Study Title: Delivering Health: An Integrated Approach to Address Diabetes in the Context of Food Insecurity

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Background and Rationale

Decades of increasing incidence of type 2 diabetes (T2D) present a multifaceted challenge to the health of a growing number of Americans, affecting their diets and how they live life. Approximately 30 million (~9%) of all people in the US have T2D,[1] and this number is expected to continue to rise. It is estimated that the prevalence will increase to more than 54 million Americans by 2030.[2] At the same time, 15 million (11.8%) US households experience food insecurity,[3] which is associated with 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 17.3%,[6] respectively. T2D and food insecurity are strongly associated for U.S. adults: Very low food security is associated with an over 100% increase in prevalence of T2D compared with adults from high food-secure households.[4] Even for adults in marginally food secure households, probability of T2D increases by 59%.[4]

~40 million Americans are food insecure,[3] and food insecurity is associated with double the prevalence of T2D.[4] Food insecure people 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 attack, stroke, and death.[19]

~46 million Americans per year turn 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]

However, food pantries are not a long-term solution to improve health for food insecure people with 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.[22] Current food pantry clients' diet quality is insufficient for caloric intake, fruits, vegetables, and dairy.[23]

Diabetes self-management education (DSME) is an approach with documented efficacy in helping people manage T2D. DSME supports informed decision-making, encourages goal setting and problem solving, and improves self-care behaviors.[24] Across many populations, DSME improves glycemic control;[25] lowers body mass index (BMI);[26] improves diabetes knowledge,[27] diet quality,[28] physical activity,[29] and self-efficacy;[27] reduces health care costs and hospitalizations;[30,31] and increases use of primary care and preventive services.[32]

Recent studies have shown promise for DSME among food pantry clients with T2D. One study paired DSME classes with T2D-appropriate food boxes distributed at food banks and found significant improvements in glycemic control.[33] However, this study suffered from problems with attendance and retention, retaining only 42% of participants. In a follow-up trial, only 20% engaged fully with the DSME and food box intervention (i.e., picked up ≥9 of 11 food distributions, attended 2 DSME classes, etc.).[34]

By removing barriers to attendance and retention, our research team will leverage the full potential of home-delivered T2D-appropriate food boxes paired with DSME. We have

successfully adapted diabetes education for delivery in community settings, including homes, faith-based organizations, and community centers.[35] We have adapted DSME for people from diverse cultural backgrounds who face economic, transportation, health care, and health literacy barriers.[36] We are experienced at developing interventions to improve health of low-income food insecure people, including food pantry interventions to improve access to healthy food.[37,38]

We propose a study to develop and evaluate the efficacy of a plain-language DSME curriculum to improve the nutritional health, physical activity, and health outcomes of low-income food insecure people with T2D. We will home-deliver this curriculum along with T2D-appropriate healthy food boxes to mitigate difficulties associated with access to healthy food and attendance at DSME sessions outside of the home. *We hypothesize that this approach will lead to improvements in participants' glycemic control, diet quality, and other outcomes*.

Objective

Develop, implement, and evaluate the effectiveness of an intervention to use home-delivery of T2D-appropriate food boxes with plain language adapted education materials, in English, Spanish, and Marshallese, to improve the nutritional health, physical activity, and health outcomes of low-income food insecure people with T2D.

Study Design and Procedures

Stakeholder involvement Stakeholders were involved in problem selection and project development. Stakeholders will participate in adapting the DSME curriculum. To ensure the study captures outcomes important to each stakeholder group, stakeholders helped choose study outcomes. Stakeholders will be invited to help interpret study results and to participate in dissemination as co-authors of manuscripts, reports, and presentations.

Project activities 1. Adapt DSME curriculum for use by low-income food insecure communities. As part of the development, we will incorporate T2D-appropriate recipes and information on cooking and shopping when on a limited budget and with foods commonly found at food pantries. In addition, 12 videos will be created and posted on a freely accessible UAMS website to introduce and reinforce key DSME concepts.

Table 1. 12-week Adapted ACP Curriculum Modules
1. What is Diabetes?
2. Healthy Eating Part 1Healthy
3. Healthy Eating Part 2
4. Physical Activity Part 1
5. Physical Activity Part 2
6. Monitoring Diabetes
7. Acute Complications
8. Chronic Complications Part 1
9. Chronic Complications Part 2
10. Medication Management
11. Healthy Coping
12. Problem Solving

The 12 adapted modules are presented in **Table 1**. In the study, these modules will be delivered to the participants on paper in the T2D-appropriate food boxes and in easy to access online versions, which link to the videos summarizing the key concepts and demonstrating cooking techniques. All materials are translated into English, Spanish, and Marshallese.

2. Design T2D-appropriate food boxes. The project team led by an endocrinologist, registered nurse, and registered dietitian designed 12 weekly food boxes to be home delivered to each participant. The boxes were adapted from the American Diabetes Association Create Your Plate method,[49] which emphasizes non-starchy vegetables, proteins, and grains, consistent with the meal pattern promoted in the ACP DSME.[48] In addition, the boxes will include food that largely reflects Feeding America's Foods to Encourage framework,[50] which was developed by nutrition experts and food bank leaders to meet USDA dietary guidelines[51] and MyPlate framework.[52]

The boxes will include ~9,000 calories of food, equivalent to the amount the average household would receive *pro-rated per week* from an average Arkansas food pantry.[37] Each box will include fresh fruits and vegetables, as well as the ingredients necessary to prepare the recipes included with that week's DSME curriculum. If a certain item is unavailable or out of stock, there is a list of potential substitutions that are of equal nutritional content compared to the first choice food item. Each week's box will include an educational fact sheet of the week's DSME module, including links and QR codes leading to the videos. Links to the week's online materials, which present the same content as the paper materials, will be texted or emailed to each participant based on their preferred contact method on the day each box is delivered. **Table 2** shows an example T2D-appropriate food box.

Table 2. Example of T2DM-appropriate Food Box

Fruit	• 1- 20 oz. Canned Pineapple Tidbits in Natural Juice • 1- 15 oz. Canned Lite Sliced Peaches • 3 Fresh Apples
Vegetables	• 1- 15 oz. Canned Mixed Vegetables • 1- 14.5 oz. Canned No Salt Added Green Beans • 2 Fresh Sweet Potatoes • 1 Fresh Onion • 1- 10 oz. bag Frozen Spinach
Meat/Protein	• 1- 15 oz. can No Salt Added Black Beans • 1- 10 oz. Canned Chicken • 1- 12 oz. Canned Tuna • 1- Dozen Large Eggs
Whole Grains	• 1- 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)

3. Recruit and enroll up to 110 participants. Study participants may be recruited from waiting areas of food pantries located in Benton and Washington Counties in northwest Arkansas. (See Letters of Support from local food pantries.) Due to social distancing and public health guidelines related to COVID-19 each of the food pantries have established drive-thru clinics where participants can remain isolated in their vehicles while completing data collection. Participants may use these drive-thru clinics for consent and all biometric collection.

If COVID-19 regulations are lifted and food pantries are welcoming clients inside, consent and biometrics will be collected in a private area of the facility. In our preliminary data from 247 food pantry clients, 95% of clients in this region screen positive for food insecurity, and ~30% report at least one household member diagnosed with T2D. Participant inclusion criteria include: report food insecurity (confirmed by adapted 10-item screener[53]); 18 years of age or older; report T2D (confirmed by having an HbA1c equal to or greater than 7 at initial data collection immediately following consent. Participant exclusion criteria include conditions making it unlikely the participant will be able to follow the protocol, such as terminal illness, non-ambulatory, severe mental illness, severely impaired vision or hearing, eating disorder, pregnant, or plans to move out of the geographic region. Only one adult per household will be enrolled. Individuals under 18 years old are not included in the proposed study because the intervention is designed for adults with T2D.

Consent materials will be available in English, Spanish, or Marshallese and will use plain language. Eligible participants will be provided a copy of the consent to review, and participants will have the opportunity to ask questions, consent, and enroll in the study. The consent process will include providing information to the potential participants and the opportunity to have bilingual Marshallese or Spanish speaking staff answer questions regarding study participation. The consent document will be given to the participant, and the informed consent process will be documented in the participant's research record. Consent with the participant's signature will serve as documentation. An opportunity will be provided to all potential participants for individual, private discussion of the study and the consent document before they sign the consent. All members of the research team will be trained and certified in participant consent procedures, the study protocol, human subjects protection, and HIPAA regulations.

Enrollment is expected to begin in Year 2 Quarter 3, and will remain open until recruitment goals are met, which is expected to be Year 4 Quarter 2.

4. Collect data. For each participant, participation will take place over 22 weeks (Weeks 1-4: Pre-intervention data collection; Weeks 5-16: Intervention; Weeks 17-22: Post-intervention data collection). **Table 3** describes the study measures and outcomes. Data collection will take place at pre-intervention and post-intervention for each participant. At enrollment (i.e., pre-intervention) and one week after the 12th food box delivery (i.e. post-intervention), participants will provide data on glycemic control (measured by HbA1c), physical activity, body mass index (BMI), T2D self-management behaviors, T2D knowledge, T2D self-efficacy, and food security. To enhance the study's significance in characterizing the diet patterns and fruit and vegetable consumption of low-income food insecure people with T2D, we are collecting extensive diet quality data measures pre-intervention and post-intervention. Specifically, *we will collect 24-hour dietary recalls. Participants will be asked to document their dietary intake over a 24-hour period three times within four weeks. Two of the dietary recalls must be collected from a weekday and one of the recalls must be collected from a weekend day. Also, Skin carotenoid level will be 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. Participants will be asked to complete a survey via (email, text or in person) asking about their preference for the food provided in the food boxes.

Initial data collection will take place in a private space immediately following enrollment. The remaining pre-intervention data collection and post-intervention data collections will take place via telephone and at locations of each participant's choosing (e.g., HbA1c will be collected at home or at a community-based location such as a food pantry). Our team has necessary expertise and equipment to complete data collection in homes or community-based locations, having successfully completed thousands of such data collection events.[37,43,54-61]

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 DSME materials). Our target sample size for recruitment is 100. Assuming a repeated measures t-test, two-sided α=.05, and a Pearson correlation between repeated measures of r=.5, we will have 80% power to detect a Cohen's d effect size of 0.28. For context, Chrvala, Sherr, & Lipman's (2016) meta-analysis found that on average DSME led to a 0.6% improvement in HbA1c.[25] 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 DSME interventions in the context of research trials, and smaller than the effect found in previous food pantry-based DSME interventions.[33,34]

Table 3. *Delivering Health* study measures and outcomes

Variables	Instrument(s) or Measure(s)
COVARIATES	
Demographic & Socioeconomic	Demographic (age, gender, marital status, race, number of adults and children in the household) and socioeconomic (education, employment status, insurance coverage, WIC and SNAP benefits) variables will be captured using validated questions from the Behavior Risk Factor Surveillance System (BRFSS)[62] and National Health Interview Study (NHIS).[120]
EFFECTIVENESS OUTCOMES	
HbA1c	Finger stick blood collection will be used to test HbA1c using a Siemens DCA Vantage analyzer that can be taken into the field.[63]
Diet Quality and Fruit and Vegetable Consumption	Skin carotenoid level will be 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. 24-hour dietary recalls will be collected using the widely-used Nutrition Data System for Research (NDSR) software, which includes over 18,000 foods.[64] NDSR will be used to calculate Healthy Eating Index-2015 (HEI) scores and fruit and vegetable consumption. HEI-2015 scores comprise nine

	component scores (e.g., vegetables, dairy) and are recommended by National Cancer Institute to assess impact of diet quality interventions.[65,66]
BMI	Weight and height will be used to compute a continuous measure of BMI using the Quetelet Index (kg/m^2). Weight will be measured in light clothing to the nearest 0.5 lb. (0.2 kg) using a calibrated digital scale. Height (without shoes) will be measured to the nearest 0.5 in. using a stadiometer.
Medical Conditions	BRFFS self-report items will assess lifetime prevalence of medical conditions.[62]
T2D Self-Management Behaviors	The Summary of Diabetes Self-Care Activities (SDSCA) will be used to measure self-care activities. The SDSCA consists of 12 items to assess the frequency of performing diabetes self-care tasks.[67] SDSCA was validated in minority populations, including the Marshallese.[68]
Oral Health	Oral health will be assessed by a single-item taken from the BRFFS survey.[62]
T2D Self-Efficacy	Self-efficacy for health behaviors will be assessed through the Diabetes Management Self-Efficacy Scale (DMSES), which assesses the extent to which respondents are confident in managing their blood sugar, diet, and exercise.[69] DMSES was validated in several studies of minority populations, including the Marshallese.[68]
T2D-related Distress	Psychological distress related to type-2 diabetes will be assessed through PAID-5 scale of the Diabetes Attitudes, Wishes, and Needs second study questionnaire (DAWN2)[122]
Food Security	Food security will be assessed using the adapted 10-item USDA screener.[121]
Food Pantry Utilization	Food pantry utilization will be assessed through modified items from Feeding America's Hunger in America Client Survey[123]
Medication Adherence	Measures of diabetes medication adherence will be collected with measures from BRFFS[62], NHIS[120], and ARMS-D.[124]
Cooking Skills and Knowledge	Assessment of participants confidence in following a simple recipe and cooking from basic ingredients will be assessed using items developed for use in low socioeconomic populations.[125]
PROCESS EVALUATION MEASURES	
Process Indicators	Process evaluation will include 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 will include open-ended questions about satisfaction with food boxes and suggestions to improve intervention.

5. Implement intervention. **Table 4** summarizes the intervention.

Table 4. DSME and T2D-appropriate Food Boxes Intervention	
Evidence-based DSME Curriculum	■ Consistent with the American Association of Diabetes Educators, the adapted ACP DSME will cover the topics of understanding diabetes, eating right, being active, checking blood sugar, taking medicines, keeping feet healthy, and insulin. The adapted curriculum consists of 12 modules, which will include recipes and information on cooking and shopping when on a limited income and with foods commonly found at food pantries.
T2D-appropriate food boxes	■ Each weekly food box will include ~9,000 calories of food, equivalent to the amount the average household receives *prorated per week* from an average Arkansas food pantry.[37] The boxes will follow the American Diabetes Association Create Your Plate method, consistent with the ACP DSME. Food will be purchased from a local grocery store.
Intervention Delivery	■ Food boxes will be delivered to participants' homes once per week. Each week's box will include a two-page educational fact sheet version of the week's DSME module, including links and QR codes leading to videos supporting the week's curriculum module. Links to the week's online materials, which present the same content as the paper materials, will be texted or emailed to each participant the day their box is delivered.
Dosage	■ 12 food boxes (including curriculum) delivered once per week over 12 weeks

Given the study's longitudinal design, participant retention will be crucial. We engaged stakeholders to develop a retention plan. The plan specifies that study staff responsible for recruitment and retention will be bilingual (Spanish/English or Marshallese/English). Study staff will obtain each participant's contact information and preferred method of contact. Before each follow-up data collection visit or call, research staff will contact participants about the upcoming data collection.
"Participants will be offered a $40 gift card for participation in each of the two data collection events for a total of $80. Those participants who only participate in the survey or biometric data collection will receive $20 for their time. Participants will also be offered $10 gift cards at each of the dietary recall phone interviews for a total of $60. Participants will only receive gift cards for the data collection events they complete. If a participant drops out, the study team will document who dropped out and why the drop out occurred. Participants will be able to choose a Tango electronic gift card at each of the data collection events.

Study Population

Up to 110 study participants will be recruited from food pantries located in Benton and Washington Counties in northwest Arkansas.

Inclusion Criteria

- 18 years of age or older
- Food insecure (confirmed with adapted 10-item screener)
- HbA1c levels of ≥7

Exclusion Criteria

- Conditions making it unlikely the participant will be able to follow the protocol, such as terminal illness, non-ambulatory, severe mental illness, severely impaired vision or hearing, eating disorder, or plans to move out of the geographic region
- Pregnant
- Only one adult per household will be enrolled

Risks and Benefits

A risk to study participants is the potential for loss of confidentiality of study data. Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

A finger stick is required to collect a small amount of blood for testing, this may cause some discomfort.

The food box deliveries will be packaged to hold the correct temperature of perishable foods for three hours. After that time, or if the box is in any way damaged there is a risk of potentially eating spoiled foods from the food box delivery. There is also a risk of consuming a food item that the participant is unknowingly allergic to. We will do our best to ensure the integrity of the food box deliveries and are always available to contact with any questions regarding the food items in the deliveries.

Potential benefits include provision of nutritionally balanced food to participant's home for the 12 week period of the study. Participants may experience improved health status, specifically related to type 2 diabetes.

In addition to the potential of benefits to the participants, knowledge gained from the study could potentially benefit patients in the future.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study.

All study subject material will be assigned a unique identifying code or number. The key to the code will be stored in a secure location in the Office of Community Health and Research. Only the principal investigator and the study coordinator will have access to the code and information that identifies the subject in this study. During data collection events survey data will be collected on a UAMS iPad or laptop using REDCap mobile app (with built in encryption technology). As soon as the data collectors return to UAMS, they will upload the data to the REDCap instance housed on a secure UAMS server and delete the data from the iPad or laptop. Blood specimens collected for HbA1c testing are only used for point of care testing, they will be discarded immediately after the test is performed. At the conclusion of the study the key to the code will be shredded, the data will be permanently de-identified.

The study will comply with UAMS Admin Guide Policy 3.2.01 – research data, reports and analyses be retained for seven years after final reporting or publication of a project, or longer if required by a sponsor or regulation.

Data Analysis

Analyses will be performed with SAS 9.4. 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 Healthy Eating Index-2015 (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.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and private room, and subjects may take as much time as needed to make a decision about their participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject and the person obtaining the consent. A copy of the consent will be given to the participant, and the informed consent process will be documented in the research record.

A $40 Walmart gift card will be provided to the participant each time they complete a data collection event. If they complete both data collection events, they will receive a total of $80 in Walmart gift cards.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant. The study will be listed on clinicaltrials.gov in accordance with funder requirements. A summary of results will be returned to participants in an infographic that is provided to them in person and/or mailed to the participants. 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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