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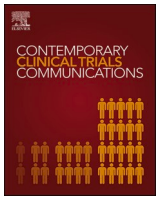

An integrated approach to address diabetes in the context of food insecurity: Delivering health study protocol

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ABSTRACT

Background: Diabetes self-management education and support (DSMES) interventions among food insecure individuals with type 2 diabetes (T2D) have found modest improvements in nutrition and health outcomes but are limited by barriers to attendance and retention. This study applies a community-based participatory research approach, engaging community members at all levels of intervention planning, development, implementation, and dissemination, to deliver a plain-language DSMES curriculum to food insecure community members with T2D.

Methods: This is a single-arm, pre-post design assessing the efficacy of a 12-week home-delivered DSMES curriculum and T2D-appropriate food box intervention to improve the nutrition and health outcomes of food insecure individuals with T2D. The intervention consists of a weekly food box delivery and handout with video links on key DSMES topics, developed and refined using community advisor feedback. Up to 100 English-, Spanish-, or Marshallese-speaking adult participants with T2D (HbA1c $\geq$ 7%) and food insecurity are being recruited from food pantries in northwest Arkansas. Data is collected at pre-intervention and immediately post-intervention. The primary study outcome is change in HbA1c. Secondary measures include diet quality (Healthy Eating Index-2015, calculated from 3 24-h dietary recall interviews via phone), body mass index, blood pressure, skin carotenoids, food security, T2D self-management behaviors, T2D self-efficacy, and T2D-related distress.

Results: Recruitment began in August 2021 and enrollment is anticipated to be complete in March 2023.

Conclusion: Findings from this study will provide a rich understanding of diabetes-related health outcomes and dietary patterns of individuals with food insecurity and T2D and inform future food-focused DSMES interventions in this setting.

1. Introduction

Approximately 34 million (~10.5%) people in the United States (US) have type 2 diabetes (T2D) [1], and this number is expected to continue to rise to more than 54 million Americans by 2030 [2]. Approximately 34 million Americans experienced food insecurity in 2021 [3], which is associated with increased risk for T2D and other chronic diseases [4]. Both T2D and food insecurity are even more prevalent in Arkansas, with rates of T2D and food insecurity at 12.2% [5] and 14.7% [6], respectively.

Very low food security (i.e., disrupted eating patterns and reduced food intake due to lack of money and other resources for food) is associated with an over 100% increase in prevalence of T2D compared with adults from high food-secure households (i.e., no anxiety about consistent access to enough food) [4]. Marginal food security (i.e., anxiety about consistent access to enough food, but no change in dietary intake)

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is associated with a 59% increase in prevalence of T2D compared with high food security [4], Individuals who experience food insecurity face many risk factors for unmanaged T2D [7], including poor diet quality [8–12], insufficient physical activity [13–15], and lack of access to health care [16–18]. Unmanaged T2D can lead to increased risk of serious complications, including neuropathy, nephropathy, retinopathy, atherosclerosis, heart disease, stroke, and death [19].

The high prevalence of food insecurity results in approximately 46 million Americans per year turning to food pantries and related programs to help meet household nutritional needs [20]. An estimated 33% of food pantry client households have at least one member with T2D [20]. Among these, 46% use food pantries at least six times per year [21]. In northwest Arkansas, food pantry clients are disproportionately comprised of members of the Hispanic and Marshallese Pacific Islander populations, each of which are groups at higher risk of T2D [1,22–26].

Food pantries, however, are not a long-term solution to improve health for people with food insecurity and T2D. Most food pantries do not provide food of sufficient dietary quality to support a healthy lifestyle, particularly for vitamins A and C and calcium [27]. Current food pantry clients' diet quality is insufficient for caloric intake, fruits, vegetables, and dairy [28].

Recent research has shown promise for diabetes self-management education and support (DSMES) among food pantry clients with T2D. DSMES supports informed decision-making, encourages goal setting and problem solving, and improves diabetes-related self-care behaviors [29]. Across many populations, DSMES improves glycemic control [30]; lowers body mass index (BMI) [31]; improves diabetes knowledge [32], diet quality [33], physical activity [34], and self-efficacy [32]; reduces health care costs and hospitalizations [35,36]; and increases use of primary care and preventive services [37]. For example, one study paired DSMES classes with T2D-appropriate food boxes distributed at food banks and found significant improvements in glycemic control [38]. However, this study encountered problems with attendance and retention, retaining only 42% of participants. In a follow-up trial, only 20% of participants engaged fully with the DSMES and food box intervention (i.e., picked up $\geq$ 9 of 11 food distributions, attended 2 DSMES classes, etc.) [39].

To leverage the full potential of T2D-appropriate food boxes paired with DSMES, it is necessary to reduce barriers to attendance and retention (e.g., by delivering the food boxes and DSMES to participants' homes). Efforts to improve the food security and nutritional health outcomes of individuals with T2D must also engage community members to address the problem at multiple levels. This paper presents a protocol to implement the *Delivering Health* study, which is led by a multidisciplinary study team with expertise in food insecurity, diabetes, nutrition, and health education. This study will implement and evaluate the efficacy of a plain-language DSMES curriculum and T2D-appropriate healthy food box intervention to improve the nutritional health, physical activity, and health outcomes of people with food insecurity and T2D. We will home-deliver the curriculum and food boxes to mitigate difficulties associated with access to healthy food and attendance at DSMES sessions outside of the home. We hypothesize that this approach will lead to improvements in participants' glycemic control, diet quality, and other outcomes. The study was reviewed and approved by the University of Arkansas for Medical Sciences Institutional Review Board (IRB #260304).

2. Methods

2.1. Study aim and design

The aim of this study is to develop, implement, and evaluate the effectiveness of an intervention to use home-delivery of T2D-appropriate food boxes with plain language adapted diabetes care education materials to improve the nutritional health, physical activity, and health outcomes of people with food insecurity and T2D. The study has a single-arm, pre-post study design. All participants will receive the intervention (i.e., 12 weekly food boxes including the adapted DSMES materials).

2.2. Partnership

The study integrates a community-based participatory research approach [40]. *Delivering Health* engaged diverse community members throughout its development and will engage community members in project implementation, evaluation, and dissemination. Community advisors, including health care professionals, food bank staff, and public health professionals, were involved in problem selection and project development and participated alongside the study team in adapting the DSMES curriculum. This has consisted of quarterly advisory meetings to provide project updates and ask for feedback regarding intervention development and implementation plans. The DSMES curriculum was initially drafted by a Registered Dietitian Nutritionist (RDN)/Certified Diabetes Care and Education Specialist (CDCES) and a Registered Nurse. Subsequently, three community advisors — a Dental Hygienist at a community partner serving uninsured dental patients and dietitians from two hunger relief organizations — reviewed all materials and provided feedback related to readability and usability. All materials were revised using community advisor feedback and then edited by health literacy professionals. The RDN/CDCES also designed T2D-appropriate food boxes and recipes to meet the needs of diverse community members with food insecurity. Focus groups were held with Spanish- and Marshallese-speaking staff members at the study team's university to ensure the curriculum, food boxes, and recipes were culturally appropriate for those communities. Within study implementation, partnerships were formed with a grocery store chain, food delivery service, and a local non-profit that facilitated the relationship between the food delivery service and study team. These implementation partners are working with the study team for food procurement and delivery. Community advisors will be invited to help interpret study results and to participate in dissemination as co-authors of manuscripts, reports, presentations, and social media infographics.

2.3. Sample size and recruitment

This study will recruit and enroll 100 participants from food pantries located in Benton and Washington counties in northwest Arkansas. Enrollment is limited to one adult, age 18 years or older, per household. Consent materials are in English, Spanish, and Marshallese (i.e., the most commonly spoken languages among food pantry clients in the recruitment region). In all three languages, recruitment materials use plain language. Recruitment is completed by bilingual staff (Spanish and English; Marshallese and English) with time for questions and answers. Food pantry clients are approached with a study information flyer and invited to participate in a free health screen collecting HbA1c, height, weight, and blood pressure. Research staff inform clients that if they have diabetes, they may be eligible to enroll in a study and receive free home delivered food boxes. Interested clients who meet the initial eligibility criteria of HbA1c $\geq$ 7.0% fill out a questionnaire to determine full study eligibility.

2.4. Participant eligibility

Participant inclusion criteria include: report food insecurity (confirmed by the 2-item Hunger Vital Sign screener [41]); 18 years of age or older; HbA1c equal to or greater than 7.0% (confirmed during the free health screen). Participant exclusion criteria include conditions making it unlikely the participant will be able to follow the protocol, such as having terminal illness, severe mental illness, severely impaired vision or hearing, or eating disorder; being non-ambulatory; not having regular access to a kitchen with working appliances; or planning to move out of the geographic region during the study period. Potential

participants will also be excluded if they are pregnant, if they have participated in another DSMES program in the past 5 years, or if another member of their household has already enrolled in the study.

2.5. Intervention

The intervention includes two components to improve the nutritional health, physical activity, and health outcomes of food insecure people with T2D: DSMES curriculum and food boxes appropriate for people with T2D. The DSMES curriculum was adapted into 12 modules based on the eight core content areas identified within the 2017 National Standards for Diabetes Self-Management Education and Support [42], inclusive of the American Diabetes Care and Education Specialist 7 (ADCES7) Self-Care Behaviors™ [43]. The core content areas cover all topics recommended by the American Diabetes Association (ADA) and ADCES and address understanding diabetes, healthy eating, physical activity, monitoring and using patient-generated health data, taking medicines, preventing complications, healthy coping, and problem solving [42]. These core DSMES content areas have been shown to improve patients' self-efficacy, diabetes-related distress, self-management behaviors, and knowledge [42,44]. A central aspect of the adaptation process was that all content in the modules was examined by the study team and community advisors to ensure that it reflected the experiences and challenges for individuals with food insecurity and/or low incomes. A list of the 12 adapted modules is presented in Table 1.

Each module was developed as a two-page plain language handout including color graphics. For each module, the study team incorporated T2D-appropriate recipes using the foods provided in the food boxes. Additionally, each module contains a 3-to 6-min video and a shorter 1-to 2-min version of the video created by the study team. These videos illustrate and elaborate upon the information presented in the paper handouts. The shorter videos were created to summarize key concepts for participants who do not have enough time to review longer videos. The videos are posted on a publicly accessible study website to introduce and reinforce key DSMES concepts [45]. In addition to receiving the paper version of the week's DSMES curriculum in the food box, participants receive text messages on the day each box is delivered. The text messages include links to an online copy of the week's module in each participant's preferred language and links to the week's videos. All materials have been translated into English, Spanish, and Marshallese. The Spanish-language and Marshallese versions of the videos feature Hispanic and Marshallese actors, respectively.

The 12 weekly food boxes follow the ADA Create Your Plate method [46], which emphasizes non-starchy vegetables, proteins, and grains, consistent with the meal pattern promoted in the ADA T2D nutrition therapy guidelines [47]. In addition, the boxes include food that largely reflects Feeding America's Foods to Encourage framework [48], which was developed by nutrition experts and food bank leaders to meet United States Department of Agriculture (USDA) dietary guidelines [49] and the MyPlate framework [50]. The boxes include ~9000 calories of food, equivalent to the amount the average household would receive pro-rated per week from an average Arkansas food pantry [22]. Each box includes fresh fruits and vegetables, as well as the ingredients necessary to prepare the recipes included with that week's DSMES curriculum. Peanut and tree nut products were excluded from the food box to include potential participants with nut allergies. Table 2 shows an example of T2D-appropriate food box content.

Table 1
Diabetes self-management and education and support (DSMES) module topics.

12-Week Adapted DSMES Curriculum Modules
1 What is Diabetes?
2 Eating Healthy – Part 1
3 Eating Healthy – Part 2
4 Physical Activity – Part 1
5 Physical Activity – Part 2
6 Monitoring Your Blood Glucose
7 Acute Complications
8 Chronic Complications of Diabetes – Part 1
9 Chronic Complications of Diabetes – Part 2
10 Medication Management
11 Healthy Coping with Diabetes
12 Problem Solving for Diabetes

2.6. Data collection and measures

This intervention takes place over 20 weeks. Weeks 1–4 are pre-intervention data collection, Weeks 5–16 are the 12-week intervention, and Weeks 17–20 are post-intervention data collection. The primary measure of intervention effectiveness is change in glycemic control (measured by fingerstick HbA1c using a Siemens DCA Vantage analyzer) from pre-to post-intervention. Other outcomes to be evaluated include changes in diet quality, BMI, blood pressure, T2D self-management behaviors, T2D knowledge, T2D self-efficacy, T2D-related distress, food security, and skin carotenoids. Table 3 presents the instruments used to assess these outcomes. Each of these measures is collected at enrollment (Weeks 1–4) and in the weeks following the 12th food box delivery (Weeks 17–20). All measures are collected in a private space at the food pantry from which the participants were recruited, with the exception of diet quality.

Dietary intake is collected using three 24-h dietary recall interviews, covering two weekdays and one weekend day per data collection window, for a total of six dietary recalls across the study. Dietary recalls are collected via telephone call by trained interviewers using the USDA multiple-pass methodology to gather all foods and beverages consumed in the previous day [51]. All dietary data are collected and analyzed using Nutrition Data System for Research (NDSR) software versions 2021 and 2022, which contains data for 178 nutrients, nutrient ratios, and other food components [52]. NDSR also facilitates calculation of Healthy Eating Index (HEI)-2015 scores [53]. The HEI is a tool that measures the alignment of a set of foods with the Dietary Guidelines for Americans (DGA) and is recommended by the National Cancer Institute to assess the impact of interventions on diet quality [53,54]. HEI consists of 13 separate nutrient components. Nine nutrients are categorized as adequacy components (i.e., total fruits, whole fruits, total vegetables, greens and beans, whole grains, dairy, total protein, seafood and plant proteins, fatty acids), and four are moderation components (i.e., refined grains, added sugars, sodium, saturated fats). The HEI-2015 is scored from 0 to 100, with higher scores representing a more desirable diet quality and better alignment with the DGA.

Within Weeks 9–12 of food box deliveries, participants are asked to complete an online survey of their food preferences for the food provided in the food boxes. The food preferences survey asks participants

Table 2
Example of T2DM-appropriate food box.

Food Group	Items Provided
Fruit	• 20 oz. Canned Pineapple Tidbits in Natural Juice • 15 oz. Canned Lite Sliced Peaches • 3 Fresh Apples
Vegetables	• 15 oz. Canned Mixed Vegetables • 14.5 oz. Canned No Salt Added Green Beans • 2 Fresh Sweet Potatoes • 1 Fresh Onion • 1–10 oz. Bag Frozen Spinach
Meat/ Protein	• 15 oz. Can No Salt Added Black Beans • 10 oz. Canned Chicken • 12 oz. Canned Tuna • 1- Dozen Large Eggs
Whole Grains	• 10 Count Whole Wheat Tortillas • 1–14 oz. Box Instant Brown Rice
Dairy	• 1 Gallon 1% Milk • 1–10 oz. Bag Part Skim Mozzarella String Cheese
Other	• 1–8 fl oz. Bottle Extra Virgin Olive Oil (this is included in the calorie count)

Table 3
Study measures and outcomes.

Variables	Instruments or Measures
Demographic and Socioeconomic	Demographic (age, gender, marital status, race/ethnicity, number of adults and children in the household) and socioeconomic (education, income, employment status, health insurance coverage, WIC and SNAP benefits) variables are collected using adapted questions from the Behavior Risk Factor Surveillance System (BRFSS) [56] and the National Health Interview Study (NHIS) [57], with study-specific questions created by the study team.
HbA1c	Finger stick blood collection is used to test HbA1c using a Siemens DCA Vantage analyzer that can be taken into the field [58].
Diet Quality and Fruit and Vegetable Consumption	24-h dietary recalls are collected using the Nutrition Data System for Research (NDSR) software, which includes over 18,000 foods [52]. NDSR will be used to calculate Healthy Eating Index-2015 (HEI) scores and fruit and vegetable consumption. HEI-2015 scores comprise thirteen component scores (e.g., vegetables, dairy) and are recommended by National Cancer Institute to assess impact of interventions on diet quality [53,54]. Skin carotenoid level is measured using a Veggie Meter® optical skin scanner, which uses Raman Spectroscopy. The Veggie Meter assesses frequency changes in reflected light to calculate carotenoid presence. Skin carotenoid levels are a biomarker of fruit and vegetable dietary intake [59].
BMI	Weight and height are used to compute a continuous measure of BMI using the Quetelet Index (kg/m^2). Weight is measured in light clothing to the nearest 0.5 lb. (0.2 kg) using a calibrated digital scale. Height (with flat or no shoes) is measured to the nearest 0.5 in. using a stadiometer.
Blood Pressure	Systolic and diastolic blood pressure is measured using an Omron Intellisense digital blood pressure monitor with the participant seated and arm elevated. Two blood pressure readings are taken with 1 min in between. If the two blood pressure readings are not within 5 mmHg (systolic and diastolic) a second two readings are taken, and the average of the four readings are used.
Medical Conditions	BRFFS self-report items assess lifetime prevalence of medical conditions [56].
T2D Self-Management Behaviors	The Summary of Diabetes Self-Care Activities (SDSCA) is used to measure self-care activities. The SDSCA consists of 12 items to assess the frequency of performing diabetes self-care tasks [60]. SDSCA was validated in minority populations, including the Marshallese [61]. Study-specific questions developed by the study team measure how participants control and monitor their T2D (e.g., insulin, oral medications, continuous glucose monitor).
Oral Health	Oral health (e.g., time since last teeth cleaning) is assessed by a single-item taken from the BRFFS survey [56].
T2D Self-Efficacy	Self-efficacy for health behaviors is assessed through the Diabetes Management Self-Efficacy Scale (DMSES), which measures the extent to which respondents are confident in managing their blood sugar, diet, and exercise [62]. DMSES was validated in several studies of minority populations, including the Marshallese [61].
T2D-Related Distress	Psychological distress related to T2D is assessed through PAID-5 scale of the Diabetes Attitudes, Wishes, and Needs second study questionnaire (DAWN2) [63].
Food Security	Food security is assessed using the 2-item Hunger Vital Sign™ [41].
Food Pantry Utilization	Food pantry utilization is assessed through modified items from Feeding America's Hunger in America Client Survey [20], in addition to questions developed by the study team.
Medication Adherence	Measures of diabetes medication adherence is collected using questions from the NHIS [57] and ARMS-D [64].
Cooking Skills and Knowledge	Assessment of participants confidence in following a simple recipe and cooking from basic ingredients is assessed using items developed for use in low socioeconomic populations [65].
Process Evaluation Measures	Process evaluation includes tracking indicators of retention (e.g., numbers of participants enrolled, data collection events completed) and dosage (e.g., food boxes successfully received). Post-intervention data collection includes open-ended questions about satisfaction with food boxes and suggestions to improve intervention.

whether they versus someone else in their household ate "some or all" or "none" of each item they receive in the food package. These diet quality and food preferences data will provide a detailed characterization of the dietary patterns of people with food insecurity and T2D, the extent to which their diets adhere to dietary guidelines, and the extent to which the participants themselves ate the food provided by the intervention.

Participants receive a $40 gift card for participation in each of the two data collection events and a $10 gift card for participation in each of the six dietary recall phone interviews, for a total of up to $140. Participant data is stored and managed using Research Electronic Data Capture (REDCap) [55]. Data quality checks of electronic entries within REDCap are conducted by research support staff as part of the data management plan. Tools within the software are also used to minimize data entry errors (e.g., validate data entries, branching logic). Potential adverse events or unanticipated problems are immediately reported to the study Principal Investigator, who determines level of severity and reports to the IRB per the study protocol.

3. Data analysis plan

3.1. Power and sample size

The study has a single-arm, pre-post study design. All participants receive the intervention (i.e., 12 weekly food boxes including the adapted DSMES materials). Assuming a repeated measures *t*-test, two-sided $\alpha = 0.05$, and a Pearson correlation between repeated measures of $r = 0.5$, we will have 80% power to detect a Cohen's d effect size of 0.28. For context, Chrvala, Sherr, & Lipman's meta-analysis found that on average DSMES led to a 0.6% improvement in HbA1c [30]. Assuming a standard deviation of 1.5%, this translates to Cohen's d of 0.4 (i.e., $0.6/1.5 = 0.4$). Thus, the proposed intervention with a sample size of 100 is powered to detect a small-to-medium effect consistent with the expected effect size for standard DSMES interventions in the context of research trials and smaller than the effect found in previous food pantry-based DSMES interventions [38,39].

3.2. Planned analyses

Analyses of changes in glycemic control and secondary outcomes will be performed with SAS 9.4. Dietary analyses will be conducted using STATA 17. Data will be examined for distributional normality and outliers prior to analyses. Descriptive statistics will be generated for all variables of interest. We will examine patterns and predictors of missing values. If the percentage of missing values is larger than approximately 10%, we will compare models using multiple imputation with those using complete case analysis to examine the potential impact of missing values on the results.

To examine the intervention's effect on the primary outcomes of

glycemic control as measured by HbA1c and diet quality as measured by HEI scores, we will use mixed effects regression models for repeated measures. These analyses will focus on testing for a statistically significant difference between pre-intervention versus post-intervention measures. Additional analyses will include relevant covariates such as sex or age. We will also explore models that include process indicators of dosage of intervention received (e.g., number of food boxes received) to examine whether dosage predicts change in primary outcomes. The diet quality data will also be evaluated for pre-to post-intervention changes in HEI scores and the extent to which diets adhere to dietary guidelines. This will involve comparing HEI scores to the maximum scores overall and within each nutrient component, to determine nutrients to target in future interventions.

4. Results

Recruitment for this study began in August 2021, and enrollment is anticipated to be complete in March 2023.

5. Dissemination plan

Findings from this research will give a rich characterization of diabetes-related health outcomes and dietary patterns of people experiencing food insecurity and T2D and provide data to guide refinement, larger implementation, and further evaluation of the home delivery DSMES and food box intervention. As such, it is imperative to disseminate this information back to study participants and community members. All DSMES curriculum (handouts, videos) are available on a public website in English, Spanish, and Marshallese. Early in the research process, we engaged project community advisors to incorporate dissemination planning, and we will invite them to help interpret study results and participate in dissemination as coauthors. Presentations and publications will include examples of ways in which community advisors' advice shaped study implementation. In reports, presentations, publications, and social media, we will also disseminate results to local food system and health care organizations, statewide and regional food insecurity interest groups, food banks and pantries, and fellow researchers. After publication of the major findings in peer-reviewed journals, we will make the dataset available to other researchers for further analyses.

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Declaration of competing interest

None.

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