Official Title: The National Diabetes Prevention Program in Rural Communities

NCT Number: 00146055

Approval Date: August 23, 2021

Document: Study Protocol with Statistical Analysis Plan

Specific aims

Approximately 72% of adults in the U.S. are overweight (39.8%) or obese (31.8%) of which 9.5% have diagnosed type 2 diabetes (T2D) (1). The prevalence of prediabetes, based on fasting glucose or hemoglobin A1C, is estimated to be 33.9% in U.S. adults age 18 yrs. and over, and 48.3% in those age 65 yrs. and above (2). Approximately 70% of those with prediabetes will eventually develop T2D (3). The burden of diabetes disproportionately impacts the 60 million individuals living in rural areas (19.3% of the U.S. population) where the prevalence of T2D and obesity, a modifiable risk factor for T2D, are higher than their urban counterparts (4). The proportion of the U.S. population age 65 yrs. and older, where the prevalence of prediabetes is extremely high, is greater in rural (17.5%) compared with urban areas (13.8%). Thus, interventions designed to improve weight loss and reduce the rate of conversion from prediabetes to T2D in rural adults would have a significant public health impact.

The Centers for Disease Controls (CDC) Diabetes Prevention Program (DPP) is a 12-mo. lifestyle intervention (6 mos. weight loss -16 core sessions, 6 mos. maintenance- 6 sessions) designed to prevent the development of T2D in individuals with prediabetes. The DPP targets healthy eating, weight loss (5-7%) and increased physical activity (≥150 min./wk.) (5). Results from the multi-site DPP effectiveness trial (2002) indicated that adults (≥ 25 yrs.) and older adults (≥ 60 yrs.) with prediabetes who lost ≥ 5% of baseline body weight and achieved ≥ 150 min./wk. of physical activity demonstrated 58% and 71% reductions in conversion to T2D, respectively (6). Subsequent to the publication of results from the original DPP trial, the DPP protocol has been modified for delivery to groups rather than individuals, and remote delivery using video conferencing, and text messages etc (7). To date, DPP has been effectively delivered by health educators, physicians, nurses, lay people, and pharmacists in a variety of settings such as hospitals, community centers, churches, schools, pharmacies, physician's offices, and through the Cooperative Extension Service (CES) (7-9). However, a recent report found that DPP was available in 14.6% of rural, compared with 48.4% of urban counties (10). Currently the primary sites for the delivery of DPP in rural areas are hospitals/medical centers (6.5%) followed by health departments (3.5%), medical clinics (2.1%), and wellness centers (1.5%) (10).

The effectiveness of the DPP protocol delivered in an individual or in-person group format, in predominately urban populations, has been well documented (11, 12). Although the CDC endorses remote delivery of DPP, limited information is available regarding the effectiveness of DPP in rural areas, or differences in effectiveness between DPP delivered in an on-site group or remotely delivered group format. Remote delivery eliminates the time and expense required to attend an on-site program and may be attractive to individuals in rural areas where income is low and public transportation is limited or non-existent (13). Additionally, the use of remote delivery could have a substantial impact on the reach and cost of delivery of DPP to underserved rural populations (14).

The proposed 6-mo. pilot trial will compare the feasibility and effectiveness of DPP delivered through Facebook (DPP-FB) or group format delivered remotely by phone conference call (DPP-R) in 30 adults (age ≥ 18 yrs.) with prediabetes. Both interventions will be delivered through the CES, which serves as the community outreach arm of all land grant universities through over 2,900 offices across the U.S. The Kansas State Research and Extension (KSRE) (Kansas version of CES), is well positioned, but underutilized for the delivery of DPP in rural areas. Delivery of DPP by a well-recognized entity, such as the KSRE, may improve the probability of dissemination and long-term program sustainability. Two CES offices serving rural counties in Kansas will be randomized (1:1) to the DPP-FB or DPP-R arms. Our research team will train 2 professional staff from KSRE (with backgrounds in nutrition programming and family consumer science) who will deliver the DPP intervention. Outcomes will include body weight

and moderate-vigorous physical activity assessed at baseline, 3 mos. and 6 mos., participant retention, i.e. weight assessed at 6 mos., program attendance (percentage of 16 sessions attended), and the fidelity of intervention delivery. i.e., the delivery of ≥ 80% of scheduled content as determined by reviewing audio recordings of all DPP sessions. This project will address the following aims:

Primary aim: Compare weight and MVPA between DPP-FB and DPP-R across 6 mos. We expect greater weight loss and MVPA in the DPP-R arm compared with the DPP-FB arm.

Secondary aim: Compare the feasibility of DPP-FB and DPP-R across 6 mos. based on participant retention and program attendance. We expect greater participant retention and program attendance in the DPP-R arm compared with the DPP-FB arm.

This study will provide the pilot data necessary to apply for NIH funding to conduct a larger, adequately powered trial comparing the effectiveness of remote and Facebook group delivery of DPP through the KSRE to adults living in rural counties. Compared with DPP delivered in-person, Facebook or remote delivery of DPP eliminates the time and cost burdens of travel to attend behavioral sessions and may increase sessions attendance, which is strongly associated with weight loss success. Demonstrating that remote and Facebook delivery of DPP are at a minimum non-inferior to in-person, may be helpful in weight management providers ability to obtain reimbursement through the Centers for Medicare and Medicaid Services for remotely delivered DPP, which currently reimburses for in-person DPP programs only.

BACKGROUND/SIGNIFICANCE

Diabetes in rural residents. Approximately 72% of adults in the U.S. are overweight or obese of which 9.5% have diagnosed type 2 diabetes (T2D) (1). The prevalence of prediabetes based on fasting glucose or hemoglobin A1C is estimated to be 33.9% in U.S. adults age 18 yrs. and over, and 48.3% in those age 65 yrs and above (2). Approximately 70% of those with prediabetes will eventually develop T2D (3). The burden of diabetes disproportionately impacts the 60 million individuals (19.3% of the U.S. population) living in rural areas where the prevalence of T2D and obesity, a modifiable risk factor for T2D, are higher than their urban counterparts (4). Rural residents experience higher rates of chronic disease included diabetes, metabolic syndrome, cardiovascular disease, have higher coronary heart disease and all-cause mortality and higher rates of disability compared to their urban counterparts (15-19). These health disparities may, in part be, associated with a higher prevalence of obesity in rural (~40%) compared to urban residents (~33%). The proportion of the U.S. population age 65 yrs. and older, where the prevalence of prediabetes is extremely high, is 17.5% in rural areas compared with 13.8% in urban areas. Effective prevention of T2D in rural adults would have a significant public health impact.

Diabetes prevention program. The Centers for Disease Controls (CDC) Diabetes Prevention Program (DPP) is a 12-mo. individually delivered lifestyle intervention (16 core sessions over 6 mos., 6 maintenance sessions over 12 mos.) designed to prevent the development of T2D in individuals with prediabetes by targeting healthy eating, weight loss and increased physical activity (≥150 min./wk.). Results from the multi-site DPP effectiveness trial indicated that adults (≥ 25 yrs.) and older adults (≥ 60 yrs.) with prediabetes who lost ≥ 5% of baseline body weight and achieved ≥ 150 min./wk. of physical activity demonstrated 58% and 71% reductions in conversion to T2D, respectively (6). To date, DPP has been effectively delivered by health

educators, physicians, nurses, lay people, and pharmacists in a variety of settings such as hospitals, community centers, churches, schools, pharmacies, physician's offices, and through the CES (7-9). However, information on the effectiveness of DPP in rural adults, and specifically DPP delivered through the CES or delivered remotely are limited or nonexistent. For example, Vadheim et al (20) evaluated the feasibility of delivery of a group-based modification of the DPP protocol delivered in-person through a health care facility in a single group trial in 101 rural adults at high risk for diabetes and cardiovascular disease. Eighty-three percent of participants (n=84) completed the 16-session core program and 64% (n=65) attended one or more maintenance sessions. Following the core program 65% of participants met the 150 min/wk. physical activity goal. Mean weight loss following the core program was 7.5% with 78% of participants achieving ≥ 5% weight loss. Based on the last recorded weight after completion of the core program a weight loss of ≥ 5% was observed in 66% of participants (20). The Vadheim group also compared a group-based modification of DPP delivered on-site (OS, n=256) or by telehealth (T, n=638) in a non-randomized trial rural adults (21). No significant between group differences were noted in the number of core (OS=12.4, T=12.4) or maintenance sessions attended (OS=3.9, T=3.9), or percent achieving the 150 min/wk. physical activity (OS=47%, T=48%) or 7% weight loss goals (OS=38, T=41). Telehealth video conferencing has the potential to increase access for rural residents; however, telehealth still requires participants to travel a clinic site with telehealth capabilities, which may be a barrier for rural residents. Perri et al (22), reported a mean 6 mo. weight loss (SE) of 10.0(0.4) kg in a sample of 234 obese (BMI=36.8 kg/m^2), middle age/older women who completed a group-based modification of the DPP protocol delivered on-site through CES in 6 rural counties. In summary, the limited available literature suggests feasibility and potential effectiveness of delivery of DPP in rural areas. The feasibility and effectiveness of DPP delivered remotely to rural residents in their homes by the CES using group video conferencing or Facebook is unknown.

Reimbursement of DPP. The CDC maintains a registry of community organizations that have satisfied requirements for delivery of the DPP program. The CDC recognizes multiple delivery options for the DPP including: in-person, online, distance learning and a combination program. Recognized programs are eligible for cost reimbursement from the Centers for Medicare and Medicaid Services (CMMS); however, only in-person programs are currently eligible for reimbursement. Additional research to evaluate the feasibility and effectiveness of alternative delivery methods such as group video conferencing and Facebook, as we have proposed, will contribute to the knowledge base required to obtain CMMS reimbursement in the future.

INNOVATION

Innovative aspects of this proposal include: 1) Targeting an under-served, at-risk group, i.e., rural residents at risk for T2D, 2) Partnering with Kansas State Research and Extension (KSRE) that is an established and a widely utilized community outreach arm across the state of Kansas, 3) Using existing KSRE infrastructure for intervention delivery in rural communities which may increase the probability of perpetuation and reach of the intervention.

APPROACH

Design overview. The proposed 2-arm trial will compare the feasibility and effectiveness of Facebook or remote-delivery of the DPP in rural adults with prediabetes both delivered through the KSRE. The CES is a non-formal educational program, implemented in the U.S. through each state's designated land grant university, to help people use research-based knowledge to

improve their lives. The KSRE maintains local units which are comprised of single counties or multi-county districts. Two KSRE local units serving rural counties will be identified by our partners at KSRE and randomized to the Facebook or remote delivery arms. Members of the KUMC research team will recruit and consent participants and will train KSRE personnel to deliver the 30 core-sessions of the DPP protocol over 12 mos. Outcomes will be assessed by the research team at the local CES offices at baseline, 3 mos. 6 mos. and 12 mos.

Meets At-Risk Qualification:

Complete the questions below based on the candidate's responses.	*Yes - Points*	*No - Points*
Is the candidate a woman who has had a baby weighing more than 9 pounds at birth?	☐ - 1	☐ - 0
Does the candidate have a parent with diabetes?	☐ - 1	☐ - 0
Does the candidate have a brother or sister with diabetes?	☐ - 1	☐ - 0
Does the candidate weigh as much as or more than the weight listed for their height?	☐ - 5	☐ - 0
Is the candidate younger than 65 years of age and gets little or no activity in a typical day?	☐ - 5	☐ - 0
Is the candidate between 45 and 64 years of age?	☐ - 5	☐ - 0
Is the candidate 65 years of age or older?	☐ - 9	☐ - 0
Total Risk Score (score must be 9 or greater to qualify for enrollment in 'At-Risk' category):		

Participants/Recruitment: Men and women (n=15 per arm) who satisfy the inclusion/exclusion will be recruited through local physician's offices, social media, KSRE offices, marketing/listservs, and local businesses. Interested potential participants will fill out an initial eligibility questionnaire via website or over the phone with a study team member. If they pass the screening, a consent session will be scheduled over the phone or over Zoom. The consent form will be emailed to participants prior to the consent session so ensure understanding of the study. The participant will have the option to sign the consent form and email it to the study coordinator or sign the consent form in REDCap.

Inclusion/exclusion criteria. *Inclusion*: 1) Prediabetes as defined as A1C = 5.7-6.4%, fasting glucose = 100-125 mg/dl, (confirmed from physician/medical record in the previous year), history of gestation diabetes mellitus OR a positive result based on the CDC- DPP screener (see figure), 2) Age ≥18 yrs., 3) Willing to commit to participate on a weekly basis for the 6 month intervention, 4) Living in the county of a rural KSRE local unit. Rural counties will be defined using the American Community Survey definition which categorizes a county as rural if the population is < 65,000 (23), 5) Internet access and capability to use Zoom, 6) Clearance from primary care physician and 7) Access to a scale. *Exclusion*. 1) Diagnosis of T2D, 2) Unable to participate in physical activity.

Randomization: Two rural KSRE local units will be randomized in a 1:1 ratio to either DPP-FB or DPP-R.

Intervention overview: The DPP is an evidenced based lifestyle intervention based on Social Cognitive Theory which includes topics on nutrition and physical activity in addition to behavior change strategies such as self-monitoring, environmental control, positive reinforcement and accountability (24). Six-month weight loss and physical activity goals, i.e. following completion of the 24-session core curriculum, are 5%-7% and ≥ 150 min/wk. of moderate intensity activity such as brisk walking, respectively. The nutrition portion of the DPP curriculum focuses on reducing fat intake to reduce caloric intake. The physical activity portion of the curriculum focuses on incorporating physical activity throughout the day to reach the goal of 150 min/wk. Increasing lifestyle activities such as taking the stairs, stretching, gardening, and parking further away at the grocery store, etc. are encouraged. At the baseline visit, participants in both

intervention arms will receive a notebook which includes contact information for study personnel, instructions and guidelines for phone calls (DPP-R only), descriptions of the diet and physical activity protocols, handouts/worksheets/assignments specific to each meeting, and charts to self-monitor, weight, physical activity, and fruits and vegetables consumption.

DPP-R intervention delivery. Weekly 60 min. group meetings (12-15 participants) will be held by Zoom over 6 months followed by monthly 60 min. group meetings for the later 6 months. Approximately 5 min prior to the meeting time (typically early evening) participants will receive call in information to join the group meeting by video conferencing or phone.

DPP-FB intervention delivery. Formal meetings will not be scheduled. Logistics. Participants will be asked to join a *secret*, lifestyle coach moderated, Facebook® group. The content in a *secret* Facebook® groups is accessible only to invited members, and the existence of the page is hidden from the public. Participants with existing Facebook® accounts will be advised on adjusting privacy settings to control access by other members of their *secret* Facebook® group. Participants will access Facebook® with the iPad provided using Wi-Fi, thus participant's personal data plans will not be impacted. The lifestyle coach will post new modules of the Prevent T2 curriculum to Facebook® weekly over months 1-6 (modules 1-24) and monthly over months 7-12 (modules 25-30). New modules will be posted prior to 9 a.m. on Mondays. De-identified individual participant self-monitoring data (diet, PA, weight loss) and a brief comment from the lifestyle coach regarding the performance of the group will be posted on Tuesday a.m. This allows participants to assess their progress relative to others in the group. Brief discussion points such as "what strategies to increase your level of PA will you try this week?" will be posted on Wednesday and Friday AM. These posts are designed to reinforce the primary objectives of each module and to facilitate inter-participant discussion around these topics. Participants will be asked to comment on each of the discussion point posts. The lifestyle coach will monitor the responses to the discussion point posts daily and will answer questions and/or correct any misinformation that may be included in participant posts. The Friday morning post will include a reminder to sync self-monitoring devices by midnight on Sunday. New posts will be "pinned" to the top of the wall and included in the "announcements section", to ensure the new posts are easily identified. Participant engagement, which will be tracked across the 6-mo. trial, can take the form of "liking" or "commenting" on the posts, or contributing new posts. Lifestyle coaches will monitor the Facebook® group on the Monday following the posting of a new curriculum module to determine if the module has been accessed. This is analogous to attendance in the Zoom® group. Lifestyle coaches will send email reminders to participants who do not access 2 consecutive module postings. Participants will be encouraged to contact lifestyle coaches with any questions that arise during the intervention using Facebook® messenger, which automatically alerts lifestyle coaches that a message has been received.

No data is downloaded from Facebook and transferred to KUMC servers.

Self-monitoring. Participants will be asked to self-monitor weight, minutes of physical activity, steps (Fitbit provided), and fruit and vegetable intake each week. Participants in both intervention arms will be required to enter their data into REDCap, including weight (scale provided), diet and physical activity between weekly meetings. Self-report data will be used by lifestyle coaches to inform individual participant feedback.

Attendance at group meetings and self-reported weights will be recorded weekly.

Selection and training Lifestyle Coaches: Part of the translational nature of the DPP is that the lifestyle coaches can be 'lay-persons' without advances degrees in exercise physiology, behavioral psychology or health education. A primary lifestyle coach will be selected at the randomized KSRE offices in conjunction with our partners at KSRE (Dr. Proctor and Ms. Price). The study coordinator will be trained to ensure there is adequate coverage in the event of illness, job change, etc. The study coordinator will provide a 1-day on-site training at each KSRE local unit prior to initiating the intervention. DPP-R training. Prior to the intervention lifestyle coaches at the DPP-R site will attend, four 1-hr training sessions via video chat. Audio recordings of previous group remote delivery recordings from our NIH trial (DK108732) will be utilized to demonstrate effective leadership and facilitation techniques in a group call setting. The 4 training sessions will be used to reinforce strategies taught during on-site training. Prior to initiating the intervention all lifestyle coaches will be required to successfully conduct 3 simulated sessions over the phone with members of the research staff serving as participants. DPP-FB training. Lifestyle coaches at the DPP-FB site will also attend four 1-hr follow-up training sessions via video chat. Audio recordings of in-person group sessions from previous studies will be utilized. Prior to initiating the intervention, lifestyle coaches for the DPP-FB group will be required to successfully conduct 2 simulated discussions in a mock Facebook group conducted with CES or KUMC research staff as participants. These sessions will be observed and evaluated by the study coordinator either via FaceTime or Zoom. A standardized checklist, which includes the important skills/strategies taught during training, will be used to assure that lifestyle coaches for both intervention arms demonstrate mastery of these skills.

Intervention fidelity: To assure quality control and standardization of intervention delivery all DPP-R sessions will be audio recorded and compared with a standardized checklist of content to be delivered. For the DPP-FB group, the private group will also be audited to ensure quality control and standardized intervention delivery. Our study coordinator will randomly review 1 session/mo. (total of 6 sessions for each intervention arm). Lifestyle coaches who fail to deliver at least 80% of the scheduled content will receive additional training with the study coordinator using video chat over Zoom. In the event the primary lifestyle coach is unable to lead a DPP session, the secondary lifestyle coach will be available as substitute or the study coordinator, thus assuring continuity of the intervention.
Incentives: Participants will be compensated $20 for baseline, 3 mo. and 6 mo. outcome testing assessments.

OUTCOME ASSESSMENTS

All outcome assessments will be completed by KUMC research staff at the KSRE local unit at baseline, 3 mo. 6 mo. and 12 mo. KUMC research staff will follow all COVID procedures for testing that are outlined in the CPAWM COVID-19 Procedures- Off-Site attachment.

Anthropometrics measurements. Body weight will be assessed to the nearest 0.1 kg with a calibrated scale (Belfour Inc., Model #PS6600, Saukville, WI). All participants will be weighed between the hours of 6 and 11 am following a 12 hr. fast in a standard hospital gown. Standing height will be assessed to the nearest cm with a stadiometer (Model PE-WM-60-84, Perspective Enterprises, Portage, MI).

Physical activity. Physical activity will be assessed using an ActiGraph (wGT3x-BT) portable tri-axial accelerometer (ArchiMed Co, Lyon, Auvergne-Rhone-Alpes, France) which has been

shown to provide valid and reliable assessments of PA in adults. Participants will wear the ActiGraph on a belt over the non-dominant hip at the anterior axillary line during waking hours for 7 consecutive days, except for bathing, swimming, and contact sports. A 7-day monitoring period provides a reliable estimate of moderate-to-vigorous PA. ActiGraph data, aggregated over 1-min epochs, will be processed using the protocol used for adults in the 2003-2004 and 2005-2006 cycles of NHANES using the following intensity cut-points: sedentary (< 1.0 METs ≤ 100 counts/min), light (METs 1.1-2.99; 101-2019 counts/min.), moderate (METs 3.0-5.99; 2020-5998 counts/min) and vigorous (≥ 6 METs; ≥ 5999 counts/min). ActiGraphs will be given to participants during outcomes testing with a prepaid envelope to mail back to the investigators after wearing for 7 days. Participant retention/program attendance. Lifestyle coaches in both intervention arms will maintain records of participant retention and program attendance. Retention will be defined as attendance at 6 mo. and 12 mo. outcome testing. Program attendance will be defined as being present as the beginning and end of the class/call and reporting weekly data.

End study survey. At the end of the 6 mo. intervention, a survey will be conducted to ask about your experience with the program.

Focus group. At the end of the 6 mo. intervention, a recorded focus group will be conducted in all participants to gather information on the overall ease and enjoyment of the program. Questions on barriers to healthy eating and physical activity, time commitment, recommending the program to friends/family,

Statistical analysis & Data management: Baseline measures and demographic characteristics will be summarized for the complete sample using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Weight loss will be calculated as the difference in body weight between baseline and 6 months. All analyses will be conducted using SAS 9.4 (SAS Institute, Cary, NC). We will compare change in body weight and MVPA between groups at 6 mos. and 12 mos. by using a two-sample t-test. Feasibility will be calculated as the percentage of participants who attended > 75% of the scheduled sessions. We will also conduct a qualitative analysis of focus group and end study surveys to gain insight on the acceptability and enjoyment of the program and suggestions for improvement.

Online Safety

A list of ground rules and code of conduct has been created for the DPP-FB group to follow while utilizing the group page and resources on Facebook. The study specific Facebook page will be available to study group members only. While on the study Facebook page, we will be monitoring their usage of the recordings and other posted materials as well as participant posts and comments on the feed to ensure the content is appropriate. We will not monitor whether or not they visit other pages within the Facebook platform. This risk is no different than the risk associated with having internet. Facebook is free and has many public domains open to anyone who has a username and login. Therefore, anyone who takes part in the study must agree to the disclaimer and limits of liability for Facebook.

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