Applying the Pragmatic–Explanatory Continuum Indicator Summary Model in a Primary Care–Based Lifestyle Intervention Trial

Lisa G. Rosas, PhD, MPH,1,2 Nan Lv, PhD,1 Kristen Azar, RN, MSN/MPH,1 Lan Xiao, PhD,1 Veronica Yank, MD,1,2 Jun Ma, MD, PhD1,2

The majority of adults in the U.S. can be classified as overweight or obese (68%), putting them at risk for Type 2 diabetes, cardiovascular diseases, and other adverse health outcomes. The U.S. Preventive Services Task Force recommends that providers offer or refer obese adults to intensive, multicomponent lifestyle interventions. However, there is a critical need for interventions that have been shown to be pragmatic and effective among diverse populations, scalable across different clinical settings and systems, and sustainable over time. The Pragmatic–Explanatory Continuum Indicator Summary (PRECIS) tool can be used to assess the degree to which trials of behavioral lifestyle interventions provide evidence to support this need. We used our recently completed trial, Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE), as a case study and assessed the domains of PRECIS to explore the degree to which we felt it achieved its intended pragmatic design (completed in December 2014). Overall, the systematic assessment using the PRECIS tool revealed that the E-LITE trial design was very pragmatic in nature. Its results and the subsequent adoption of the intervention into actual practice also suggest high potential for implementation of primary care interventions.

(Am J Prev Med 2015;49(3S2):S208–S214) © 2015 American Journal of Preventive Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Introduction

The majority of adults in the U.S. can be classified as overweight (33%) or obese (35%),1 putting them at risk for Type 2 diabetes, cardiovascular diseases, various cancers, and other physical and mental health problems,2,3 which have high personal, societal, and healthcare costs.4 The magnitude and breadth of this crisis call for multisectoral approaches for obesity prevention and treatment.

Given their unique position as a usual point of contact between patients and the healthcare system, primary care staff and providers hold high potential for screening, activating, and engaging the large portion of U.S. adults who would benefit from a weight management program.5,6 Behavioral lifestyle interventions that use evidence-based strategies to promote healthy diet and moderate physical activity have been shown to be effective for weight loss and cardiometabolic risk reduction among high-risk individuals.7,8 As a result, the U.S. Preventive Services Task Force (USPSTF) recommends that providers offer or refer obese adults to intensive, multicomponent lifestyle interventions.7,8 In response to the Affordable Care Act’s preventive services coverage mandate,9 the Centers for Medicare and Medicaid Services reimburses intensive behavioral therapy for obesity when it is furnished by qualified providers during brief (15-minute) visits in primary care settings.10 However, there have been numerous barriers to successfully operationalizing these policies.11 An important need exists for interventions that have been shown to be pragmatic and effective among diverse populations, scalable across different clinical settings and systems, and sustainable over time. The Pragmatic–Explanatory Continuum Indicator Summary (PRECIS) tool can be used to assess the degree to which trials of behavioral...
lifestyle interventions provide evidence to support this research need.\textsuperscript{12} The tool acknowledges the continuum between trials that are strictly explanatory (efficacy trials) and those that are highly pragmatic (effectiveness trials). We used our recently completed trial, Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE), as a case study and assessed the domains of PRECIS to explore the degree to which we felt it achieved its intended pragmatic design (completed in December 2014). We also discuss the implementation of our research findings within the healthcare system to demonstrate the pragmatic nature of the trial. Although the PRECIS tool is ideally utilized during the planning stages of a trial, it is also useful as a heuristic to inform implementation and dissemination of study results as well as informative for identifying future research goals in the area of primary care–based lifestyle interventions.\textsuperscript{12}

The E-LITE study, described in detail elsewhere,\textsuperscript{13,14} was a three-arm, primary care–based RCT designed to evaluate the effectiveness and implementation potential of two adapted behavioral weight loss interventions for 15 months compared with usual care among overweight or obese adults with prediabetes, metabolic syndrome, or both (conducted from 2009 to 2013). Participants in both intervention groups received an adapted, 12-session lifestyle intervention curriculum, Group Lifestyle Balance (GLB)\textsuperscript{TM}, which was developed by investigators at the University of Pittsburgh after conclusion of the Diabetes Prevention Program (DPP) trial.\textsuperscript{15} Participants were trained to use the American Heart Association’s (AHA’s) free, secure Heart360 web portal for weight and physical activity goal setting and self-monitoring and were given a weight scale and pedometer.

Participants randomized to the coach-led arm participated in group sessions in the clinic led by a lifestyle coach, whereas those in the self-directed arm engaged in the intervention through accessing a DVD at home. The intensive phase for both interventions was followed by a 12-month maintenance phase (via secure messaging for ongoing lifestyle coaching within an electronic health record [EHR] system and the AHA Heart360 website). Both intervention groups achieved statistically greater reductions in BMI, accompanied by improvements in waist circumference and fasting plasma glucose, as compared with usual care.\textsuperscript{14} At 15 months, the mean (SE) change in weight from baseline was \(-6.3\) (0.9) kg in the coach-led intervention; \(-4.5\) (0.9) kg in the self-directed intervention; and \(-2.4\) (0.9) in the usual care group.\textsuperscript{14} The E-LITE trial was included as key evidence in the 2014 USPSTF guidelines for behavioral counseling in primary care.\textsuperscript{16}

### PRECIS Domains and the E-LITE Trial

The PRECIS tool utilizes a sum (range, 0–50) of ratings (1=most explanatory; 5=most pragmatic) on each of ten domains described in Table 1.\textsuperscript{17} We used E-LITE as a case study to illustrate the degree to which the design was explanatory or pragmatic in nature. To summarize the research teams’ perspectives, each author independently assessed the ten domains and provided a whole number score between 1 and 5 (1=extremely explanatory; 2=very explanatory; 3=explanatory/pragmatic nexus; 4=very pragmatic; 5=extremely pragmatic). To create a visual representation of the explanatory versus pragmatic nature of the trial, known as a pragmascope (Figure 1), an approach by Tosh et al.\textsuperscript{17} was adapted. The median of each author’s score was plotted on the pragmascope. Subsequently, the authors discussed each domain and came to a consensus on a summary rating and narrative description for each domain (Table 1).

In general, the E-LITE trial was rated as very pragmatic or extremely pragmatic across the majority of domains (80%), with a total score of 40.5 out of 50 (Figure 1). Domains noted to be extremely pragmatic included the comparison group of usual care, the practitioner expertise for the usual care group, and the analytic approach based on the intent-to-treat principle and including all participants regardless of level of adherence. The follow-up intensity was rated as very explanatory given the protocol that included three in-person visits conducted by trained research assistants blinded to treatment assignment. Overall, the systematic assessment using the PRECIS tool revealed that the E-LITE trial design was very pragmatic in nature, reflecting the initial study aims. Without confirmation by a sufficient sample of external scientists, we cannot formally test the hypothesis that the E-LITE study was pragmatic in nature. However, our exploration can serve as a case study and example exercise that can be used in the planning stages for similar studies.

### Potential for Dissemination and Implementation in Primary Care Settings

Results from the trial and a subsequent evaluation of its potential for widespread adoption\textsuperscript{18} contributed to the implementation of a coach-led intervention modeled after the E-LITE intervention within the large, multi-specialty outpatient healthcare system in Northern California where the trial was conducted. Since 2011, the healthcare system has launched a gradual rollout at five of its more than 40 clinic sites. The service is intended for overweight or obese adult patients with high cardiometabolic risk as identified by provider or self-referral.
Table 1. Assessment of PRECIS Domains for the E-LITE Trial

<table>
<thead>
<tr>
<th>PRECIS Domaina</th>
<th>E-LITE description</th>
<th>Ratingb</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Eligibility criteria** | Extremely explanatory: Restrictive inclusion criteria, exclusion criteria that make the study population less reflective of the target population  
Extremely pragmatic: Open to entire target population, few if any exclusions |         |
|                 | The trial enrolled participants from a single primary care clinic within the Silicon Valley (Los Altos, California) that is part of a large multispecialty group. Participants were eligible to participate if they were 18 years or older, had a BMI greater than 25, and had pre-diabetes (defined by impaired fasting plasma glucose of 5.6–6.9 mmol/L) or metabolic syndrome. | Very pragmatic: The study included all patients in the target population with limited exclusions related to research requirements only. The study was only conducted in one geographic region, which precluded the designation of extremely pragmatic. |
| **Interventions and expertise** | There were two interventions being tested in this trial. Participants in both intervention groups completed a 3-month intensive intervention phase and a 12-month maintenance phase. Both groups were trained to use the AHA free Heart360 Web portal for weight and physical activity goal setting and self-monitoring and were given a weight scale and pedometer.  
**Self-directed:** Curriculum was delivered via home-based DVD. We made no modifications to the GLB DVD. Via secure e-mail embedded in the EHR, the Lifestyle Coach sent standardized biweekly reminder messages about self-monitoring to self-directed intervention participants throughout the intensive and maintenance phase and standardized motivational messages to participants during the maintenance phase. The Lifestyle Coach also answered questions and responded to messages.  
**Coach-led:** The curriculum was delivered face-to-face in 12-weekly classes. In addition to receiving GLB intervention materials, coach-led intervention participants had food tastings at check-in and 30–45 minutes of guided physical activity at the end of each weekly class. Participants received the same standardized messages as in the self-directed as well as personalized messages on at least a monthly basis that provided progress feedback and lifestyle coaching based on their Heart360 self-monitoring records. | Very pragmatic: There were two interventions tested:  
**Self-directed:** The self-directed nature of this intervention allows for a high level of individual variation and adaptation.  
**Coach-led:** The coach-led intervention allows for significant individual tailoring and adaptation to real-life circumstances. Attendance at the group sessions is monitored and encouraged, which makes it less pragmatic than the self-directed approach. |
| **Practitioner expertise for experimental intervention** | The E-LITE Lifestyle Coach, a registered dietitian certified to deliver the GLB program, and a contracted fitness instructor jointly taught all the classes at the participating clinic. The dietitian was part of the primary care workforce at the setting prior to joining the study. Both the dietician and the fitness instructor had no prior research experience. | Very pragmatic: A central issue for this domain is the role of a lifestyle coach within primary care. Although not currently routine practice in primary care across the U.S., lifestyle coaches and health promoters with some level of training in lifestyle behavior change are increasingly being incorporated into the primary care setting. |
| **Practitioner expertise for comparison intervention** | The comparator of usual care in the E-LITE trial was provided by existing primary care staff and providers. | Extremely pragmatic: The usual care comparison did not involve any additional training or resources. |

(continued on next page)
To date, there have been 493 participants. The majority (79%) of participants have been women in their mid 50s, with an average BMI of 35 and a large proportion (45%) with a BMI greater than 35. Of those who participated for at least 3 months ($n=442$), 70% completed at least six, and 40% completed at least ten, of the 12 weekly group sessions. At 3 months, mean (SD) weight loss was $-3.6$ (3.9) kg. For patients who had data available in the EHR, weight loss was $-5.6$ (6.3) kg at 6 months ($n=227$) and $-4.5$ (5.4) kg at 12 months.

Table 1. Assessment of PRECIS Domains for the E-LITE Trial (continued)

<table>
<thead>
<tr>
<th>PRECIS Domain(^a)</th>
<th>E-LITE description</th>
<th>Rating(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flexibility of comparison intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely explanatory: High divergence from routine care</td>
<td>The interventions were compared to usual care. The study provided no information about weight loss or weight-loss goals to participants in the usual care group.</td>
<td>Extremely pragmatic: The trial design did not include any additional resources aside from what is normally available to participants in usual care.</td>
</tr>
<tr>
<td>Extremely pragmatic: Currently happening in everyday practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up and outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely explanatory: Pre-specified data collection visits with incentives for participation</td>
<td>In-person data collection visits conducted by research assistant were scheduled at baseline, 3, 6, and 15 months. At each time point, research assistants conducted an interview and performed anthropometric and blood pressure measurements using standard protocols.</td>
<td>Very explanatory: The intensity and participant burden of the follow-up visits determined the explanatory nature for this domain.</td>
</tr>
<tr>
<td>Extremely pragmatic: Covert assessments that are part of routine patient care</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary trial outcome</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely explanatory: Important only to the researcher, highly complex measurement that can only be carried out by specialists</td>
<td>The primary outcome of the E-LITE trial was change in BMI from baseline to 15 months.</td>
<td>Very pragmatic: Weight change was of primary interest to the participants, making it very pragmatic. Additionally, BMI can be easily measured in routine primary care, furthering the degree to which the outcome falls on the pragmatic side of the continuum. Psychosocial outcomes assessing patient’s overall well-being, such as a measure of health-related quality of life, were secondary outcomes.</td>
</tr>
<tr>
<td>Extremely pragmatic: Patient-centered, long-term, easy to measure as part of routine clinical care</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Compliance/adherence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant compliance</td>
<td>The data from this trial were analyzed using intent to treat and thus recognized that non-compliance is a reality in routine primary care. Compliance to participation in the group sessions for participants randomized to the coach-led group was monitored. Similarly, the number of secure e-mail messages was monitored for both groups. However, no special strategies were used to enhance compliance.</td>
<td>Very pragmatic: The analytic design allowed for real life variation in adherence to the intervention protocol, making the trial very pragmatic. Because adherence was monitored, the trial does not meet criteria for extremely pragmatic.</td>
</tr>
<tr>
<td>Extremely explanatory: Strictly monitored with participants excluded based on non-compliance with the intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely pragmatic: Non-compliance is assumed as part of real-world settings; compliance is not even monitored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioner adherence</td>
<td>In the coach-led intervention, the intervention practitioner followed a set curriculum for the group sessions. In addition, by design, practitioners were encouraged to individually tailor the strategies using practical and creative strategies. The fidelity of the intervention was assessed as part of the trial design.</td>
<td>Very pragmatic: The practitioner adherence falls on the pragmatic end of the spectrum. The monitoring of practitioner adherence prevents a rating of extremely pragmatic.</td>
</tr>
<tr>
<td>Extremely explanatory: Strictly monitored and continuously addressed throughout the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely pragmatic: Delivery is assumed to be variable to reflect the diversity of patient needs/scenarios</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Analysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely explanatory: Data excluded based on adherence and compliance</td>
<td>An intention-to-treat analysis was conducted with no restrictions, including all participants regardless of dose of intervention received.</td>
<td>Extremely pragmatic: The analytic design followed an extremely pragmatic approach.</td>
</tr>
<tr>
<td>Extremely pragmatic: No data are excluded and subgroup analyses are not conducted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Description of the domains and definitions for “extremely explanatory” and “extremely pragmatic” were adapted from Tosh et al.\(^{17}\)

\(^b\) Rating system: 1=extremely explanatory, 2=very explanatory, 3=explanatory/pragmatic nexus; 4=very pragmatic; 5=extremely pragmatic.
These data have motivated expanded implementation of the service at the existing and additional sites with more invested efforts to further improve session enrollment and attendance.

Although not yet adopted at this same Northern California organization, the self-directed E-LITE approach is especially well suited for delivery in diverse primary care settings given its exportability, low cost, and convenience for patients. The self-directed approach can be adopted within existing healthcare infrastructure and requires modest personnel and other resources to implement. The GLB DVD is available in both English and Spanish, making it accessible to a large and at-risk ethnic minority group. Each session is brief (approximately 20 minutes in length) and patients can view the 12 GLB sessions on a weekly basis at home. As an alternative to DVD viewing at home, participants may watch the GLB DVD through a secure website or potentially at libraries and community centers. Primary care providers may directly serve as an educator and distributor of the program, or may serve in a consultative and supportive role, referring patients to GLB-trained lifestyle coaches who can distribute the GLB DVD to patients and monitor their progress for offering personalized coaching.

**Conclusions and Key Recommendations**

In summary, the E-LITE trial was designed to offer evidence of the effectiveness of implementing intensive lifestyle interventions into routine primary care. The design successfully reflected its pragmatic aims. Its results and the subsequent adoption of the coach-led intervention into actual practice also suggest high potential for implementation of primary care interventions based on the GLB and DPP.

Experience with the E-LITE trial and its implementation within the healthcare system has prompted several recommendations for future research to expand scientific understanding of pragmatic approaches to behavioral weight loss treatment in primary care settings:

1. **Tailored approaches are needed to promote scalability in diverse populations and primary care settings.** The E-LITE trial provided evidence of effectiveness among a target population of highly educated, primarily non-Hispanic white men and women. E-LITE succeeded in recruiting and retaining a study population of more than half men, far surpassing the usual proportion of men recruited into lifestyle intervention trials (0%–20%). Building on this
success among both genders, future research should focus on approaches tailored for specific ethnic groups as well as diverse settings, such as community health centers, which are of high importance.\(^{19,20}\)

2. **Information technology can be used to increase reach and effectiveness.** Technology enables reaching patients in settings outside of the healthcare system and tailoring to patients’ individualized perspectives and circumstances. E-LITE utilized secure e-mail messaging embedded in an EHR for lifestyle coaching and the AHA Heart360 web portal for self-management. Emerging technologies, such as virtual lifestyle coaches, online social networks for social support, mobile phone applications, and novel sensors, should be rigorously evaluated for potential inclusion in lifestyle interventions in primary care settings.\(^{21,22}\)

3. **Engage multiple sectors to address lifestyle behaviors for synergy that promotes sustainable behavior change.** Building upon the success in E-LITE in the primary care setting, strategies that add linkages to other potential spheres of influence on people’s health behavior such as community-based programs should be rigorously tested.\(^{23,24}\)

4. **Take advantage of teachable moments across the life course.** Using a life course approach, lifestyle interventions may be most effective if tailored for individuals in specific time periods of life when they may be at high risk for obesity or uniquely open to changing lifestyle behaviors.\(^{25,26}\) Examples of these time periods may include adolescence/puberty, first year of university/junior college, first job, marriage, pregnancy, diagnosis of a chronic disease, and retirement.

The E-LITE trial also highlighted several best practices for researcher and practitioners interested in pragmatic lifestyle intervention research. First, strong partnerships and engagement with key stakeholders in primary care including the administration, staff, providers, and patients in all phases of the research (e.g., design, implementation, follow-up) are key to successfully completing pragmatic trials. Second, transdisciplinary teams engaged in team science approaches are important for the design, implementation, and dissemination of pragmatic lifestyle trials. Importantly, the key stakeholder engagement and multidisciplinary scientific teams should focus on issues of scalability across patient groups and settings as well as sustainability at the patient and setting level. These best practices, coupled with utilization of the PRECIS framework, have high potential for evidence that will promote reducing the burden of obesity in the U.S.

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that AHRQ support the operations of the USPSTF.

The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ, the USPSTF, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the American Heart Association, or the Palo Alto Medical Foundation Research Institute. No statement in this report should be construed as an official position of AHRQ or the U.S. Department of Health and Human Services.

Administrative and logistical support for this paper was provided by AHRQ through contract HHSA290-2010-00004i, TO 4.

The Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE) study was supported by grant R34DK080878 from the NIDDK, a Scientist Development Grant award (0830362N) from the American Heart Association, and internal funding from the Palo Alto Medical Foundation Research Institute. Dr. Veronica Yank acknowledges support from NIDDK (K23DK097308).

No financial disclosures were reported by the authors of this paper.

### References


