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Design and participant characteristics of a primary care adaptation of the Look AHEAD Lifestyle Intervention for weight loss in type 2 diabetes: The REAL HEALTH-Diabetes Study

Linda M. Delahanty, MS, RD^{1,2}, Yuchiao Chang, PhD³, Douglas E. Levy, PhD^{2,4}, Bianca Porneala, MS³, Amy Dushkin, BS¹, Laurie Bissett, MS, RD¹, Valerie Goldman, MS, RD¹, Jeanna Perrotta, MS, RD¹, Anthony Romeo Rodriguez, BS¹, Barbara Chase, ANP, APRN^{3,5}, Rajani LaRocca, MD^{2,3,6}, Amy Wheeler, MD^{2,3,7}, and Deborah J. Wexler, MD, MSc^{1,2}

¹Massachusetts General Hospital (MGH) Diabetes Research Center, Diabetes Unit, and Department of Medicine, Boston, MA

²Harvard Medical School, Boston, MA

³Division of General Internal Medicine, Massachusetts General Hospital, Boston, MA

⁴Mongan Institute Health Policy Center, MGH, Boston, MA

⁵MGH Chelsea Health Center, Boston, MA

⁶MGH Charlestown Health Center, Boston, MA

⁷MGH Revere Health Center, Boston, MA

Abstract

Background/Aims—The REAL HEALTH -Diabetes Study is a practice-based clinical trial that adapted the Look AHEAD lifestyle intervention for implementation in primary care settings. The trial will compare the effectiveness and cost-effectiveness of in-person group lifestyle intervention, telephone group lifestyle intervention, and individual medical nutrition therapy (MNT), the current recommended standard of care in type 2 diabetes. The primary outcome is percent weight loss at 6 months with outcomes also measured at 12, 18, 24 (intervention completion), and 36 months.

Corresponding author: Linda M. Delahanty MS, RD, Massachusetts General Hospital Diabetes Research Center, 50 Staniford St Suite 340, Boston, MA 02114, Phone: 617-724-9727, ldelahanty@partners.org.

Author information

DJW and LMD conceived of the study and drafted the manuscript. YC and PB performed statistical analyses. DEL, AD, LB, VG, JP, AR, BC, RL, and AW contributed to study design, collection and interpretation of data, and revised the manuscript critically for intellectual content. All authors give 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 as a whole, including the study design, data integrity, and accuracy of the analysis.

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Disclosures

LMD serves on the Advisory Boards of Omada Health and JanaCare.

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Here, we describe the adaptation, trial design, implementation strategies, and baseline characteristics of enrolled participants.

Methods—The study is a three-arm, patient-level, randomized trial conducted in three community health centers (CHCs) and one diabetes practice affiliated with one academic medical center.

Results—The study used existing clinical infrastructure to recruit participants from study sites. Strategies for successful conduct of the trial included partnering with health-center based co-investigator clinicians, engaging primary care providers, and accommodating clinical workflows. Of 248 eligible patients who attended a screening visit, 211 enrolled, with 70 randomly assigned to in-person group lifestyle intervention, 72 to telephone group lifestyle intervention, and 69 to MNT. The cohort was 55% female, 29% non-white, with mean age 62 years and mean BMI 35 kg/m². Enrollment rates were higher at CHC sites.

Conclusions—A practice-based randomized trial of a complex behavioral lifestyle intervention for type 2 diabetes can be implemented in community health and usual clinical settings. Participant and provider engagement was higher at local CHC sites reflecting the study implementation focus.

Keywords

Lifestyle intervention; type 2 diabetes; research translation to practice; practice-based research; randomized controlled trial; telephonic intervention; implementation research

Introduction

Twelve percent of U.S. adults have diabetes, with the vast majority having type 2 diabetes; prevalence will increase to 1 in 3 by 2050, if current trends continue.[1, 2] Diabetes significantly impacts overall health, quality of life, and national healthcare costs, with \$176 billion in direct medical costs and \$69 billion in indirect medical costs, including disability, work loss, and premature mortality.[3, 4] Eighty-seven percent of adults with diabetes are overweight or obese, and 40.8% are physically inactive.[2] Moderate weight loss of 5–10% of body weight is a highly effective treatment for type 2 diabetes.[5] Lifestyle intervention, including diet and exercise, to achieve sustainable weight loss of this degree is effective and cost-effective for prevention of diabetes and its sequelae over time, as demonstrated by NIDDK's Diabetes Prevention Program (DPP) and other lifestyle interventions.[6–8] It has also been particularly effective in preventing and treating burdensome and costly diabetes comorbidities that are not impacted by medications, such as impaired mobility, physical function, and sleep apnea as demonstrated in the Look AHEAD trial. [9–13]

The Look AHEAD trial compared a DPP-adapted lifestyle intervention aimed at sustaining a 7% weight loss and 175 minutes of weekly activity to a program of diabetes support and education (DSE) in people with type 2 diabetes. Look AHEAD 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 service expenditure to treat these conditions. Improvements persisted at 4 and 8 years.[10, 14–17]

There is abundant evidence supporting both the DPP and Look AHEAD interventions.[5, 18–20] Nevertheless, adoption in clinical practice has been slow. This may be in part due to the complexity of the interventions and possibly due to a concern that outcomes achieved in highly screened clinical trial participants may not be replicable in less motivated participants or using less intensive interventions. The challenge of translational research is to ensure that interventions adapted for clinical practice are practical, effective, and easily delivered. In the case of the DPP, Medicare approved coverage of DPP lifestyle intervention programs [21] only after successful translation was demonstrated.[22, 23] Look AHEAD is similar to the DPP in that it is a complex behavioral lifestyle intervention, but it has the added challenge of diabetes medication adjustment as participants alter diet and activity levels. The high intensity intervention used in Look AHEAD has had only limited adaptation for delivery and testing in practice-based settings.[24]

The aim of the REAL HEALTH-Diabetes (Reach Ahead for Lifestyle and Health-Diabetes) Study is to implement and test the effectiveness of an adapted Look AHEAD lifestyle intervention in real-world settings, including community health centers. Secondary aims include determining the reach, cost-effectiveness, and sustainability of the program. Two lifestyle intervention formats, in-person group lifestyle intervention or telephone group lifestyle intervention, are being compared in a patient-level randomized controlled trial to referral to a dietitian for individual medical nutrition therapy (MNT), the currently recommended standard of care. REAL HEALTH-Diabetes is a practice-based translational research effort meant to bridge the gap between what has been found to be effective in clinical trials and what is feasible in clinical settings. This paper describes the study design, interventions, enrolled population, and implementation challenges and solutions associated with the launch of the project.

Research design and methods

Background

Look AHEAD was an 11-year study that tested the hypothesis that intensive lifestyle intervention (ILI) would reduce the risk of cardiovascular disease compared to diabetes support and education (DSE) in adults with type 2 diabetes. Although both the ILI and DSE arms resulted in excellent control of cardiovascular risk factors, the ILI participants achieved the same cardiometabolic outcomes with fewer medications, and had more favorable outcomes in weight, fitness, sleep, mood, sleep apnea, musculoskeletal disease and numerous other conditions. However, the ILI program was very intensive and costly.[25] Participants received 42 sessions (30 group sessions and 12 individual sessions) in the first year and up to 30 sessions per year (12 individual and 12–18 group refresher sessions) in year 2 and beyond, limiting the cost-effectiveness and scalability of the program. Building on the successful model of lower cost DPP ILI group intervention, we adapted and tested a modified Look AHEAD lifestyle intervention in a pilot trial.

Pilot work

The IDOLc (Improving Diabetes Outcomes through Lifestyle change) study was a 57-participant pilot translation in which the original Look AHEAD lifestyle intervention was

adapted for delivery in a 19-week group program.[26] The program recruited from the MGH primary care network and MGH Diabetes Center; intervention meetings and research visits were conducted at the MGH Diabetes Center. At 6 months, 46% of in-person group lifestyle intervention vs. 21% of individual medical nutrition therapy (MNT) referral patients lost 5% body weight ($P=0.04$). Mean weight loss was 6.6 (SD 7.0) kg with group lifestyle and 2.1 (SD 3.5) kg with MNT ($P=0.004$). Eighty-two percent vs. 38% stopped or reduced diabetes medications ($P<0.001$), and HbA1c improved by 0.70 (SD 1.13) vs. 0.39 (SD 1.51) in group lifestyle vs. MNT ($P=0.4$), respectively. Weight loss remained significantly greater among the in-person group compared to MNT at one year, justifying further adaptation.

Before launching REAL HEALTH, we conducted structured exit interviews with IDOLc participants and separate interviews with potential study candidates to develop the telephone delivery intervention and anticipate barriers. We learned that the 19-week program length was important in helping participants to learn and integrate the lifestyle skills into their daily routines, but would be boosted by monthly group and individual session follow up to manage lapses, reinforce skills, and tailor goals and behaviors. In addition, we conducted a 6-week telephone conference call pilot to test this new format. The 7 participants in the telephone pilot had an average weight loss of 3% over 7 weeks and attended an average of 5 out of 6 sessions. The telephone pilot demonstrated that lack of face-to-face contact would not be a barrier to forging group relationships, attendance, completing intervention tasks or safely adjusting diabetes medications; nor would cell phone minute limits be a barrier to participation. Details of the qualitative analysis regarding attitudes toward the two group lifestyle intervention formats and MNT will be reported separately.

Adaptation for primary care

The goals of the adaptation for this project were to retain the evidence-based, effective components of the original Look AHEAD intervention as well as the benefit of group support while delivering the material in a usual or convenient place of care at lower cost by offering primarily group sessions. In addition, we aimed to recruit people receiving routine care in “real world” practice settings, in contrast to the highly screened participants who participated in Look AHEAD, who, by virtue of being able to commit to a long-term clinical trial, were not representative of most people with type 2 diabetes.

In this adaptation, we used the published Look AHEAD curriculum[27] (materials available at <https://www.lookaheadtrial.org/publicResources/interventionMaterial.cfm>) as the basis of both English and Spanish language interventions. We used the same intervention goals: 7% weight loss and 175 minutes of activity per week.[28] Session materials were culturally sensitive and had a Flesch Reading Ease score of 74.0 and a Flesch-Kincaid grade level of 5.3. To adapt the Look AHEAD curriculum to be delivered at lower cost, the number of sessions was reduced from 48 group sessions and 24 individual sessions in the first 2 years of Look AHEAD to 37 group sessions with up to 5 optional individual sessions over 2 years in REAL HEALTH. Thirty-seven sessions includes weekly sessions for the first 14 weeks, biweekly sessions until the 6 month point, followed by monthly maintenance sessions to complete the two year intervention; this approach balanced a sufficient degree of intensity to induce weight loss while reducing the intensity in follow up to promote scalability and

reduce cost. The number of individual sessions was chosen to offer quarterly follow up after the first 6 months of the program.

Study design and Intervention

REAL HEALTH-Diabetes is a three-arm patient-level randomized trial that uses a repeated measures design to compare two lifestyle interventions targeting weight loss: in-person group and telephone group vs. MNT, the currently recommended standard of care (Figure 1, **Study Design**; Clinical Trial Registration: NCT02320253).

For both lifestyle arms, the interventionists are registered dietitians who deliver the intensive lifestyle intervention either through in-person group or telephone group format. The groups were comprised of 4–12 patients, ensuring time for questions and participation. During each group's weekly meeting, dietitians led interactive sessions covering nutrition, physical activity, and behavioral strategies to promote weight loss, with an emphasis on goal-setting, self-monitoring, and stimulus control. The publicly available Look AHEAD group session materials and accompanying counselor guide formed the basis of the intervention with slight modifications, including an expanded definition of meal replacements to include shakes, bars, and prepackaged entrees. Use of meal replacements was recommended (but not supplied by the study) for 1–2 meals per day starting in week 3 based on the Look AHEAD protocol. The interventionists reviewed participant food, activity, and self-monitored blood glucose diaries after each group meeting. Diaries were submitted in person, by email, or by mail. Preset threshold levels of hypo- or hyperglycemia triggered medical provider review and medication adjustment (insulin and sulfonylurea) per protocol. Specifically, in weeks 1–8, when patients made the most dramatic changes in diet and physical activity, including starting the meal replacements in week three, those with 2 or fewer blood glucose levels <100 mg/dl per week had dose reduction of 0–50%, those with 3 or more blood glucose levels 80–100 mg/dl per week had dose reduction of 25–75%, and those with 3 or more blood glucose levels <80 mg/dl or a single episode of severe hypoglycemia or symptomatic hypoglycemia 2 or more times per week had dose reduction of 50–100%. The new medication dose was documented in the electronic medical record and communicated to the primary care provider.

The group intervention schedule includes 19 sessions in the first 6 months (14 weekly sessions followed by 5 bi-weekly) and 18 monthly sessions from 6 months until the end of year 2. Group sessions were 60–90 minutes in length as in Look AHEAD. In addition, based on the feedback from exit interviews in the pilot trial, participants are offered 5 individual sessions over the two-year intervention to address tailored goals and behaviors. Sessions target diabetes-specific concerns (e.g., consistent carbohydrate intake to address erratic blood glucose patterns) and behavioral strategies to reduce barriers to achieving activity and weight loss goals.

In-person group meetings were held in the community health center or clinic conference rooms. Telephone group “conference call” meetings were used rather than internet-assisted technology based on evidence from a successful group telephone delivery of the DPP lifestyle intervention program,[29] other successful telephone interventions, and their low cost.[30–33]

Lifestyle interventionist training focused on both delivery of session content and group facilitation skills (e.g., use of open-ended questions, sharing of ideas, reflective listening, promoting and reinforcing self-initiated behaviors) that promote autonomy, competence, and relatedness to enhance motivation. Both the in-person and telephone groups were audited to ensure adherence to intervention format, content, and process. Each health center had the same dietitian-interventionist for the in-person and telephone group arms to reduce confounding by interventionist.

Participants assigned to the MNT arm received “facilitated referral” to a registered dietitian at their health center or preferred location, per current recommendations. The study team ordered the referrals, alerted the primary care provider to the referral, and encouraged participation, emphasizing its proven effectiveness for weight loss and improved diabetes control. Individual MNT referrals did not contain any prespecified approach, content, or number of sessions. As is typical of MNT, dietitians and participants discussed tailored treatment strategies for weight loss and diabetes control based on individual nutrition assessment and agreed upon the number and frequency of follow up visits based on progress towards goals and willingness to return for follow up, as would occur in clinical practice. As part of informed consent, all participants were informed that MNT sessions would be billed per usual health insurance coverage as part of usual care and that the study would not cover the cost of co-pays or deductibles.

Adaptation for Spanish

We adapted Spanish-language materials tested and used in Look AHEAD as the primary basis for the Spanish language intervention. All study materials and minor intervention material revisions were translated by bilingual study staff and reviewed by a certified medical interpreter and medical anthropologist who is a native Spanish speaker. Details of the Spanish-language implementation will be reported separately.

Settings

The intervention enrolled primary care patients from practices affiliated with Massachusetts General Hospital (MGH), North Shore Medical Center (NSMC), and Newton-Wellesley Hospital (NWH), three hospital systems that are members of Partners HealthCare, a not-for-profit health care system in Eastern Massachusetts. The project was led by a research team at the Massachusetts General Hospital Diabetes Center. Intervention groups were conducted in three community health centers and at the MGH Diabetes Center in Boston.

The project was launched at MGH Charlestown Health Center, MGH Chelsea Health Center, and MGH Revere Health Center, three community health centers that work closely with local governments, schools, and community organizations to provide comprehensive primary medical care, some specialty care, and many programs that benefit their culturally and socio-economically diverse anchor communities. Each health center treats a patient population with diabetes prevalence at or above the state and national average. Each health center site was led by a co-investigator medical provider (physician or nurse practitioner) who contributed to study design and implementation and performed study-related medication adjustments.

After targeting the first two waves of enrollment to the health centers, in order to enroll sufficient numbers of patients to test the intervention in a timely fashion, enrollment expanded beyond the health centers, drawing from an MGH primary care diabetes population of approximately 12,000 and three endocrinology practices based at MGH, NSMC, and NWH. To make the intervention more accessible to patients located in areas which lack easy transportation to the health center neighborhoods, in the late phase of recruitment the program was offered at the MGH Diabetes Center, located in downtown Boston; however, the program could have been offered in any practice conference room.

Participants

Study participants met the major inclusion and exclusion criteria listed in Figure 2. In addition, completion of at least 5 of 7 days of a food diary was required to demonstrate readiness to engage in a fundamental component of the lifestyle intervention, as it would be in any implementation of a lifestyle change program.

Practice-based implementation and recruitment

Study implementation at each health center site began with a focus on facilitating stakeholder engagement. This was accomplished by designing procedures in collaboration with a health-center based co-investigator and by having the co-investigators introduce the project to clinicians at their health centers. The study team worked with primary care providers, nurse practitioners, and dietitians to review the rationale and ensure an understanding and comfort level with the program at training sessions and informational presentations at practice meetings.

Recruitment leveraged diabetes population health management infrastructure to identify and reach patients. We used electronic health record patient registries to identify potentially eligible patients by primary care provider. Requests to providers to contact participants were sent in the name of the health center co-investigator. Patients approved for contact received an introductory opt-out letter signed by their primary care physician accompanied by a brochure describing the project, identifying the study team, and inviting them to attend an informational meeting to learn more about the study. Patients who did not opt-out of further recruitment received outreach and recruitment calls inviting them to attend an informational meeting or to screen for eligibility on the telephone and then attend an initial study visit. In addition, the study team also actively sought referrals from primary care providers.

Randomization and blinding

All participants completed the food record requirement and gave informed consent prior to randomization or performance of any study procedures. A computer randomization scheme stratified by sex in randomly alternating blocks of 3 and 6 within each intervention site was used to promote balance across study arms. Each health center was assigned a specific dietitian interventionist who interviewed participants, reviewed food records for completion, and conducted the computer-based randomization. Although interventionists and study participants were not blinded to treatment assignment, the research assistants who obtained outcomes measures were blinded.

Study outcomes

Research visits are being conducted at the community health centers and the MGH Diabetes Center at baseline, 6 months (after the conclusion of the weekly/biweekly intervention), 12 months (while monthly sessions are ongoing), 24 months (end of intervention), and 36 months (to assess maintenance/sustainability). Cost and health care utilization data are additionally collected via telephone at 18 months to minimize recall bias.

The primary outcome is percent body weight loss at 6 months, the timepoint of expected maximum weight loss. Secondary outcomes include weight loss over the duration of the intervention, HbA1c, and lipid levels, blood pressure, changes in glucose-lowering and cardiovascular medications, psychological and behavioral measures, and cost-effectiveness. Study measures were selected to capture medical efficacy, health behavior change, psychological constructs related to the theoretical underpinning of the Look AHEAD model, socioeconomic status and economic insecurity including health literacy and food insecurity, and health care utilization and cost. The list of measures and instruments can be found in Appendix Table 1.

Sample size planning and statistical analysis

IDOLc preliminary data showed mean weight loss of 6.7% at 6 months in the lifestyle intervention group, which was 4.1% greater than the MNT group. The standard deviation of percent weight loss in the pilot cohort was 5.5. We aimed to detect a clinically meaningful 3.5% difference between any of the two study arms. Using the conservative Bonferroni method to adjust for 3-arm multiple comparisons, the two-sided significance level was reduced to 0.0167 (0.05/3). Assuming a standard deviation of 5.5%, the study would need 54 subjects per arm to detect a 3.5% difference with 80% power. We assumed a conservative intra-class correlation coefficient of 0.02 within intervention groups, which corresponds to an inflation factor of 1.2, and 10% drop-out rate based on our prior results. The final planned sample size was 210, or 70 per arm.

Chi-square tests were used to compare recruitment and enrollment efforts among different practice settings. Among those who were eligible for enrollment, continuous variables were compared using two-sample t-tests or Wilcoxon rank sum tests and categorical variables were compared using chi-square tests between those enrolled and not enrolled. Baseline characteristics were compared across recruitment sites using ANOVA for continuous variables and chi-square tests for categorical variables.

Results

Recruitment and enrollment

Recruitment started in January 2015 at the community health centers, then expanded sequentially to meet the enrollment target starting with 1) patients who lived nearby but did not receive primary care at that health center, 2) a community endocrinology practice near one of the health centers (NSMC), 3) all MGH primary care patients, 4) MGH Diabetes Center patients, and finally 5) Newton-Wellesley Hospital endocrinology practice patients. Recruitment concluded in July 2017. A total of 449 health care providers were contacted;

87% of community health center (CHC) physicians and 60% of general primary care providers responded to recruitment outreach. Of patients who were screened, 12.8% of CHC and 22% of general primary care patients were eligible ($P<0.0001$). Of those screened in person and eligible, the enrollment rate of CHC patients was 95%, compared to 68% from general primary care ($P<0.0001$).

Recruitment is depicted in the CONSORT diagram, Figure 3. We screened 1,829 participants via telephone, 70.5% of whom declined participation. The primary reasons for declining participation were reluctance to be in a clinical trial (32.4%), not being interested in a weight loss program (24.2%), lack of time to participate due to work or childcare commitments (22%), and distance or transportation issues (15.7%). A small proportion of those screened (6.7%) were ineligible based on medical comorbidities, glycemic control, literacy or weight status; 5 patients had gastric bypass surgery. Of the 417 (22.8%) who were eligible and interested, 248 (59.2%) attended the screening visit, and 211 enrolled in the study (69 were assigned to MNT, 70 to in-person group and 72 to telephone group). Comparing those eligible who did not enroll ($N=206$) to those who enrolled, there was no difference in weight or gender distribution. However, compared to those who did not enroll, patients who enrolled were older, more likely to be white and English-speaking, and had better glycemic control (Appendix Table 2).

Baseline characteristics of the randomized cohort

The characteristics of enrolled participants are shown in Table 1. Mean age was 62 (SD 10.1) years, 55% were women, 77% were white, and mean BMI was 35 (SD 5.5) kg/m^2 . Twenty-eight percent of the cohort had high school education or less. Demographic characteristics and medical comorbidities were balanced across treatment arms.

Baseline characteristics by practice settings

Baseline characteristics differed across treatment sites reflecting the composition of the local communities (Table 2). Age, gender, glycemic control, cholesterol, body mass index, depression status and medication use were similar across sites; racial composition, language, and other socioeconomic status (SES) characteristics differed across sites, reflecting the composition of the host communities.

Discussion

The REAL HEALTH-Diabetes Study has met its initial goals of adapting the Look AHEAD lifestyle intervention to be delivered at lower intensity in a predominantly group format and enrolling a sufficient number of participants to test the effectiveness of the adaptation and different delivery formats compared to referral to individual medical nutrition therapy. The study population is diverse and representative of a usual primary care population drawn from community health centers, community endocrinology practices, and academic medical center-affiliated primary care practices. The primary outcome is weight loss at 6 months, which is anticipated to be the point of maximum weight loss before the transition to less intensive monthly follow up. Sustainability of weight loss at 12 and 24 months, and then at 36 months, after 1 year without any intervention, will be reported.

However, while this was a practice-based intervention, aspects of the research design introduced biases and challenges that would not pertain if the same intervention were offered as a clinical program. For example, about one third of eligible patients reported interest in the group intervention but did not want to participate in a clinical trial or accept random assignment. Similarly, in order to initiate a cohort, because of the three-arm randomization, the study team was required to accrue a sufficient number of patients to fill each arm, and do so in three separate health centers. This made enrollment less efficient than it might have been in a clinical program. Still, only one out of every nine participants who underwent a phone screen ultimately enrolled.

What is relevant to clinical program implementation is the fact that 61% of the participants contacted were not ready, willing, or able to participate in a weight loss program. Enrollment rates among eligible participants were lower for those who were less than 60 years old and had higher HbA1c levels. Another generalizable aspect of the program was the need to engage stakeholders to ensure referral and success. To that end, recruiting primary care leadership and primary care providers preceded any attempt at participant recruitment. It is notable that the health care provider response rate (84% vs. 66%) and the enrollment among eligible patients was significantly higher (95% vs. 68%; P value for both, <0.0001) at sites with primary care co-investigators than from the general primary care population.

Adoption at the health center level was facilitated by having co-investigators at each site who supported study design and implementation and served as local champions, a factor we believe contributed to higher participant enrollment rates at those centers compared to general primary care settings, which lacked an on-site champion. The intervention can be carried out in primary or specialty care settings as long as a conference room is available, in-person or on the phone, likely with some trade-offs in reach depending on the setting and format. For example, if a health system wished to implement a lifestyle intervention program, there might be higher engagement in conducting the program at different practices, but higher efficiency from having one central program. Within this trial, we are conducting the intervention in high and low SES settings, with a fair degree of heterogeneity within some groups, and we will be able to evaluate effectiveness according to these parameters. At the patient level, conducting the study and study procedures at a convenient location in the usual place of care rather than a central research center minimized barriers to participation and facilitated follow up and retention. These factors likely contributed to higher rates of participation at those sites. For both patients and providers, medical management was integrated into usual care process and facilitated by use of a common electronic health record (EHR). Co-investigators followed a protocol based on the Look AHEAD study to reduce glucose-lowering medications to avoid hypoglycemia as glycemic control improved with weight loss, and to increase medication dose back to baseline if required. Co-investigators updated medications and records in the EHR to ensure safety and coordination of care. This integration would also be beneficial in a clinical program run within a large health system.

Implementation challenges were largely related to the research, rather than the clinical, aspects of the project. The initial approach of obtaining study measures using clinical practice staff was thwarted by several barriers including staff turnover at each site and the

time needed to undergo research training to serve as protocol staff. We consolidated our efforts and hired a dedicated bilingual research coordinator who became embedded in the practices to help collect study outcomes. Consequently, REAL HEALTH-Diabetes was a hybrid practice-based trial, with the research team acting as a “coordinating center” for central research activities such as screening and outcome assessment, and health center primary care provider co-investigators trained and funded to carry out the work in real-world settings. We are aware of one other translation of the Look AHEAD intervention which is using a different approach for enrollment and intervention delivery.[24] Comparison of the reach and effectiveness of these two approaches will inform real-world implementation.

There are several other aspects of this project that must be taken into account when evaluating the generalizability and scalability of this Look AHEAD adaptation. First, we used dietitian interventionists due to the complex nature of the intervention and the need for medication adjustment, which was best communicated via certified diabetes educator (CDE)-equivalent interventionists, rather than trained community health workers, as has been done in other lifestyle translations of DPP or Look AHEAD. [24, 34] Dietitian interventionists are well suited to carry out the intervention, can receive reimbursement for group medical nutrition therapy, and can scale the intervention by use of a phone delivery format, but this approach may not be applicable in areas with a limited dietitian workforce. Nonetheless, It is likely that personnel with CDE or CDE-equivalent training, rather than trained health workers, will be necessary to carry out the intervention unless there is significantly more medical oversight, which has cost implications as well. While the requirement to complete 5 of 7 days of a food diary may not seem realistic, in fact we would propose that this be an eligibility criterion for any lifestyle intervention, since participants who are unwilling or unable to do this are unlikely to benefit from the intervention.

Conclusions

REAL HEALTH-Diabetes successfully enrolled a diverse cohort into a practice-based group adaptation of the Look AHEAD lifestyle intervention. Although the initial intervention was targeted to community health centers, enrollment was expanded to other sites to meet the recruitment target in a timely fashion. Nonetheless, provider engagement and enrollment of eligible patients was highest at community health centers owing to the engagement of program leaders based at each health center. REAL HEALTH-Diabetes is a practice-based clinical trial that will determine the effectiveness of two different modalities of lifestyle intervention in a real-world cohort.

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Figure 1.
Study Schema

Major inclusion criteria	
Diagnosis of type 2 diabetes	
Age 18 years or older	
Overweight or obese (BMI >25 kg/m ² or 23 kg/m ² if Asian ancestry)	
HbA1c 6.5-11.5%	
Systolic blood pressure (SBP) <160 mmHg, diastolic blood pressure (DBP) <100 mmHg	
Willingness to lose 5-7% of body weight	
Ability to understand and communicate effectively in English or Spanish	
Major exclusion criteria	
Weight greater than 350 lbs.	
Pregnant or planning pregnancy in the next year	
Currently seeing a dietitian or participating in a weight-loss program	
Weight loss or gain of more than 3% in the previous month	
Previous or planned bariatric surgery	
Long term use of medications likely to cause weight gain or inhibit weight loss (e.g. corticosteroids, with the exception of maximum dose of prednisone 10 mg or equivalent)	
Medical or psychiatric condition that interferes with ability to carry out intervention procedures (e.g. medical exclusions would be those that limit ability to increase physical activity to at least 175 minutes/week, such as active CHF or COPD; psychiatric exclusions would include serious mental illness such as schizophrenia or uncontrolled depression)	

Figure 2.
Inclusion and exclusion criteria

Figure 3.
CONSORT Diagram

Table 1

Participant Baseline Characteristics

	MNT	IP-GLI*	TCC-GLI*
N	69	70	72
Age (mean, SD)	60.9 (10.5)	60.7 (10.3)	62.0 (9.7)
<60 years (%)	43.5	37.1	37.5
60 years (%)	56.5	62.9	62.5
Sex (%)			
Female	56.5	52.9	56.9
Male	43.5	7.1	43.1
Race or ethnicity (%)			
White	71.0	78.6	80.6
Black	8.7	2.9	2.8
Latino	15.9	14.3	9.7
Other	4.3	4.3	6.9
Language (%)			
English	91.3	92.9	91.7
Spanish	8.7	7.1	8.3
Intervention site (%)			
Charlestown	21.7	18.6	19.4
Chelsea	14.5	12.9	13.9
Revere	27.5	28.6	27.8
Diabetes Center	36.2	40.0	38.9
Weight (kg, mean, SD)	100.4 (21.4)	98.8 (17.0)	96.1 (18.2)
BMI (kg/m ² , mean, SD)	35.9 (6.4)	35.0 (4.9)	34.5 (5.0)
HbA1c (% , mean, SD)	7.8 (1.2)	7.8 (1.2)	7.6 (1.1)
Systolic blood pressure (mean, SD)	125.5 (16.3)	126.0 (13.9)	123.6 (10.5)
Diastolic blood pressure (mean, SD)	76.1 (10.0)	76.6 (7.2)	77.5 (7.5)
Total cholesterol, mg/dl (mean, SD)	162.2 (37.6)	164.7 (37.6)	162.8 (39.5)
HDL-C, mg/dl (mean, SD)	45.1 (12.5)	42.7 (10.2)	43.7 (12.1)
LDL-C, mg/dl (mean, SD)	87.7 (29.1)	90.4 (31.3)	88.3 (30.1)
Triglycerides, mg/dl (mean, SD)	144.3 (97.6)	196.5 (289.9)	152.2 (94.0)
Glucose-lowering medications (%)			
Insulin alone or plus other	27.5	32.9	33.3
Sulfonylurea alone or plus other	29.0	38.6	26.4
GLP-1 alone or plus other	7.2	7.1	5.6
Other combination regimen	2.9	11.4	9.7
Metformin alone	20.3	17.1	19.4
None	14.5	5.7	9.7

	MNT	IP-GLI*	TCC-GLI*
Blood pressure medication (%)	72.5	82.9	80.6
Statin (%)	75.4	61.4	75.0
Depression (%)**			
None or minimal depression	60.9	60	56.9
Mild depression	20.3	25.7	30.6
Moderate depression	13.0	10	9.7
Severe or moderately severe depression	5.8	4.3	1.4
Highest level of education (%)			
12 th grade or less	29.0	25.7	30.6
1–3 years of college	27.5	28.6	30.6
4 or more years of college or graduate school	43.5	45.7	38.9
Household income distribution (%)			
Less than \$30,000	24.6	24.3	19.4
\$30,000–\$49,999	4.3	12.9	12.5
\$50,000–\$99,999	27.5	32.9	38.9
\$100,000 or more	39.1	24.3	26.4
Employment status (%)			
Employed full time	42.0	45.7	40.3
Employed part-time	11.6	10.0	9.7
Unemployed	7.2	4.3	4.2
Retired	33.3	32.9	38.9
Other	5.8	7.1	6.9

* IP-GLI: In-person group lifestyle intervention;

TCC-GLI: telephone conference call group lifestyle intervention

** Measured by PHQ-8.

Table 2

Baseline characteristics by intervention site

	Charlestown	Chelsea	Revere	General Primary Care	P value*
N	42	29	59	81	
Age (mean, SD)	57.9 (11.2)	61.5 (7.0)	61.0 (10.8)	63.0 (9.7)	0.075
<60 years (%)	52.4	37.9	42.4	30.9	
60 years (%)	47.6	62.1	57.6	69.1	0.13
Sex (%)					0.32
Female	54.8	62.1	62.7	48.1	
Male	45.2	37.9	37.3	51.9	
Race or ethnicity (%)					<0.0001
White	88.1	27.6	88.1	80.2	
Black	4.8	0	3.4	7.4	
Latino	2.4	72.4	5.1	3.7	
Other	4.8	0	3.4	8.6	
Language (%)					0.0007
English	100	41.4	100	100	
Spanish	0	58.6	0	0	
Weight (kg, mean, SD)	104.3 (19.6)	90.4 (16.3)	98.6 (18.3)	98.0 (19.1)	0.024
BMI (kg/m ² , mean, SD)	36.9 (5.9)	34.5 (4.7)	35.4 (5.0)	34.2 (5.7)	0.056
HbA1c (% , mean, SD)	7.8 (1.3)	8.0 (1.0)	7.6 (0.9)	7.7 (1.3)	0.44
Insulin use (%)	33.3	44.8	28.8	27.2	0.34
Highest level of education (%)					<0.0001
12 th grade or less	33.3	72.4	18.6	17.3	
1–3 years of college	21.4	17.2	47.5	23.5	
4 or more years of college or graduate school	45.2	10.3	33.9	59.3	
Household income distribution (%)					<0.0001
Less than \$30,000	11.9	62.1	28.8	9.9	
\$30,000–\$49,999	11.9	6.9	11.9	8.6	

	Charlestown	Chelsea	Revere	General Primary Care	P value*
\$50,000–\$99,999	35.7	13.8	37.3	35.8	
\$100,000 or more	35.7	10.3	18.6	42.0	
Employment status (%)					<0.0001
Employed full time	59.5	27.6	39.0	42.0	
Employed part-time	7.1	6.9	13.6	11.1	
Unemployed	4.8	10.3	5.1	3.7	
Retired	26.2	20.7	39.0	42.0	
Other	2.4	34.5	3.4	1.2	

* ANOVA for continuous variables and chi-square tests for categorical variables

Appendix table 1

Biomedical Measure	Method	RV1 (0 Mo)	RV2 (6 Mo)	RV3 (12 Mo)	18 Mo	RV4 (24 Mo)	RV5 (36 Mo)
Weight	Calibrated Scale (without shoes)	X	X	X		X	X
BMI	BMI = Weight (kg)/Height ² (m ²)	X					
Height	Stadiometer	X					
Blood Pressure	Calibrated Sphygmomanometer	X	X	X		X	X
Lipid Panel	MGH Clinical Laboratories	X	X	X		X	X
Hemoglobin A1c	MGH Clinical Laboratories	X	X	X		X	X
Health and Weight History	Demographics, Weight, and Health History (S)	X					
Medications	Medication and Health Services Utilization (I)	X	X	X	X	X	X
	*(S) Self-administered, (I) Interviewer-administered						
Psychometric Measure	Method	RV1 (0 Mo)	RV2 (6 Mo)	RV3 (12 Mo)	18 Mo	RV4 (24 Mo)	RV5 (36 Mo)
Literacy	Newest Vital Sign ¹ (NVS) (I)	X					
Autonomy	Treatment Self-Regulation Questionnaire ² (S)	X	X			X	X
Perceived Autonomy Support	Health Care Climate Questionnaire ² (S)		X			X	
Exercise Self-efficacy	Exercise Self-Efficacy Scale ³ (S)	X	X	X		X	X
Diet Self-efficacy	Low Fat Diet Self-Efficacy Scale ⁴ (S)	X	X	X		X	X
Relatedness	Social Support for Healthy Behaviors Scale ⁵ (S)	X	X	X		X	X
Activity Behavior	Paffenbarger Survey ⁶ (S)	X	X	X		X	X
Dietary Behavior	Fat-Related Diet Behavior Questionnaire ^{7,8} (S)	X	X	X		X	X
Dietary Behavior	Restraint Subscale of Dutch Eating Behavior Questionnaire ⁹ (S)	X	X	X		X	X
Satisfaction with care	Diabetes Quality of Life Measure (Adapted) ¹⁰ (S)		X			X	
Medication adherence	Morisky Medication Adherence ¹⁰ (S)	X	X	X		X	X
Health-related quality of life	EQ-5D ¹¹ (S)	X	X	X		X	
Diabetes -specific quality of life	Problem Areas in Diabetes (PAID) Scale ¹² (S)	X	X	X		X	X
Depression	Patient Health Questionnaire-8 ¹³ (S)	X	X	X		X	X
Food Insecurity	U.S. Household Food Security Survey ¹⁴ (S)	X		X		X	X

Biomedical Measure	Method	RV1 (0 Mo)	RV2 (6 Mo)	RV3 (12 Mo)	18 Mo	RV4 (24 Mo)	RV5 (36 Mo)
	*(S) Self-administered, (I) Interviewer-administered						
Cost							
Measure	Method	RV1 (0 Mo)	RV2 (6 Mo)	RV3 (12 Mo)	18 Mo	RV4 (24 Mo)	RV5 (36 Mo)
Medication Cost	Medication and Health Services Utilization (I)	X	X	X	X	X	X
Transportation Cost	Self-reported		X	X	X	X	
Patient time lost from work	Self-reported		X	X	X	X	X
Personal Expenditure	Self-reported		X	X	X	X	X
	*(S) Self-administered, (I) Interviewer-administered						

Appendix table 2

	Enrolled	Not Enrolled	P value *
N	211	206	
Age (mean, SD)	61.2 (10.1)	58.3 (11.5)	0.007
<60 years (%)	39.3	51.9	
60 years (%)	60.7	48.1	0.010
Sex (%)			
Female	55.5	55.3	
Male	44.5	44.7	0.98
Race or ethnicity (%)			
White	76.8	58.3	
Latino	13.3	18.0	
Other	10.0	23.8	<0.0001
Language (%)			
English	91.9	84.0	
Spanish	8.1	16.0	0.012
Weight (kg, mean, SD)	98.4 (18.9)	95.7 (19.2)	0.15
BMI (kg/m ² , mean, SD)	35.1 (5.5)	34.6 (5.8)	0.32
HbA1c (%) (mean, SD)	7.7 (1.2)	8.2 (1.3)	0.0003

* T-test for continuous variables and chi-square tests for categorical variables