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Effective recruitment for practice-based research: Lessons from the REAL HEALTH-Diabetes Study

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ABSTRACT

Background: Aims: The REAL HEALTH Diabetes Study is a practice-based randomized clinical trial that compares the effectiveness of lifestyle intervention aimed at weight reduction to medical nutrition therapy in primary care patients with type 2 diabetes. This paper describes a tiered approach to recruitment, the resultant enrollment rates of sequentially more intensive recruitment strategies, and identifies barriers to participation.
Methods: Potential participants were identified using patient health registries and classified by recruitment site. Four recruitment strategies were used to achieve target enrollment: (1) mail/telephone outreach; (2) direct referral from providers; (3) orientation sessions; and (4) media/advertising. Reasons for ineligibility and non-participation were tracked.
Results: Fifteen thousand two hundred sixty-nine (15,269) potential participants were identified from all sources, with the clear majority coming from patient registries. Mail/telephone outreach alone had the lowest enrollment rate (1.2%). Direct referral and orientation sessions superimposed on mail/telephone outreach was used for fewer participants but had greater enrollment rates (27% and 52%.) Media/advertising was ineffective. The most commonly reported reasons for non-participation were not wanting to be in a research (30%) or a weight loss program (22%); time commitment (20%); and distance/transportation (14%).
Conclusions: The use of population registries to identify potential participants coupled with successively more intensive recruitment strategies, executed in a tiered approach moving toward personal engagement to establish trust and credibility, maximized recruitment enrollment rates. Our findings regarding facilitators and barriers to recruitment could be used to inform other practice-based research or to engage patients in group interventions in usual care settings.
Clinical trial registration: NCT02320253.

1. Introduction

REAL HEALTH-Diabetes is one of the first "real world" adaptations of the Look AHEAD (Action for Health in Diabetes) lifestyle intervention targeting weight loss for type 2 diabetes in the primary care setting. The Look AHEAD trial compared an intensive lifestyle intervention (ILI) aimed at sustaining a 7% weight loss and 175 min of weekly activity to a program of diabetes support and education. Look AHEAD's intensive lifestyle intervention demonstrated significantly greater weight loss (8.6% vs. 0.7%) and fitness after 1 year, resulting in improvements in glycemic control, blood pressure, and lipids, with simultaneous reductions in medications and health care expenditures to treat these conditions. Improvements persisted at years 4 and 8, and a weight loss of 6% was sustained after a median of 9.6 years of follow-up [1–5]. However, the Look AHEAD intensive lifestyle intervention program was very intensive, costly, and delivered to rigorously screened participants in an alternating individual and in-person group format, limiting the cost-effectiveness, generalizability, and scalability of the program.

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In contrast, REAL HEALTH-Diabetes is a three-arm, randomized, practice-based clinical trial designed to examine the comparative effectiveness of two less intensive, lower cost, and more scalable adaptations of the Look AHEAD intensive lifestyle intervention (in-person group lifestyle intervention and telephone group lifestyle intervention) compared with a referral to a dietitian for medical nutrition therapy (MNT), which is the current recommended standard of care. Descriptions of the pilot work [6] and REAL HEALTH-Diabetes study design and baseline characteristics of the enrolled participants have been previously reported [7]. REAL HEALTH-Diabetes achieved its enrollment target of 210 participants by recruiting from three community health centers (CHCs) and one additional practice at which the intervention was conducted (intervention sites) as well as other recruitment sites, including all patients in the primary care network affiliated with our institution and other endocrine practices in our health care system.

This paper describes a tiered approach to recruitment and the resultant enrollment rates of sequentially more intensive recruitment strategies. Further, it reviews implications for future practice-based research and clinical programs seeking to enroll participants in usual care interventions.

2. Methods

2.1. Setting

The study initially recruited from three community health centers (MGH Charlestown, MGH Chelsea, and MGH Revere) and the MGH Diabetes Center (the intervention sites). The study enrolled patients who received diabetes care at these intervention sites and also recruited from other practices, including primary care patients from practices affiliated with Massachusetts General Hospital (MGH), and endocrinology practices affiliated with North Shore Medical Center (NSMC) and Newton-Wellesley Hospital (NWH), both of which are affiliated with Partners HealthCare, a not-for-profit health care system in Eastern Massachusetts and located within 30 miles of the city of Boston. The study was led by a research team at the Massachusetts General Hospital Diabetes Research Center (the Research Center).

2.2. Description of recruitment implementation

REAL HEALTH-Diabetes leveraged existing clinical infrastructure to identify and enroll participants. The Research Center locale served as the Coordinating Center where the study staff supervised all aspects of recruitment and provided study oversight. Modifications to the basic recruitment strategies were implemented if necessary. The staff communicated with primary care physicians (PCPs), clinical managers, population health managers, nurses, and dietitians at each site. The study team engaged and funded a health care provider from each of the three CHCs to serve as co-investigators and oversee recruitment and implementation of the study at their respective intervention sites. The team conducted training sessions for staff at each of the CHCs on the overall study protocol, recruitment targets, and recruitment and retention strategies to achieve those targets. Follow-up in-person meetings or conference calls were held biweekly among the research team and CHC co-investigators to discuss recruitment progress, intervention delivery, protocol fidelity, and retention issues. In addition, the study coordinator and a study dietitian assigned to each CHC trained nurses and other CHC staff in recruitment procedures, outcomes data collection, and the importance of conveying an understanding and empathetic demeanor to facilitate recruitment and retention of study participants. Once recruitment was underway, the staff participated in weekly staff meetings to review progress, brainstorm solutions to challenging issues, and fine-tune recruitment strategies. All recruitment strategies and study procedures were approved by the Partners HealthCare IRB. The trial is registered at clinicaltrials.gov (NCT02320253).

2.3. Identification of target population

Recruitment began by identifying potential participants in compliance with IRB-approved procedures. Three patient registry lists (TopCare, Research Patient Database Registry [RDPR] and Research Opportunity Direct to You or RODY) were used to acquire names, addresses, and phone numbers of patients receiving primary and/or diabetes specialty care. TopCare was an institution-based population health management clinical application that contained a curated list of patients with diabetes affiliated with each practice and provider. The RPDR is an institutional data repository that may be queried for research recruitment with IRB approval, but is less specific. RODY identified patients who had already “opted-in” to be directly contacted by researchers. All three lists were refined to include only patients who met the primary eligibility requirements: diagnosis of type 2 diabetes and an HbA1c within the range of 6.5%–11.5%.

2.3.1. Recruitment StrategiesMail/telephone outreach

The TopCare and RDPR lists were sorted by provider and sent to 449 PCPs requesting approval to contact their patients. (As patients on the RODY list opted-in to be contacted directly, no PCP permission was necessary to contact them). All PCP-approved patients were mailed a letter with a general introduction to the study signed by their PCP using secretarial notation, paired with a study brochure. RODY patients were sent the same letter signed instead by the study PIs. The letters provided the recipients with 7 days to “opt out” of further contact. Follow-up telephone contact was attempted with those who did not opt out, but only after an initial electronic medical record review to confirm eligibility based on basic inclusion and exclusion criteria (BMI, co-morbidities, etc.). If telephone contact was made, staff provided more information about study goals, participation requirements, and answered questions. If the potential participant was willing, staff completed a phone screen for behavioral eligibility and scheduled a screening visit, for which parking was provided.

2.3.2. Direct referral

Study staff attended practice meetings with providers at the CHCs and other endocrine practices in the area to describe the study aims, eligibility criteria, the three treatment arms, and referral methods. They asked the providers to discuss the study with appropriate patients to encourage participation. In-person meetings were followed up with facilitated referral in individual provider emails. Study staff at the Research Center personally approached providers at the MGH Diabetes Center. The research team's immediate proximity to the MGH Diabetes Center made it feasible for staff to perform on-site, real-time recruitment: if a patient voiced interest, staff conducted the 20–30 min behavioral screen in-person immediately after the appointment with the provider. Intervention site-based co-investigators directly approached PCPs at their site to ask them to discuss the study with their appropriate patients to encourage participation.

2.3.3. Orientation sessions

Orientation sessions were added to the list of recruitment strategies during the last six months of recruitment to help reach the goal. Invitations to attend these informal, informational sessions were mailed to those on the patient lists who had not opted out and were initially screened using electronic medical records. To foster potential participants’ familiarity with the program, the orientation sessions were held at the intervention site where participants would be attending groups and research visits if they decided to enroll. At each 90-min session, a dietitian-interventionist explained the study and answered questions. Attendees were provided lunch and free parking. The PIs attended many of these orientation sessions as well to meet potential participants, discuss the goals of the study, and describe the relevance of the

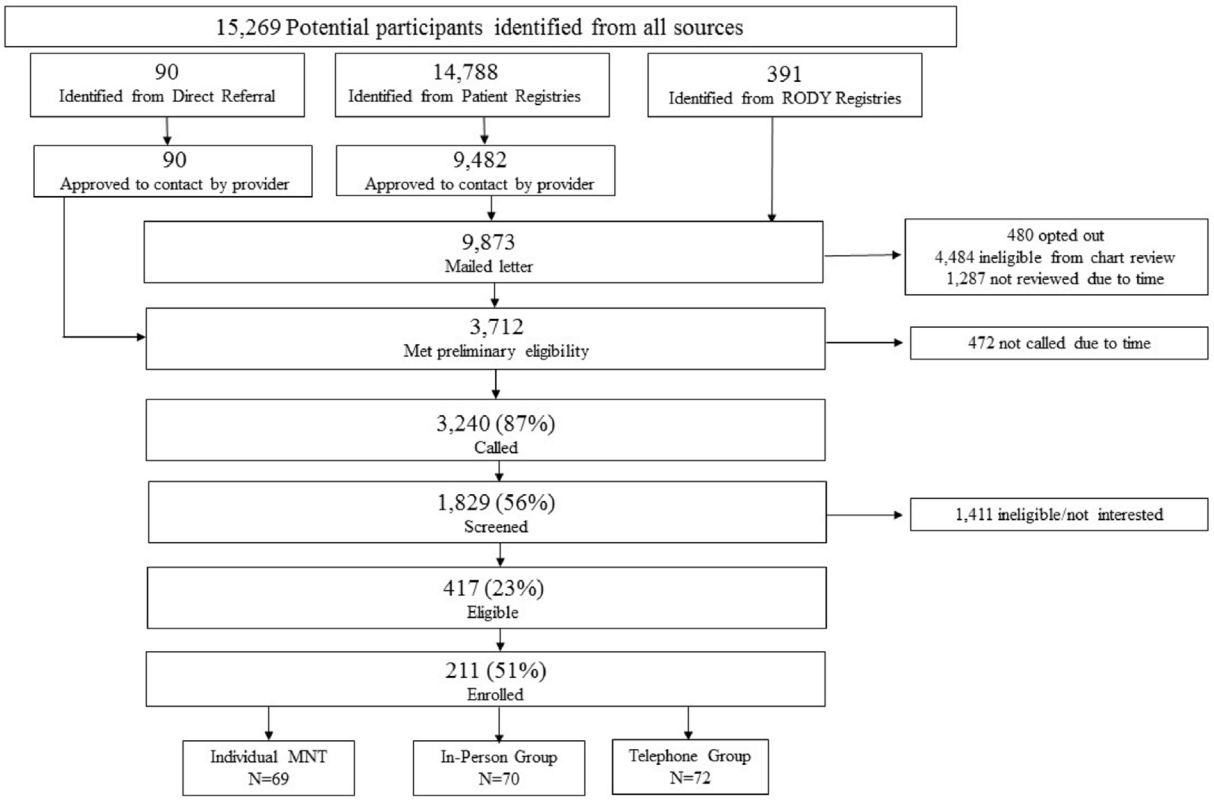

Fig. 1. Recruitment funnel.

research. If any were interested in proceeding, staff members met with them after the session to complete the behavioral screen, and if eligible, schedule an initial research visit.

2.3.4. Media/advertising

In addition to the above strategies, posters and flyers were displayed in the MGH Diabetes Center and at the CHCs' waiting rooms, exam rooms, and lavatories. A weekly Broadcast Email, sent out by the MGH Human Research Department to all MGH employees, listed a general study description and contact numbers for those interested in more information. Few volunteers contacted us via this method, but those who did received phone screens and were invited to orientation sessions.

2.4. Initial screening and behavioral screening

Staff conducted medical record reviews to identify potential participants for basic inclusion/exclusion criteria (initial screening). When reached by phone, a 20–30-min telephone behavioral screening was completed to explain the protocol, answer questions, confirm availability to participate, and willingness to be randomly assigned to a treatment focused on weight loss and increased physical activity. Alternatively, if the potential participant was directly referred by a provider after an appointment or attending an orientation session, the staff met with them in-person to complete the screen. Eligible patients were mailed or provided a 7-day food record to complete and the randomization visit was scheduled. Notably, the study dietitian conducted an interview at this visit to further assess behavioral readiness by probing about commitment to join the study, focusing on completion of the 7-day food record (why/why not); motivations for joining the study; preferred randomization arm in terms of convenience/expected success; potential reaction to not being assigned to the preferred arm (e.g., would they "drop out"?); major life stressors that might hinder participation; and available support network. This helped to assure, before randomization, that those eligible were fully informed of the commitment and helped them decide whether the study was a good "fit." After this visit, the patient was randomly assigned to one of the treatment arms and provided with study materials.

2.5. Incentives

Free lunch and free parking were provided to those attending orientation sessions. Free parking was provided to those who were assigned to and attended in-person group intervention. Parking was not provided for those assigned to MNT visits (usual care). All were provided free parking and honoraria for data collection visits as follows: Research Visit 1: $0; Research Visits 2 and 3: $25; Research Visit 4: $50; and Research Visit 5 (end of study): $100.

2.6. Statistical methods

For purposes of this report, the term "enrolled" refers to subjects who gave written informed consent to participate and were randomly assigned to one of the three treatment arms. We used the enrollment rate, the percentage of participants ultimately enrolled via each sequential recruitment strategy, to compare the outcomes of each approach. We categorized patients and primary care providers by recruitment site to determine whether intervention sites had different enrollment rates compared to non-intervention sites. Continuous variables were summarized using the mean with standard deviation while categorical variables were summarized using frequency and proportion. Chi square tests were used to compare response rates and yields among the 4 recruitment sites. All analyses were conducted using SAS version 9.4 (The SAS Institute, Cary, NC). A two-sided p value of 0.05 or less was considered statistically significant.

3. Results

Recruitment began in September 2014 and concluded in July 2017 having met the goal of enrolling 210 participants in this three-arm trial. Fig. 1 shows 15,269 potential participants identified from all sources and includes loss at each step of the recruitment screening process with attendant numbers and percentages, culminating in randomization assignments.

Staff received approval to contact and mail opt-out letters to 9,873 people, approximately two-thirds of the 15,269 potential participants who were identified from all sources. Of these, 480 opted out, 4,484 were ineligible after preliminary review, and 1,287 were not reviewed due to time constraints, leaving 3,712 to be called. Study staff called 3,240 potential participants, and over half (1,829) of those completed a phone or in-person screening; 23% (417) were eligible. Of the 417 found to be eligible after screening, 141 (34%) did not return phone follow-up calls, 35 (8%) were unavailable for the scheduled group times, 15 (4%) declined randomization, 12 (3%) were inappropriate for a group program, 2 (0.5%) fell out of the HbA1c eligibility range, and 1 (0.2%) did not complete the food diary.

Ultimately 211 or 51% of the 417 eligible were enrolled, representing 1.4% of the original 15,269 potential participants identified from all sources. It is estimated that roughly 9 phone screens were completed to yield 1 enrolled participant (1,829 phone screens yielded 211 enrolled). The 211 participants were randomly assigned as follows: intensive lifestyle in-person group (n = 70), intensive lifestyle telephone group (n = 72), or individual MNT (n = 69). Participants were on average 61 years old, 55.5% female, 76.8% white, 13.3% Hispanic, and 4.7% Black or African American, with mean BMI of 35.1 kg/m^2. Complete baseline characteristics are described elsewhere [7].

3.1. Provider response rate and enrollment rate

Table 1 depicts outreach to the total of 449 health care providers for permission to contact their patients. Nearly 66% (N = 296) of the providers responded, approving 9,572 patients for contact. The highest response rate (100%) was among the endocrine practices. Next, with a response rate of 89%, were the CHCs, followed by the MGH Diabetes Center providers (88%) and the MGH primary care providers (55%). One hundred fifty-three providers did not respond at all, eliminating 3,248 (21%) of patients from the original number identified of 15,269. In addition, among providers who did respond, staff did not receive permission to contact 2,449 (20%). Therefore, a total of 5,697 potential participants (37%) could not be contacted due to lack of provider response or permission.

Recruitment rates varied with respect to provider response: patients with providers from the MGH Diabetes Center had the highest enrollment rate at 4.6%, and the endocrine practices from affiliated hospital systems had the lowest enrollment rate at 0.6%.

Table 2
Reasons for ineligibility based on preliminary chart review.

Number	4,484 (100%)
HbA1c below 6.5%	1,219 (27)
Medical co-morbidities	926 (21)
Not diagnosed with type 2 diabetes	565 (13)
BMI < 25 kg/m^2	466 (10.4)
Language other than English or Spanish	301 (6.7)
History of bariatric surgery	201 (4.5)
Psychological co-morbidities	149 (3.3)
HbA1c above 11.5%	143 (3.2)
Substance use disorder	76 (1.7)
Other	438 (9.8)

3.2. Preliminary screening: medical records review to determine eligibility

Table 2 describes the results of medical record review to determine preliminary eligibility and reasons for exclusion. Nearly 30% were ineligible due to an HbA1c out of range (too high or too low), the majority being under 6.5%. Medical co-morbidities and lack of diagnosis of type 2 diabetes eliminated an additional 21% and 13%, respectively.

3.3. Secondary screening (phone) to reconfirm criteria and behavioral eligibility

Table 3 describes the results of the phone screening and reasons for non-participation after a phone screen, including newly identified medical or behavioral ineligibility criteria and reasons for lack of interest in participating. Barriers to participating included “not interested in being in a study” (30%), and “not interested in a weight loss program” (22%), and time commitment required (20%).

3.4. Recruitment strategies and enrollment rates

Table 4 describes the enrollment rates from the sequential recruitment strategies. The mail/telephone strategy had an enrollment rate of 2% or less. Media/advertising was ineffective. Direct referral had an enrollment rate of 27%. The more intensive orientation session strategy was offered to 1,364 potential participants. These participants, having been identified from all sources, were mailed invitations, or invited via telephone, or in person. Ultimately, 71 attended 14 orientation sessions and 37 enrolled (52%).

4. Discussion

Whether for a traditional trial, a practice-based trial, or a clinical program, effective recruitment is a fundamental component of success. After identifying the target population, methods to contact those identified must be employed and sufficient interest must be generated to ensure the requisite number of participants are enrolled in a reasonable period of time with minimal staff effort.

A search of the current medical literature produced scant literature

Table 1
Provider response rate and recruitment rate by recruitment site.

Provider response to study outreach	Overall	CHCs	MGH Diabetes Center	MGH Primary Care	Endocrine Practices	P value
Number of providers contacted	449	119	17	304	9	
Any response to study contact, n (%)	296 (66)	106 (89)	15 (88)	166 (55)	9 (100)	< 0.0001
Recruitment rate, incorporating provider response rate	**Overall**	**CHCs**	**MGH Diabetes Center**	**MGH Primary Care**	**Endocrine Practices**	**P value**
Number of patients identified	15,269	4,820	633	7,314	2,502	
Permission to contact, n (%)	9,572 (63)	2,982 (62)	453 (72)	3,724 (51)	2,413 (96)	< 0.0001
Enrolled of identified, n (%)	211 (1.4)	76 (1.6)	21 (3.3)	100 (1.4)	14 (0.6)	< 0.0001
Enrolled of permitted to contact, n (%)	211 (2.2)	76 (2.5)	21 (4.6)	100 (2.7)	14 (0.6)	< 0.0001

Table 3
Reasons for non-participation or ineligibility after phone screen.

Number	1411 (100%)
Declined participation	1290
Ineligible	121
Reasons identified at phone screen among those who declined participation or were ineligible	
Not interested in being in a study	418 (30)
Not interested in a weight loss program	312 (22)
Time commitment prohibitive	284 (20)
Distance/Transportation prohibitive	202 (14)
Low literacy	20 (1.4)
Unwilling to keep records	15 (1.1)
Unwilling to lose weight	6 (0.4)
Other Reasons including other comorbidities or A1C criteria not previously identified	154 (10.9)

Table 4
Recruitment Strategies and proportion enrolled.

Recruitment Strategy	Number Identified	Enrolled
Mail/phone from Patient Registries (TopCare/RPDR)	14,788	179 (1.2%)
Mail/phone from Patient Registries (RODY)	391	8 (2.0%)
Direct Referral	90	24 (27%)
Orientation session[a]	71[b]	37 (52%)

[a] Subset of the other categories-participants who attended orientation luncheons were identified via patient registries or direct referral.

[b] 71 attended the information sessions. All were part of the 15,269 identified.

adequately describing the entire recruitment process (i.e., identification of target population, strategies employed, enrollment yield). Rather than beginning at the number of "eligible" patients as CONSORT diagrams do, the recruitment funnel presented here (Fig. 1) expands the lens and captures the earliest stage of recruitment showing the broad spectrum of the potential target population identified using patient registries. Thus, this report more accurately characterizes the generalizability and scope of the effort.

Patient registries are often used to identify many potential participants, especially for disease-specific studies [8]. Although use of registries identified thousands of potential participants in this study, considerable staff time was expended on the IRB-mandated task of securing providers' permission to contact their patients. Overall, 34% of providers did not respond to attempts at outreach, limiting access to only 21% of patients initially identified. There was variation in physician response and enrollment rates across sites. Provider response rates were highest at intervention sites and practices where study staff had strong working relationships. The robust response rate at community health centers was presumably due to on-site staff presence and having an "on-the-ground", dedicated, and funded clinician co-investigator to oversee study implementation via regular communication with staff. Provider response rate was lowest among primary care providers who had little "personal engagement" in the project, illustrating the difficulty of recruiting for a practice-based trial in the absence of an on-the-ground effort.

The higher provider response rate at intervention sites and other endocrine practices compared to general primary care non-intervention sites did not translate into higher enrollment rates. Enrollment rates were similar at the community health centers where the intervention was based and in general primary care, suggesting if potential participants could participate at a location convenient for them, not having a group based at their own primary care practice was not a barrier.

Although mailings alone have been demonstrated to be a successful, low-cost recruitment strategy in other contexts [9,10], we found that only a small fraction of recipients called for more information. The relatively poor success in generating interest by letter only could have many causes, not least of which is the possibility that many did not read the letter. Anecdotally, when recipients were reached by phone, few recalled receiving it, rendering the outreach call on par with "cold calling", a rather poor marketing strategy [11]. Although this is not well-described in the medical literature, the marketing literature addresses the challenges of modern telemarketing: people are apt to screen their calls by not answering the call or not responding to a voicemail from an unrecognized number, due to concerns of privacy, hectic lives, and technology fatigue [11]. Research is needed to determine if texting or emailing would generate better results, although the hurdles of privacy and recruitment policy would have to be overcome.

While awaiting responses to mail outreach, staff completed medical record screenings to target outreach calls to only those likely to be eligible. Of the approximate 8,000 records reviewed, half did not meet inclusion criteria. Medical record screening staff time was the equivalent of one full-time staff member working for 33 weeks, based on an estimate of 10 min per chart reviewed/call made, illustrating yet another labor-intensive task when using patient registries.

Direct referral, compared to mail/phone outreach, proved more successful in this as well as other clinical trials [12]. Time spent by staff travelling to the sites, giving presentations, and speaking directly to individual providers proved to be well-spent, as personal engagement bolstered provider engagement as has been seen previously [13]. A limitation to this approach is that finding time to review patient lists or introduce a study to a patient during a visit cannot be a priority for practicing clinicians [14].

Orientation sessions added the enhancement of "personal engagement" with potential participants and yielded the greatest enrollment rate. Although most who attended the orientation sessions were identified from the patient registry lists and had previously been mailed a letter and brochure, *it was only after receiving an invitation to an orientation session that they showed interest.* Providing appropriate foods for lunch, plus a small "treat," mirrored the interventional tenets of the study: a flexible, feasible, "non-diet" philosophy. Attendees met other potential participants and perhaps gained insight by listening to the variety of questions discussed. While potential participants who attended these sessions were already more engaged than those who did not, sessions likely helped further increase the comfort level with participation. Problem-solving may also have taken place among attendees openly contemplating fitting the study into their schedules and hearing others with the same issues brainstorming solutions. As two of the study arms involved group education settings, meeting potential participants face-to-face in a group setting allowed staff to determine if the study was a good fit for particular individuals through their overall demeanor and questions and comments. Orientation sessions offered several advantages when compared to mail/phone: addressing only those already interested and engaged; capitalizing on face-to-face meeting with staff and PIs to build credibility and trust; helping overcome barriers to participation via group discussion and problem-solving; and expending less staff time by introducing the study to groups versus one-at-a-time via phone calls.

Information from those who opted out after mail/phone outreach provided valuable information on the barriers to participation. Almost 30% did not want to participate in a research study, perhaps stemming from beliefs about participating in research in general: unwillingness to follow a non-traditional treatment path, perceived lack of benefits of participation, lack of awareness of the importance of medical research, or lack of trust [15,16]. Twenty-two percent of otherwise eligible people did not want "to join a weight loss program." Previous lack of weight loss success and feeling that "it's too late for me to do anything about it" are just some of the possible underlying factors. The time commitment barrier may have been related to the study design [15,16]. However, lifestyle intervention studies inherently require a great deal of time for educational and behavioral training, and multiple visits to

assess participants' progress.

Future clinical trials or weight loss programs might boost recruitment rates by incorporating a screening and automatic referral system for eligible participants into existing electronic health record (EHR) work flows for providers. Time spent creating decision-making flags to alert primary care providers about eligible patients and educating and informing both providers and administrative staff about how to route their patients into effective research or clinical programs might enhance recruitment rates. Use of patient navigators as part of the registry system might help decrease patients' distrust of research or weight management programs and increase the number of patients referring themselves to relevant intervention programs.

5. Conclusions

There are many challenges to engaging patients in practice-based research and weight loss programs. Leveraging patient registries to identify potential participants for a practice-based clinical trial was only the first step required to facilitate recruitment for this complex practice-based behavioral weight loss intervention. Population-based strategies are useful to identify eligible and interested participants, but they are labor-intensive. Using a tiered approach, with successively more intensive strategies employing "personal" engagement with providers and potential participants appeared to enhance enrollment rates. Insights gained from the relative effectiveness of these recruitment strategies and the reasons for non-participation could be used to inform other practice-based clinical trials or to engage participants in clinic-based weight loss programs.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100374.

Disclosures

Author information

DJW and LMD conceived of the study. VG and AD drafted the manuscript. YC and BP performed statistical analyses. DWJ, LMD, LB, VG, JM, AR, BC, RL, and AW contributed to the recruitment design, collection, and interpretation of data, and revised the manuscript critically for intellectual content. All authors gave approval of the manuscript version to be submitted.

Guarantor

DJW and LMD had full access to the data in the study and take full responsibility for the work including the study design, data integrity, and accuracy of the analysis.

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