



Feasibility of a food-based diabetes self-management education intervention for food insecure patients with type 2 diabetes: a convergent mixed methods study

Eliza Short^{1,*} , Debbe Thompson², Douglas Taren³, Holly Bryant⁴, Rhonda Gonzalez⁵, Jessi Sheava⁵ and Melanie Hingle¹

¹University of Arizona School of Nutritional Sciences and Wellness, 1177 E 4th St, Tucson, AZ 85721, USA:

²USDA/ARS Children's Nutrition Research Center, Baylor College of Medicine, 1100 Bates St, Houston, TX 77030, USA: ³University of Colorado School of Medicine, 12631 East 17th Avenue, Mail Stop F561, Aurora, CO 80045, USA: ⁴El Rio Community Health Center, 450 W Paseo Redondo, Tucson, AZ, 85701, USA:

⁵Community Food Bank of Southern Arizona, 3003 S Country Club Rd, Tucson, AZ 85713, USA

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Abstract

Objective: To assess the feasibility of a food-based diabetes self-management education and support (DSMES) intervention delivered to persons with type 2 diabetes (T2DM) and food insecurity.

Design: This single arm pre-/post convergent mixed methods study tested the feasibility of a 3-month intervention using food boxes, recipes, DSMES and dietitian visits. Feasibility benchmarks assessed were acceptability (> 50 % participants satisfied), demand (> 50 % used program components) and implementation (75 % adherence, 80 % retention). Assessments included: self-reported food security, health-related quality of life, diabetes self-efficacy, socio-demographic and dietary intake, height, weight, and HbA1c and one in-depth interview with participants and key staff. Enrollment, recruitment and retention rates were summarised; qualitative data were analysed using structured thematic analysis (participant interviews) and key point summaries (staff interviews). Quantitative/qualitative data integration was conducted using a joint display.

Setting: Food bank and Federally Qualified Health Center in the Southwestern U.S.

Participants: English- or Spanish-speaking adults with T2DM and food insecurity.

Results: In total, 247 patients with T2DM and food insecurity were recruited, seventy-one expressed interest and twenty-five consented. Twenty-one participants completed study measurements. 71 % (*n* 15) received six home food deliveries and ≥ 1 dietitian visit. *A priori* benchmarks were approached or met within each feasibility criterion – most participants found the intervention to be acceptable, used most or all intervention components, and reported some challenges within intervention implementation (e.g. timing of food deliveries). Data integration provided deeper understanding of reported intervention implementation challenges, yet high adherence to the intervention.

Conclusions: The intervention was feasible. Next steps include a clinical trial to establish intervention efficacy.

Keywords
Feasibility study
Qualitative research
Food insecurity
Type 2 diabetes
Primary care

Type 2 diabetes mellitus (T2DM) and food insecurity are two significant and highly related public health concerns associated with increased morbidity and mortality^(1,2). In 2019, T2DM affected more than 14 % of U.S. adults, with related social, financial and medical costs exceeding \$327 billion^(3,4). The presence of household food insecurity has

been associated with decreased ability to manage T2DM⁽⁵⁾. Individuals experiencing food insecurity and T2DM are often faced with trade-offs when investing scarce financial resources (e.g. choosing to *either* obtain nutritious food *or* pay utilities/rent *or* seek medical care)⁽⁶⁾. These trade-offs contribute to overall poor diet quality, difficulty managing

*Corresponding author: Email ershort@arizona.edu

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T2DM and worse health outcomes⁽⁷⁾. In 2020, 10.5 % of U.S. households were food insecure; low-income households and racial and ethnic minorities were the most affected⁽⁸⁾. In light of these disparities and the projected increase in diabetes prevalence to 17.9 % by 2060⁽⁹⁾, it is essential to develop accessible, affordable and acceptable interventions for those experiencing the dual challenges of food insecurity and T2DM management.

Food-insecure households often utilise food assistance programs (e.g. food banks, food pantries) to help meet food needs⁽¹⁰⁾. Frequent use of these programmes has been associated with improved food security and diet quality⁽¹¹⁾, both of which are critical to effective T2DM management⁽¹²⁾. Several studies conducted with clients of food banks or meal assistance programs have evaluated provision of food and diabetes self-management education and support (DSMES) on T2DM outcomes^(13–16). Positive effects on food security were observed in three of the four studies, and improvements in dietary intake were observed in all four studies; only one study showed significant effects on HbA1c⁽¹⁴⁾. Two similar interventions were conducted at health clinics^(17,18). In one of these studies, HbA1c was significantly improved, although there was no evaluation of intervention feasibility and acceptability⁽¹⁷⁾. In the second clinic-based study, HbA1c was improved, but statistical and clinical significance was not reported⁽¹⁸⁾.

Recent shifts to prioritise food and nutrition security in the USA has resulted in the incorporation of food-based nutrition programs into healthcare settings. These 'Food is Medicine' programs aim to use food as a foundational approach to prevent and/or treat chronic diet-related diseases like T2DM^(19,20). Medically tailored groceries are recommended to address T2DM among individuals experiencing food insecurity who have the ability to cook and prepare their own meals⁽²⁰⁾. Across the handful of published medically tailored grocery or meal intervention studies of T2DM management with food insecure persons, there has been very limited consideration and evaluation of the factors influencing intervention uptake^(13–16). Regional food banks and Federally Qualified Health Centers (FQHCs) each provide critical services to address the food and health needs of low-income Americans with T2DM, and partnerships between these organisations are recommended to create successful Food is Medicine programs⁽¹⁹⁾. Further, understanding and addressing food insecurity within the context of T2DM care is an emerging priority of FQHCs^(20,21), and the existing infrastructure of a health care system can be leveraged to incorporate the diabetes-related expertise of health care professionals. A collaboration between food banks and FQHCs has the potential to be scaled and replicated, given that networks of these organisations are located throughout the USA. Formal partnerships between these two types of organisations offer a novel, and to our knowledge, untested way to address the food and nutrition security of persons with T2DM who struggle to manage their disease.

The purpose of the Food and Resources Expanded to Support Health (FRESH) study was to test the feasibility of a food-based diabetes self-management intervention delivered by a regional food bank on nutrition and diabetes outcomes in FQHC patients with T2DM experiencing food insecurity using a convergent mixed methods design⁽²²⁾. Feasibility studies are recommended to provide guidance in determining whether an intervention is ready for testing in a fully powered trial⁽²³⁾.

Methods

Partnership

This intervention was co-designed with food bank and FQHC partners, with significant input from community members accessing the food bank. In 2017–2018, partnerships with the food bank and health clinic were formed to develop an intervention approach that was responsive to the needs of clients and patients at both organisations. Initial work by our team provided insight into the dietary patterns of community members accessing the food bank⁽²⁴⁾ and a deeper understanding of the perspectives of individuals with T2DM experiencing food insecurity⁽²⁵⁾. Findings from these two studies informed the food and educational resources in the current feasibility study, including an emphasis on culturally acceptable foods and recipes.

Study design

Mixed methods research designs integrate quantitative and qualitative data to leverage the combined strengths of both datasets, with the goal of a more holistic evaluation of intervention feasibility than would be possible from either dataset alone⁽²⁶⁾. This convergent mixed methods feasibility study consisted of a one group design with pre- and post-intervention data collection⁽²²⁾. Prior to the intervention initiation, we established *a priori* benchmarks focused on three criteria determined to be critical in order to progress to a larger definitive clinical trial: acceptability (> 50 % of participants are satisfied with the intervention), demand (> 50 % of participants use most or all intervention components) and implementation (participants receive > 75 % of food boxes and at least one dietitian visit; 80 % of participants are retained) – Table 1⁽²³⁾. These benchmarks were based on retention and adherence challenges identified in prior research^(15,27). The retention benchmarks also considered the sample size needed to generate estimates to inform a future definitive clinical trial. Acceptability and demand benchmarks were further refined based upon discussions with food bank and FQHC partners who identified their minimum thresholds to progress to a larger definitive clinical trial, while considering their respective goals, time and resource constraints. Consistent with mixed methods research⁽²⁶⁾,

Table 1 Summary of select feasibility criteria, assessment methods and *a priori* benchmarks

Feasibility criteria Definition	Outcomes	Benchmarks
Acceptability Suitability of programme, fit within daily life	<ul style="list-style-type: none"> Satisfaction with foods and resources Perceived usefulness to participants and key staff delivering the program 	<ul style="list-style-type: none"> Majority of participants satisfied with intervention components
Demand Extent the programme is utilised	<ul style="list-style-type: none"> Use of foods and resources Barriers and promoters to use of intervention components and intervention delivery 	<ul style="list-style-type: none"> Majority of participants used most of intervention components
Implementation Extent programme is delivered as planned	<ul style="list-style-type: none"> Recruitment and retention rates Adherence to intervention components Factors affecting ease of engaging in intervention components Changes made to organisational standard operating procedures for delivery 	<ul style="list-style-type: none"> Recruitment rates: Recruit 25 participants within 2 months Retention rates: $\geq 80\%$ of participants will complete follow-up measures at 3 months Adherence: <ul style="list-style-type: none"> Food box delivery: most participants will receive 4 of 6 food boxes Dietitian visit: most participants will complete ≥ 1 dietitian visit

quantitative and qualitative data addressing these criteria were collected and analysed in parallel. These data were then merged to compare results by transforming the qualitative data into numeric counts and linking quantitative and qualitative data in a joint display^(26,28). Transformation of qualitative data into quantitative counts (i.e. quantitising⁽²⁹⁾) facilitated integration and helped determine both whether the minimum quantitative benchmarks were met and whether the intervention was a feasible approach with this target population.

Setting, participants, recruitment

Twenty-five patients with T2DM were recruited from an FQHC in Southern Arizona between March and July 2021 to participate in a 3-month food-plus DSMES-focused intervention. Patients were identified through provider referrals and electronic health record (EHR) screening conducted by FQHC staff. Study inclusion criteria included: FQHC patient, ability to read and speak English or Spanish (the most common languages spoken by patients at the FQHC), ≥ 18 years of age, diagnosis of T2DM with HbA1c $\geq 9\%$ (a priority patient population identified by our FQHC partners), home address, phone number, access to a kitchen and at risk for food insecurity per the Hunger Vital Sign^{TM(30)}. Eligible and interested respondents provided informed consent, were assigned a study ID, and completed baseline measures. Participants completed the intervention between May and October 2021. All participants received a \$10 farmer's market voucher, a can opener, a small paring knife and a set of measuring cups and spoons at the beginning of the study and a \$25 gift card upon completion of the study activities. The University of Arizona Institutional Review Board reviewed and approved the study protocol.

Intervention

Components of the FRESH intervention included: a bi-monthly food package consisting of high-fibre and

low-refined carbohydrate foods that met American Diabetes Association nutrition therapy recommendations⁽³¹⁾ (e.g. dried beans, rolled oats, canned mixed vegetables and canola oil), recipes that incorporated FRESH foods, DSMES materials from the American Diabetes Association and two, 30-minute virtual or in-person visits with an FQHC Registered Dietitian Nutritionist familiar with the intervention (see online Supplementary Appendix Tables 1–3 for all intervention components). Federally Qualified Health Center Registered Dietitian Nutritionists attended a 1-h training led by the study's graduate research assistant to learn about the intervention and orient to the contents of the food and resource package. The FRESH food and resource package was designed to be a source of supplementary food to support the management of T2DM; contents were selected based on typical food packages distributed by the food bank and refined in response to feedback from food bank clients with T2DM⁽²⁵⁾. Selected recipes featured 30 min or less of preparation time, and educational resources included information on batch cooking of high-fibre foundational ingredients (e.g. brown rice, beans). The FRESH food and education package was assembled by staff members at the food bank and delivered directly to participants' homes twice per month by food bank drivers.

Quantitative data collection and analysis

Self-reported socio-demographic and health data were collected using the fifteen-item PRAPARE questionnaire at baseline and 3 months via telephone by trained interviewers from the University of Arizona Behavioral Measurement and Interventions Shared Resource⁽²¹⁾. Health-related quality of life was assessed using the four-item 'Healthy Days Measures' developed by the Centers for Disease Control and Prevention which asked participants to rate their recent physical and mental health⁽³²⁾. The six-item United States Department of Agriculture food security module was used to determine level of food security as high/marginal, low or very low food security⁽³³⁾.



The eight-item Diabetes Self-Efficacy Scale asked participants to rate their confidence in engaging in behavioural and medical management issues related to diabetes, on a scale of 1–10⁽³⁴⁾.

Height, weight and HbA1c data were extracted from the EHR and entered into Research Electronic Data Capture tool⁽³⁵⁾. The EHR data extraction protocol included obtaining measures that aligned most closely to study baseline and 3-month follow-up dates. BMI (kg/m²) was categorised using the WHO cut-points (healthy, 18.5–24.9 kg/m²; overweight, 25–29.9 kg/m² and obese, ≥ 30 kg/m²)⁽³⁶⁾.

Dietary intake was assessed using two, non-consecutive interviewer-administered 24-h dietary recalls (one weekday, one weekend day) collected at baseline and follow-up (for a total of four) conducted telephonically using the USDA multiple-pass method⁽³⁷⁾. Dietary data were entered into the Nutrient Data System for Research software versions 2020 and 2021⁽³⁸⁾. Diet quality was calculated using the Healthy Eating Index (HEI-2015), a valid and reliable measure of diet quality that allows for the assessment of how individual intake aligns with national dietary guidelines^(39,40).

Socio-demographic, health-related quality of life, food security, diabetes self-efficacy, diet quality and EHR variables were summarised at baseline using median (interquartile range) or frequency counts and percentages. Quantitative data collected at 3-months ('post-intervention') were not reported in this manuscript due to our *a priori* emphasis on feasibility as a primary study aim, including assessment and refinement of data collection tools and procedures for a future definitive clinical trial. Recruitment, retention and adherence (i.e. food box delivery, dietitian visits) rates were tracked by the research team and calculated across the three-month intervention. Quantitative data were summarised using Stata 16.1 (StataCorp, Stata Statistical Software).

Qualitative data collection and analysis

Participants were invited to complete one, semi-structured in-depth phone interview at the end of the study in English or Spanish (online Supplementary Appendix, Table 4). A ten-item interview script was designed by the study team to explore the feasibility of intervention components (e.g. acceptability and use of program). Two trained research assistants completed the interviews which were digitally recorded and then transcribed directly into English by GMR Transcription Services, Inc. Transcripts were coded by trained coders using structured thematic analysis⁽⁴¹⁾, in which a codebook was created *a priori* based on the study feasibility criteria and served as an audit trail of key decisions made during analysis. Subcodes were identified that captured dimensions of overall codes (e.g. positive *v.* negative dimensions of acceptability).

Two researchers independently coded transcripts using NVivo (release 1.6.1, QSR International Pty Ltd, 2022) using the codebook and routinely met to compare and discuss any coding discrepancies. A third senior researcher served as an external auditor by independently coding two transcripts (one at the start of transcript coding and one halfway through coding) and meeting with the team to resolve any coding discrepancies. The first audit prompted the expansion of codebook definitions to ensure consistent application of codes. A second audit (conducted halfway through transcript coding) confirmed that definitions were sufficient and that codes were being consistently applied. After coding was complete, the senior researcher and one graduate research assistant met to review participant responses and to group codes into categories within feasibility domains. Select participant quotes that represented feasibility domains were identified by ethnicity and gender to provide context to participant responses, including potential differences in how the intervention was perceived based on participants' social identities. During this process, participants' responses within the feasibility domains grew repetitive, signalling that theoretical saturation was met.

One-on-one scripted interviews were also conducted with FQHC and regional food bank staff involved in the development and delivery of the intervention. Interviews were guided by a seven-item semi-structured interview script, with four additional questions tailored to the FQHC, and included perceived intervention demand among patients and staff, issues with implementation, perceived fit within organisational operations, potential for sustainability and suggestions for improvement. Following each staff interview, a trained graduate research assistant reviewed interview recordings and composed written summaries using the Key Point Summary (KPS) method, a qualitative method that enabled rapid summarisation and incorporation of qualitative findings into the mixed methods analysis⁽⁴²⁾. The KPS summarised key ideas from each interview that reflected feasibility criteria. This rapid analysis method was chosen due to staff feedback being primarily related to the overall implementation and identification of factors to consider in future intervention implementation, while more structured qualitative analysis methods were used for participant feedback to give greater weight to the recipients of the food package and resources.

Data integration

Mixed methods research integrates both qualitative and quantitative data to provide deeper insights and a more nuanced understanding to a research question compared with analysing each dataset separately. This may be accomplished through data transformation and integration using a joint display⁽²⁸⁾. In this study, qualitative data from



participant interviews were transformed into quantitative data⁽²⁹⁾ to take a deeper look at acceptability and demand feasibility benchmarks. This process consisted of grouping qualitative categories into quantitative categories (e.g. number of participants with positive comments about intervention acceptability, number of participants that reported using intervention components). Participant quotes were the unit of measure, meaning a participant could share multiple comments within each feasibility criterion. However, similar comments were only counted once per participant for each category within a feasibility criterion (e.g. two positive quotes from a participant about the overall intervention would be counted once). A side-by-side joint display was created from which the research team were able to draw inferences regarding confirmation or discordance between the quantitative and qualitative datasets (Table 2)⁽²⁸⁾.

Results

Quantitative results

Two hundred forty-seven patients were assessed for eligibility. Seventy-one were interested and eligible and mailed consent forms; 25 (35.2%) returned consent forms and were enrolled in the study. Three participants did not begin the intervention due to not speaking English or Spanish fluently (n 1) or loss of interest in the study (n 2). A fourth person was administratively removed, leaving twenty-one participants. Of those twenty-one participants, eighteen (85.7%) received four or more (out of six possible) bimonthly food packages; fifteen (71.4%) received all six packages. Sixteen participants (76.2%) completed one or more dietitian visits (out of two possible). Eighteen participants (85.7%) completed post-intervention questionnaires and 16 (76.2%) completed both dietary recalls at follow-up. Sociodemographic and health characteristics are summarised in Table 3.

Qualitative results

Participant interviews

Sixteen of the twenty-one participants completed a follow-up phone interview (eleven English-speaking, five Spanish-speaking). Interviews lasted an average of 25 min (range 15–50). Data were categorised into three *a priori* domains representing feasibility: acceptability, demand and implementation. Representative quotes are provided to illustrate examples in each category.

Acceptability. Most participants commented about the quantity of food being adequate or more than adequate. The few participants who mentioned inadequate quantities referred to specific food items they desired in higher amounts. Most participants were very positive about the foods and thought the foods generally fit with what they

typically ate or helped contributed to healthy eating. A majority discussed individual or household food preferences during their interviews, with most highlighting multiple foods they liked while a few stated they did not like specific foods due to texture or taste (e.g. brown rice).

Participant 3, Hispanic female

'[The foods fit] right in our palette. Right in – they all mixed in right. The same thing that we would usually go to the store to buy, to purchase.'

Participants' opinions about the recipes were varied. Some mentioned the recipes were well aligned with their cooking preferences and fit with the foods sent in the food package, while others stated the recipes did not align with cooking preferences or did not sound appetising.

Participant 1, Hispanic female

'I am very picky. So, I like to cook a certain way. So, maybe having more options for recipes – more variety... I like a lot of Mexican, so I normally just cook Mexican food. Um, so like making a Mexican dish.'

Most participants found the educational handouts to be practical and a good fit with their daily life, stating that the handouts reinforced existing knowledge, taught them something new, or helped them with specific T2DM concepts such as portion guidance.

The dietitian visit was generally regarded as positive and helpful for T2DM meal planning, understanding the importance of managing T2DM, label reading and increasing knowledge about T2DM management. Some participants cited that the combination of health care professionals with the food and educational handouts were especially useful to increase foundational T2DM knowledge, correct misconceptions and learn new ways to eat healthy.

Participant 10, Non-Hispanic female

'I didn't know I could eat vegetables and fruit. Um, it took my dietitian to tell me that... Sometimes your dietitian will tell you something and you'll, you'll kind of understand it but when you read it, you get a better handle on it or you can remind yourself, if it's something that you have written down.'

Demand. Most participants reported using all or most of the food items in the FRESH package. Food use was influenced by perceived health, whether their family members ate the foods, how frequently they used the foods in their cooking and health conditions that prevented use of the food (e.g. gastric bypass surgery, being sick with COVID-19). During the interview, participants shared how they prepared each food item, often as a component in recipes (e.g. refried beans) or in combination with other food package items (e.g. tuna with bread, spaghetti pasta with sauce).

Table 2 Integration of qualitative and quantitative data through a joint display

Feasibility criteria	Quantitative results*	Participant interview results	Staff interview results	Mixed methods interpretation and benchmark comparison
Acceptability Suitability/satisfaction of program, fit within daily life	<ul style="list-style-type: none"> Overall intervention satisfaction: <i>n</i> 13/16 Recipes: neutral or negative comments (<i>n</i> 5/16), positive comments (<i>n</i> 5/16) Education: positive (<i>n</i> 11/16), negative (<i>n</i> 0) Dietitian visit: positive (<i>n</i> 7/16), negative (<i>n</i> 0) Staff: positive about overall intervention (<i>n</i> 5/5) 	<ul style="list-style-type: none"> Quantity of foods adequate/more than adequate Foods generally fit with typical eating or helped contribute to healthy eating Individual/household food preferences influenced food acceptability Mixed responses about recipes (aligned/not aligned with cooking preferences) Educational handouts practical and fit within daily life Dietitian visit helpful for T2DM management (e.g. meal planning, label reading) 	<ul style="list-style-type: none"> Staff positive about FRESH overall, due to program being evidence based, ability to help people in need, helped close the gap in food insecurity 	<ul style="list-style-type: none"> Confirmation of transformed quantitative findings with qualitative interview findings from both participants and staff. A priori benchmark met
Demand Extent the program is utilized	<ul style="list-style-type: none"> Used all or most of foods (<i>n</i> 16/16) Used educational handouts (<i>n</i> 10/16); no use (<i>n</i> 4/16) Used recipes (<i>n</i> 5/16); no use (<i>n</i> 9/16) Reported completed dietitian visit (<i>n</i> 5/16); did not complete visit (<i>n</i> 5/16) 	<ul style="list-style-type: none"> Most/all food used, depending on household preferences, perceived health; gave away unused food Foods were prepared as part of recipe or paired with other food items in package Food use influenced by T2DM nutrition recommendations (Some) recipes used for new meal ideas, portion size guidance; others thought recipes not appetising, or already knew how to prepare foods Education read and reviewed, used to learn, reinforced T2DM management concepts Dietitian visit provided new information, facilitated questions, understanding T2DM concepts; some did not have dietitian visit 	<ul style="list-style-type: none"> – 	<ul style="list-style-type: none"> Confirmation of transformed quantitative findings with qualitative interview findings from participants. A priori benchmark met
Implementation Extent program is delivered as planned	Recruitment rate: 25/71 consent forms returned = 35.2 % Recruited 25 participants over 5 months Food Box Delivery: <ul style="list-style-type: none"> ≥ 4 boxes (<i>n</i> 18/21): 86 % Dietitian Visit: <ul style="list-style-type: none"> ≥ 1 visit (<i>n</i> 16/21): 76 % Retention: <ul style="list-style-type: none"> Diet recalls: 76 % Questionnaires: 86 % EHR – HbA1c: 67 % EHR – height/weight: 76 % In-depth interview: 76 % 	Challenges: <ul style="list-style-type: none"> Management of other health conditions (e.g. surgery, chronic health conditions, illness) Scheduling dietitian visit Problems with food package delivery Limited home cooking time Broken can opener 	<ul style="list-style-type: none"> Food bank: Changes to sourcing, packing, delivering food, training of employees to implement FRESH – positive experience working with new people; challenges in learning the new program without a standard operating procedure in place; challenges in home food delivery with small time window FQHC: major challenges with recruitment of participants; attendance at dietitian visit 	<ul style="list-style-type: none"> Confirmation: recruitment rate was lower than other studies and took longer than anticipated; staff commented about recruitment challenges. Discordant: Participants commented about challenges in food package delivery and dietitian visit scheduling, but still high adherence (receipt) of food packages to households, and high adherence to at least one dietitian visit. A priori benchmark approached or met

*Data from participant interviews were transformed into quantitative values for the criteria acceptability and demand.

**Table 3** Baseline socio-demographic and health data obtained in the food and resources expanded to support health (FRESH) study (*n* 21)

Characteristic	Median	IQR
Age	48.0	38.0–63.0
Number of household members ≥ 18 years	2.0	2.0–3.0
Number of household members < 18 years	0.0	0.0–1.0
	<i>n</i>	%
Gender		
Male	6	28.6
Female	15	71.4
Other	0	0.0
Prefer not to answer	0	0.0
Ethnicity*		
Hispanic	13	61.9
Non-Hispanic	8	38.1
Race		
White	8	38.1
Black	3	14.3
American Indian/Alaska Native	3	14.3
Other†	7	33.3
Food pantry visits in the last 12 months		
0	10	47.6
1–6	6	28.6
7–12	4	19.1
Missing	1	4.8
Employment		
Unemployed and seeking work	7	33.3
Full-time work	4	19.1
Part-time or temporary work	2	9.5
Unemployed but not seeking work	6	28.6
Retired	2	9.5
Household income		
<25 000	13	61.9
25–49 999	4	19.1
50 000–74 999	2	9.5
≥75 000	1	4.8
Missing	1	4.5
Education		
<High school degree	8	38.1
High school diploma/GED	7	33.3
College, 1–3 years	5	23.8
College 4 or more years	1	4.8
Household participation in public assistance programs‡		
SNAP	10	47.6
Unemployment	3	14.3
Social security	9	42.9
WIC	0	0.0
Veterans affairs	1	4.8
Disability payments/SSDI	7	33.3
Free or reduced school lunch/breakfast	3	14.3
Other	0	0.0
None	4	19.1
Prefer not to respond	1	4.8
Difficulty accessing resources‡,\$		
Food	5	23.8
Utilities	5	23.8
Medicine	2	9.5
Phone	3	14.3
Clothing	3	14.3
Childcare	0	0.0
Other	3	14.3
None	11	52.4
Lack of transportation¶		
Yes	7	33.3
No	13	61.9
Missing	1	4.8

Table 3 *Continued*

Characteristic	Median	IQR
General health		
Excellent	0	0.0
Very good	2	9.5
Good	2	9.5
Fair	13	61.9
Poor	4	19.1
Food security status		
High/Marginal food security	6	28.6
Low food security	6	28.6
Very low food security	9	42.9
	Median	IQR
Diabetes self-efficacy score (0–10)	6.4	5.9–7.0
Diet quality (HEI-2015, 0–100)	55.9	51.8–63.9
HbA1c (%)	10.0	8.2–10.9
	<i>n</i>	%
BMI categories		
Normal weight (18.5–< 25.0 kg/m ²)	2	9.5
Overweight (25.0–< 30.0 kg/m ²)	6	28.6
Obese (≥30.0 kg/m ²)	13	61.9

GED, General Education Development; SNAP, Supplemental Nutrition Assistance Program; WIC, Special Supplemental Nutrition Program for Women, Infants and Children; SSDI, Social Security Disability Insurance.

*Every person who chose Hispanic ethnicity identified as Mexican/Mexican American.

†Other race: three participants identified as Mexican when asked about race; description of 'other' race not captured for four participants.

‡Total *n* > 21, participants could select more than one option; each response option reports % as *n*/21.

\$In the past year, have you or any family members you live with been unable to get any of the following when it was really needed?

||Other resources needed but unable to obtain included: food stamps, pet resources and transmission for car.

¶Has lack of transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?

Participant 8, Hispanic male

'The cans of vegetables. Those are, uh, you can't really use those for much, if you're trying to go for like, for like, like flavor. But if you're just trying to feed yourself, those are perfect. Like, for example, um, with the tuna cans. The vegetables and tuna, those are pretty good for like, tuna salad sandwiches.'

Participants reported that they received too much of some foods (e.g. spices, canola oil), and they gave away foods that they did not want or could not use to friends, family or to a local church. Some participants stated that they planned to learn how to prepare specific foods but needed a recipe (e.g. lentils, chickpeas). Participants also mentioned they had not yet used some of the food items or they did not typically cook with specific foods. A few participants stated that they tried some foods and were slowly becoming more accustomed to them (e.g. whole wheat pasta and brown rice). Participants reported that T2DM nutrition guidelines affected their use of food; for example, one participant used brown rice instead of white, while another participant did not eat whole wheat pasta due to its impact on blood glucose.



Participant 13, Hispanic female

'My husband eats it [spaghetti] very often. He prepares, he prepares salads and all that, but due to my diabetes sometimes I can't eat that [spaghetti]. He has diabetes too but sometimes he prepares and we use it.'

Participants reported using recipes for portion size guidance, to generate cooking ideas and to try something new. Some participants reported not using the recipes yet (but were planning to) or that they passed the recipes along to friends or family. Other participants who reported not using recipes stated that the recipes were not appetising or not aligned with cooking preferences, that they already knew how to prepare the food or that they were ill and did not cook for a period of time. A few participants commented that they used the knife and can opener, and that the measuring cups were useful for carbohydrate portion control.

Education handouts were read and reviewed by most participants. Some participants stated that the handouts allowed them to learn something new, reminded them of information they already knew, or reinforced information learned from the FQHC dietitian. Some participants reported discussing handouts with family members who also had T2DM. Participants appreciated the printed materials as they were accessible to keep around and refer to when needed. The participants who did not use educational materials cited reasons of the materials being thrown out on accident, illness, upcoming surgery or no internet access (to view embedded video links).

Participants who completed at least one dietitian visit had positive reactions and reported that they learned new information and asked questions, gaining a deeper understanding of why T2DM management was important. Participants who completed at least one dietitian visit also reported that they received help with meal planning.

Participant 14, Hispanic female

'Uh, honestly, very – well, a little impactful because of the way she explains the seriousness of my condition and how – how to take care of it, and the importance of why to do it.'

Some participants stated they did not complete a dietitian visit, with reasons that they were ill, had an upcoming surgery, or had challenges with scheduling.

Implementation. Participant comments associated with intervention implementation were primarily related to external circumstances that affected participants' ability to fully utilise intervention components, including ongoing management of other health conditions, logistical problems with receiving the FRESH food box delivery, lack of internet access, confusion regarding scheduling the dietitian visit, limited home cooking time and broken equipment (i.e. can opener). One participant reported that their recipes and education materials were accidentally thrown away by a family member before they could read

them. Specific health challenges noted by participants included surgery, chronic health conditions and illness. Challenges reported by participants that related to the delivery included missing recipes and handouts due to not receiving the first food package delivery and being sent materials in English instead of Spanish.

Participant 1, Hispanic female

'Um, so, in the process of this, I actually went through gastric bypass surgery. So, I have to wait a little bit to be able to go back to eating normal. So, most of my – the food that I just have saved is for when I start eating again.'

Staff interviews

Eight staff members from the food bank and FQHC were invited to participate in one-on-one interviews; five completed the interviews. Interviews lasted 13–40 min.

Acceptability. All staff interviewed answered either 'somewhat likely' or 'very likely' (as opposed to 'not at all likely') when asked about how likely they were to recommend that FRESH was offered as a permanent programme by their organisation. Staff stated that standard operating procedures needed to be developed prior to widespread implementation, including a system for tracking inventory that came back to the facility after unsuccessful deliveries and designated space in the warehouse for intervention food. Positive aspects of the program noted by interviewees included the evidence-based nature of the program and the use of participatory research methods throughout the development of the FRESH intervention.

Key Staff Member: *'Because if there's people out there who this can help, you want to get it out and help them. I think, the devils in the details about how would you do that best, how would you do it most sustainably. You have to do it efficiently and you have to do it in a way that creates value for people.'*

An FQHC staff member stated that the FRESH program helped close the gap in food insecurity among low-resource patients who were often told by providers to 'go to the food bank' without follow-up assistance. Interviewees also mentioned it was helpful to know what foods the participants were getting and how much so that they could tailor nutrition recommendations made to the patients.

Implementation. Food bank staff reported changes to standard operating procedures during FRESH implementation, including logistics associated with sourcing, packing and delivering food and the training of employees involved in these processes. One staff member reported that this was positive experience since they were able to establish a working relationship with departments they had not worked with in the past. Another staff member had a more challenging experience with learning about the FRESH intervention, since there was not an existing standard operating procedure and they did not know who to contact when questions arose, citing communication and lack of



training as barriers. One employee stated it was relatively easy to integrate the intervention with their standard operating procedures due to an existing home delivery. However, this staff member also commented about adjustments that were made after a few weeks of intervention implementation because some participants did not receive the correct food package. One interviewee shared that most food sourced by the food bank is ordered in bulk approximately 18 months in advance. Since FRESH was a pilot program, food sourcing involved multiple small orders which contributed to additional staff time processing the orders.

Potential implementation barriers from an FQHC standpoint included identifying and recruiting participants to the programme, and patient attendance at dietitian visits. One staff member explained that medical providers had varying levels of interest in the FRESH program, and that many participants were recruited from a specific clinic where a provider was championing the program. They recommended that more time be spent finding ways to make the program visible to providers who see patients with the most need. Multiple participants who were scheduled for a dietitian visit did not show up to their virtual appointment; however, this 'no-show' rate was about the same as FQHC patients who were not enrolled in the FRESH program.

Mixed methods integration results

Transformed qualitative findings for acceptability and demand criteria confirmed quantitative results; further, it was determined that *a priori* feasibility benchmarks were approached or met (Table 2).

Acceptability

Thirteen of sixteen participants indicated that they liked or were satisfied with the overall intervention. Eleven participants rated educational handouts as a positive aspect of the intervention, and seven rated dietitian visits as a positive aspect of the intervention; five participants either had neutral or negative comments about the recipes. Staff interviews showed alignment with participant acceptability findings: all interviewed staff (*n* 5) were positive about the overall intervention. Qualitative data provided a deeper context to these findings – for example, participants shared a variety of reasons why the overall intervention was acceptable, including that foods contributed to healthier eating (Table 2).

Demand

All interviewed participants (*n* 16) stated that they used all or most of the FRESH foods. When asked about other intervention components, ten participants reported using the educational materials (four did not use them), five reported using recipes (nine did not use them), and five reported completing at least one dietitian visit (five did not complete any). Five participants discussed the dietitian visit

within the context of demand; their comments emphasised the utility of the visit in advancing their T2DM management.

Implementation

Both confirmation and discordant findings were identified within the integration of qualitative and quantitative implementation data, and met or approached *a priori* benchmarks (Table 2). The recruitment goal of twenty-five participants was met, although achieving this took longer than anticipated (5 months compared with the *a priori* benchmark of 2 months). Evidence of challenges with recruitment was corroborated by the staff interviews, who also provided suggestions to improve recruitment rate and yield in the future (e.g. expand recruitment network to other clinics serving patients with T2DM and food insecurity, start recruitment earlier). Retention rates at follow-up ranged from 67–86 % depending on the assessment (e.g. dietary recalls and questionnaires). Qualitative implementation findings suggested that participants experienced challenges in receiving food packages delivered to their homes and with scheduling dietitian visits; however, when comparing these findings with quantitative adherence data, we observed mostly successful deliveries to households (86 % received at least 4/6 packages), and a majority completing at least one dietitian visit (76 %).

Discussion

To our knowledge, this is the first study to use mixed methods to assess the feasibility of a food-based diabetes self-management education and support intervention in patients with type 2 diabetes and food insecurity. Through this approach, we were able to confirm that the *a priori* benchmarks established for acceptability, demand and implementation were met. Recruitment of participants took several months longer than anticipated. The recruitment rate – 35.2 % of those who were eligible and sent consent forms, and ultimately enrolled – was lower than another food-based DSME study taking place at a health clinic (56.9 %)⁽¹⁷⁾, although recruitment methods in the current study involved mailed consent forms to accommodate FQHC policies enacted in response to the SARS-CoV-2 pandemic.

Our quantitative and qualitative findings were aligned, with the exception of one discordant finding – during interviews, participants reported challenges related to receiving food package deliveries and scheduling the dietitian visits, while our adherence data suggested successful implementation of these intervention components. This finding is partially explained by participants who elaborated that being present in their home for the food delivery was a scheduling challenge. Due to food safety and food bank policies, FRESH food packages could not be left at the participants' homes without someone available to accept the delivery. Regional food bank and FQHC staff made repeated



efforts to call participants to remind them of food deliveries and enabled virtual dietitian visits through a patient engagement platform, which helped to address these challenges and contribute to the overall successful implementation of the intervention. Other barriers to intervention implementation reported during interviews included being ill or having surgery which prevented some participants from fully utilising intervention components. This feedback provided important context to the individual circumstances that led some participants to engage with the intervention to a different degree than others. Future intervention implementation strategies should consider staggered or otherwise flexible enrollment into the study for individuals experiencing challenges to participation.

There are very few prior clinic-based studies aimed to address food insecurity and T2DM self-management together through direct food provision. Ferrer et al. conducted a randomised controlled pilot study including a mobile food pantry stationed at a health clinic providing fresh produce and canned food, teaching by a registered dietitian nutritionist and home visits from a community health worker to reinforce diabetes self-management concepts⁽¹⁷⁾. This study included twenty-nine control and twenty-nine intervention participants and reported a 1.4% greater decrease in HbA1c among intervention participants compared with control ($P=0.012$); however, only nineteen of the twenty-nine participants completed the intervention⁽¹⁷⁾. Feinberg et al. enrolled ninety-five participants with food insecurity and diabetes with HbA1c $\geq 8\%$ in a 'Fresh Food Farmacy' program providing healthy foods and recipes and 15 h of group diabetes classes⁽¹⁸⁾. Feinberg et al. reported a decrease in HbA1c levels from an average of 9.6% to 7.5%; however, no retention or adherence data were reported⁽¹⁸⁾. Prior research has not adequately considered feasibility as a primary aspect of intervention development. Our findings demonstrated a high level of intervention acceptability among participants (whose input was also integral in the initial development of the intervention⁽²⁵⁾) and is promising in light of prior work showing that interventions designed in conjunction with the intended group were acceptable and effective when tested at scale^(42,43).

Staff interviews also provided valuable insights into programme feasibility that prompted the development of strategies to further improve recruitment, adherence and retention. In general, successful recruitment and strong adherence and retention to community-based interventions is a major challenge, and this is especially true for persons living in low-resource households⁽⁴⁴⁾. Prior to intervention implementation, the research team worked with staff at our partner organisations to develop multiple ways to enhance recruitment and adherence, including emphasising the benefits of participation, providing incentives (e.g. voucher for local farmers market, gift card) and minimising respondent burden (e.g. delivery of food to participants' homes, no requirement for in-person study

visits). Studies of barriers to recruitment of underrepresented groups to interventions have suggested potential lack of understanding of research information, process or significance as possible factors influencing study recruitment⁽⁴⁴⁾. In the present study, eligible respondents were encouraged to call the study team with any questions completing the consent form; however, there may have been other barriers that prevented participation among those who did not return the consent form of which we are unaware. Following up with these individuals to the extent possible to determine reasons for non-participation could provide important guidance to the study team. This is especially important to consider in future research, given that individuals at the greatest risk for poor health outcomes are also often the hardest to reach⁽⁴⁴⁾. Investing in food rather than higher doses of medication or health care visits has potential to decrease the high health and financial burden on individuals with uncontrolled T2DM. These research and practice implications are particularly timely given the recent shift to address food and nutrition security in the USA⁽²⁰⁾.

The combined feedback from participants and staff in this study, as well as the deeper insights gained from integration of qualitative and quantitative data have informed changes to the intervention in anticipation of a definitive clinical trial. Changes made in response to participant feedback include decreasing the amounts of canola oil and spices; more recipes, with an emphasis on less familiar foods such as chickpeas and lentils; additional guidance around portion sizes of carbohydrate-rich foods (e.g. whole wheat pasta, brown rice) to lower the impact of those foods on blood glucose and the addition of fresh produce. Community Health Workers employed by the FQHC will distribute the food box along with brief nutrition education every 2 weeks at a clinic location. Transportation (ride-share) will be provided by the clinic for those who do not have reliable access.

Our study strengths included our primary goal to explore the feasibility of a food-focused diabetes self-management intervention in a food-insecure population. To our knowledge, feasibility (including acceptability, demand, and implementation) has not been a priority of prior food-based research interventions among similar populations^(13–18), and our mixed methods study design allowed for a greater understanding of participant feedback in relation to quantitative data assessed through surveys and EHR data and qualitative data assessed through in-depth interviews.

One potential limitation was the requirement of a home phone number. By restricting access to the intervention to individuals with phone access, we might have limited programme reach and excluded certain community members in need. Participants were also required to have consistent access to a kitchen to prepare foods, a challenge for people experiencing housing insecurity. An FQHC staff member recommended that a future study should include



findings from the dietitian assessment and monitoring notes in the electronic health record. Although we recorded the number of dietitian visits, we did not evaluate the quality of those visits or describe the topics covered in those visits. Exclusion of those data might have limited our ability to identify unmet needs related to T2DM management. Although we invited key informants at each organisation to interview with us, some staff members did not respond, potentially biasing our results.

Conclusions

Overall, this study found a food-based DSMES intervention for food-insecure patients of an FQHC to be feasible for study participants and key organisational staff involved in intervention delivery. Our mixed methods approach provided deeper insight into both successes and challenges associated with interventions implemented in this setting. Next steps include a comprehensive recruitment strategy developed in partnership with FQHC staff to expand intervention reach; a standard operating procedure for food package assembly and delivery at scale and additional tailoring of the intervention in response to participant feedback (e.g. greater alignment of food quantities with household size, additional recipes and educational materials with visuals). Our findings support the progression to a definitive clinical trial to test the efficacy of the FRESH intervention on biological and behavioural outcomes as well as key social determinants of health associated with T2DM management.

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Conflicts of interest

Dr. Taren receives an honorarium from the International Life Sciences Institute for being the Editor-in-Chief for

Nutrition Reviews. Dr. Thompson – United States Department of Agriculture/Agricultural Research Service, Cooperative Agreement No. 58-3092-5-001. All other authors have no conflicts of interest to declare. All authors have no non-financial conflicts of interest to report.

Authorship

E.S., D.Taren., H.B., R.G., J.S., and M.H. designed the research plan. E.S. and H.B. collected the data, and E.S. analysed the data. D.Thompson., D. Taren and M.H. guided data analysis. E.S. wrote the first draft with contributions from M.H. All authors reviewed and commented on subsequent drafts of the manuscript.

Ethics of human subject participation

This study was conducted according to the guidelines laid down in the Declaration of Helsinki, and all procedures involving human participants were approved by the Institutional Review Board at the University of Arizona. Written informed consent was obtained from all participants.

Supplementary material

For supplementary material accompanying this paper visit <https://doi.org/10.1017/S1368980023002082>

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