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TEEN HEED: Design of a Clinical-Community Youth Diabetes Prevention Intervention

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Introduction

According to the US SEARCH study, the prevalence of type 2 diabetes in youth between 10 and 19 years rose by 30.5% between 2001 and 2009.¹ Type 2 diabetes in adolescents is difficult to treat,² with higher rates and earlier onset of complications.³ Progression from pre-diabetes to diabetes may be rapid with continued weight gain. Conversely, obese pre-diabetic adolescents can revert to normal glucose tolerance with cessation of weight gain.⁴ Efficacy studies among pre-diabetic adults show that lifestyle interventions resulting in modest weight loss or increased physical activity lessen diabetes progression by 33% to 68% and eliminate racial/ethnic disparities in incident diabetes.^{5,6} Unfortunately, there are a

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paucity of effective interventions for youth, particularly for minority youth who are disproportionately affected by the disease.⁷

Peer-led education programs represent an effective low-resource diabetes prevention strategy for adults in high-risk communities.^{5,8–10} Research suggests that like adults, young people are more likely to hear and personalize messages, and thus to change their attitudes and behaviors, if they believe the messenger is similar to them and faces the same concerns and pressures. Youth peer led interventions have been shown to be effective in other behavioral interventions,^{11–14} and peers influence several weight-related behaviors in adolescents.^{15–17} The few studies to date focusing on youth peer led lifestyle interventions have been demonstrated to have beneficial effects for both participants and peer leaders on outcomes such as fruit and vegetable intake, fat intake and levels of sedentary activity.^{18–24} However, no studies have explored the use of youth peer leaders to deliver programs for diabetes prevention.

Another challenge identified in existing youth health interventions is keeping youth engaged to enhance program participation and impact.²⁵ One potential strategy is the use of mobile technologies. Nearly three-quarters of teens have or have access to a smartphone, including minority youth.²⁶ A typical teen sends and receives at least 30 texts per day, and 71% report using more than one social network site.²⁶ Compared to wealthier teens, teens from lower-income households are just as likely to own a smartphone and more likely to use their phone to access online social networks and health information.^{27,28} However, despite the potential for technology to support weight management in youth,²⁹ research to date has focused mostly on text-messaging. Although these interventions have been shown to be effective in supporting disease management behaviors,^{30,31} there is limited information about the most effective message content and timing.^{31–35} Other tools including “apps” and social media have limited evidence among adults,^{36–42} but generally have not yet been studied among youth.⁴³

We are using community-based participatory research (CBPR), a collaborative approach to research that equitably involves all partners in the research process,⁴⁴ to develop a peer-led adolescent diabetes prevention intervention incorporating mobile technologies. The *central hypothesis* is that such an intervention will lead to maintenance or decrease in BMI, improved dietary, physical activity and weight control behaviors, and decrease in diabetes risk. In this manuscript, we describe how results from a pilot study informed a study protocol to test the effectiveness of the intervention.

Methods

Study Setting and Intervention Development

Our work focuses on East Harlem, also known as El Barrio, located in the northeast corner of Manhattan. Its residents, 46% of whom identify as Latino and 30% of whom identify as Black, are predominantly low income and have among the highest obesity prevalence and diabetes mortality rate in New York City.⁴⁵ The East Harlem Partnership for Diabetes Prevention (EHPDP) is a community-academic partnership formed in 2005 to design and implement diabetes prevention strategies for the community. The partnership developed

Project HEED, **H**elp **E**ducate to **E**liminate **D**iabetes, which used Community-Based Participatory Research (CBPR) to design and test the impact of community-based, peer-led group workshops on weight among adults with pre-diabetes. In a randomized controlled trial, pre-diabetics in the intervention group had statistically significant weight loss maintained at one year and a leveling of their glucoses, as compared with controls.¹⁰

In 2010, the Partnership's Community Action Board expressed interest in expanding diabetes prevention efforts to young people in the community. To gain a better understanding of adolescent developmental needs and the multi-level factors that influence adolescents' diabetes risk, we first conducted in-depth interviews (audiotaped and transcribed) with eleven directors of youth programs in East Harlem. These key stakeholders endorsed a peer education model for diabetes prevention, and provided information about available nutrition and physical activity programs to support and provide context for the intervention to be developed. Suggestions for program design included interactive workshops, offering choices of topics, use of personal connections and stories, and strategies such as field trips, games and competitions. We then conducted focus groups with adolescents recruited from collaborating community sites, to explore their diabetes knowledge and health concerns, determinants of diabetes related health behaviors, and barriers to healthy lifestyles.⁴⁶

Using the adult intervention as a model, we worked with community partners to develop a conceptual model for diabetes risk reduction in racial/ethnic minority adolescents by adapting an existing model⁴⁷ using focus group results. (See Figure 1) The model includes constructs from Social Cognitive Theory, the Health Belief Model, the Theory of Planned Behavior and the Ecological Model of behavior change.⁴⁷ The final model depicts determinants of behavioral intentions (a person's perceived likelihood of engaging in a given behavior), including knowledge, attitudes, beliefs, social structure and environment. Behavioral influences (self efficacy and social influences) ultimately impact both behaviors (diet and physical activity) and clinical outcomes (weight and diabetes risk).

Community and academic partners then developed TEEN HEED, a pilot peer-led youth diabetes prevention program. In keeping with CBPR principles, board members chose all strategies, co-developed the intervention and its evaluation, and directed the researchers to provide the tools, support and expertise necessary to meet study goals. The overall goals were to: 1) screen at-risk adolescents for pre-diabetes, 2) enroll pre-diabetic adolescents into peer-led diabetes prevention workshops and 3) conduct follow up assessments post intervention.

The partnership accomplished study goals through development of subcommittees.

The **Curriculum subcommittee** developed the pilot workshop curriculum through review of the adult HEED curriculum, existing adolescent lifestyle intervention curricula and guidelines for recommended dietary and physical activity behaviors in youth. The group first created an outline of the workshop sessions with topics and activities to be included and discussed strategies for making the curriculum developmentally and culturally appropriate for teens in the East Harlem community. Teen-led workshops (8 weekly 90 minute workshops) covered behavioral skills including goal setting (weekly action plans), self-

monitoring, brainstorming, problem solving, contingency management, coping skills, and social support. Workshop topics included explanation of pre-diabetes/diabetes, label reading, healthy plate planning, portion control, finding affordable healthy foods, strategies to increase physical activity, and coping with eating triggers and social pressures. The subcommittee developed creative methods for keeping teens engaged including use of interactive activities such as games and competitions.

The **Evaluation/Outcomes subcommittee** decided what types of data to collect and how to analyze and share these data, including presentation of findings to the community and to scientific audiences. Primary and secondary outcomes (See Table 1) included measures related to diabetes risk, which have not been measured in this at-risk, understudied population. The group developed a lifestyle/health risk survey to assess knowledge, attitudes, beliefs, behaviors, cognitive mediators and demographic factors, using validated scales (or formulated supplemental questions if there are no previously validated scales) to test the domains in the conceptual model. The subcommittee reviewed potential questions and chose items that captured important constructs, were easily understood, and would be helpful in measuring intervention effectiveness. The group also discussed feasibility and acceptability of other assessments including blood tests and how best to share results with participants and parents so that information was easily understandable and presented in a sensitive manner.

The **Recruitment/Retention subcommittee** developed communication, marketing, outreach and recruitment strategies to help enroll teens in the study. The group figured out how to effectively communicate to the East Harlem community the urgent message about pre-diabetes in teens and how to prevent or delay diabetes. The subcommittee developed messages to reach teens most at risk for diabetes, identify sites to recruit participants, and gain community and youth support for the project. The subcommittee developed a recruitment tool kit including description of the study protocol for participants and parents, methods for maintaining confidentiality and responses to anticipated concerns about participation in the study. The subcommittee evaluated recruitment efforts by meeting regularly to discuss recruitment progress, highlight successful techniques, and brainstorm ways to address challenges.

TEEN HEED Trial

Based on preliminary results from the pilot study (described below in Results section), we obtained funding (NIH grant K23DK101692-01) to further refine the intervention and conduct a randomized controlled trial.

The study protocol for the upcoming trial has been approved by the institutional review board at the Icahn School of Medicine at Mount Sinai and the study is registered on www.clinicaltrials.gov (NCT02458131). We will recruit adolescents from collaborating community youth organizations, health centers and schools. We will complete an eligibility screen (overweight/obese by measured BMI, English speaking, without known diabetes, not on medications which may affect blood sugar, non-pregnant, no history of gastric bypass surgery, no electronic device implants, and not moving from New York City in the next year) and then invite eligible participants to return fasting for further evaluation. Participation will

be contingent on adolescent assent/parental consent (ages 13–17) or participant consent (ages 18 years or older). We will screen 300 at-risk East Harlem adolescents for pre-diabetes using an oral glucose tolerance test (OGTT), obtain body measurements and blood pressure, and administer the health and lifestyle survey. For adolescents found to have pre-diabetes, we will obtain other metabolic and inflammatory markers and detailed diet and physical activity information, and then randomize them into intervention and wait-list control groups. We will collect data at baseline, immediately after the intervention (3 months), at 6 months and at one year and compare outcomes between groups to test the efficacy of the intervention.

Data Analysis

The proposed sample size provides 80% power to detect an estimated difference in pre-post changes in BMI (the primary outcome) between intervention and wait list control groups based on an adolescent behavioral weight management study⁵⁴ (using an independent samples *t*-test (two-sided alpha of .05)). We will use descriptive statistics to summarize demographic characteristics of participants and outcome measures in age, gender and racial/ethnic subgroups. We will examine prevalence of pre-diabetes and whether those with and without pre-diabetes differ in sociodemographic variables, behaviors and the host of attitudes and beliefs depicted in the conceptual model. Because many of the dependent variables will be based on a Likert scale or binary responses, we will use logistic and ordinal logistic regression with race, age, and gender as independent variables and other possible covariates in exploratory analyses.

We will compare baseline characteristics between study groups using 2-sided *t*-tests for continuous variables and chi-square and other nonparametric tests for categorical variables. We will use intention-to-treat analysis, assigning participants to groups regardless of whether participants complete the intervention. We will compare changes in outcomes between baseline and 3 months (immediate post-intervention follow-up), baseline and 6 months, and baseline and 12-months in intervention and control participants. Initial bivariate comparisons will use *t*-tests to compare continuous endpoints and the Wilcoxon matched pairs signed-rank test to compare ordinal endpoints. We will then conduct multivariable analyses (using logistic regression, general linear models, and mixed models) to adjust for potential confounders (such as age, race/ethnicity, gender, SES, and baseline BMI) and to account for the repeated observations per participant. Additional analyses will examine changes in outcomes by constructs in the conceptual model (such as self efficacy, intention to change and social influences) and by program attendance. Analyses will include the baseline level of each endpoint as a covariate, indicator variables for study group and a continuous variable for time. We will estimate effect sizes for each measure using correction for small sample bias.

Process Evaluation

An experienced adult peer leader will supervise classes to ensure quality and provide feedback as necessary. Study investigators and trained research assistants will make unannounced visits to workshop sessions twice during each course and observe a random

subset of intervention sessions in person using a checklist to measure the fidelity of intervention delivery and provide feedback to peer leaders.

We will record several process measures (e.g., # of participants pre-screened, eligible for pre-diabetes screening, screened using oral glucose tolerance testing, enrolled in workshops and completing workshops). Analyses will identify participant characteristics associated with higher or lower intervention potency (e.g., class attendance, satisfaction with intervention). We will complete written surveys and conduct audiorecorded debriefing sessions with participants and peer leaders in which we will ask about their experiences with the intervention, reactions to the intervention, and ideas for intervention refinement.

To monitor the community-academic partnership, we will track activities such as the communication between community-academic partners, number of participants at CAB meetings, number of manuscripts and presentations by academic-community partners, and policy-related outcomes. We will also ask CAB members to complete annual surveys to gauge how closely the research project aligns with principles of CBPR, including factors they may feel less comfortable discussing in a group, such as level of inclusion and trust.

Results

We completed a pilot study of the intervention in 2012. Community and clinical recruitment were both effective in diagnosing at-risk adolescents with pre-diabetes.⁵⁵ Overall, 47% of 186 adolescents screened (ages 13–19, non-pregnant and without known diabetes or pre-diabetes) were at risk for diabetes based on measured BMI, 64% (n=56) of whom returned for diabetes testing. Fully 19 (34%) tested positive for pre-diabetes and 1 (1.8%) tested positive for diabetes. Demographic information from the survey was available for 55 teens (not obtained for participant diagnosed with diabetes) and is presented in Table 2 below:

Pre-diabetic adolescents were invited to complete 8 weekly peer led diabetes prevention sessions in a community setting and post intervention (3 month) follow-up evaluations. Most (14/19) pre-diabetic adolescents identified enrolled in the workshop; 9 completed >50% of the sessions, and 16 returned for 3 month follow up. Five of 9 adolescents completing the workshop no longer had pre-diabetes at follow up. Other results are presented in Table 3 below:

We analyzed pre/post intervention survey data for teens who completed the workshop to examine changes in attitudes, beliefs, and behaviors, using the paired samples t-test for continuous variables and the McNemar-Bowker test for categorical variables. Analysis revealed that workshop participants had significant improvements in portion control, dietary and physical activity self-efficacy, and availability of healthy foods in the home. (See Table 4 below) Participants also had an improvement in perceived support from friends for healthy behaviors and lower scores on the depression scale (borderline significance). At follow up, more workshop participants also reported eating the recommended portion of protein, eating breakfast 7 days per week and reading nutrition labels.

Finally, we conducted structured interviews with study participants to get feedback about the recruitment process, logistics, workshop activities, study impact and suggested

improvements. Participants understood the purpose of the pre-diabetes screening and felt that results were explained in a way that was easy for them to understand. Feedback about testing locations, timing, reminders, research staff and study incentives was positive though teens did feel that the study visits were lengthy. Teens who took part in the workshops endorsed the workshop location, timing, frequency and length. Common challenges affecting workshop attendance included school, work and participation in other programs. Favorite activities included making weekly action plans, learning how to read food labels, games (described as a fun and exciting way to review what they learned), and exercise circuits. Workshop participants liked the peer leaders and recommended that future peer leaders should be chosen based on interest in learning/teaching, personality (“energetic, not shy”) and having gone through a similar experience so that they may understand what the participants are going through. Participants reported that being told they were at risk for developing diabetes did make them feel scared and sad but motivated them to change their lives (“because after we knew we did everything to get away from it”). Participants also reported improvements in their eating habits (limiting intake of foods high in fat and sugar, better portion control, increasing fruit and vegetable intake, drinking more water and eating out less), and feeling encouraged to get more exercise. Teens reported positive impact on their friends and family members by encouraging them to eat out less and cook less fattening foods. Most teens recommended incorporating additional support and resources through use of online groups, texting or “apps” but emphasized the importance of meeting in person to develop friendships and keep them motivated. All participants stated that they enjoyed the program, found it helpful and would recommend the program to a friend or classmate.

Discussion

The number of youth with type 2 diabetes is predicted to quadruple by 2050, with a disproportionate increase among minority youth. The Diabetes Prevention Program (DPP) is recognized as a sentinel study demonstrating the effectiveness of lifestyle interventions for diabetes prevention among pre-diabetic adults, but it has not yet been replicated in youth. The proposed research will use community-based participatory research methodology as well as novel strategies (peer education and mobile health technologies) to design, implement and evaluate a diabetes prevention intervention for at-risk ethnic minority youth in an urban community with high disease burden.

During our pilot study, we were able to successfully recruit adolescents from both clinical and community-based sites in East Harlem.⁵⁵ Of those who were at risk for diabetes based on measured BMI, about two thirds returned for pre-diabetes screening, and one third of those tested were diagnosed with pre-diabetes. Almost three fourths of the pre-diabetic teens enrolled in the workshops, and most returned for follow up. Participants gave positive feedback about both the pre-diabetes screening process and the workshop structure and content, including use of youth peer leaders.

We obtained both quantitative and qualitative data to measure the effectiveness of the pilot intervention. Five of nine adolescents who completed the workshop no longer had pre-diabetes at follow up. In comparing participants completing more than half of the workshops (“workshop completers”) and participants completing less than a quarter of the workshops

(“workshop non-completers”), there was a trend for workshop completers to have decreases in BMI and fasting glucose, though these changes were statistically insignificant due to small sample size. Analysis of pre/post intervention survey data revealed that workshop participants had improvements in portion control, dietary and physical activity self-efficacy, availability of healthy foods in the home, breakfast frequency and label reading. During structured interviews of workshop participants, teens reported additional improvements in their dietary and physical activity behaviors and positive impact on friends and family members.

As a next step in developing and testing the intervention, we have completed additional focus groups to explore the best strategies for using peer education for diabetes risk reduction in youth, and the potential role of mobile health technologies in improving adherence to behavioral modification plans. We will utilize findings from these qualitative studies to adapt the pilot program, screen 300 at-risk East Harlem adolescents for pre-diabetes and randomize pre-diabetic teens into intervention and wait-list control groups to evaluate the intervention. The outcomes we will examine include: 1) maintenance/reduction of BMI (primary outcome), 2) improvement in adolescent dietary, physical activity and weight control behaviors, and 3) improvement in other measures of diabetes risk.

In preparation for the upcoming trial, the **Curriculum Subcommittee** will update and refine the workshop curriculum and develop procedures for finding, training and supervising youth peer leaders (older teens and young adults) who will run the workshops. A new **Technology/Social Media Subcommittee** (comprised of teens and young adults) will develop the technology component of the TEEN HEED intervention. We will develop a mobile health application (“app”) to reinforce workshop topics, help with goal setting and self-monitoring of behaviors and provide individualized recommendations and feedback. We will also use social media (a private Facebook group for workshop participants) to keep participants engaged and provide additional resources and social support. The **Evaluation Subcommittee** will revise the TEEN HEED survey, finalize protocols for assessment of other study outcomes, and devise strategies for evaluation of the technology component of the intervention. The **Recruitment Subcommittee** will update the recruitment toolkit and outline strategies for program sustainability so that successful work may be replicated and disseminated more broadly in the community.

The proposed study incorporates many innovative components:

- **Youth Diabetes Prevention Program:** As diabetes prevention is a priority for the CDC and NIH, and there is an increasing risk of diabetes in youth, this project aims to develop a feasible and scalable youth prevention model in an urban, ethnic minority community with high disease burden. If successful, this could be the first youth diabetes prevention program sanctioned by the CDC that could be sustained and scaled.
- **Transdisciplinary:** A diverse team of investigators (including accomplished researchers in the areas of endocrinology, obesity/diabetes, community-based participatory research, qualitative research, nutrition, behavioral interventions, youth health interventions and health technology/social media), as well as

community collaborators, will adapt a successful adult peer led lifestyle intervention for adolescents.

- **Use of Community-Based Participatory Research (CBPR):** This collaborative approach to research⁴⁴ will guide all aspects of our study. Our “TEEN HEED Community Action Board” (CAB) has been working with academics on study design and implementation. Scientific and content advisors helped develop the model, intervention and analytic plans, and also helped build capacity of community partners to engage in and benefit from the research process. This partnership and formative work will allow us to develop an intervention that truly meets the needs of low income, minority youth. Unlike other “drive-by” research studies which show positive results and then end when funding lapses, this intervention will be designed to be sustained by the community given its low cost, and strong community buy-in.
- **Use of youth peer leaders:** No studies to date have incorporated adolescent peer leaders in a behavior modification intervention for diabetes prevention. If effective, this may be a novel and sustainable approach to community-based diabetes prevention in youth.
- **Incorporation of novel mobile health technologies:** We are using Fitbit devices to track physical activity throughout the study, and we will work with target youth to develop additional tools (social media, mobile applications, and messaging) that are feasible and acceptable for young people to promote goal-setting, self-monitoring and social support for weight management.

While this research is situated within a particular sociocultural context, we aim to produce generalizable methods and results that can be applied in other settings. We therefore hope that this project will provide a model for the development, implementation and evaluation of other community-based youth health interventions.

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Figure 1.
Conceptual Model for Diabetes Risk Reduction in Racial/Ethnic Minority Adolescents

Table 1

TEEN HEED Outcomes

Potential outcome/Mediator/Covariate	Instrument/Methods
1° Outcome: Body Mass Index (BMI)	Calculated as kg/m ² using measured weight and height
2° Outcome: DM Risk: <i>Blood sugar</i>	Oral glucose tolerance test (OGTT) ⁴⁸
2° Outcome: DM Risk: <i>Metabolic/Inflammatory</i>	Insulin, HbA1C, lipids, hs-CRP
2° Outcome: <i>Other DM Risks</i>	Waist circumference ⁴⁹ ; %body fat: Bio-electric impedance analysis (Tanita)
2° Outcome: Blood pressure	NHANES protocol ⁴⁹
2° Outcome: Dietary Behaviors	Block FFQ ⁵⁰
2° Outcome: Physical Activity Behaviors	Fitbit One ⁵¹
Mediators: attitudes, beliefs, behavioral intentions, behavioral influences	Project EAT survey ⁵² , New Moves survey ⁵³
Covariates: Demographic variables	Project EAT survey ⁵² , NHANES

Table 2

Demographic Characteristics for Adolescents in Pilot TEEN HEED Study

Characteristic	N (%)
Gender	
Female	34 (62%)
Male	21 (38%)
Race/Ethnicity	
Hispanic	32 (58%)
Non-Hispanic Black	23 (42%)
Age	
13–15	27 (49%)
16–19	28 (51%)
Parent Country of Birth	
United States	27 (49%)
Other	28 (51%)
Parent Education (N=54)	
High School or less	23 (43%)
More than High School	31 (57%)

Table 3

Changes in BMI and Fasting Glucose for Adolescents in Pilot TEEN HEED Study

Group	Mean change in BMI p=0.3	Decreased BMI N (%)	Mean change in fasting glucose P=0.2	Decreased fasting glucose N (%)
Completed >50% of workshop (n=9)	-0.3 kg/m ²	5 (56%)	-6 mg/dl	7 (78%)
Completed <25% of workshop (n=7)	+0.3 kg/m ²	2 (29%)	+1 mg/dl	4 (57%)

Table 4

Pre/post Intervention Survey Data for Teens Completing Workshops

Measure [*]	Pre/Post Intervention – Mean Difference (sd) or % Change	P value
Portion Control (scale 1–4)	+0.9 (0.6)	0.002
Dietary Self Efficacy (scale 1–5)	+0.6 (0.7)	0.039
Physical Activity Self Efficacy (scale 1–5)	+1.2 (0.9)	0.005
Home Food Environment (scale 1–4)	+0.5 (0.3)	0.01
Friend Support (scale 1–4)	+1.9 (2.6)	0.085
Depression (scale 1–3)	–1.5 (1.5)	0.06
Eating Recommended Protein Portion	0% (pre) to 37.5% (post)	
Eating Breakfast 7 Days per Week	25% (pre) to 50% (post)	
Reading Nutrition Labels	50% (pre) to 87.5% (post)	

^{*} For scales, higher number indicates better portion control, greater self-efficacy, healthier home food environment, more perceived friend support for healthy behaviors, higher depression score