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## Baseline reach and adoption characteristics in a randomized controlled trial of two weight loss interventions translated into primary care: A structured report of real-world applicability

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### Abstract

**Background**—Although the Diabetes Prevention Program (DPP) lifestyle intervention reduced type 2 diabetes incidence by 58% among high-risk adults at academic centers, it requires translation into typical primary care settings. Using baseline data from the Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE) randomized controlled trial, we evaluated the potential of its two DPP-based interventions to reach their target populations and be adopted into routine use.

**Methods**—Overweight/obese adults with increased cardiometabolic risk enrolled from one primary care clinic. Using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model, we assessed reach with data on patient identification, participation, and representativeness, and adoption with data on intervention feasibility and potential for organizational diffusion.

**Results**—The target population was identified by searching electronic health records. Contact was attempted for 2391 patients who completed initial screening by phone (56% uptake) or online (44%). Most (88%) of those screened ineligible were not within the target population; 12% were excluded because of research requirements. Conservatively estimated participation rate was 44%. Participants (n=241) included 54% men and had a mean (SD) age of 52.9 years (10.6) and body mass index of 32 kg/m<sup>2</sup> (5.4). Regarding adoption, all clinic physicians agreed to participate. The feasibility of intervention implementation and dissemination was enhanced by leveraging existing intervention, training, and primary care resources.

**Conclusions**—E-LITE's lifestyle interventions had fair-to-good potential for primary care reach and adoption. Our trial evidence and structured reporting may inform real-world implementation of translational trials by health networks, physicians, and payers.

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## Keywords

Behavior therapy/methods; Metabolic syndrome X/prevention and control; Obesity/therapy, overweight/therapy; Prediabetic state/therapy; Primary health care/methods; Translational medical research/methods

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## 1. Introduction

Sixty-eight percent of American adults are overweight or obese, and 34% are obese [1]. Many have comorbidities (e.g., metabolic syndrome) that further increase their risk for morbidity and mortality. While the obesity epidemic threatens to overwhelm scarce healthcare resources, emerging evidence suggests that its dire health consequences may be blunted or even reversed by lifestyle interventions that are efficacious, safe, and cost effective, as long as such interventions are appropriately disseminated.

The highly successful Diabetes Prevention Program (DPP), tested in a rigorous efficacy trial, convincingly demonstrated that an intensive lifestyle intervention led to sustained, clinically significant weight loss and reduced the risk for incident type 2 diabetes mellitus (diabetes) by 58% among high-risk adults [2–5]. The DPP intervention was delivered primarily in individual face-to-face meetings, which is resource intensive. To achieve widespread dissemination and uptake in primary care practice, the DPP intervention needs to retain (or improve upon) its demonstrated efficacy but be delivered in more cost-effective formats. These may include formats that are group-based, take advantage of information technologies, or both.

A recently-published randomized controlled trial (RCT) reported promising one-year outcomes for a group-based DPP translation conducted in the community [6]. An earlier, cluster-randomized trial showed that a DPP-based group intervention delivered in the YMCA resulted in significant and sustained weight loss among group participants compared to controls [7]. The remainder of published studies of group-based DPP translations have largely used nonrandomized designs, with many [7–13], but not all [14–17], conducted in primary care settings. Alternative delivery modalities (e.g., DVD) have also begun to emerge, although their effectiveness is less well documented [18]. Taken together these studies suggest that group- or DVD-based DPP translations are feasible and likely to be effective, and already are being disseminated. However, rigorous evaluations of scalable DPP translational interventions remain necessary.

During this intermediate stage of experimentation between introduction of the original DPP intervention and widespread dissemination of effective and scalable translations, it is worthwhile to scrutinize emerging translations with the following questions: does this specific DPP-based intervention have the potential to achieve the levels of reach and adoption necessary for its widespread dissemination, and if so what is it about the intervention that indicates this potential? A corollary question for trialists and other researchers is: how should characteristics of reach and adoption be reported in order to assist providers, healthcare networks, and payers to understand whether the trial and its intervention is pertinent to their patient and health delivery needs?

We seek to assist stakeholders and researchers to answer these important questions through structured reporting of intervention characteristics that pertain to applicability in real-world settings. In this report we used recruitment and baseline assessment data from a 3-arm RCT, E-LITE (Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care), a recently completed randomized controlled trial (RCT), to assess the

potential reach and adoption in primary care settings [19,20] of its two translations of the original DPP lifestyle intervention. Participants in both active E-LITE intervention groups sustained significantly greater weight loss at 15 months compared to the usual care group, with approximately 50% in each achieving 5% or greater weight loss from baseline (an accepted cut-point indicative of clinically meaningful weight loss), results which are in press [21]. Thus, we hope the current assessment will serve as a model for how emerging successful DPP translational interventions and other translational trials can report reach and adoption characteristics. Such reporting may promote their appropriate dissemination, for example, by enabling comparisons across variants of the original DPP intervention or trials in general.

## 2. Research design and methods

### 2.1. RCT characteristics

**2.1.1. Study setting and design**—The E-LITE study protocol has been previously reported [22]. Briefly, the trial was designed to examine the effectiveness of two lifestyle interventions adapted from the DPP-based Group Lifestyle Balance™ program for weight management and cardiometabolic risk factor reduction in primary care practice, with the a) group-based delivery and b) DVD-based delivery, compared to each other and also to the third study arm of c) usual care control. Although the core DPP content was delivered using different modalities in the two active intervention arms, both received similar technology-mediated self-management support and long-term follow-up, as further described under “RCT Interventions” below.

**2.1.2. Eligibility**—Patients were eligible for enrollment if they were overweight or obese adults (body mass index (BMI) 25 kg/m<sup>2</sup> or greater) with elevated cardiometabolic risk (pre-diabetes, metabolic syndrome, or both) routinely seen at a single primary care clinic that is part of a community-based multi-specialty practice group within a large California Bay Area health network. Patients were ineligible if they had existing diabetes, cardiovascular disease, or other serious medical condition (e.g., kidney disease, cancer), were using a weight loss drug or planning bariatric surgery, were transferring care out of the clinic site, did not speak English or had no computer access, or were participating in another research study or lifestyle management program.

**2.1.3. Recruitment**—We identified overweight or obese, at-risk adults receiving care from the 21 active primary care providers (PCPs) at the study clinic site using the electronic health records (EHR) system (Fig. 1). PCPs reviewed lists of these potentially eligible patients and excluded those whom they deemed inappropriate for study inclusion. Approved patients were mailed invitation letters signed by or for their PCPs and, if they did not indicate a desire for no contact, were contacted for screening. Because of early recruitment success, not all PCP-approved patients were mailed an invitation letter or contacted for screening.

The screening process involved two stages. First, patients were offered the option of completing initial screening online on their own or being phoned for screening by research staff. The initial screening process did not require clinical evaluation, asking instead about logistical constraints (e.g., transfer of care elsewhere), known exclusionary medical conditions or treatments, and willingness to consider participation and undergo further screening. Those not excluded at the initial screening then underwent medical screening (e.g., BMI measurements, laboratory testing) to confirm clinical eligibility (overweight/obesity and pre-diabetes or metabolic syndrome). Eligible patients were then invited for final written consent at a baseline evaluation and those who met all eligibility criteria were randomized. Target sample size was 240.

**2.1.4. Randomization and blinding**—Patients were randomly assigned on a 1:1:1 basis to one of the three study arms using randomization and blinding procedures previously described [22].

**2.1.5. Interventions and outcome measurements**—Throughout the trial, all participants continued to receive standard care from their PCPs, including any behavioral obesity management provided in that context. Participants in the two active intervention arms completed a 3-month intensive intervention phase and a 12-month maintenance phase. The intensive interventions followed the University of Pittsburgh Diabetes Prevention Support Center (DPSC)'s standardized, packaged Group Lifestyle Balance™ translations of the original DPP using group- or individual, at-home DVD-based delivery. During the 3-month intensive phase, 12 weekly classes for the group-based participants were given by a dietitian (lead lifestyle coach) and exercise physiologist and covered diverse topics related to healthy eating, exercise, and behavioral self-management. To assure intervention fidelity, the DPSC provides training and certification of instructors who will be delivering the intervention to patients. The E-LITE dietitian lifestyle coach completed this DPSC instructor certification. During group sessions, the DPSC group-based DPP intervention manual [11,23] was followed, with the only exceptions being two additional activities added to all group sessions: a food-tasting at check-in and a 30- to 45-minute physical activity demonstration and practice at the session end. Participants in the DVD-based arm attended a single group orientation during which they received the DPSC DVD, which covered the same topics as the group sessions and which they were instructed to view and follow on a weekly basis on their own. During the intensive and maintenance phases, participants in both active intervention groups received technology-mediated self-management support and counseling in two forms. First, participants were encouraged to use the secure email messaging system available through their EHR patient portal to communicate with the study lifestyle coach regarding self-management activities, barriers to progress, or other aspects of behavioral weight management. Second, they were trained to use the award-winning American Heart Association (AHA) free online patient Web portal Heart360® that gave them access to interactive self-management tools that enable easy tracking of weight, physical activity, and cardiometabolic risk factors ([www.heart360.org](http://www.heart360.org)).

The primary outcome measure for E-LITE was BMI at 15 month follow-up. Secondary outcome measures are described in detail elsewhere [22] and included other clinical measures (e.g., fasting plasma lipid and glucose levels, blood pressure), as well as measures of quality of life, mental health, adherence, and healthcare utilization.

**2.1.6. Statistical analyses**—The primary analysis compared BMI between each active intervention arm and the usual care control arm. Statistical analyses have been reported previously in greater detail [22].

## **2.2. Assessment of intervention potential for reach and adoption using baseline data**

The RE-AIM Framework (reach, effectiveness, adoption, implementation, and maintenance) was designed to assess an intervention's potential for sustainable implementation and public health impact in real-world settings—and thereby to enhance the translation of research into practice [19,24].

Independent efforts to broadly disseminate the DPSC's group and DVD programs have already been underway [11,18]. To help inform the furtherance of these efforts, we used recruitment process and baseline data from the E-LITE trial to assess the reach and adoption potential of its two active interventions. Other RE-AIM dimensions (effectiveness, implementation, and maintenance) will be evaluated separately with outcome data from E-

LITE. We applied a grading scale (good, fair, poor) for the applicability of reach and adoption components to real-world practice and provided descriptive summaries for these determinations.

We assessed *reach* components of participation number, rate, and representativeness. We used the conservative estimation of participation rate proposed by Glasgow et al. [25]:

$$\text{Participation rate} = \frac{\text{(number of participants who were randomized)}}{\text{(number of participants for whom contact was attempted and eligibility was assumed or confirmed)}}$$

We also evaluated how E-LITE reached the target population by assessing its methods for identifying and recruiting the target population [19,20].

We assessed *adoption* components of setting representativeness and organizational spread. We also explored potential barriers to or support for organizational spread by evaluating the feasibility of intervention modalities and resource requirements [19,20].

### 3. Results

We successfully randomized 241 patients (Fig. 1). Compared with participants in the original DPP trial [2], E-LITE participants were more likely to be male (54%), have educational attainment beyond high school (97%), and self-identify as white (78%) or Asian (17%), rather than black (0.4%) or Latino/Hispanic (4%). The educational and race/ethnicity profiles represented the general adult patient population at the enrolling primary care clinic site. Otherwise, E-LITE and DPP participants had similar baseline age and clinical characteristics (Table 2).

#### 3.1. Reach characteristics

**3.1.1. Methods of potential participant identification**—Use of the EHR to define an initial pool of the target population was efficient, with good applicability to sites with similar technologies.

**3.1.2. Target population size**—For the single study site, the original EHR search identified 3800 potential participants of whom 3439 were deemed eligible by their PCPs indicating that within one clinic there were many potential participants to be targeted for intervention. (Fig. 1)

**3.1.3. Target population risk factors**—Certain risk factors (BMI, blood pressure measurements) were determined to have good applicability to real-world practice because they were low-cost and routinely performed. Other risk factors were found to have fair applicability because they were either more costly to assess (laboratory measurements of plasma cholesterol or glucose levels) or not done routinely in current practice (waist circumference measurements) but remained readily obtainable in general clinical practice.

**3.1.4. Recruitment strategies**—Patients who were approved for contact by their PCPs were mailed a hardcopy invitation letter signed by or for the PCP. The letter described two methods for initial screening: by phone with a research assistant (traditional method) or online on their own (technology enhanced method). Of those who chose to accept screening (n=1567), 876 (55.9%) completed screening by phone and 691 (44.1%) did so online. (Table 2) Of patients ultimately randomized, 124 of 241 (54%) completed the initial screening online on their own. Patients who chose to perform the initial screen online were significantly more likely to be older, female, and self-identified as white, although absolute

age or percent differences between groups were not pronounced. (Table 2) Mailed invitation letters were classified as having good real-world applicability for participant first contact because they were cheap and efficient. Similarly, the performance of initial screening online was deemed to have fair-to-good applicability because online contact with patients was also cheap and efficient and is becoming more common, particularly in practices with EHRs. Screening by phone was deemed to have fair applicability because it was more accessible for some patients but also more costly – based on personnel requirements – than online screening.

**3.1.5. Eligibility and ineligibility determinations**—Twenty-two percent (279 of 1246) of patients who agreed to undergo full screening (to the point of confirmed eligibility or ineligibility determination) were found eligible. Among ineligible patients (other than those with no reason recorded, n=4), 119 of 963 (12%) were excluded for research-specific reasons that were not likely to be applicable in general clinical practice (e.g., cardiovascular disease or diabetes already present), but the majority (844, 88%) were excluded because they were not within the population expected to be targeted in the real world (e.g., were not overweight/obese). Ineligibility criteria were thus deemed to have fair applicability for real-world translation. (Table 3)

**3.1.6. Participation rate**—Overall, PCPs reviewed 3800 patients and approved 3439 (91%) to be screened for participation. (Fig. 1) Primarily due to rapid recruitment success, invitation letters were sent to only 3119 approved patients, and for 728 of these, further contact was not attempted. Of the 2391 for whom contact was attempted for initial screening, 351 (15%) were unreachable, 783 (33%) declined to participate, 359 (15%) failed initial screening, 143 (6%) failed between screenings (e.g., labs newly out of range), and 465 (19%) failed the subsequent medical screening. Participation rate using the conservative formula was 44% [25], (Table 1) a rate assessed to have fair real-world applicability.

**3.1.7. Characteristics of participants versus non-participants**—While participants who were randomized were more likely than non-participants to be older and self-identified as white, other demographic differences across various stages in the recruitment process were not pronounced, (Table 2) indicating fair applicability for real-world translation.

## 3.2. Adoption characteristics

**3.2.1. Setting**—Regarding adoption, the E-LITE clinic site was determined to have good applicability for private practice, urban primary care clinics, but to be less applicable to other contexts (e.g., county public health clinics, rural health clinics). (Table 2)

**3.2.2. Intervention modalities**—The intervention modality of group classes was deemed to have good real-world applicability because of its use at a diversity of clinics. Use of technology-based interventions – namely, DVDs for the DVD-based intervention group and the EHR secure messaging system and AHA free patient self-management web portal for both active intervention groups – was determined to be most applicable to clinics with patient populations who are computer and internet users, resulting in a determination of fair real-world applicability.

**3.2.3. Resource requirements**—Group class training and content were supported by the DPSC, which offered (and continues to offer) staff certification, manuals, and handouts on how to conduct these. Similarly, the DVDs with content parallel to the group classes' were produced and supported by the DPSC. Certification training is currently offered for \$275 per person for on-site training in Pittsburgh, PA (<http://www.diabetesprevention.pitt.edu/docs/registration.pdf>). Manuals and handouts can be downloaded from the Support Center

website (<http://www.diabetesprevention.pitt.edu/glbmaterials.aspx>) for free as long as they will be used for non-commercial purposes. These resource requirements were assigned fair applicability, because clinics must also have the financial capability to purchase and assign personnel for certification training and to reproduce manual and handout materials.

**3.2.4. Organizational spread**—All 21 providers actively involved in patient care at the lone study clinic site during the recruitment period agreed to participate in the study. The parent health network adopted the Pittsburgh group-based DPP translation program – but without the E-LITE modifications to session content (i.e., food tasting and guided physical activity) or technology-mediated support – within all four California Bay Area counties in which it operates. Within each county, the health network has one or more “centers” that offer primary care to large numbers of patients (n=12 total). There are 5 additional “offices” that are smaller sites for primary care provision. In each county, at least one of the “centers” offers the group-based DPP translation program, which equates to 5 of 12 (42%) centers or 5 of 17 (29%) total primary care sites (i.e., including the smaller “offices”) offering the program within the health network. Yet, for a self-paid fee, patients who receive care at any primary care site are eligible to enroll in the program even if it is not being conducted at their personal clinic site. Together, the 17 primary care sites have more than 66,000 obese adult patients. The health network has staggered roll-out of the program to the 5 initial sites in order to assure that existing resources could adequately support it. Thus, organizational spread was determined to have fair-to-good applicability.

## 4. Discussion

The E-LITE interventions have fair-to-good real-world applicability on the dimensions of reach and adoption. While prior studies have explicitly applied the RE-AIM Framework [19,24] to translational RCT interventions, few studies of behavioral weight management interventions in primary care settings have done so and even fewer have reported RE-AIM characteristics in a structured fashion useful for researchers and potential end users of the intervention being tested [26]. Regarding the reach component of participation rate, three internet-based diabetes self-management trials among primary care practices reported participation rates (using the same conservative formula as applied in the present paper) of 37%, 38%, and 50% [25,27], respectively, similar to E-LITE's 44% participation. A recent translational weight loss trial conducted among county health departments reported an average participation rate of 1.2%, although this was based on an estimated target population that was defined to include all low-income obese women living in the participating counties; thus it encompassed a much broader target population than the one in E-LITE [26]. We were unable to identify papers that applied the RE-AIM Framework to other DPP-based translational weight loss interventions. Yet structured reporting on RE-AIM dimensions within reports of translational interventions may promote better understanding of intervention characteristics in the same way that other reporting initiatives have for study structure and conduct [28–30]. In turn, better understanding may assist comparisons between interventions and promote appropriate (versus inappropriate) dissemination if stakeholders are better able to identify and understand the pertinence of a given intervention to their particular patient populations and organizations [26].

Innovations that may be worthy of particular attention in E-LITE are its uses of information technology. Use of an online screening tool to reach potential participants is an emerging approach in the scientific literature and likely to be even less common in routine clinical practice. We identified three nutrition-related trials that described use of patient-completed online screening for enrollment. Two nutrition trials noted an increase in recruitment success and decrease in staff time allocated to screening with use of online screening compared to telephone screening [31,32]. A third trial noted variability in use of online screening

according to user age, income, and race/ethnicity, but that a diverse participant population was ultimately enrolled by this means [33]. Similarly, the E-LITE patients who chose to screen online rather than by phone were significantly older and more likely to be female and self-identified as white than their phone-screening counterparts. Yet the absolute age or percentage differences between the two groups were generally modest. Regarding adoption characteristics, a recent AHA review on “New and emergent weight management strategies for busy ambulatory settings” emphasized the potential importance of internet strategies to promote weight loss but did not identify any studies that incorporated EHR systems into weight management interventions [34]. The literature is also limited on credible, public internet-based self-management portals like the AHA’s Heart360®. Evaluation of EHR secure messaging and internet self-management tools in E-LITE provides information on the effectiveness of these emerging intervention modalities [21].

Regarding adoption characteristics and leveraged use of lifestyle intervention materials from the DPSC, we identified one RCT and one cluster-RCT that used locally developed, group-based “adaptations” of the DPP intervention (not ones developed by the DPSC). These were delivered at a community diabetes care center and community YMCA gyms, respectively [6,7]. The former demonstrated greater reductions in the primary outcomes of waist circumference and plasma glucose and insulin levels among intervention group participants versus controls at 12 months [6]. The latter found a greater mean decrease in percent body weight among intervention group participants than controls (6.0 versus 2.0) at 6 months [7]. In an additional two studies, DPSC-affiliated researchers performed non-randomized trials of the DPSC group-based and DVD-based materials in primary care settings [11,18]. At 3 month follow-up, participants in these studies achieved significant mean decreases in percent body weight (range 3.5 to 6.6). Percent weight loss was comparable among those who received the group-based intervention (3.5% and 6.6%) [11,18] and the DVD-based interventions (5.6%) [18]. These results are similar to those achieved and sustained in E-LITE at 15 month, rather than 3 month, follow-up [21].

The implications of our analysis of reach and adoption characteristics may vary for different stakeholders. Health professionals (e.g., physician and nurse champions of obesity management) may be most interested in methods of patient identification and their recruitment and representativeness. For instance, the ability to leverage EHR and online resources to identify, screen, and provide self-management support to patients may allow primary care clinics to systematically focus on their subpopulation of obese patients. In addition, they may want to know what proportion of patients were excluded for reasons likely to apply at their clinics (e.g., BMI not in range of overweight/obese) or whether those patients who participated in the program resemble their clinic patients. For their part, healthcare organizations may be particularly interested in staff training requirements and in adoption characteristics—whether the program has a good chance of being disseminated throughout the organization or whether they have the ability to replicate the E-LITE intervention modalities (e.g., group classes, secure messaging). Finally, payers may be most concerned with having a target population that is clearly defined and sizable enough to warrant covering or subsidizing the intervention as a new benefit.

Our evaluation has multiple limitations. First, the E-LITE participants derive from a clinic located within the Silicon Valley region of the San Francisco Bay Area, an area known for its information technology expertise. This means that E-LITE participants are likely, on average, to have more information technology exposure and knowledge than the average American adult, although we also recognize that the majority of American households now contain at least one computer. Second, we had incomplete race/ethnicity data on patients who were mailed invitation letters, although PAMF was the first large ambulatory care organization to begin to collect self-reported race/ethnicity data in an outpatient setting and



has more detailed data than most outpatient centers [35]. Third, our evaluation of adoption is limited to assessment of one clinic site for physician adoption and one health network for organizational diffusion. Finally, we recognize that our determinations of real-world applicability (“good, fair, or poor” in Table 1) are not based on quantitative data that would validate their scaling; at the same time, we provide descriptive information to explain the determinations, so that others can follow our reasoning and also come to their own determinations.

## 5. Conclusions

We found that E-LITE translations of DPP-based weight loss interventions into primary care practice have fair-to-good real-world applicability, with innovative strengths being leveraged use of information technologies and existing DPP Support Center resources. We hope that our experience with this analysis will encourage other researchers to report the reach, adoption, and additional RE-AIM characteristics of their DPP-related and other translational interventions in a structured fashion. Such reporting may help health professionals, healthcare organizations, and payers make informed judgments about which translational interventions best fit their practice and patient needs. It may also spur their greater confidence and investment in ground-level diffusion of evidence – that is, dissemination beyond trials – which must be the goal for widespread propagation and public health impact of translational research.

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## Abbreviations

<b>DPP</b>	Diabetes Prevention Program
<b>RE-AIM model</b>	Reach, Effectiveness, Adoption, Implementation, Maintenance model
<b>DVD</b>	digital versatile disc
<b>E-LITE trial</b>	Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care trial
<b>RCT</b>	randomized controlled trial
<b>DPSC</b>	Diabetes Prevention Support Center
<b>AHA</b>	American Heart Association

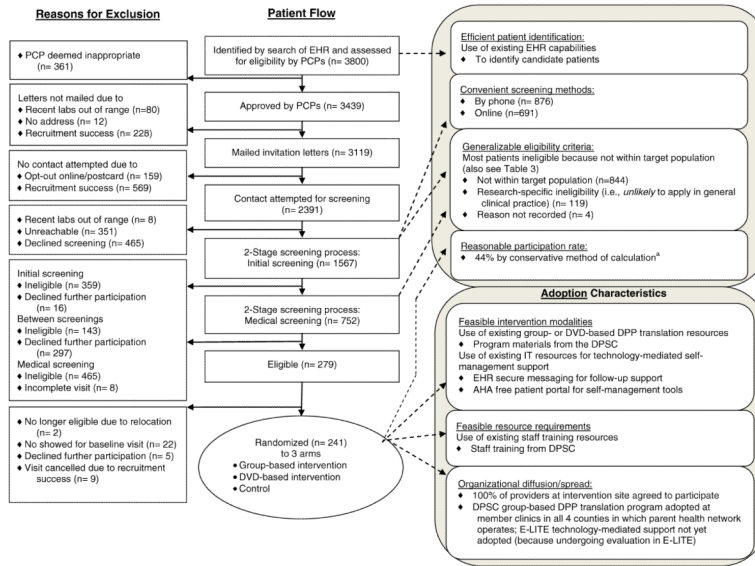
<b>BMI</b>	body mass index
<b>PCP</b>	primary care provider
<b>EHR</b>	electronic health record

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**Fig. 1.** Study participant flow and intervention characteristics related to potential for reach and adoption. PCP = primary care provider. HER = electronic health record. DVD = digital versatile disc. DPP = Diabetes Prevention Program. DPSC = Diabetes Prevention Support Center. IT = information technology. AHA = American Heart Association. E-LITE = Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care. <sup>a</sup>Conservative calculation method for participation rate uses the Glasgow et al. approach [25]:

$$\text{Participation rate} = (\text{number of participants who were randomized}) / (\text{number of participants for whom contact was attempted and eligible})$$

**Table 1**

Reach and adoption categories and characteristics of E-LITE: applicability for translation into real-world practice.

Category	Characteristic in E-LITE	Applicability for translation into real-world practice (good, fair, or poor)
<i>Reach</i> (identification, recruitment, and representativeness of participants)		
Methods of identification	Use of EHR to identify candidate patients	<ul style="list-style-type: none"> <li>Fair to good—applies well to clinics with EHR capabilities, which are growing in number</li> </ul>
Target population size	3880 patients identified in initial search of clinic EHR with PCPs approving 3520 for further evaluation	<ul style="list-style-type: none"> <li>Good—obesity/overweight is highly prevalent within a single clinic</li> </ul>
Risk factors	Patients with obesity/overweight and also cardiometabolic risk factors (pre-diabetes and/or metabolic syndrome) (Table 2)	<ul style="list-style-type: none"> <li>Good—for low-cost measurements (e.g., BMI)</li> <li>Fair—for lab-based criteria (e.g., cholesterol panel) and some clinical measurements, because are more costly or are not routinely performed but also are readily available</li> </ul>
Recruitment strategies	Mailed letter as first invitation contact 1st stage of screening performed either online or by phone Of those patients ultimately randomized over half completed the initial screening online	<ul style="list-style-type: none"> <li>Good—for letters, because cheap and easy to do</li> <li>Fair to good—for online contact, as this kind of contact with patients is growing and increasingly applicable in the real world</li> <li>Fair—for phone calls, because more costly/labor intensive</li> </ul>
Eligibility and ineligibility	22% of those screened were determined to be eligible <sup>a</sup> (Fig. 1) 88% of ineligibility determinations were due to reasons likely to apply in the real world. (Table 3)	<ul style="list-style-type: none"> <li>Fair—acceptable distribution of ineligibility reasons that have face validity and are easy for patients/physicians to determine</li> </ul>
Participation rate	Conservative estimate = 44% <sup>b</sup> (Fig. 1) More liberal estimate = 98% <sup>b</sup>	<ul style="list-style-type: none"> <li>Fair—reasonable when compared to RCTs in which conservative participation rates were calculated</li> </ul>
Participants vs. non-participants	Age, sex, and race/ethnicity data demonstrate no compelling differences in demographics, with the possible exception of older and white patients being overrepresented (Table 2)	<ul style="list-style-type: none"> <li>Fair—no strong selection bias by demographics</li> </ul>
<i>Adoption</i> (research interface with potential program settings)		
Setting	Single private, urban primary care clinic with all PCPs agreeing to participate	<ul style="list-style-type: none"> <li>Fair to good—applies well to private, urban clinics but less well to others</li> </ul>
Intervention modalities	Group classes and DVDs with parallel content; EHR secure messaging system; AHA online portal of self-management tools	<ul style="list-style-type: none"> <li>Good—for group classes, which are commonly used in many clinic settings</li> <li>Fair—for DVDs, EHR messaging, and use of online portal, because these require personal IT access and skills. However, use of DVDs and online interactions/tools with patients is growing in frequency and is increasingly applicable in real world settings</li> </ul>
Resource requirements	Research staff with intervention training and materials provided by the DPSC	<ul style="list-style-type: none"> <li>Fair—applicable to clinics that can allocate resources for personnel training<sup>c</sup>/materials but not applicable to other clinics</li> </ul>
Organizational diffusion/spread	100% of providers at intervention site agreed to participate Modified version of group-based intervention has been adopted by the health network of which the study clinic is a part	<ul style="list-style-type: none"> <li>Fair to good—applicable at local study clinic and modified group-based intervention adopted early by health network, but latter lacks certain components of intervention (i.e., search of clinic EHR, online screening, EHR secure messaging, use of AHA portal) so is unclear how these intervention components will apply</li> </ul>

E-LITE = Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care. EHR = electronic health record. PCP = primary care provider. DVD = digital versatile disc. AHA = American Heart Association. DPSC = Diabetes Prevention Support Center. BMI = body mass index ( $\text{kg}/\text{m}^2$ ).

<sup>a</sup>Based on eligibility determinations for those patients who underwent full screening processes: (eligible)/(ineligible+eligible).

<sup>b</sup>The conservative estimate of participation rate uses the Glasgow et al. approach [25]: participation rate=(number of participants who were randomized)/(number of participants for whom contact was attempted and eligibility was assumed or confirmed). The more liberal estimate is the percent of patients who were eligible who then became participants.

<sup>c</sup>Personnel training currently costs \$275 for the 2-day training program provided on-site at the Pittsburgh DPP Support Center.

**Table 2**  
 Characteristics of Potential E-LITE Participants During Sequential Stages of Recruitment and at Randomization in E-LITE vs. DPP.

	E-LITE				Original DPP								
	Mailed letter (n = 3119)	Initial screen <sup>a</sup> (n = 1567)	Medical screen (n = 752)	Eligible (n = 279)	Randomized (n = 241)	Randomized (n = 3234) Overall							
	By phone (876)	Online (691)	P value <sup>b</sup>	Overall	By phone initial screen (117)	Online initial screen (124)	P value <sup>b</sup>	Overall					
Age, yr (SD)	48.4 (13.1)	49.9 (12.7)	51.6 (12.1)	0.010	50.7 (12.4)	51.4 (11.3)	53.5 (10.7)	51.9 (9.8)	53.9 (11.3)	52.9 (10.6)	50.6 (10.7)	0.13	52.9 (10.6)
Female, %	45.5	44.3	52.2	0.002	47.8	47.8	45.0	39.3	53.2	46.0	67.7	0.03	46.0
Race/ethnicity, %				0.003								0.40	
White	71.2 <sup>d</sup>	69.1	77.4		72.9	75.1	75.6	76.9	79.0	78.0	54.7		78.0
Asian <sup>c</sup>	18.5 <sup>d</sup>	22.3	14.5		18.7	17.7	19.3	16.2 <sup>c</sup>	17.7 <sup>c</sup>	17.0	4.4		17.0
Latino/Hispanic	7.6 <sup>d</sup>	6.4	5.8		6.1	5.8	4.4	6.0	2.4	4.2	15.7		4.2
Black	1.7 <sup>d</sup>	1.5	1.6		1.6	1.0	0.4	0	0.8	0.4	19.9		0.4
Other	1.0 <sup>d</sup>	0.6	0.7		0.7	0.4	0.4	0.9	0	0.4	5.3		0.4
Educational attainment 13 + yr, %										97.2	74.3		97.2
Clinical characteristics (SD)													
BMI, kg/m <sup>2</sup>										32.0 (5.4)	34.0 (6.7)		32.0 (5.4)
Pre-diabetes, %										54.5	100		54.5
Metabolic syndrome, %										86.7	52.9		86.7
Waist circumference, cm										41.9 (4.7)	41.4 (5.7)		41.9 (4.7)
Fasting plasma glucose, mg/dL										99.9 (9.5)	106.5 (8.3)		99.9 (9.5)
Triglycerides, mg/dL										171.1 (69.2)	159.1 (85.8)		171.1 (69.2)
HDL, mg/dL										46.1 (12.4)	43.9 (10.5)		46.1 (12.4)
Systolic BP, mm Hg										118.8 (11.7)	123.7 (14.7)		118.8 (11.7)
Diastolic BP, mm Hg										73.6 (8.3)	78.3 (9.3)		73.6 (8.3)

E-LITE = Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care. Yr = year. SD = standard deviation. BMI = body mass index. BP = blood pressure. HDL = high density lipoprotein cholesterol.



<sup>a</sup>Missing race/ethnicity data on 95 (6.1%) of all patients who underwent initial screening: 14 (2.0%) who completed screening online, 81 (9.3%) who completed by phone.

<sup>b</sup>P value calculations are for comparisons of by phone vs. online groups.

<sup>c</sup>Two randomized participants were of Pacific Islander race—one who initially screened online and the other by phone. The remaining patients in this row were of Asian race.

<sup>d</sup>For race/ethnicity data at the “mailed letter” recruitment stage, n= 1499 because the remainder of the original 3151 patients declined to answer/left blank the race/ethnicity question on the questionnaire used by the health system at the time of their entrance into the health network.

**Table 3**

Reasons for ineligibility and whether these are likely to apply in clinical practice.

Reason for ineligibility is...	Count (n = 963) <sup>a</sup>	Percent
...Likely to apply in clinical practice (i.e., patient is not within target population)	(844)	(87.6)
Unable to confirm high risk for cardiometabolic disease	516	53.6
Unable to confirm pre-diabetes or metabolic syndrome	467	48.5
BMI<25	49	5.1
Logistical constraints	247	25.6
Care elsewhere/moving elsewhere	113	11.7
Unable to commit to time/effort required	101	10.5
No computer access	14	1.5
Planning bariatric surgery soon/enrolled in other program	10	1.0
Not English proficient	9	0.9
Medical conditions	81	8.4
Pregnant or plan for pregnancy in near future	40	4.2
Recovering from/in treatment for cancer	19	2.0
Severe psychiatric disturbance	16	1.7
Systolic 160 and/or diastolic 100	5	0.5
Living in a long-term care facility	1	0.1
...Unlikely to apply in clinical practice (i.e., reason is research-specific)	(119)	(12.4)
Logistical constraints	13	1.3
Household member involved in study	13	1.3
Medical conditions	106	11.0
On weight loss or diabetes medication	33	3.4
Cardiovascular disease and/or diabetes already present	27	2.8
Change in certain classes of medication in prior 3 months <sup>b</sup>	27	2.8
BMI>=40 <sup>c</sup>	10	1.0
TG>=400	5	0.5
eGFR<60	4	0.4

BMI = body mass index (kg/m<sup>2</sup>). TG = triglyceride level (mg/dL). eGFR = estimated glomerular filtration rate.

<sup>a</sup>Of the 967 potential participants who were determined to be ineligible, four had no reason recorded for ineligibility.

<sup>b</sup>Class of medication includes antidepressant, antihypertensive, or antihyperlipidemic agents.

<sup>c</sup>Removed as an ineligibility criterion in 8/2009.