, and self-efficacy to abate disease progression.

One such approach is personalized health planning (PHP), a proactive model of shared goal-setting that is tailored to an individual’s health risks, care preferences, and priorities (2). This model has been validated in diverse primary care settings as a feasible means to enhance patient-clinician engagement, establish shared health goals, and increase patient satisfaction (3).

A second approach is shared medical appointments (SMAs), an evidence-based care redesign enabling clinicians to see multiple patients together in a group visit for a shared chronic condition. SMAs have been shown to be more effective than traditional primary care visits for managing chronic diseases that require lifestyle modification, including diabetes (4). Group visits are often longer than traditional one-on-one primary care appointments, thereby enabling education, peer support, and ongoing monitoring. A meta-analysis of 17 studies compared SMAs with usual care for patients with diabetes and demonstrated reductions in A1C levels and systolic blood pressure (5). Applications of SMAs for diabetes prevention have been limited but represent a critical early intervention point for patients at risk for developing diabetes (6).

By combining the complementary evidence-based components of SMAs and PHP, a new approach—known as the personalized medical group visit (PMGV) model—was developed to more effectively engage patients in their care and health self-management. Specifically, this care model consisted of SMAs, integrative health coaching (7,8), PHP (3,9), and mindfulness meditation (10), delivered alongside self-management education based on American Diabetes Association guidelines. These synergistic and evidence-based components support both guideline-concordant medical care and collaborative patient engagement (Figure 1). The PMGV model aligns with the Veterans Health Administration’s (VHA) Whole Health approach, which emphasizes patient empowerment and skill-building. VHA’s Whole Health initiatives include staff and clinician training to promote shared decision-making and health coaching (11–13); the introduction of “Taking Charge of My Life and Health,” a wellness-focused, peer-led program (14,15); and the expansion of evidence-based complementary and alternative care modalities (e.g., yoga, tai chi, and acupuncture) (16,17). Notably, the Whole Health system and care redesign promote evidence-based approaches, including self-management education (18,19), mindfulness, health coaching, integrative health approaches, and proactive patient-centered health goal-setting through PHP as a unified clinical approach (3,17). Preliminary evidence suggests that these tenets could constitute a feasible and acceptable clinical care model for patients with poorly controlled diabetes, but it has not been evaluated for the primary prevention of diabetes (20).

The goal of this pilot study was to evaluate the feasibility of the PMGV model to engage and motivate people with prediabetes to achieve meaningful health and therapeutic goals. Based on previous literature and research, the research team hypothesized that the model would be acceptable and feasible to these individuals with prediabetes. By establishing the feasibility of this model for the primary prevention of diabetes, this study would validate a new patient-centric, efficient, and scalable approach to care and inform care redesign efforts to enhance care quality for those at risk for developing type 2 diabetes.
Research Design and Methods

Study Setting

This pilot study was conducted at a clinic within a primary care and behavioral health care facility in a regional Veterans Affairs (VA) health care system that serves a diverse, metropolitan population in the southeastern United States. The clinic offers both primary care and behavioral health care to veterans, as well as specialty referrals to a larger VA medical center nearby.

Patient Eligibility and Recruitment

Beginning in November 2018, eligible patients with prediabetes (A1C 5.7–6.4%), a working phone number, and a home address located within 2 hours’ drive of the study site were invited to participate in the pilot trial via a mailed letter from study personnel. The trial conducted the PMGV intervention with two cohorts of adult Veteran patients (n = 13). Patients with type 2 diabetes, serious physical or mental illness, or cognitive impairment were excluded. The primary care providers were given the opportunity to opt out their eligible patient panel or select individuals at their discretion. If patients did not respond to the letter within 2 weeks, they were called by study personnel up to two times. Eligible patients were scheduled into the group based on verbal commitment and willingness to participate. All patients completed informed consent and Health Insurance Portability and Accountability Act authorization forms before the start of the first group session. Patients were given a small monetary incentive determined by the number of sessions attended.

PMGV Program Model

The PMGV offered eight biweekly, 90-minute sessions over ~4 months. Each included 30 minutes allotted in the beginning of each session for check-in and data collection. The model included providing each participant with a participant notebook and a pedometer to track physical activity, as well as an initial health self-assessment, a collaborative patient-provider health goal-setting process, mindfulness meditation practice, and creating a personal health plan to document health goals developed by the patient and provider (9). The participant notebook included patient education material, interactive worksheets to be completed during group sessions and at
Before session 1, patients arrived for the visit and waited in the clinic waiting room until they were called into a conference room for the group session. A health coach facilitator led the didactic and interactive Whole Health curriculum as part of the group visit. The curriculum was designed to foster a semi-structured and interactive learning environment and included, for example, problem-solving for barriers to self-management, trivia, demonstrations, and a mindfulness meditation activity at the beginning of each session. At the end of each session, patients shared progress on their PHP; specific, measurable, action-oriented, realistic, and timed (SMART) goal-setting; and action steps with their peers. Patients who achieved their goals or action steps were encouraged to set new goals in the group setting.

While the group session was being conducted, each patient met sequentially with the provider in a separate examination room for a brief individualized consultation, medication reconciliation, and motivational interviewing session to establish or evaluate progress on the PHP. In the first and second group sessions, this consultation included developing clinically relevant and patient-direct shared goals through a shared decision-making process.
Measures

Data were collected through paper-based surveys by a trained study staff member.

Clinical Indicators

The primary outcome of interest was systolic blood pressure measured at rest with an electronic cuff. Secondary clinical outcomes included BMI and cholesterol levels, including both LDL and HDL cholesterol. Blood pressure and BMI were recorded at every session. Cholesterol levels were recorded during sessions 1 and 8 only. Patients’ medical records were reviewed after completion of the program to obtain data on medication changes and whether patients remained in the pre-diabetic range up to 6 months after completion of the study.

Demographics

Demographic information, including age, sex, race/ethnicity, education, marital status, income, employment, and health insurance coverage, was collected at session 1.

Goal Progress

During sessions 3 and 7, patients reported on their goal progress using a six-point Likert goal progress visual analog scale. This scale was developed by the research team based on goal attainment scaling and ranged from 0 = “I do not have a goal in this area” to 5 = “I have greatly exceeded my goal” (21).

Health Behaviors

During sessions 1, 4, and 8, patients reported on the frequency of key health behaviors such as tobacco use, fruit/vegetable intake, sugary drink consumption, and water consumption. For example, patients were asked, “How many cups (1 cup = 8 ounces) of water do you drink each day?” and could select the numbers of cups consumed.

Physical Activity

During sessions 1 and 8, patients reported on the frequency and duration of their exercise using the International Physical Activity Questionnaire, a seven-item measure used to ascertain frequency and duration of vigorous to moderate physical activity over a 7-day period (22).

Medication Adherence

During sessions 1 and 8, patients reported on their medication adherence using a three-item measure created by the research team. For example, patients were asked how often they did not take a dose of their medicine over a 1-week recall period. The response scale ranged from 0 = every time to 4 = none of the time.

Patient Satisfaction

During the final session (session 8), patients were asked to provide feedback on their experience during the group and their overall satisfaction through a brief patient satisfaction survey developed for Whole Health programs in the VHA. The four questions were: 1) Did you feel you were treated with respect during this visit? 2) Did you feel the visit gave you valuable lessons to fully participate in decision-making related to your health needs? 3) Is the Whole Health approach easy to understand? And 4) How likely are you to recommend this approach to other veterans?

Statistical Analysis

Demographic and clinical characteristics were reported using descriptive statistics, including means, SDs, counts, and proportions. Wilcoxon signed-rank tests were used to evaluate changes in outcomes over time with two-sided P values reported; no adjustments were made for multiple comparisons in this exploratory analysis. The study was approved by the local VA Medical Center Institutional Review Board, and all analyses were conducted with Stata v. 16 statistical software (Stata Corp., College Station, TX).

Results

Sixteen participants were enrolled in this pilot; however, one participant dropped out of the study, and two missed more than half of the sessions, leaving a final sample size...
of 13 participants for analysis. At the program’s conclusion, nine of the participants had perfect attendance at all eight sessions. Across the 13 participants included in this analysis, the session attendance rate was 92.3% (96 of 104 sessions). Veteran participant demographics are reported in Table 2 and are similar to the demographic composition of the veteran population served by the health system (31% female; median age 68 years; 54% white and 46% black; 54% retired; and 54% high school or general education diploma education level). Changes in clinical and behavioral characteristics from baseline to the final recorded value are summarized in Figure 2.

Statistically significant improvements were observed from baseline to final value in systolic and diastolic blood pressure, as well as the secondary outcomes of interest, including decreased BMI, increased water consumption, self-reported progress on health goals during the program, reduced sugary drink consumption, and increased physical activity (Table 3).

All notes from prescribing providers were reviewed from the date of consent to the study end date. Two subjects each had one blood pressure medication increase, both done by the study provider; no primary care provider nor specialty care providers increased blood pressure medication while the patient was enrolled in the study.

Patients’ post-study A1C levels were characterized as prediabetes (5.7–6.4%), diabetes (≥6.5%), normal (≤5.6%), or unknown (i.e., no A1C measured within 6 months of the end of the study). By this characterization, one patient had an A1C indicative of diabetes, nine had A1C values in the prediabetes range, none had normal A1C levels, and three had unknown A1C values.

In addition to clinical and behavioral improvements, satisfaction levels were very high, suggesting acceptability of the program. All 13 participants reported the highest level of satisfaction when asked if they felt they were treated with respect, learned valuable self-management lessons, thought the Whole Health approach was easy to understand, and would suggest the PMGV program to another veteran.

In the PHP process, patients set a median of two goals, with a maximum of three goals, at sessions 3 and 7. The most commonly set health goals related to nutrition and physical activity (Figure 3). At session 7, nine participants
(69%) had met at least one of their goals, compared with only three participants (23%) at session 3.

Discussion

This study presents evidence of the feasibility and acceptability of the unique PMGV model that combined a Whole Health and PHP approach, group visits, and strategies to develop and sustain patient engagement. The high levels of visit attendance and patient satisfaction lend support for the hypothesis that this model would be acceptable to patients and feasible to implement. Furthermore, there is preliminary evidence demonstrating the model’s efficacy to facilitate beneficial behavior change and improved relevant clinical and patient-reported outcomes. Most notable were improvements in blood pressure, BMI, physical activity, and diet (i.e., water intake increased, and sugary beverage intake decreased). Participants reported goal progress as a result of the PHP process across several health self-management areas, the most common of which were nutrition and exercise. However, these improvements could have been the result of meetings with the study provider, which may not be sustained in many
institutions. Additional research is needed to understand the effect of varying levels of clinician involvement on outcomes of interest.

The PMGV model provides a scalable approach that is feasible and acceptable in the active clinic environment to better engage patients at risk for developing diabetes, as indicated by high levels of visit attendance and patient satisfaction. These findings contribute to an emerging evidence base to identify the core components and patient engagement strategies of SMA interventions associated with the greatest benefit to patients. This endeavor is a challenge because of heterogeneity among components of SMA interventions and because the intervention components are often poorly defined, with varying effect sizes (5). This ambiguity of best practices for SMA implementation and sustainment has led to low adoption rates (23).

This study suggests that the incorporation of PHP and other complementary intervention components can constitute a new approach to enable primary prevention of chronic diseases such as diabetes. Although the study focused on the care of patients with prediabetes, the underlying model may be applicable to other chronic diseases wherein patient behavioral change is important for achieving better outcomes.

Study limitations include the small sample size and lack of a comparison group. Planned research includes the adaptation of the model for telehealth delivery, in addition to a larger hybrid randomized controlled trial to evaluate 1) the model’s clinical effectiveness (e.g., impact on A1C) compared with usual care and 2) implementation factors to inform broader scaling of the PMGV model for diabetes prevention.

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DUALITY OF INTEREST
C.D. has a financial relationship with ZealCare, Inc. R.S. has financial relationships with ZealCare, Inc., CareDx, iRhythm Technologies, and the Whole Health Institute. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS
C.D., R.S., B.W., and D.E. contributed to the study conception, framing, and design. C.D., M.C., and H.B. contributed to study administration, data preparation, and data extraction. C.D., R.S., T.L., B.W., C.C., and D.E. contributed to the data analysis and interpretation. The first draft of the manuscript was written by C.D., R.S., M.C., H.B., and T.L., and all authors commented on subsequent versions of the manuscript. All authors read and approved the final manuscript. C.D. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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