Evaluating a Brief Type 2 Diabetes Prevention Program with Greater Scalability NCT05822648

April 16, 2023

1. PURPOSE OF THE STUDY

a. Brief Summary

This study aims to test the effectiveness of a Type 2 Diabetes (T2D) prevention program for individuals who have been diagnosed with prediabetes compared to a T2D educational control group. Project health is an obesity prevention program and has produced a 42% to 53% reduction in future onset of overweight/obesity and also produced greater reductions in negative affect compared to assessment-only controls that persisted. Project Health has been adapted to prevent onset of T2D among individuals with prediabetes. The study aims to test the effectiveness of Project Health at reducing BMI, HbA1c levels, increase physical activity and improve glucose control.

b. Objectives

Aim 1 is to test the hypothesis that participants who complete the T2D Project Health will show significantly greater reductions in BMI and HbA1c, the primary outcomes, by 3-month follow-up than participants randomized to the T2D education video control condition.

Aim 2 is to test the hypothesis that participants who complete the T2D Project Health will show significantly greater reductions in self-reported caloric intake and greater increases in physical activity by 3-month follow-up than participants randomized to the T2D education video control condition.

If this pilot and feasibility trial provides evidence that Project Health significantly reduces weight gain and improves glucose control, we plan on conducting a fully-power trial that will test whether this brief, cost effective prevention program significantly reduces future onset of T2D among individuals with impaired glucose control. As such, this represents a translational study on the prevention of T2D.

c. Rationale for Research in Humans

The purpose of this study is to test the effectiveness of a Type 2 Diabetes prevention program, adapted Project Health. This study must use humans due to the nature of the educational aspect because the programs require speech as a method of communication.

2. STUDY PROCEDURES

a. Procedures

Participants will be recruited through flyers, online postings, and other postings at various clinics in the Bay Area. To determine eligibility, during screening participants will be asked their age, gender.

On the flyers and other recruitment materials, participants will be directed to a short survey on a secure platform that only asks for contact information to show interest in the study. The study team will use the contact information provided to set-up a phone screen for interested individuals. IF the participant shows interest through one of the Honest Broker methods (such as MyChart) or through ResearchMatch.org which shares the contact information with the research team, then a member of the research team will reach out to the individual using the contact information provided to thank them for their interest and schedule a phone screen. See section 13 for the phone screen.

After the participant completes the phone screen, a member of the study team will contact them to confirm eligibility. Consent (for ages 18- 65) will be secured prior to enrollment.

Baseline Assessment:
After eligibility is confirmed but before groups begin, the participant will come in for their baseline assessment. At baseline, participants will complete the the Paffenbarger Activity Questionnaire to assess physical activity, the Beck Depression Inventory, and the Eating Disorder Diagnostic Scale. We will also have participants get an HbA1c test and fasting glucose test through the Stanford CTRU. Finally, participants will complete a Bod Pod Assessment, measuring Body Fat. Prior to the start of groups, participants will complete the Automated Self-Administered 24-hr Dietary Recall (ASA-24) to assess dietary intake on 2 weekdays and 1 weekend.

Prevention program:
After baseline assessments are completed, participants will be randomized to either the Project Health groups or the educational control.

Randomization:

We will use a random number generator to determine if participants will be in Project Health or the educational control. If an even number is generated, the participant will be assigned Project Health. If an odd number is generated, the participant will be assigned to educational control. As there is a 50% chance the number will be either even or odd, there is a 50% chance that someone will be assigned either to Project Health or the educational control. It is only after the baseline assessment that individuals will be randomized. This will prevent the assessor at baseline from being influenced by which group the participant will be in. The assessor completing the assessments at post-test and 3-month follow-up will be blind to the participant's condition.

Project Health:
Project Health will be delivered in six 1-hour group sessions that will be held weekly. In addition, participants will be asked to complete 30 mins of response inhibition and attention trainings once per week between the sessions. This program promotes to retain the gradual lifestyle modification designed to bring energy intake into balance with energy output and the food response inhibition and attention training, but will adapt the dissonance-induction activities to focus on the negative

effects of developing T2D in addition to the negative effects of obesity, overeating, and a sedentary lifestyle.

Participants who are assigned to the Project Health condition will receive reminders and writing prompts via a secure text messaging platform, TextMagic. The text reminders will be used to remind participants to complete the writing prompts and one computer task between group sessions. This computer task is a choice of one game that the participants had played during their intervention group. The writing prompts being used will help to reinforce the response inhibition and attention trainings. No personal participant information will be shared or asked for via TextMagic.

Educational Control:

We selected a T2D management psychoeducational comparison condition. To match Project Health, the educational videos will be delivered in 6 1-hour blocks. The educational group will be instructed to watch videos on nutrition, exercise, and how to maintain general health during the lifespan

If participants are randomized to Project Health, they will meet in groups of 6 individuals led by clinician. Groups will meet once a week in-person for an hour, for six weeks. Each week involves homework that participants are asked to complete before the next session. If participants are assigned to the Education intervention, they will be asked to watch one-hour of videos including information about T2D each week for six weeks.

Post-Test:
After the six weeks of either Project Health or the educational control, participants will be asked to complete the same assessments that they did at baseline, but not the blood tests.

3-Month Follow-up:
At 3-month follow-up, participants will again complete the assessments. After the 3-month follow-up, participants have completed all study responsibilities.

1-Year Follow-Up:
We propose to collect A1c data over 1 year follow up
First we will check to see in Epic if the participant is a Stanford patient.
If they haven't had a recent test or not in Stanford system we will ask if they would be willing to send any recent A1c blood test results.
If no to both, the participant will be offered to have an HbA1c kit sent to them to do a finger prick at home. The participant will send the kit to the research lab in Minnesota to be processed. Kits come with already pre-paid shipping labels that are addressed only to the Minnesota lab, no return address or any PHI from the participant is included. The participant will be offered a $10 Amazon gift card for completing and shipping the HbA1c kit.

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b. Procedure Risks

These research procedures provide minimal risk to subjects. We are using
current and empirically evaluated measures and research staff available who have been fully trained both in administrating physiological interviews. Project Health has also been tested in

multiple trials and has produced only positive effects, there has been no history of symptoms worsening as a result of participating in the program.

The above procedures present minimal risk. Engaging in the intervention modules carries minimal risk for emotional discomfort or stress. Subjects will have the option of not participating in conversations or exercises in the intervention modules that cause them any discomfort. They will also be free to withdraw from participating in the intervention and/or overall study at any time. Survey measures are non-invasive and present minimal risk. Using blood draws for A1c may be minimally invasive but provide no added level of risk or discomfort beyond routine diabetes management tasks.

c. Use of Deception in the Study

Deception will not be used.

d. Use of Audio and Video Recordings

Participants will be informed that we will make video recordings of Project Health groups for clinical supervision and quality assurance purposes. These recordings will be reviewed by the primary investigator to assess intervention fidelity and therapeutic competence of the group leaders. Email supervision based on these ratings will be provided to facilitators which has been found to maximize intervention effects. After they are viewed and rated for fidelity and competence, all records of the recordings will be deleted from devices and destroyed. Recordings are not optional. As the group sessions are in-person it is possible for someone to go out of view of the camera, but their voices will still be recorded. There are three main factors that increase cognitive dissonance: public accountability, level of effort, and voluntary basis. By recording the sessions, public accountability is greatly increased, and the effect of the intervention improves. Thus, if they are in Project Health individuals must be willing to be recorded.

e. Alternative Procedures or Courses of Treatment

There are not any programs designed to decrease risk of T2D.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

If Project Health produces significantly larger improvements than the educational lectures, we will offer the Project Health to educational controls.

g. Study Endpoint(s)

It is important to test whether effects persist at 3-month follow-up even if there are good effects at posttest, as it is possible that the effects may not persist. The effects of this brief prevention program typically have shown good persistence through 3- year follow-ups.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Type 2 diabetes (T2D) is a chronic condition which affects the way the body regulates and uses glucose as a fuel, resulting in excess blood glucose levels, which contributes to disorders of the circulatory, nervous and immune systems. T2D affects approximately 415 million people

globally; an estimated 642 million will be affected by 2040 (International Diabetes Federation, 2015). T2D is the leading cause of end-stage renal failure, adult-onset blindness, and nontraumatic amputations, and markedly increases risk for cardiovascular morbidity and mortality (World Health Organization, 2010), resulting in a significant burden on individuals and the healthcare system (Li, Qu, Zhang, et al. 2015).

Three randomized trials have now confirmed that lifestyle modification interventions, which teach lifestyle modifications that reduce excess body weight can significantly reduce progression to T2D among individuals with prediabetes (Pan, Li, Hu, et al, 1997; Tuomilehto, Lindstrom, Eriksson, et al, 2001; Diabetes Prevention Program Research Group, 2002). However, these interventions were very intensive, often requiring over 40 hours of individual counseling and coaching delivered over 1- to 2-year periods. Such intensive interventions, particularly when delivered on an individual basis, are extremely difficult to broadly implement (Damschroder & Hagedorn, 2011). A briefer intervention that would be less expensive to deliver would be much easier to implement on a broad enough scale to reduce the population prevalence of T2D. For instance, we have been able to implement a brief 4-hour eating disorder prevention program to over 6 million adolescent girls in 140 countries to date (Stice et al., 2021).

Fortunately, our research team created a brief obesity prevention program that has produced a 42% to 53% reduction in future onset of overweight/obesity in three randomized controlled trials (Stice et al., 2008; 2014; 2020). The 3-hour Healthy Weight obesity prevention program produced a statistically significant 53% reduction in overweight or obesity onset over 3-year follow-up versus assessment-only controls for adolescent girls and young women with body image concerns and produced.

b. Findings from Past Animal Experiments

N/A

4. RADIOISOTOPES OR RADIATION MACHINES

a. Standard of Care (SOC) Procedures

Identify Week/Month of Study	Name of Exam	Identify if SOC or Research
<Enter text or "NA">	<Enter text or "NA">	<Enter text or "NA">

b. Radioisotopes

i. Radionuclide(s) and chemical form(s)

N/A

ii. Total number of times the radioisotope and activity will be administered (mCi) and the route of administration for a typical study participant

N/A

iii. If not FDA approved: dosimetry information and source documents (package insert, Medical Internal Radiation Dose [MIRD] calculation, and peer reviewed literature)

N/A

c. Radiation Machines – Diagnostic Procedures

i. Examination description (well-established procedures)

N/A

ii. Total number of times each procedure will be performed (typical study participant)

N/A

iii. Setup and techniques to support dose modeling

N/A

iv. FDA status of the machine and information on dose modeling (if procedure is not well-established)

N/A

d. Radiation Machines – Therapeutic Procedures

i. Area treated, dose per fraction/number of fractions, performed as part of normal clinical management or due to research participation (well-established procedures)

N/A
FDA status of the machine, basis for dosimetry, area treated, dose per fraction and
N/A

ii. Source: eProtocol Section 4d (box 2)

5. DEVICES USED IN THE STUDY

a. Investigational Devices (Including Commercial Devices Used Off-Label)

Investigational Device 1	
Name:	N/A
Description:	N/A
Significant Risk? (Y/N)	N/A
Rationale for Non-Significant Risk	N/A
Investigational Device 2	
Name:	N/A
Description:	N/A
Significant Risk? (Y/N)	N/A
Rationale for Non-Significant Risk	N/A
Investigational Device 3	
Name:	N/A
Description:	N/A
Significant Risk? (Y/N)	N/A
Rationale for Non-Significant Risk	N/A

b. IDE-Exempt Devices

IND-Exempt Device 1	
Name:	N/A
Description:	N/A

IND-Exempt Device 2	
Name:	N/A
Description:	N/A
IND-Exempt Device 3	
Name:	N/A
Description:	N/A

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

a. Investigational Drugs, Biologics, Reagents, or Chemicals

Investigational Product 1	
Name:	N/A
Dosage:	N/A
Administration Route:	N/A
Investigational Product 2	
Name:	N/A
Dosage:	N/A
Administration Route:	N/A
Investigational Product 3	
Name:	N/A
Dosage:	N/A
Administration Route:	N/A

b. Commercial Drugs, Biologics, Reagents, or Chemicals

Commercial Product 1	
Name:	N/A
Dosage:	N/A
Administration Route	N/A
New and different use? (Y/N)	N/A
Commercial Product 2	
Name:	N/A
Dosage:	N/A
Administration Route	N/A
New and different use? (Y/N)	N/A
Commercial Product 3	
Name:	N/A
Dosage:	N/A
Administration Route	N/A
New and different use? (Y/N)	N/A

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

(i) All subjects will be enrolled at Stanford. We expect to enroll 62 participants.
(ii) N/A
(iii)Participants are overweight adults (BMI between 25 and 40 kg/m2) between 18-65 years old who have been diagnosed with prediabetes, defined as having elevated HbA1c (5.7-

6.4%). As this is the first test of an adapted Project Health for individuals with Type 2 Diabetes, recruiting a sample that will most likely benefit from it is important in testing its effectiveness.

b. Age, Gender, and Ethnic Background

All participants will be 18-65 year-olds. All ethnicities and genders will be recruited and included.

c. Vulnerable Populations

This study will only enroll adults. All individuals will be consenting on behalf of themselves. We are not specifically recruiting from vulnerable populations, although as long as they meet eligibility criteria then they will be able to participate in the study. We are not specifically recruiting students or employees, but if they are interested in participating, they will not be excluded. The consent form notes the voluntary nature of their participation and that they will not lose any benefit or medical care that they are otherwise entitled for withdrawing from the study.

d. Rationale for Exclusion of Certain Populations

Children are not included as Type 2 Diabetes is not common among children.

e. Stanford Populations

Stanford students, employees, and laboratory personnel may be eligible to participate in this research study. We cannot estimate how many that might be. If any such participants are enrolled, they will go through the informed consent process as any other participant would and receive payment for their participation.

f. Healthy Volunteers

N/A

g. Recruitment Details

Recruitment will take place using both online and in person strategies. Online - Ads will be posted on the internet using social media sites: Twitter, Facebook, and Instagram, community forums: Craigslist and Reddit, and the study website. We will manage an instagram and facebook page with postings about the study using the approved images and captions. All posts on the page will be moderated by the research team and set to block commenting or posting by the public. Posting of online ads will be managed based on inclusion criteria, i.e. within the area of the sites, age, etc. If not possible to post within the geographic area we are recruiting (such as on Reddit), then we will specify within post that potential participants must live near the Bay Area. the Social media recruitment posts will be set up such that the security settings do not allow participants or others from the public to post on the wall/public forum. If this is not possible due to the social media platform's settings, the social media posts

will be monitored and any disclosures of PHI removed.

Additionally, all participants who call the Stanford or associated clinics for services are asked about their willingness to be contacted for research. We will put flyers in the community as well as send postcards via email. We will also be able to recruit at clinics around the Bay Area.

Potential participants will also be contacted through our endocrine and IRB approved patient recruitment lists, including the Stanford Diabetes Research Center's clinical registry (in which subjects have already consented to be recruited for research studies). Stanford Diabetes Research Center's clinical registry is composed of individuals who have expressed interest in participating in research and have voluntarily included their name in the registry to be contacted for potential participation in studies. More information on the SDRC registry can be found at: https://sdrc.stanford.edu/clinical-research-registry.

Participants will also be recruited through online flyers sent out through established diabetes-related listervs run by diabetes organizations.

The IRB-approved recruitment flyer and email will also be circulated through online websites, forums newsletters, emails listervs, and social media pages (primarily run by diabetes organizations such as DYF and JDRF) and shared with diabetes providers and clinics within and outside of Stanford.

We are also going to use Researchmatch.org.

In addition, we will partner with the Research Participant Engagement Program (RPEP) team for Honest Broker outreach. Potential participants are identified via STARR and invited by RPEP team (honest broker) on behalf of study team. See Section 16 for Honest Broker study invitation letters. We will be using Direct Email / SHC Epic MyHealth / Postal Mail honest broker outreach. For Direct Email, RPEP team provides (via secure Box folder) contact info from interested participants to study team. For Epic MyHealth, study team receives only the interested responses via Epic MyHealth InBasket. For Postal Mail, study team may support the process by sticking pre-printed address labels (created by RPEP, the honest broker) on the envelopes. Invitations will not be sent to the same individual via more than one honest broker outreach method, unless as a separate reminder. The study team will respond to the patient via MyHealth thanking them for their interest, ask them to set up a time to talk on the phone, obtain verbal consent before questions are asked over the phone, and then send our screening survey link that includes a consent and HIPAA Authorization, and confirm their availability for an initial visit.

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h. Eligibility Criteria

i. Inclusion Criteria
(1) 18-65 years of age
(2) BMI (kg/m2) ≥ 25 or ≥ 23 for Asian Americans
(4) high-risk prediabetes, defined as 1 of 3 criteria: (1) FPG value = 110-125 mg/dL,

(2) HbA1c value = 6.0-6.4%, or (3) both FPG 100-109 and HbA1c 5.7-5.9%
(3) ability to read and speak English at an 8th grade level (to complete assessments and potentially participate in the group intervention)

ii. Exclusion Criteria

(1) a medically confirmed diagnosis of type 1 diabetes,
(2) use of anti-hyperglycemic medications (e.g., Metformin) or weight-loss medications
(3) having a medical condition that would interfere with engagement in a behavior change program (e.g., cancer)
(4) pregnancy

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i. Screening Procedures

Participants will indicate interest by completing a short survey on a secured platform, such as REDCap, that asks them for contact information. From there, a member of the research team will contact them to conduct the telephone screening where verbal consent will be obtained. Prior to the phone screen, the research team will send the potential participant the consent to review before going through it with the research team.

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j. Participation in Multiple Protocols

As a part of the informed consent process, subjects will be asked if they are participating in any other research projects. Their participation in other protocols will not exclude them from participation in this study.

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k. Payments to Participants

Participants will be eligible to earn up to $150 for completion of all study activities. $25 will be awarded per completion of each assessment and blood testing (pre-test, post-test, 3-month) and then an additional $25 if all assessments are completed. With a $10 gift card for 1-year follow-up.
(1) baseline = $25
(2) baseline blood tests = $25
(3) post-test = $25
(4) 3 month follow-up = $25
(5) 3-month follow-up blood test = $25
(6) completion of all the previous five = $25
(7) 1-year follow-up blood test = $10 Amazon gift card

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l. Costs to Participants

There will be no cost to participants.

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m. Planned Duration of the Study

It is estimated that the study will take one year. The screening is expected to take 10-15 minutes. Active participation will last about 4 months. Participants will complete the baseline assessment (1.5 hours) and collect HbA1c levels, then complete the six-week intervention (each session is one hour), and then a post-test assessment (about 1.5 hours) and HbA1c. After the initial baseline assessment and the post-test, participants will have completed all necessary tasks until the 3-month follow-up where they will complete the same tasks as the baseline and post-test assessments. While the groups are running, data analysis on baseline data will begin. Once we have complete data for posttest and 3-month follow-up, we will conduct data analysis on the outcome measures. We propose to collect A1c data over 1 year follow up.

First we will check to see in Epic if the participant is a Stanford patient. If they haven't had a recent test or not in Stanford system we will ask if they would be willing to send any recent A1c blood test results. If no to both, the participant will be offered to have an HbA1c kit sent to them to do a finger prick at home and send it to a lab in Minnesota to be processed.

9. RISKS

a. Potential Risks

i. Investigational devices

N/A

ii. Investigational drugs

N/A

iii. Commercially available drugs, biologics, reagents or chemicals

N/A

iv. Procedures

Data Collection: Self-reported survey will be kept confidential and collected online via secure RedCap database system. There are no known psychological risks to subjects completing self-report subjective rating scales or participating in the intervention sessions. However, the survey and intervention may contain items or questions that make the subjects feel uncomfortable in that they ask about their physical and psychological health and feelings/emotions. Subjects will be informed that any items on questionnaires or topics discussed in the intervention modules that produce these effects may be skipped or ignored.

Protections Against Risk. All research staff have completed rigorous training in the protection of human subjects, including CITI training. The plan for protecting privacy and confidentiality recognizes that the protection of privacy in studies involving sensitive data is of utmost importance. We will attempt to do this in several ways. The research assistant will introduce the study to eligible participants and explain the purposes, benefits, and risks of the project to the subjects, and offer them an opportunity to ask questions and/or decline participation. The voluntary and confidential nature of the

research, as well as limits to confidentiality, will be highlighted during informed consent process. Study participation will not interfere with clinical care and all patients have standard access to the treatment team on a routine (clinical care) and emergency basis. All responses to interview items will be given by subjects in private. Survey data collection will only occur through tools and resources that have acceptable security features. We will minimize all communications that involve names or other identifying information. All clinically-relevant and study information will be kept in locked files in locked offices or password protected files

All recordings of intervention sessions will be saved on a password-protected secure server. Information about subjects will not be accessible to any non-authorized study personnel without the written consent of the subject. In all datasets we will use ID numbers only. A separate dataset linking names with ID numbers will be accessible only to authorized study personnel under the direction of the PI.

There's a small chance there will be some discomfort upon pricking their finger and collecting their HbA1c levels if they have never done one before. Sometimes the discomfort can last a day or two but often is mild and goes away. If the discomfort persists, we will ask them to contact us.

v. Radioisotopes/radiation-producing machines

N/A

vi. Physical well-being

There is a chance of some discomfort upon having their blood drawn and collecting their HbA1c levels if they have never done one before. Sometimes the discomfort can last a day or two but often is mild and goes away. If the discomfort persists, we will ask them to contact us.

vii. Psychological well-being

Psychological discomfort may result from some of the questions in the questionnaires, but participants may choose not to answer questions if they feel uncomfortable. Additionally, participants may feel uncomfortable sharing in the group setting. If they feel uncomfortable, they will be able to communicate with the group leaders, RA, or principal investigator to express feelings of discomfort and hopefully be comforted. In past trials Project Health, participants have not reported discomfort discussing sensitive materials in group sessions.

viii. Economic well-being

N/A

ix. Social well-being

N/A

x. Overall evaluation of risk

Minimal risk.

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

Confidentiality: All materials, such as questionnaires and data collected from each participant will be identified by an ID number in order to ensure confidentiality. Additionally, all researchers will have a thorough understanding of the participants' rights to confidentiality.

Emotional discomfort: Participants will be reminded of their right not to answer specific questions during the research visit. Research assistants will be sensitive to signs of exhaustion or other distress and will schedule breaks or will end the visit as warranted to protect the comfort of participants. All participants will receive information about whom to contact if they have lingering questions, concerns, or distress regarding any aspect of the study.

Beck Depression Inventory: The Beck Depression Inventory will be included as one of our study surveys. Once this survey is filled out by a participant, the study team will check all responses, specifically question #9 that addresses suicidal ideation. If anything above a “0” is answered, the study team will follow appropriate procedures and talk with the participant. The study team has undergone crisis management training and been given a crisis protocol sheet that includes questions to assess the severity of the suicidal ideation with the participant. This protocol contains a resourcing tool and steps that the participant can take if future suicidal ideation occurs. We will also provide a counseling referral list with contacts in the Palo Alto area.

All research staff have completed and will maintain rigorous training in the protection of human subjects, including CITI training. The plan for protecting privacy and confidentiality recognizes that the protection of privacy in studies involving sensitive data is of utmost importance. We will attempt to do this in several ways. Research staff will introduce the study to eligible participants and explain the purposes, benefits, and risks of the project to the subjects, and offer them an opportunity to ask questions and/or decline participation. The voluntary and confidential nature of the research, as well as limits to confidentiality, will be highlighted during informed consent process. Study participation will not interfere with clinical care and all patients have standard access to the treatment team on a routine (clinical care) and emergency basis. Survey data collection will only occur through tools and resources that have acceptable security features. We will minimize all communications that involve names or other identifying information. All clinically-relevant and study information will be kept in locked files in locked offices or password protected files.

All recordings of intervention sessions will be saved on a password-protected secure server. Information about subjects will not be accessible to any nonauthorized study personnel without the written consent of the subject. In all datasets we will use ID

numbers only. A separate dataset linking names with ID numbers will be accessible only to authorized study personnel under the direction of the PI.

d. Study Conclusion

If the subject wants to end their participation in the study at any time, they can do so. If the investigator determines that participation would be harmful to the subject or investigator in any way, they can terminate the experiment. If not ended early, participate participation will end after the 3-month follow-up.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

N/A

ii. Person(s) responsible for Data and Safety Monitoring

N/A

iii. Frequency of DSMB meetings

N/A

iv. Specific triggers or stopping rules

N/A

v. DSMB Reporting

N/A

vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Yes

vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

No

f. Risks to Special Populations

N/A

10. BENEFITS

Participants, in both the Project Health groups and the educational control, may experience a reduction in weight gain and an improvement in glycemic control. Thus, we anticipate that participants will show improvements in both mental and physical health, but that improvements will be greater for intervention verses educational control participants. If the Project Health is found to be effective there is justification to test it on a larger scale and hopefully implement it broadly among this high-risk population.

11. PRIVACY AND CONFIDENTIALITY

Health information including height and weight information, medical diagnosis, date of diagnosis, A1c levels, psychological and behavioral measurements (surveys), and demographic information such as age, gender, ethnicity, and psychological history. We will also obtain names and contact information (phone number and email) for study coordination purposes, but this information will be securely kept separate from research data and only accessed by research staff. We will not disclose this information to others.

All patient information will be strictly confidential and protected health information will not be released to those outside of the research study. The only information that will be released will be de-identified information reported at the group (not individual) level so that individual information will not be identifiable in any way. After obtaining electronic consent for study participation, all participants will be assigned a unique identification number that will be used for all study documentation. A list of participant names and unique identifiers will be kept in a password-protected database on a secure server accessible only by the PI and trained research staff. The list will be destroyed after publication of study findings. All information a password-protected computer. Other Stanford University's Lucile Packard Children's Hospital staff may become aware of an individual's study participation; however, hospital regulations require that all healthcare providers treat medical records information confidentially. All recordings of intervention sessions will be saved on a password protected secure server. Information about subjects will not be accessible to any non-authorized study personnel without the written consent of the subject. In all datasets we will use ID numbers only. A separate dataset linking names with ID numbers will be accessible only to authorized study personnel under the direction of the PI.

The Research Participation team will create an Honest Broker Export file based on the inclusion/exclusion criteria entered by the study team in the STARR Cohort Discovery Tool. The following information will be used to create the Honest Broker export file: name, age, address, diagnosis, gender, contact information. Only after patients (identified via STARR and invited via honest broker) express interest in the study will the study teams use Epic to help obtain contact information as to set up a time for the initial phone screening.

The following information from Epic will be required to confirm inclusion/exclusion criteria: name, age, address, diagnosis, gender, contact information. Only after patients (identified via STARR and invited via honest broker) express interest in the study will study teams use Epic to help confirm inclusion/exclusion criteria. The PHI accessed will be the minimum necessary to determine eligibility.