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Couple-based lifestyle intervention to prevent type 2 diabetes: protocol for a randomised pilot trial

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ABSTRACT

Introduction Type 2 diabetes is prevalent among US adults. Lifestyle interventions that modify health behaviours prevent or delay progression to diabetes among individuals at high risk. Despite the well-documented influence of individuals' social context on their health, evidence-based type 2 diabetes prevention interventions do not systematically incorporate participants' romantic partners. Involving partners of individuals at high risk for type 2 diabetes in primary prevention may improve engagement and outcomes of programmes. The randomised pilot trial protocol described in this manuscript will evaluate a couple-based lifestyle intervention to prevent type 2 diabetes. The objective of the trial is to describe the feasibility of the couple-based intervention and the study protocol to guide planning of a definitive randomised clinical trial (RCT).

Methods and analysis We used community-based participatory research principles to adapt an individual diabetes prevention curriculum for delivery to couples. This parallel two-arm pilot study will include 12 romantic couples in which at least one partner (ie, 'target individual') is at risk for type 2 diabetes. Couples will be randomised to either the 2021 version of the CDC's PreventT2 curriculum designed for delivery to individuals (six couples), or PreventT2 Together, the adapted couple-based curriculum (six couples). Participants and interventionists will be unblinded, but research nurses collecting data will be blinded to treatment allocation. Feasibility of the couple-based intervention and the study protocol will be assessed using both quantitative and qualitative measures.

Ethics and dissemination This study has been approved by the University of Utah IRB (#143079). Findings will be shared with researchers through publications and presentations. We will collaborate with community partners to determine the optimal strategy for communicating findings to community members. Results will inform a subsequent definitive RCT.

Trial registration number NCT05695170

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Community-based participatory research principles, including collaborative and equitable partnerships between researchers and community members, were used to adapt the CDC's National Diabetes Prevention Program (DPP) curriculum, 2021 PreventT2, to be broadly applicable to romantic couples across communities and cultures (ie, in PreventT2 Together).

⇒ PreventT2 Together is the first lifestyle intervention to systematically incorporate romantic partners in primary prevention of type 2 diabetes.

⇒ This randomised pilot trial of individual versus couple-based diabetes prevention will be carried out in collaboration with an organisation offering the National DPP with 'Full Recognition' status through the CDC's Diabetes Prevention Recognition Program, ensuring those randomised to the individual comparison condition receive the highest quality intervention.

⇒ This pilot trial assesses feasibility in a small sample of couples, and will guide a definitive randomised trial. In this larger trial, we intend to recruit a sample with adequate statistical power to detect between-condition differences in health behaviours, physical and mental health, and relationship functioning.

⇒ PreventT2 Together is likely only applicable to adults in stable and supportive romantic relationships in which both partners want to make lifestyle changes.

INTRODUCTION

Type 2 diabetes was the eighth-leading cause of death in the USA in 2020, and increases risk for the two leading causes of death, cardiovascular disease and cancer.[1–3] Nearly 15% of US adults have diabetes and 90%–95% of these individuals have type 2 diabetes, defined by elevated blood glucose or HbA1c values.[4] Approximately 11% of individuals at high risk for type 2 diabetes convert to type 2 diabetes annually without intervention.[5 6] Individual risk for type 2 diabetes can be determined based on both non-modifiable and modifiable risk factors such as family history, elevated

glucose levels and lifestyle.[7] Furthermore, people from communities of colour experiencing systemic inequities have higher rates of pre-diabetes and type 2 diabetes compared with white individuals,[8] disparities that are expected to increase over time.[9] Thus, there is a need for interventions that are broadly applicable across communities, including for people from racial and ethnic groups that have been marginalised.[4]

Fortunately, lifestyle intervention is efficacious in delaying or preventing progression to type 2 diabetes among individuals at risk.[10] In the large-scale NIH-funded Diabetes Prevention Program (DPP) efficacy trial, type 2 diabetes incidence was lower at the end of the 2.8-year active intervention phase among individuals randomised to the lifestyle intervention arm (58% lower incidence) or the metformin (medication) arm (31% lower incidence) compared with those randomised to the placebo control arm.[5] Participants randomised to the lifestyle intervention arm improved their health behaviours (eg, physical activity, nutrition) and lost weight during the active intervention phase of the DPP trial. Specifically, 74% of participants in the lifestyle intervention arm achieved the physical activity goal (ie, ≥150 min moderate-to-vigorous physical activity (MVPA) per week) and 50% attained the weight loss goal (ie, ≥7% body weight loss).[5] Nonetheless, there is substantial room for improvement, as more than 70% of participants in the individual lifestyle intervention arm did not meet either the physical activity or nutrition change goals of the programme at the end of active treatment, and still half did not meet the weight loss goal.[11] However, results from the DPP efficacy trial demonstrate the lasting preventive effects of both the lifestyle intervention and metformin on type 2 diabetes incidence. At 15-year follow-up, the type 2 diabetes incidence rate remained lower in the original lifestyle intervention and metformin conditions compared with the control condition, despite the fact that all participants (across the three arms to which they were originally randomised) were offered group-based lifestyle intervention following the active intervention phase of the DPP.[6]

Over the past decade, in the largest-scale translation to date, the Centers for Disease Control and Prevention (CDC) has implemented the National DPP, a group-based lifestyle intervention based on the lifestyle intervention arm of the DPP efficacy trial.[12] Unfortunately, recruitment and retention rates in the National DPP have been substantially lower than those in the DPP trial, with just 10.4% of individuals who begin the National DPP completing the full year-long intervention.[13] Low recruitment and retention rates disproportionately affect men[14] and individuals who are members of groups that have been marginalised (eg, individuals identifying as Hispanic or non-Hispanic black, and individuals with low educational attainment or income).[15–17] In part due to ineffective participant engagement, health behaviour change goal attainment over the first 4 years of the National DPP was substantially lower than those observed in the lifestyle intervention arm of the DPP. Only 41.8% of National DPP participants met the physical activity goal of at least 150 minutes of MVPA per week, compared with 74% in the DPP efficacy trial.[5 13] Similarly, just 35.5% of National DPP participants met the weight loss goal (ie, ≥5% body weight loss), compared with 50% in the DPP efficacy trial, which included a more stringent goal (ie, ≥7% body weight loss).[5 13] Similar to engagement challenges, people of colour were significantly less likely to meet the physical activity and weight loss goals compared with non-Hispanic whites.[13] Thus, although lifestyle intervention has great promise, further work is needed to extend the reach, engagement and outcomes of the National DPP to more individuals at risk for type 2 diabetes, and particularly members of groups that have been marginalised who have not been effectively reached.

Involving close others in diabetes prevention efforts may increase engagement, outcomes and reach of the National DPP among adults at risk for type 2 diabetes. Across chronic illnesses, interventions delivered to patients and partners together yield superior health improvements compared with interventions delivered to patients alone,[18] and relationship processes (eg, support) are related to levels of health behaviours.[19 20] For the prevention of type 2 diabetes, there is preliminary evidence suggesting potential benefits of including close others in lifestyle intervention to prevent type 2 diabetes.[21 22] For example, individuals who attended the National DPP with another member of their household demonstrated greater engagement and attendance.[21] Additionally, in a large-scale translation of the DPP in American Indian and Alaska Native communities, attending with a family support person was associated with significantly reduced risk of retention failure (ie, not attending all sessions or becoming lost to follow-up).[23] Similarly, in a healthy lifestyle intervention for African Americans, individuals enrolling with a partner had a 2.95 greater odds of retention (ie, participating in all data collection time points) compared with individuals enrolling alone.[24] Involving partners may also address known barriers to National DPP engagement. For example, Lifestyle Coaches indicate that lack of family support within the household is a barrier to participation and lifestyle change in the National DPP.[25] National DPP participants primarily from communities that are underserved also identify lack of social support as a barrier to health behaviour change.[26] Finally, Lifestyle Coaches with experience delivering the National DPP to individuals and close others identified benefits consistent with these findings (eg, having a partner in lifestyle change, superior outcomes and increased engagement, and positive 'ripple effects'.)[22] Taken together, these findings suggest that participation in lifestyle interventions with a partner may improve retention and engagement, especially for members of groups that have been marginalised. However, despite the preliminary evidence for the benefits of incorporating close others, existing interventions to prevent type 2 diabetes among adults have not systematically involved family members. Results of evaluations of type 2 diabetes management programmes that

include romantic partners have been mixed, likely in part due to low methodological quality of the studies.[27 28] There are also mixed results reported from trials of lifestyle interventions for couples in which one partner is at risk for a condition other than type 2 diabetes (eg, breast cancer, adverse pregnancy outcomes and cardiac disease).[29 30] There is a need for rigorous intervention research that builds on findings from relationship science to better understand type 2 diabetes prevention in a relationship context.

Although systematically involving close others in type 2 diabetes prevention is an important direction, it is critical that this work simultaneously aim to reduce the substantial diabetes disparities, particularly among communities of colour. Given its primary goal of reducing health disparities, community-based participatory research (CBPR) is a particularly promising research orientation to optimise lifestyle interventions.[31 32] CBPR focuses on engaging and empowering community members throughout the research process[33] by establishing bidirectional relationships between researchers and community members in which power is shared.[34] We are not aware of research leveraging the strengths of both relationship science and CBPR to optimise type 2 diabetes prevention, a combination with unique potential to reduce disparities. The formation of a community advisory board (CAB) is a specific CBPR method that empowers stakeholders by soliciting feedback and input on the research.[35] As described below, we formed a CAB composed of individuals and a romantic couple with relevant personal and/or professional expertise in diabetes prevention among groups that have been minoritised.[36] The CAB provided feedback and recommendations on optimally adapting the CDC's diabetes prevention curriculum to be delivered to couples across communities.

Although the intervention adaptation team included key stakeholders and the CDC approved the couple-based adaptation as an 'Alternate Curriculum' for use in the National DPP, this trial is the first evaluation of the programme. The purpose of this trial is to describe the feasibility of the adapted intervention and the study protocol in preparation for a future definitive randomised clinical trial (RCT). We carefully reviewed and adhered to guidance from the conceptual framework for randomised feasibility and pilot studies[37] and the Consolidated Standards of Reporting Trials (CONSORT) extension to pilot and feasibility trials.[38] The objectives of this trial are:

1. To describe the feasibility of the adapted couple-based intervention from the perspectives of (A) participating couples and (B) Lifestyle Coaches delivering the intervention.
2. To describe the feasibility of the study protocol for use in a definitive trial, with a specific focus on (A) recruitment, (B) randomisation and (C) measurement of key outcome domains.

METHODS

Patient and public involvement

Prior to submission of a proposal for extramural funding, in January 2017, the research team collaborated with the University of Utah Clinical and Translational Science Institute (CTSI) Community Collaboration and Engagement Team to conduct a one-time focus group meeting. Participants (n=8) in the focus group included individuals with relevant personal and/or professional expertise from five community organisations within the Salt Lake Valley: Best of Africa, Calvary Baptist Church, the Hispanic Health Care Task Force, the National Tongan American Society of Utah and the Urban Indian Center of Salt Lake. The grant proposal, which integrated feedback from this focus group on the overall research question and planned methods, was funded by the National Institute of Diabetes and Digestive and Kidney Diseases in June 2018.

Once the grant proposal was funded, the team invited former focus group participants as well as other stakeholders with professional and/or personal expertise (eg, National DPP Lifestyle Coaches and Master Trainers, dietitians, community health workers and a married couple coping with type 2 diabetes) to serve as stakeholders on a CAB. The 12-member CAB was racially and ethnically diverse, with at least one member from each of the five organisations described above. See Aguirre *et al*[36] for a detailed description of the CAB members and procedures. All CAB members are invited to contribute as coauthors on project products (including this paper), and are compensated for their time attending CAB meetings and otherwise supporting the project. The CAB met monthly from January 2019 to December 2020 to review the 2016 CDC PreventT2 curriculum and suggest adaptations for couple-based delivery across communities. Although the primary focus of the CAB was on couple-based adaptations to the intervention that would be broadly applicable across cultures, the team reviewed and provided feedback on this study protocol, including the burden on participants and constructs assessed. The CDC published a revised National DPP curriculum (2021 PreventT2) while the pilot trial was delayed due to the COVID-19 pandemic. Two additional meetings with 10 of the CAB members were held in June 2022. These meetings focused exclusively on content that was substantially changed in the 2021 curriculum revision.

An NIH Administrative Supplement was awarded in August 2022, providing funds for additional CAB meetings beyond those proposed in the parent grant. A meeting with eight members of the CAB was held in November 2022 to discuss recruitment processes and materials. During the pilot trial, the CAB will meet approximately every 3 months to provide feedback on initial feasibility data. Interested CAB members will be involved in communicating study findings to their respective communities and the broader public.

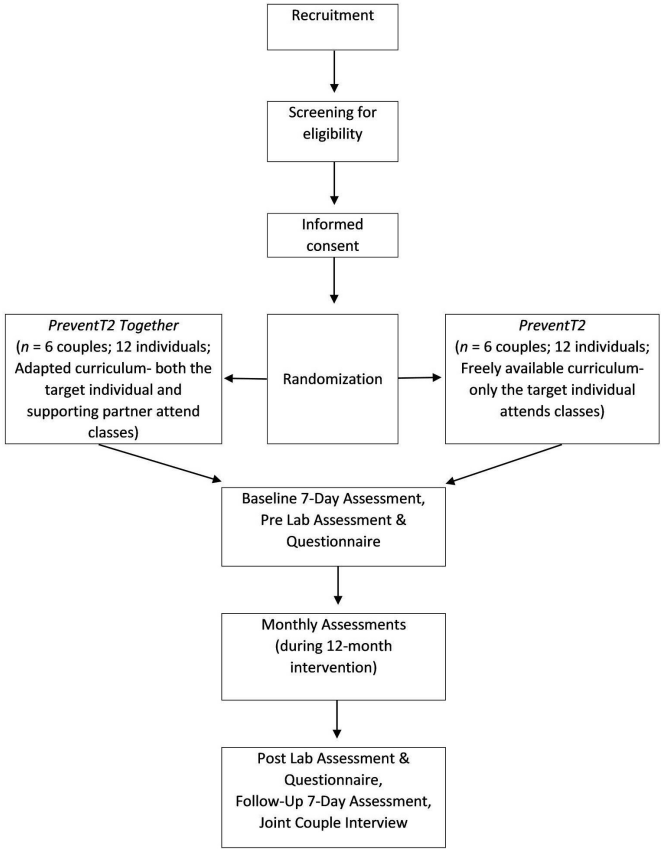

Figure 1 Participant recruitment and assessment flow chart. This figure illustrates the flow of participants through recruitment, informed consent, randomisation and assessments.

Trial design

Participating couples will be randomised (1:1) to one of two intervention conditions, an individual intervention condition (PreventT2) or the adapted couple-based intervention condition (PreventT2 Together). Regardless of the condition to which a couple is randomised, all participants will be invited to complete the same series of assessments. We used the CONSORT statement extension to randomised pilot and feasibility trials and associated checklist when preparing this report.[38]

Participants

Figure 1 presents the overall flow of participants through the study. As this is a pilot study, no sample size calculations were performed.[38] Rather, we considered the number of couples that we thought could effectively participate in a single PreventT2 Together cohort. The CDC's recommended cohort size is 10–15 individuals.[39] Although study eligibility criteria (described below) are expected to yield a sample of couples who generally communicate and collaborate effectively, high levels of conflict within even one couple in the PreventT2 Together class could have a substantial negative impact on the overall group process. Consistent with this, a previous qualitative descriptive study of perspectives of Lifestyle Coaches who delivered the (individual) National DPP to dyads (ie, family members or friends together), found that 28% of Lifestyle Coaches identified difficult relationship dynamics as a challenge of a dyadic approach to diabetes prevention.[22] We; therefore, determined an ideal couple-based cohort size of 6 couples, with 12 couples (24 individuals) in the full sample.

Eligibility criteria: Participants will be adults eligible for the National DPP (ie, target individuals) and their romantic partners (ie, supporting partners). The supporting partner does not have to be eligible for the National DPP or otherwise meet the eligibility criteria set for the target individual, as detailed in table 1.

Recruitment and Enrollment: Starting in July 2022, the research team sent contact persons at the University of Utah (including at Healthcare System Hospitals and Clinics ('UHealth'), the National DPP and the Office of Research Participant Advocacy that hosts a Study Locator website) information on the study, encouraging self-referrals and provider-referrals. A number of UHealth outpatient clinics posted paper flyers and/or electronic advertisements with a QR code that linked to a research team webpage with additional information about the study and a contact form. Study advertisements were also posted on social media, including the research team's Twitter, Facebook and Instagram accounts with reposting by university-owned accounts. Finally, the team posted flyers in community locations (eg, gyms, libraries, grocery stores, online message board) including local community-based organisations. Both the research team and interested CAB members participated in recruitment.

Potentially interested individuals contact (or are connected with) the University of Utah National DPP administrative assistant to determine National DPP eligibility via telephone or email (see table 1). The administrative assistant connects individuals who are eligible for the National DPP and interested in the study with the study coordinator for additional information and study-specific eligibility assessment via an online screening questionnaire. If eligible per the additional study criteria, participants will complete the informed consent process electronically. Participants will be encouraged to ask any questions before signing the consent document, and they may schedule a telephone call with the study coordinator.

Randomisation, blinding and treatment allocation

After completing the informed consent process, participating couples will be randomised to one of the intervention conditions using the National Cancer Institute's Clinical Trial Randomisation Tool.[40] A graduate research assistant (GRA) who is not involved in the screening process generated 12 randomised assignments to which no other team members have access. After the study coordinator enrolls a couple, the GRA shares the assignment with the study coordinator, who informs couples of the condition to which they are assigned. Given the nature of the study, participants and Lifestyle Coaches delivering the interventions will be unblinded to condition.

Table 1 Participant eligibility criteria

Inclusion	Exclusion
For target individuals only*:	**For target individuals only:**
National DPP inclusion criteria:[39] ► BMI ≥25 kg/m^2 (23 kg/m^2 in Asian individuals) And 1. High risk for type 2 diabetes based on 1+:CDC/ADA Prediabetes Risk Test score ≥5 2. Blood tests indicative of pre-diabetes in the last year including one or more for the following: – A1c: 5.7%–6.4% – 2-hour plasma glucose (after 75 g glucose load): 140–199 mg/dL – Fasting blood glucose: 100–125 mg/dL 3. Previous diagnosis of gestational diabetes	National DPP exclusion criteria:[39] ► Previous diagnosis of type 1 or type 2 diabetes ► Current pregnancy Study-specific exclusion criteria: ► Current medication for pre-diabetes or obesity ► Current participation in a lifestyle intervention for pre-diabetes or obesity ► Past participation in the National DPP ► Diagnosis of another chronic disease (unless stable or with no major events/changes for 3+ months)
For target individuals and supporting partners:	**For target individuals and supporting partners:**
Study-specific inclusion criteria:	Study-specific exclusion criteria:
► Living together for 1+ year ► Report being in a romantic relationship ► Conversational fluency in English ► Age 18 or older ► Interested in participating	► Not comfortable participating in intervention with partner

*The study team will not systematically screen supporting partners for National DPP eligibility. However, if a supporting partner seeks screening and does meet eligibility for the National DPP (ie, both partners in the couple are at high risk for type 2 diabetes), the supporting partner will not be prohibited from attending the National DPP themselves if the couple is randomised to the individual condition.
ADA, American Diabetes Association; BMI, body mass index; CDC, Centers for Disease Control and Prevention; DPP, Diabetes Prevention Programme.

However, research nurses collecting data in pre and post lab assessments will be blinded.

Interventions

This trial includes an individual and a couple-based intervention condition. The individual condition will use the CDC's 2021 PreventT2 curriculum delivered to the target individual in the context of the University of Utah's National DPP, which has 'Full' CDC recognition. The couple-based condition will use the adapted PreventT2 Together curriculum, which the CDC reviewed and approved as an alternate curriculum for the National DPP in November 2022. Consistent with CDC DPRP Standards,[39] both interventions include 22+ classes delivered over the course of 12 months (February 2023–January 2024). Each intervention will be delivered by two Lifestyle Coaches who have completed standard National DPP training through a CDC-approved entity. Interventions will be delivered to small groups, including a group of target individuals in the individual condition, and a group of couples (including target individuals as well as supporting partners) in the couple-based condition. If a couple is randomised to the individual condition, the target individual may choose to invite the supporting partner to attend PreventT2 classes. This is allowable by the CDC and consistent with standard University of Utah National DPP operating procedures. We will track partner attendance at PreventT2 classes and will consider this in our feasibility evaluations. As required by the CDC, both curricula cover content relevant to diabetes prevention including methods for improving nutrition, increasing physical activity and losing weight. However, only PreventT2 Together includes content specific to couples with prompts encouraging partners to consider and discuss how they can best support one another and stories demonstrating how couples collaborated to make healthy lifestyle changes. See online supplemental table 1 for the participant objectives for each module across the two curricula.

As the CAB advised that virtual classes may not meet the needs of local adults from racial and ethnic groups that have been marginalised, we intend to deliver these classes in person unless public health guidelines dictate otherwise. However, in both conditions, participants will be offered make-up classes via online modules and individual (PreventT2) or couple (PreventT2 Together) meetings with a Lifestyle Coach. Lifestyle Coach fidelity will be ensured through regular supervision, which will be increased as needed to ensure fidelity. Both interventions will be delivered at University of Utah sites in the Salt Lake Valley, with those in the individual condition attending PreventT2 classes in the context of the University of Utah's fully recognised National DPP, and those in the couple-based intervention attending PreventT2 Together outside of the context of the University of Utah programme. The individual condition Lifestyle Coaches will be employees of the University of Utah National DPP

programme and supervised by the programme manager (EM), while the couple-based Lifestyle Coaches will be research team members supervised by the PI (KB). To promote engagement and retention, Lifestyle Coaches delivering the interventions across conditions will email participants regularly with reminders (eg, about the schedule of classes, with recaps of key information from classes) and additional tips for improving nutrition and physical activity. Lifestyle Coaches will also provide curriculum-based incentives (eg, yoga mats, measuring spoons) for participant engagement and attendance starting at month three of the interventions, per the University of Utah's National DPP procedures.

Assessments

Figure 1 presents the flow of participants through the study. All participants across conditions will complete all assessments, except the following data will not be collected from supporting partners in couples randomised to the individual condition: (A) data collected at intervention classes and (B) data about intervention experiences. If supporting partners are eligible for the National DPP themselves, they will have the option of attending classes and these data would be collected. Participants will be compensated for completion of study assessments for a total of up to US$695.

Baseline and follow-up: Baseline physical activity will be objectively assessed for a 7-day period before the intervention using ActiGraph wGT3X-BT accelerometers. During this time, both target individuals and supporting partners will be instructed to individually wear accelerometers 24 hours/day. Participants will be sent a link to a 5 minute online questionnaire each evening for validation of the activity monitor data and additional self-report measures. This assessment will be repeated after the interventions (ie, follow-up).

Pre and Post Lab: Each participant will individually complete a 3-hour visit to the CTSI within 1 month of beginning and completing the interventions. During these visits, research nurses will conduct anthropometric measurements, draw blood for glucose tests and administer the 75 g oral glucose tolerance test. Each participant will privately complete online self-report questionnaires on a tablet during the assessment unless they completed the questionnaires from home prior to the lab visit.

Intervention classes: At each class in both conditions, weight and MVPA minutes will be collected, along with participant attendance. As noted above, these data will not be collected for supporting partners in couples randomised to the individual condition unless they are attending classes due to their own eligibility for the National DPP. In addition to the data collected from participants, Lifestyle Coaches delivering the couple-based intervention will complete a brief open-ended survey following each class.

Monthly: Beginning 1 month after the interventions begin, all participants will be asked to privately complete a monthly online questionnaire. Only participants attending classes will report on experiences in the interventions in this questionnaire.

Post Intervention Interview: We will also conduct 90 min audiorecorded joint couple interviews following completion of the intervention. A semistructured interview guide will be used by the PI (KB) to qualitatively assess couples' experiences in the interventions and study, with a focus on feasibility.

Post Intervention Lifestyle Coach Survey: In addition to these data collected from participants, Lifestyle Coaches delivering the couple-based intervention will complete questionnaires.

Outcomes

Below are the prespecified measures the team will use to describe the feasibility of PreventT2 Together (objective 1) and the study protocol (objective 2). Given the uncertainty of estimates obtained in small pilot trials,[41] we do not specify decision criteria for whether to proceed to a definitive trial. The determinations of whether to proceed to a definitive trial (vs additional piloting) and how to carry out next steps will be made together with the CAB after careful review of outcomes.

Objective 1a: Participants in couples randomised to the couple-based intervention condition will complete the Theoretical Framework of Acceptability-Based Questionnaire[42] (TFA-BQ) and two open-ended survey items developed by the research team (What positive improvements have you noticed since the last class? What challenges did you face since the last class as you attempted to meet your goals?) in the Monthly and Post Questionnaire Assessments. Participant perspectives on the feasibility of PreventT2 Together will also be assessed in the Post Intervention Interview using a semistructured couple interview guide. Participant attendance, completion of weekly activity logs and completion of make-up sessions will be reported by the Lifestyle Coaches delivering the intervention.

Objective 1b: The Lifestyle Coaches delivering PreventT2 Together will complete a series of open-ended items developed by the research team following each class (What challenges arose with module delivery? What went well with module delivery? If you could re-write this module, what would you change?). After completion of the intervention, the Lifestyle Coaches will complete a measure of barriers to participation and lifestyle change observed among their participants[25] as well as the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and Feasibility of Intervention Measure (FIM)[43] based on implementation outcomes.[44]

Objective 2: Participant perceptions of the study protocol will be assessed in the Post Intervention Interview using a semistructured couple interview guide. The guide includes specific prompts focused on recruitment (Tell me how you learnt about the study and what factors led the two of you to sign up), randomisation (In this study all couples were randomised to one of the two intervention

conditions. How do you view that approach?), and the assessment protocol (Considering the frequency of assessments, how much time the assessments took and the compensation you received for that time, how do the two of you view the assessments overall?), as well as prompts about each type of assessment (ie, long (pre/post) and short (monthly, daily baseline/follow-up) online surveys, U of U CTSI Clinical Research Unit assessment, accelerometer wear, intervention class assessments (ie, weight, MVPA)) and for the questionnaires generally.

In addition to qualitative data on participants' perspectives, data on recruitment feasibility (objective 2a) will be collected with an item in the contact form (How did you hear about our study? response options: social media, healthcare clinic/provider, other). Finally, participants will be invited to complete measures of health behaviours, physical and mental health, and relationship functioning detailed in table 2 (objective 2c), but are free to skip any items they do not wish to complete.

Study withdrawal

Participants may inform the research team at any point in the study if they no longer wish to participate and do not want the research team to use their health information. If a participant decides to withdraw, we will not collect any new information about the participant, but we will continue to use information already collected, as needed to maintain the integrity of the research.

Serious adverse events

There are no expected adverse events. Any serious adverse event will be reported to the University of Utah IRB and NIDDK within 24 hours of the event, in accordance with the standard University of Utah IRB reporting guidelines.

Statistical methods

Quantitative measures of intervention feasibility (objective 1) and protocol feasibility (objective 2) will be summarised using descriptive statistics. Objective 1 quantitative measures include: participant reports on TFA-BQ; Lifestyle Coach reports of participant attendance, activity tracking completion and make-up session completion; and Lifestyle Coach reports on the AIM, IAM, FIM and barriers to participation and lifestyle change in the National DPP. Objective 2 quantitative measures include: the number of individuals from each of the three recruitment sources who contact the study team, and enroll in the study; the number of items from each measure that were skipped by participants; and the average length of time participants spent on each questionnaire assessment.

Qualitative measures will be collected from participants (ie, open-ended monthly survey items assessing Objective 1a and transcripts of interview responses to prompts assessing objectives 1a and 2a–2c after completing the intervention) as well as Lifestyle Coaches (ie, open-ended survey items after each PreventT2 Together class to assess objective 1b). The 90 min couple interview recordings will be professionally transcribed, and transcripts reviewed and verified by trained RAs on the study team. In a separate process within each objective, the text responses (surveys) or transcripts (interviews) will be carefully read and reread by the interviewer (KB), who has experience with qualitative coding and analysis. Inductive codes will be iteratively developed and evaluated using constant comparison. After codes are finalised, they will be sorted into categories of conceptually similar codes and the frequency of codes and categories will be summarised. This qualitative descriptive approach is common in health research broadly,[45] and has been recommended in intervention work that aims to reduce health disparities specifically.[46]

DISCUSSION

Although there are no studies of diabetes prevention interventions that have systematically incorporated romantic partners, meta-analyses have demonstrated family-based psychosocial interventions for adults with chronic illnesses are superior to individual interventions.[18] As we describe below, there is preliminary support for the potential benefits of couple-based diabetes prevention. This study, with randomised allocation and blinded assessment, will examine the feasibility of the PreventT2 Together intervention package and the study protocol. Results will provide a foundation for a subsequent definitive RCT with the statistical power to directly test the overarching hypothesis that couple-based diabetes prevention will lead to improved engagement, outcomes and reach compared with the CDC's individual curriculum.

Lack of family support is a critical barrier to National DPP participation.[25 26] Involving significant others in the intervention may reduce this barrier and improve engagement. It is possible that individuals who would otherwise learn about but not enroll in the National DPP will be more likely to enroll, and that those who would otherwise enroll in but not complete the National DPP will be more likely to complete the programme, if they participate together with their romantic partner. There is support for higher engagement among those participating with other household members vs individually,[47] but it has not specifically been examined in a romantic relationship context. As the National DPP has least effectively engaged individuals from groups that have been marginalised,[15] increased engagement via a couple-based approach may reduce disparities.

Engaging romantic partners in diabetes prevention interventions may also improve outcomes for the at-risk partner who would otherwise participate individually. As greater retention and attendance are associated with increased likelihood of meeting the National DPP weight loss and physical activity goals,[15 48] improved engagement through a couple-based approach may facilitate better outcomes. Additionally, the lifestyle factors targeted for intervention in the National DPP occur in a social context, and tend to be similar between partners within a couple.[49] Changes in health behaviour at the couple level (eg, being physically active together, purchasing more

Table 2 Domains of assessment

Measures	Assessment time point				
	Pre lab	Baseline	Monthly	Post lab	Follow-up
Background					
Demographics*	X				
Adverse childhood experiences[59]	X				
Health behaviours					
Physical activity					
IPAQ-Long[60]	X			X	
IPAQ-7 day[60]			X		
Objectively assessed MVPA[61 62]		X			X
Self-reported MVPA (past week)			X†		
Diet					
ASA-24[63]	X			X	
REAP-S[64]	X		X	X	
Sleep					
PROMIS Sleep Disturbance 8a[59]	X		X	X	
PROMIS Sleep-Related Impairment 8a[65]	X		X	X	
Daily Sleep Monitoring[66]		X			X
Physical Health					
Height, waist circumference	X			X	
Weight	X		X†	X	
HbA1c, fasting blood glucose, 2 hours postglucose load	X			X	
Mental Health					
PROMIS Anxiety 8a[59]	X		X	X	
PROMIS Depression 8a[59]	X		X	X	
Positive and Negative Affect Schedule[67]		X			X
Relationship Functioning					
Relationship Satisfaction (CSI-4)[68]		X			X
Daily Emotional and Instrumental Support[69 70]		X			X
Relationship Satisfaction (CSI-16)[68]	X		X	X	
PAIR Sexual Intimacy Subscale[71]	X		X‡	X	
Social Support and Exercise Survey[72]	X		X‡	X	
Social Support and Eating Habits Survey[72]	X		X‡	X	

*Demographics include age, education, race/ethnicity, gender identity, marital status, income.
†Collected at each intervention class attended.
‡Administered every 3 months during the interventions (ie, months 3, 6 and 9).
ASA-24, Automated Self-Administered 24-Hour Dietary Assessment Tool; CSI-4, 4-item Couples Satisfaction Index; CSI-16, 16-item Couples Satisfaction Index; HbA1c, Hemoglobin A1c; IPAQ, International Physical Activity Questionnaire; MVPA, moderate-to-vigorous physical activity; PAIR, Personal Assessment of Intimacy in Relationships; PROMIS, Patient-Reported Outcomes Measurement Information System; REAP-S, Rapid Eating Assessment for Participants-Shortened.

nutritious foods when grocery shopping) may increase the likelihood of lifestyle change that is lasting. Consistent with this, spousal and family support facilitate greater health behaviour change in couple-based lifestyle intervention focused on management of type 2 diabetes,[27] although this has not yet been examined in a type 2 diabetes primary prevention context.

In addition to the potential benefits for individuals aware of their risk for type 2 diabetes and the existence of the National DPP, a couple-based approach may also extend the reach and impact of the programme to other family members who are not aware of their risk. Estimates suggest over 80% of adults with pre-diabetes in the USA are not aware they have the condition.[4] Even after

controlling for similarity in lifestyle factors, one's spouse having pre-diabetes increases one's risk for incident diabetes.[50] A couple-based approach may directly engage romantic partners who are at high risk for diabetes but would not otherwise be aware of their risk or reached by the National DPP. For couples with children and others living in the home, the approach may even have positive 'ripple effects' to the household members who are not participating in the intervention (eg, children), as demonstrated in previous weight loss intervention studies[51] and observed by Lifestyle Coaches when delivering the National DPP to dyads (family members and/or friends).[22]

There are several important limitations to this planned study. First, as this pilot trial has a primary focus on feasibility, it is underpowered to examine the preliminary efficacy or effectiveness of the intervention. In addition to evaluating these intervention outcomes in a well-powered trial, future studies should evaluate implementation outcomes across levels of analysis beyond participants and the Lifestyle Coaches delivering the intervention (eg, at the level of the organisation or setting).[44] Second, couple-based lifestyle intervention will not be indicated for all adults at risk for type 2 diabetes who are in romantic relationships.[47] There is a well-documented cross-sectional association between lower relationship quality and poorer physical health,[52] including increased risk for, and progression to, type 2 diabetes and cardiovascular disease.[53 54] We anticipate the eligibility criteria of this trial will exclude couples with extremely low levels of relationship quality that would likely impede lifestyle change in a couple context. However, it will be critical for future work to examine the role of specific aspects of relationship functioning (eg, relationship satisfaction, support) that may moderate or mediate lifestyle change in a couple context. For people who do not have supportive and/or stable romantic partners, extending the National DPP to target other kinds of relationships (eg, peers, family members more broadly) may improve social support and subsequent outcomes.

Additionally, couples interested in participating in this study may desire to participate in PreventT2 Together, and random assignment to the individual condition may reduce motivation to complete the study. While those randomised to the individual condition will not be prohibited from participating in PreventT2 as a couple if desired, we may need to alter delivery of the control condition in the definitive trial. The feasibility data we collect on randomisation will guide our consideration of alternative control conditions. Finally, although a strength of this project is the close partnership with key stakeholders in adapting the intervention, further adaptation may be necessary to tailor the intervention for specific communities. Our changes are consistent with broad 'surface structure' adaptations to include representation and content that is relevant to couples across a wide range of communities and cultures.[55] However, health beliefs and practices vary both between and within cultures.[56] Interventions intended to target a specific community may require 'deep structure' adaptations that incorporate cultural norms, beliefs and values,[55 57] or adaptative approaches that consider the variability within a given community.[58] Despite these limitations, this study is an important first step that will apply existing knowledge from relationship science and principles of CBPR, extending the literature on innovative approaches to diabetes prevention.

ETHICS AND DISSEMINATION

This study protocol was reviewed and approved by the University of Utah IRB (#143079), which will approve all potential changes to the study (if applicable). Participants will complete the informed consent process prior to initiation of study procedures. Interested and eligible individuals will be provided with a written consent document that includes all study details, invited to have a phone call with study staff to discuss any questions, and encouraged to take the time they need to decide whether they wish to participate. Those interested will sign the consent form electronically.

The study team has established policies and procedures for data management. All data will be stored on encrypted external hard drives that are kept in a locked cabinet in the PI's lab space as well as on encrypted servers. Participant identifiers will be stored separately from the coded participant data, with file access limited to only those team members who require the information.

Results will be shared with community stakeholders. We will work collaboratively with CAB members to identify the optimal strategy for sharing results within specific communities. Results will be shared with the research community through conference presentations and publications in peer-reviewed journals.

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