Family Diabetes Prevention Program Pilot Study

NCT05358444

(Updated 9/23/22)

1. Abstract

There is a rising burden of type 2 diabetes and associated risk factors among children, disproportionately affecting low-income and minority communities. Addressing lifestyle-associated risk factors is an integral component of type 2 diabetes prevention. To be most effective, efforts targeting children require caregiver engagement and a family-oriented approach. Notably, adult caregivers could also benefit from a family-oriented approach to promote health behavior change. To date, however, there have been few sustainable or widespread efforts to develop family-oriented diabetes prevention programs that have multi-generational impacts. In this research effort, we will conduct a non-randomized pilot feasibility study of a family-oriented Diabetes Prevention Program (FDPP), augmenting the CDC's existing evidence-based Diabetes Prevention Program for adults with additional sessions addressing health behaviors in children. A concurrent control group will be enrolled. The primary objective is to examine FDPP process measures of feasibility, acceptability and program delivery fidelity. We will also preliminarily explore the FDPP's impact on intervention targets and child and caregiver health behavior change and health outcomes.

We will enroll adult DPP participants who live in households with children ages 18 and under as concurrent controls, to compare adult DPP attendance and health outcome measures with the FDPP participants. .

We hypothesize that the FDPP will be feasible to deliver and acceptable to participants.

Objectives

The primary objective is to examine FDPP process measures of feasibility, acceptability and program delivery fidelity.

A secondary objective is to preliminarily explore the FDPP's impact on proximal intervention targets (parent/caregiver knowledge, attitudes, self-efficacy and parenting self-efficacy and family home environment) and child and caregiver health behavior change and health outcomes.

2. Background

The burden of type 2 diabetes (and related conditions such as obesity) is rising among children in the United States and advancing diabetes prevention efforts among high-risk children is a public health priority. Efforts that address modifiable risk factors, such as obesity or physical inactivity, have the potential to prevent premature type 2 diabetes development, and can also have lasting salutary effects on the risk of developing diabetes and other conditions, such as cardiovascular disease, across a child's life course. Further, efforts focusing on low-income and minority children, who have a higher burden of modifiable risk factors, can mitigate diabetes-related health disparities. To date, there have been few efforts that have effectively targeted modifiable risk factors in children at high-risk for diabetes.

Caregiver engagement in the National Diabetes Prevention Program's (National DPP) lifestyle change program represents a novel opportunity to address modifiable diabetes risk factors in high-risk children *and* adults in an effective and sustainable manner. The year-long, evidence-based lifestyle change program for adults at risk for type 2 diabetes is a core component of the Centers for Disease Control and Prevention's (CDC) national type 2 diabetes prevention efforts, and is increasingly being offered in community-based settings. Children of eligible adults represent a high-risk population, due to shared family history, race/ethnicity, and lifestyles.

The evidence-based National DPP curriculum consists of a minimum of 22 modules delivered in group settings over 12 months. The program's effectiveness is ascribed to its comprehensive approach to behavior change, including imparting behavioral self-management skills and strategies and frequent contact, feedback and support from lifestyle coaches. The program's content and structure provides an ideal backbone for adding supplementary, child-related modules to enable caregivers to develop similar skills for children's health behavior change.

A family-oriented approach to diabetes prevention programming could also enhance diabetes prevention efforts among high-risk adult caregivers. Our preliminary work among caregivers already participating in a National DPP lifestyle change program suggests that the opportunity to learn about improving child health would have enhanced their interest in program participation. In addition, data from

qualitative interviews of former DPP participants who are caregivers of young children, revealed that caregivers face unique challenges to lifestyle change that could be addressed via a family-oriented DPP.

Using this preliminary data, we have created a family-oriented adaptation of the DPP, to be piloted via the research efforts described in this IRB application. These proposed research efforts will leverage an existing clinical program at Johns Hopkins, the Brancati Center for the Advancement of Community Care's Diabetes Prevention Program.

3. Study Procedures

a. Study design, including the sequence and timing of study procedures

The **study design** is a non-randomized pilot feasibility study of the Family DPP lifestyle intervention compared to a concurrent control group (defined below). in which adult participants (and one index child that they care for, who is 5 through 12 years of age at time of recruitment), will be assigned to receive the family-oriented of the Diabetes Prevention Program (FDPP) pilot intervention. A separately recruited group of adult DPP participants will serve as a concurrent control group.

Of note, the DPP lifestyle intervention is currently being as a clinical program offered via community-academic partnerships by the Johns Hopkins Brancati Center for the Advancement of Community Care, with ongoing quality improvement assessment under the IRB protocol "IRB00179397: Evaluation of the Johns Hopkins Diabetes Prevention Program." The DPP intervention as carried out by the Brancati Center team consists of streamlined processes for recruitment, eligibility screening, enrollment, and continued data monitoring.

The study procedures as listed below will distinguish research procedures from this "routine care." Of note, the FDPP will consist of *all* elements of the DPP, with augmentations described as below, and thus will involve delivery of at least the standard of care.

Intervention Content Description

1) The Family Diabetes Prevention Program consists of the CDC's National Diabetes Prevention Program, augmented with additional child-related content.

The CDC's National Diabetes Prevention Program (DPP), as delivered by the Brancati Center, consists of:

- Delivery of the CDC-certified Prevent T2 curriculum, with additional CDC- approved modifications, with a total of 32-34 sessions delivered over a 12-month period. In the initial "core" period (first 6 months), there are at least 16 sessions delivered on a weekly basis. In the "post-core" period, additional (at least 6) sessions are offered over a 6 month period.
- The sessions are group-based, and led by a CDC-certified lifestyle intervention coach. Sessions are delivered either in-person, at community-partner sites or on the JH campus, or via a virtual synchronous platform (Zoom).
- The Brancati Center follows all CDC guidelines (https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf) with regards to program content and data collection. Baseline data collection includes demographics relevant to the program. Throughout the program, data are collected on participants' weight, minutes of physical activity, self-monitoring of diet, and attendance. These data are currently maintained in a secure, RedCAP database.
- In addition to delivery of the evidence-based, CDC recommended curriculum, the Brancati Center team has identified and implemented several strategies to address both long-term engagement and barriers to weight loss and dietary modification. These include:
    - For engagement:
        - Providing participants with Progress Charts that show their individual weight loss, the average weight loss of their group, and how their group's weight loss compares to other groups
        - Offering activities outside of the regularly scheduled group (e.g., informational sessions)

    - Engagement campaigns (e.g., “Spring into Summer”) where participants receive small incentives (e.g., gift cards, healthy snacks, exercise equipment) for attendance, self-monitoring, and being physically active
    - Raffles
    - Guest speakers
  - For barriers related to weight loss and self-monitoring:
    - Grocery store tours
    - One-on-one nutrition counseling from a registered dietitian
    - Providing sample recipes and food items to trial

2) Adult participants will be engaged in the Family-Oriented Diabetes Prevention Program (FDPP). There may be non-study participants (other Brancati Center DP participants) also participating in the group (as DPP participants).
   - The FDPP has been developed as an *augmented* version of the DPP. That is, adult participants would receive all the above-mentioned elements of the DPP intervention (delivered in the same manner as the DPP intervention), with a few augmentations that are not intended to alter the evidence-based DPP program, but rather supplement it to address caregivers’ own lifestyle change efforts while having children at home AND to introduce basic concepts regarding healthy child habits related to dietary intake, physical activity and screen time, and sleep. This supplementation/augmentation is achieved via:
     - Addition of content to certain DPP sessions that will ensure barriers to/facilitators of lifestyle change that other family members (including children) pose to adult participants are discussed.
     - Addition of 2 supplementary sessions during the core period that will specifically discuss making lifestyle changes while being the caregiver of children and explore how family members, including children, serve as motivation for lifestyle change.
     - Child-focused sessions in the “post-core” period of the DPP (see supplementary material which includes proposed schedule), which will be delivered to adult participants, and accompanied by separate sessions for children. Adults and children will first present together for the child-focused sessions, then separate, and come together at the end. At the end, adults and children will convene to discuss what they learned and come up with basic child or family health behavior goals related to the health behaviors. These sessions discuss pediatric guidelines or recommendations endorsed by the American Academy of Pediatrics or other relevant national society (e.g., Centers for Disease Control and Prevention, American Heart Association), and will also cover strategies and tips to enable caregivers to support children in achieving these goals. The topics to be covered will include:
       - MyPlate (discussing MyPlate guidelines, and how to achieve variety and balance in meals for children)
       - Fruit and Vegetables (discussing guidelines around children’s intake and tips and strategies to increase fruit and vegetable intake)
       - Sleep (discussing sleep recommendations, including how to promote sound sleep of good quality in children)
       - Reducing Sugary Beverages (discussing sugar intake guidelines and how to promote healthier beverage consumption)
       - Physical Activity (discussing physical activity guidelines and how to support kids to be active on a daily basis)
       - Screen time (discussing screen time guidelines, smart screen time use and strategies to help limit children’s screen time)
       - Family Exercise Activity (a session in which adults and children will be guided through a fun physical activity, such as Zumba).
       - Family Cooking Activity (a session in which adults and children will be guided through preparing a healthy meal.)
     - A sample Family DPP schedule included in this IRB application under “Supplementary Material.”

3) **Note on children as participants in the FDPP:** Both the FDPP and National DPP interventions are intended to be delivered primarily to the adult participant (caregiver of the child). For the FDPP, children may be present during child-focused modules as noted above. During these sessions, the children will engage in age-appropriate activities, games and discussions to learn basic concepts about healthy lifestyle behaviors. This would be done separate from the adult caregivers (a separate room or Zoom room, if possible\), and then they will join the adult caregivers at the end of the session for a group discussion.

4) Concurrent Control Group: The adults in the concurrent control group will be recruited (as detailed below) from participants in the Brancati Center's Diabetes Prevention Program.

Recruitment, Screening Eligibility and Enrollment: Intervention Arm

Recruitment for Intervention Arm:

We will recruit adult participants, and one index child, through several means as detailed in "Section 13"." This will include

1) Recruitment from adults who are outreached for the Brancati Center's Diabetes Prevention Program. After these adults are deemed eligible for the Diabetes Prevention Program for screening, they would be asked the following question by Brancati Center DPP team members "There is a research study for DPP participants that you may be eligible for. This study involves adults in the DPP and children ages 5 through 12 years that they care for. As part of the study, you would be enrolled in a "family-oriented" version of the DPP, which would include some sessions related to children's healthy behaviors in the second half of the program. In addition to you participating in the DPP, you and one child would be asked to complete surveys and provide some other data 3 times during the program, and potentially participate in an interview after the program. You would be compensated $50 for each of the data collection points. Would you be interested in learning more about the study?" If potential participants are interested, their contact information would then be provided to the Family DPP study team for recruitment and screening eligibility.

2) Flyers in clinical sites and community partner sites, with the flyer also posted to the Brancati Center's Facebook Page and website. We will also request community partner organizations in Baltimore to disseminate the flyers to their community members (such as through through in-person events, via e-mail or with announcements, or by posting on their social media sites). We will also advertise via paid Facebook advertisements. We will also request community partner organizations in Baltimore to share with their community members including at in-person events and via e-mail or by posting on their social media sites. We will also advertise via paid Facebook advertisements. The flyers will have a contact study email and also phone number for participants to call. The phone number will be that of a study team member; the email will only be accessible to study team members. A telephone screening script will be used when a study team member discusses the study with potentially interested participants, to assess eligibility. If a participant provides their email address as contact information, we will outreach via telephone and also if needed via email from the FamilyDPP@jh.edu email account.

The email outreach will read:

"Thank you for your interest in the Family Diabetes Prevention Program Pilot Study.

(We have tried to reach you also via the telephone number you provided [note: this will be included if applicable]).

You may also reach us via calling (410-955-9869 or 443-540-5295), or responding to this email with the phone number you would like us to call and/or if there are specific days or times you would like us to call you.

Thank you again for your interest.

Sincerely,

Maya Venkataramani MD, MPH

Principal Investigator

3) Recruitment from clinical providers (NPs, PAs or physicians) at sites such as East Baltimore Medical Center (if approved by JHCP Research committee). The study team will present to providers at this site to describe the study and general eligibility criteria; providers will be provided flyers. Providers will be asked only to provide the patient's name and contact information via a secure email to the study team. They will be asked to document in the chart "I discussed the referral of the patient to the Family Diabetes Prevention Program team for the Family DPP pilot study. The patient agreed to the referral."

4) Recruitment via the Johns Hopkins ICTR's Johns Hopkins Studies Facebook Page, which includes Facebook advertising via the ICTR to recruit study participants for Johns Hopkins Studies; the Facebook Ad Plan is uploaded as a document in question 13.

Screening eligibility for Intervention Arm

Potential adult participants who are referred by the Brancati Center DPP team as per their interest in learning more about the study, will have already undergone screening to ensure they meet DPP-related inclusion criteria (are eligible as adults for participation in the DPP), as per routine protocols for the DPP. Screening of these adults for additional inclusion criteria for the study (e.g., being a caregiver of an eligible child), will be conducted by a study team member via a separate outreach call. For those potential adult participants recruited via other means, the study team member will also conduct DPP eligibility screening as per the Brancati Center's practices.

For child participants, screening eligibility will be conducted via the adult participant. It is possible, given the definition of caregiver that is used, that the caregiver may not be able to answer specific questions regarding the child's inclusion criteria. If this is the case, the child's parent or legal guardian will be contacted to confirm the child's eligibility.

If a caregiver has more than 1 child in the eligible age range, the study team member conducting the screener will use a random number generator to select one child randomly, and assess the eligibility of this child. If the child is not eligible, then the next child's eligibility will be assessed. If the caregiver expresses a strong desire to assess the eligibility of a certain child in particular, then the study team member will be advised to start with the eligibility screening of this child.

Enrollment of the Intervention Arm

- Enrollment of adult participants (and child participants) in the intervention arm, after eligibility screening, completion of adult consent process and the child assent (with parent or legal guardian consent) process (Details regarding consent and assent as detailed in Sections 14-17 of the eIRB application).
- Any related enrollment processes related to the adult participant's participation in the DPP as routine care, will be conducted by the Brancati Center team as per routine practices for DPP enrollment.
- For the child, the enrollment form will confirm parent/legal guardian contact information (emergency contact information), the child's pediatrician, and food or other allergies to be aware of.

Randomization

- Participants will not be randomized to the intervention. All participants who are recruited for the intervention arm will be engaged in the FDPP intervention.

Recruitment and Screening Eligibility: Concurrent Control Group (Control Arm)
Recruitment of Concurrent Control Group (Control Arm):

The concurrent control group will consist of adults in the Brancati Center's DPP (who started the program within 6 months of the Intervention group) and who have children less than 18 years of age living in their household. We will recruit adult participants for the concurrent control groups through several means as detailed in "Section 13"." This will include

1) Recruitment from adults currently participating in Brancati Center DPP groups (which have started within 6 months of the Intervention Arm groups): During a DPP session, participants will be read a brief paragraph regarding the concurrent control group as follows and a flyer will also be distributed to group participants via email:

"There is a research study for DPP participants that you may be eligible for. This study involves adults in the DPP who have children less than 18 years living in their household. As part of the study, you would be asked to complete surveys once. The study team would also compare participants' DPP attendance and outcome data with that of other adult participants who are enrolled in a Family Diabetes Prevention Program pilot study. You would be compensated for your time."

If potential participants are interested, their contact information would be provided to the Family DPP study team; contact information of the study team would also be provided.

2) Recruitment from adults who are to start a Brancati Center DPP program: Individuals who are enrolled in (assigned to a DPP group, but not yet started) will be read the following during routine telephone calls conducted prior to group start:

"There is a research study for DPP participants that you may be eligible for. This study involves adults in the DPP who have children less than 18 years living in their household. As part of the study, you would be asked to complete surveys once. The study team would also compare participants' DPP attendance and outcome data with that of other adult participants who are enrolled in a Family Diabetes Prevention Program pilot study. You would be compensated for your time. Would you be interested in learning more about this study?"

Screening eligibility for the Concurrent Control Group (Control Arm)

Potential adult participants will be screened for eligibility for the concurrent control group by the study team via telephone.

Intervention Delivery (Family DPP)

- The Family DPP intervention itself will be delivered as per routine care practices of the Johns Hopkins Brancati Center's Diabetes Prevention Program. Currently, the program is being delivered via a distance-learning modality (Zoom) to participants, in the setting of the COVID-19 pandemic. Thus, we anticipate that participants will receive the Family DPP in a distance-learning format; there may be the possibility of certain sessions held in-person either at our community partner site or in a conference room of appropriate size on the Johns Hopkins East Baltimore medical campus. We will at the minimum follow Johns Hopkins related guidance regarding in-person gathering size restrictions and other precautions (physical distancing, masks).

- If the enrolled adult study participant is not the parent or legal guardian of the child for whom they identified as a caregiver as per our eligibility definition, then we will request the parent or legal guardian to complete a permission slip for the child's attendance to any session or study visit (uploaded in the eIRB application, Supplementary Materials).

Data Collection for Intervention Arm

1) Data collection associated with Routine Care (DPP protocol):
    - **Adult-related outcomes:** Adult participants who are part of the Brancati Center's Diabetes Prevention Programs (in this scenario, this will include those adults who are receiving Family DPP as well), will have data collected relevant to their participation in the program, as per the routine care protocol. This includes data collected as part of the DPP eligibility screening process and program

enrollment process. During the program, this includes participants' attendance, weight (either measured if in-person visits, or self-reported) and self-reported physical activity minutes.

2) Data collection associated with the study:
    - Survey instruments are included in the Supplementary Materials section of this eIRB application.
    - **Process Measures: Measures of program feasibility** (other than caregiver attendance, which will be collected as per the DPP protocol as above), including recruitment rate, child attendance, child outcome measurement completion, survey administration time and cost (per group) will be tracked during the study by study team members. **Measures of acceptability** will be collected via a survey tool administered to the adult participants after each child-focused session and at the end of the program (the surveys maybe administered either via telephone, in-person or participants may be asked to complete the survey via a secure RedCAP link). **Measures of fidelity** in Family DPP delivery will be collected via a Fidelity Checklist tool that will be completed by a study team member who will observe the child-focused sessions (being delivered to the adult participants). In addition, coaches will be asked to complete a Coach Reflection sheet at the end of each child-focused or child-related session, which will make note of any timing-related issues with content delivery and content-specific issues (graphics that were unclear, discussion points that should be included in future iterations of the material, etc.)
    - **Adult-related outcomes:** For adult participants, we will conduct surveys at baseline, around 6 months (after completion of core period of DPP or Family DPP curriculum) and at the end of the program (12 months). These surveys will cover domains including: household demographics, child demographic information, household social determinants of health, adult health behaviors, self-efficacy for behavior change, and parenting self-efficacy. These surveys will be administered either in-person, via telephone or via RedCAP link.
    - **Child-related outcomes: For child health behavior outcomes**, the adult participant will be asked questions regarding child health behaviors (physical activity, screen time, fruit and vegetable intake, sugary beverage intake, sleep duration). For children ages 9 through 12 years, we will also ask these questions directly of the child; the child will be interviewed with their caregiver present, either in-person or via telephone. For child health outcomes, **specifically change in BMI z-score**, we will collect child height and weight in-person. This will be done in a private space at the community-partner site or the JHM campus (offices of the Brancati Center) or at a location of the participant's preference or choosing.
    - **As per our Data Safety Monitoring Protocol** outlined in Section 32 of the IRB application, we will query participants about possible adverse events using the Adverse Events form at 6 and 12 month data collection points.

<u>Data Collection for Concurrent Control Group (Control Arm)</u>

1) Data collection associated with Routine Care (DPP protocol):
    - **Adult-related outcomes:** Adult participants who are part of the Brancati Center's Diabetes Prevention will have data collected relevant to their participation in the program, as per the routine care protocol. This includes data collected as part of the DPP eligibility screening process and program enrollment process. During the program, this includes participants' attendance, weight (either measured if in-person visits, or self-reported) and self-reported physical activity minutes.
2) Additional data collection for concurrent control group: For adults in the concurrent control group, we will conduct a baseline survey. This survey will cover domains including: household demographics, child demographic information and household social

determinants of health. The survey may be conducted over telephone or via secure REDCap online link (self-administered).

3) Also, as per our **Data Safety Monitory Protocol** outline in Section 32 of the IRB application, we will query participants about possible adverse events using the Adverse Events form at 6 and 12 month time points via telephone.

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

For both the adult intervention arm participants and concurrent control group (control arm) participants, we will obtain adult participant attendance data, as well as weight and physical activity data, from the Brancati Center's Diabetes Prevention Program participant database; these activities are undertaken under IRB protocol "IRB00179397: Evaluation of the Johns Hopkins Diabetes Prevention Program."

c. Study duration and number of study visits required of research participants.

For Intervention Arm:
Study participants would be engaged for approximately 12-14 months.
This time period would involve the delivery of the family-oriented DPP (or control group would receive DPP) lifestyle intervention, during which we would have 3 study-specific visits (at baseline, 6 months and 12 month data points).

For Concurrent Control Group (Control Arm):
Study participants would be engaged for one telephone-based survey administration call.

d. Blinding, including justification for blinding or not blinding the trial, if applicable.

We will not be blinding participants in this pilot study. It would not be feasible to blind participants in the 2 different arms/groups, as they are receiving different interventions (Family DPP versus being enrolled in the DPP).

e. Justification of why participants will not receive routine care or will have current therapy stopped.

Not applicable; the DPP itself is deemed routine care for adults with prediabetes, and enrollment in DPP does not interfere with receipt of other routine medical care. The family-oriented version of the DPP (FDPP) will consist of all elements of the DPP, with additional augmentations with respect to family or child-oriented content, as described earlier, and similarly will not interfere with receipt of other routine medical care for adults or children.

f. Justification for inclusion of a placebo or non-treatment group.

We have revised our study protocol from the original version (dated 4/20/22), to enroll all eligible study participants in the intervention arm. But we will plan on enrolling adult DPP participants with children under the age of 18 in a concurrent control group. This concurrent control group would consistent of adult participants of the Brancati Center's DPP program

who are living in a household with children. In this control group, we would examine adults' attendance and DPP outcomes related to weight loss and physical activity group. This would enable us to preliminarily explore differential impact of the FDPP versus DPP on adult health outcomes, informing elements of a larger comparative effectiveness trial comparing the FDPP versus the DPP.

g. Definition of treatment failure or participant removal criteria.

The DPP (and FDPP) interventions are designed for prevention of type 2 diabetes in adults with prediabetes. Some adult participants may progress to type 2 diabetes while participating in the FDPP; the CDC's guidelines are that these individuals can remain in the DPP lifestyle intervention (given the benefits of lifestyle modification). The Brancati Center team confers with the participant's primary care provider if this were to occur (development of type 2 diabetes) to confirm that the participant is recommended to continue in the DPP.

h. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

Participants will be instructed to continue with routine medical care when the program ends or if their participation ends prematurely.

i. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

Not applicable.

4. Inclusion/Exclusion Criteria

Intervention Arm
The study will enroll adult-child dyads in the Intervention Arm.

Adult inclusion criteria will include meeting all of the following:

1) CDC national criteria for enrollment in the DPP (as used by the Johns Hopkins Brancati Center's DPP programs):
   - Be 18 years of age or older and not pregnant at time of enrollment
   - Have a body mass index (BMI) of ≥25 kg/m^2 (≥23 kg/m^2 , if Asian American).
   - Meet either one of the criteria
     1. Have a recent (within the past year) blood test meeting one of these specifications:
        - i. Fasting glucose of 100 to 125 mg/dl (CMS eligibility requirement for Medicare DPP suppliers is 110 to 125 mg/dl)
        - ii. Plasma glucose measured 2 hours after a 75 gm glucose load of 140 to 199 mg/dl
        - iii. A1c of 5.7 to 6.4%.
     2. Clinically diagnosed gestational diabetes mellitus (GDM) during a previous pregnancy
     3. A positive screening for prediabetes based on the CDC or American Diabetes Association Diabetes Screening Test (a brief questionnaire)

2) being a primary caregiver of at least one eligible child aged 5 through 12 years at time of recruitment (defined as caring for the child, with a responsibility for the child's food, sleep and activity habits,at least 3 days out of the week)

Exclusion criteria for adults will reflect CDC national DPP exclusion criteria. Specifically, adults will be excluded if they are: 1) pregnant; 2) have end-stage renal disease; 3) have type 1 or type 2 diabetes. They will also be excluded if they are concurrently enrolled in a structured weight management program.

Children for whom the eligible adult is a primary caregiver (parent or guardian who cares for the child 3 or more days out of the week), will be considered eligible participants if 1) they are aged 5 through 12 years at time of recruitment; 2) they do not have a medical condition which leads to inability to comply with general pediatric dietary or physical activity goals; and 3) they are not concurrently enrolled in a structured weight management program.

Concurrent Control Group
Inclusion criteria for adults in the control group will include meeting all of the following:
1) Participant in the Brancati Center's Diabetes Prevention Program, in a group that has started within 6 months of Intervention Arm group start
2) Lives with a child less than 18 years of age in their household

5. Drugs/ Substances/ Devices – Not applicable

6. Study Statistics

a. Primary outcome variable.

Primary outcomes will examine process measures.
These will include:

I. Feasibility measures (measuring recruitment, retention and measurement of outcomes, cost):
   a. Recruitment rate, measured as % of eligible caregivers consented to study/time
   b. Caregiver attendance, defined as % of adult, child-focused and all sessions attended
   c. Child attendance, defined as % of sessions requiring child participation attended
   d. Survey administration, defined as mean time for administration of surveys
   e. Total cost per group of program delivery

II. Acceptability measures
   a. Including mean scores on Likert scale-based questions re: satisfaction with program content & structure, willingness to recommend to others

III. Fidelity, as measured by a fidelity checklist that will be completed by a study team member observing the child-focused sessions (specifically, the child-focused sessions delivered to adult participants), and will include measures:
   a. % of tasks/content delivery per session from coach checklist
   b. Total & average scores per domain from observer checklist

b. Secondary outcome variables.

Secondary outcome variables will preliminarily examine:
1. Proximal intervention targets
   a. Caregiver (adult participant) knowledge and attitudes towards healthy-related behaviors
   b. Perceived self-efficacy for behavioral change
   c. Parenting self-efficacy for behavioral change
   d. Family Home Environment
2. Caregiver (adult participant) Health behaviors and health outcomes
   a. Physical activity- total minutes of moderate/vigorous physical activity in weeks preceding and whether caregiver meets DPP physical activity goal of 150 minutes/week of moderate-vigorous physical activity; and dietary
   b. Dietary patterns

c. Percent weight loss from baseline

3. Child health behavior and health outcomes
   a. Physical activity- minutes/day
   b. Screen time (hours/day)
   c. Fruit and vegetable intake
   d. Sugary beverage intake
   e. Sleep duration and sleep behaviors
   f. BMI z-score change

c. Statistical plan including sample size justification and interim data analysis.

As the main objective of this study is evaluating FDPP feasibility and acceptability measures, sample size is primarily informed by budgetary constraints and our experience recruiting individuals for the DPP as well as recruitment for the study thus far.

Feasibility, acceptability and fidelity measures will be analyzed with descriptive statistics (Table 2). Intervention targets will be analyzed as continuous variables (means or numerical scores). Caregiver and child health behaviors will be analyzed as continuous variables (average value/day) and a binary variable (achievement of goal). The caregiver health outcome will be modeled as a continuous variable (percent of weight loss from baseline) and binary variable (achievement of 5% weight loss goal). The child health outcome is the BMI Z-score, a continuous variable. Within-groups, we will use 1) paired-t tests to analyze pre-post changes (from baseline to 6 months and baseline to 12 months) of continuous variables; and 2) McNemar's exact test to examine pre-post changes in proportion achieving behavioral and outcome goals (binary variables). Between groups, we will use 1) 2-sample t-tests to compare the magnitude of mean group change in values of continuous variables; and 2) Fisher's exact test to compare proportion achieving goals at 6 and 12 months. If continuous variables do not meet distribution assumptions necessary for use of parametric tests (t-tests), we will use appropriate non-parametric tests (Mann-Whitney test or, for paired data, Wilcoxon signed-rank test).

d. Early stopping rules.

Not applicable.

7. Plan for reporting unanticipated problems or study deviations.

The plan below is specifically for the **Intervention Arm.**

The PI (Dr. Venkataramani) and co-I (Dr. Maruthur) will bear the responsibility for data and safety monitoring. An independent data safety monitor (Dr. Scott Pilla, Assistant Professor, General Internal Medicine) will be employed as well as below.

During data collection points at 6 and 12 months, adult participants would be queried about possible adverse events (AEs), specifically interim ED visits or hospitalizations, for both themselves and the child enrolled in the study. (see uploaded Adverse Events form). Any and all adverse events would be reviewed by the PI, Dr. Maruthur as co-I and also the independent safety monitor for review; adverse events will be reported to the Johns Hopkins School of Medicine IRB, as well as NIH project office according to the prevailing policies of these review bodies. Study team members will receive training regarding adverse event documentation and reporting.

In addition, adult weight changes and child BMI changes will also be reviewed as follows: at 6 and 12 months, a research team member will send to the independent study monitor a report with participant study ID, age and % weight change for adults or change in BMI for children over the past 6 months. Significant changes in adult weight or child weight-for-height over the review period will prompt the independent safety monitor to notify Dr. Venkataramani or Dr. Maruthur to refer the participants to their primary care physician for additional evaluation.

Of note, the Brancati Center DPP clinical program has team members who provide medical oversight of all participants in the DPP, and adult participants in the study will also be under this as per routine care. During weekly team meetings as part of routine care, adult participants weight changes are reviewed for all participants.

8. Payment and Remuneration

Intervention Arm
Specific to study procedures, the adult participant (as the representative of the adult-child dyad) will be remunerated via $50 gift cards with completion of data collection at each time point (baseline, 6 month, 12 month), for a maximum of $150 related to study procedures In addition, the Brancati Center's DPP provides program-related supports that will continue to be the same for all participants.

Concurrent Control Group (Control Arm)
Specific to study procedures, the adult participant will be remunerated with a $30 gift card with completion of the single data collection point.