Title: Pilot Study of the Nutrition-Supported Diabetes Education Program (NU-DSMP) Among Low-Income Adults with Type 2 Diabetes

Official NIH Title: Pilot Study of the Nutrition-Enhanced Wellness for Diabetes Self-Management Program (NEW-DSMP) among Low-Income Adults with Type II Diabetes

Date: September 20, 2021
NCT Number: Not Yet assigned

NUTRITION-SUPPORTED DIABETES EDUCATION PROGRAM (NU-DSMP) PILOT STUDY
ANALYSIS PLAN

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Section 1: Administrative Information

1) Title and trial registration

a. Title: Pilot Study of the Nutrition-Supported Diabetes Education Program (NU-DSMP) Among Low-Income Adults with Type 2 Diabetes
b. Official NIH title/previous title: Pilot Study of the Nutrition-Enhanced Wellness for Diabetes Self-Management Program (NEW-DSMP) among Low-Income Adults with Type II Diabetes
c. Trial registration number: TBD

2) SAP version number with dates

a. Version 1 –09/20/2021

3) Protocol version

This SAP references NU-DSMP Protocol Version 1.1, dated 09/20/2021

4) Roles and responsibilities – names, affiliations, and roles of SAP contributors

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c. Andrea Pedroza-Tobias, MS— Analyst. University of California, San Francisco.

5) Signatures

a. PI
b. Senior statistician

Section 2: Introduction

1) Background and rationale

Improving diabetes health is a public-health imperative. Diabetes mellitus affects 30.3 million people in the US and is a leading cause of disability and cardiovascular disease.[1] In 2017, total costs for type 2 diabetes mellitus (T2DM) in the US were $327 billion.[2] Low-income individuals in the US have twice the odds of T2DM[3] compared to the general population. More than 30% of low-income households are also food insecure,[4] defined as having limited access to nutritious food for a healthy life. Food insecurity is associated with poor diabetes control,[9,10] morbidity, and mortality[7,8] via worsened nutrition (diet quality, obesity), mental health (stress, depression), and health behaviors (non-adherence, missed clinic visits).[5,6] Behavioral coping strategies triggered by food insecurity, such as purchasing and consuming cheap, energy-dense foods,[7,8] can persist into periods of food security, altering dietary habits and continuing to undermine diabetes health.[9,10]

Diabetes-healthy food support may improve diabetes health for low-income individuals, yet its optimal design, positioning (i.e. within healthcare vs. nutrition safety-net), and effectiveness is still unresolved. Our preliminary work shows that diabetes-healthy food support is feasible and may improve T2DM health for low-income individuals.[11,12] Yet where and how such food support is located may affect its impact on diabetes health. For instance, food pantries may not be the optimal setting for direct provision of diabetes self-management education with food support to improve T2DM outcomes.[13] Alternatively, locating medically tailored food support within healthcare-related settings, integrated into diabetes self-management programs, may be a more effective strategy to support the nutritional and self-management needs of low-income people with T2DM.

The Diabetes Self-Management Program (DSMP) is a national, evidence-based,[14-16] ancillary healthcare service providing group-based diabetes self-management education to people with diabetes over 6 weeks. The DSMP covers topics such as healthy eating, exercise, medication use, and symptom management, but does not address structural barriers to diabetes self-management, such as reduced access to diabetes-healthy food, which may limit its effectiveness in vulnerable populations.[16,17] While consistent access to diabetes-healthy food is essential for ongoing diabetes self-management, insights from psychology and economics suggest that access to healthy food may also promote behavior change and support habit formation for diabetes-healthy diets[17-19]. Providing diabetes-healthy food support together with the DSMP may be a promising strategy to improve T2DM outcomes for low-income individuals who face resource and behavioral constraints to healthy eating.

Together with our partners Project Open Hand, a non-profit organization providing healthy food support to chronically ill individuals, and the Contra Costa Health System, a county safety-

net health system, we are conducting the **Nutrition Supported Diabetes Education Program (NU-DSMP) Pilot Study**. Our goal for this pilot randomized trial is to investigate the feasibility, acceptability and preliminary impact of a novel, multicomponent diabetes health intervention. NU-DSMP will provide 12 weeks of diabetes-healthy food support and nutrition case-management to low-income individuals with T2DM, in conjunction with participation in a DSMP group.

2) Objectives

Aim 1: Conduct planning to refine the design of the NU-DSMP intervention and study procedures. Conduct expert consultation and stakeholder meetings across diabetes clinical providers, diabetes self-management educators, nutrition organizations and health care payers and organizations to refine the NU-DSMP intervention and identify and set up procedures with new study partners responsive to conducting the study in the context of COVID-19.

Aim 2: Pilot test the NU-DSMP intervention among low-income individuals with T2DM, compared to the DSMP alone, to assess feasibility, acceptability and preliminary impact on diabetes health. We will randomize a total of 72 adults living with T2DM 1:1 to the intervention (diabetes-healthy food support plus the DSMP) or control (DSMP only) arms and conduct surveys and medical record review at baseline (DSMP start), 6 weeks (DSMP ends - survey only), 12 weeks (end of food intervention), and 24 weeks (to assess durability). Control participants will receive diabetes-healthy food support at the end of the 24-week follow-up period. The primary outcome is glycemic control (HbA1c); secondary outcomes are health-related quality of life, acute care utilization and hypoglycemic episodes. We will also assess intermediate outcomes including preliminary impact on nutrition, mental health, and behavioral parameters.

Aim 3: Conduct process evaluation to understand strengths and weaknesses of the intervention and trial design. We will collect and analyze qualitative in-depth interview data from at least 25 intervention participants to explore perceived benefits and challenges of the intervention, program adherence and satisfaction, and suggestions for implementation. We will also review nutrition case-management notes from intervention participants and collect administrative data on intervention exposure (number of food deliveries received and case-management sessions received). Quantitative data from intervention and control participants will assess food utilization, feasibility and the acceptability of study procedures, and acceptability of the control condition.

Section 3: Study Methods

1) Trial design

A pragmatic RCT among low-income individuals with T2DM will be conducted to test the feasibility, acceptability, and preliminary impact of NU-DSMP, a twelve-week diabetes-healthy food support and nutrition case-management intervention provided in conjunction with participation in a DSMP group, compared to participation in a DSMP group alone. Participants will be randomized 1:1 to the intervention (n=36) versus control (n=36), using a parallel design.

2) **Intervention description**

NU-DSMP Intervention: The NU-DSMP intervention builds a diabetes-tailored nutrition intervention into the delivery of routine evidence-based group-based diabetes self-management education.

Base condition provided to both study arms: Diabetes Self-Management Program (DSMP): The Diabetes Self-Management Program (DSMP) is an evidence-based diabetes self-management education program consisting of weekly group sessions covering healthy eating, exercise, medication use, and symptom management. Real-world DSMP programs in English and Spanish will be used as the base condition in both intervention and control arms for testing the additional benefit of the nutritional intervention. We are not testing the impact of the DSMP nor altering the program in any way. We are testing the impact of diabetes-tailored food support in a population receiving the DSMP.

NU-DSMP Intervention:

The intervention will provide:

1) *Diabetes-healthy food support*: Twelve weeks of diabetes-healthy food support consisting of both meals and groceries (weekly meal delivery; monthly grocery box delivery) meeting American Diabetes Association guidelines and approximately one-third of daily energy requirements. Food support will include *medically tailored meals*, produced and home-delivered by Project Open Hand, and *grocery boxes* focused on diabetes-healthy, shelf-stable items from Project Open Hand's grocery center, plus a hand-out with nutritional information and recipes.

2) *Nutrition case-management*: Experienced Project Open Hand client services staff will provide three individualized encounters with intervention participants to set up and support their

receipt of medically tailored meals and groceries, including assessing preferences and any barriers, troubleshooting any issues with the intervention, and checking on participant well-being.

Additional services provided to the control condition:

Control condition: After 24-week follow-up (or about 6 months), control participants will receive monthly diabetes-healthy, home-delivered grocery boxes for three months focused on diabetes-healthy, shelf-stable items, plus educational materials with nutritional information and recipes.

5) Data collection

Study measurements using surveys and medical record review will be assessed at baseline, 6 weeks (end of DSMP), 12 weeks (end of food intervention), and at 24 weeks (to assess durability of any improvements). Qualitative interviews will be collected between weeks 12 and 24 to explore participant experiences in the study as part of our process evaluation.

At baseline, 6 weeks, 12 weeks, and 24 weeks the following data will be collected in both arms:

a) Surveys. Trained UCSF research assistants (RAs), including Spanish/English bilingual RAs, will administer the structured interview either over the phone or in person, depending on public health protocols and acceptability of in-person visits to participants due to COVID-19. When visits are conducted in-person, interviews will take place in private offices at POH, in a private room at the partner clinic (if available), in a private location at a community space (e.g., library, community center), or at a private location of the participants choosing (e.g., home visit).

   The content of the interviews will cover:

   - Socio-demographic information.
   - Food insecurity and diet quality.
   - Physical activity.
   - Mental health (e.g depressive symptoms, diabetes distress, self-efficacy for following T2DM recommendations).
   - Diabetes medications
   - Adherence to T2DM medications.
   - Health-related quality of life.
   - Diabetes co-morbidities (e.g., nephropathy, retinopathy).

- In addition, at 6-week, 12-week, and 24-week follow-up, the structured interview will also include questions to assess participant experiences in the intervention and control conditions (i.e., food utilization such as sharing or waste), barriers to intervention use, and program satisfaction in DSMP and food program).

b) Medical record review (baseline, 12 weeks and 24 weeks). Medical records from CCHS will be used during recruitment to confirm the following eligibility criteria: T2DM diagnosis, HbA1c greater than or equal to 7%, and other clinical exclusion criteria (i.e., stage 5 chronic kidney disease or on/recommended to be on dialysis, type 1 diabetes). In addition, they will confirm whether a patient has uncontrolled T2DM (<9% vs. ≥9%) for frequency monitoring during randomization. CCHS will provide the following data abstracted from their medical records from 6 months prior to enrollment through 9 months after enrollment: 1) HbA1c values (point of care test and lab serum results); 2) utilization of acute care, including hospitalizations and emergency department use; and 3) weight and height.

c) Qualitative interviews.
In-depth, semi-structured qualitative interviews of up to 90 minutes will be conducted with at least 25 (or until saturation) between weeks 12 and 24 of the study. We will interview completers and non-completers to understand barriers to study participation. The interviews will be grounded in a phenomenological perspective that centers understanding participant experience, combined with content analysis to allow focus on specific domains of interest. We will include questions about perceived health benefits (or lack thereof) due to the intervention, reasons for intervention adherence or non-adherence, preferences for meal and grocery box design, barriers and facilitators to program participation, positive and negative intervention experiences, and suggestions for implementation. Interviews will be audio-recorded and transcribed.

d) Administrative records from POH. POH will provide the following information:
   - Records of receipt of delivered food. POH will provide administrative records of weekly delivered food for each participant.

4) Randomization

72 participants will be randomized 1:1 to the intervention and control arms. Given the small sample size, we will not stratify randomization; however, our lead statistician will monitor frequencies of sex at birth and poor diabetes control (A1c < 9%, vs. ≥ 9%) in

each randomization arm. Significant imbalances may be corrected by temporarily shifting the randomization scheme to preferentially recruit participants into the arm with the underrepresented characteristic. Details of the randomization method is stored securely in REDCap. Randomization based on a computer-generated assignment will occur after the participant has provided informed consent and completed baseline assessments.

5) Sample size

We will enroll 72 adults with T2DM 1:1 to intervention or control, such that each study arm will have 36 people. This sample size balances organizational capacity to implement the intervention within R21 cost and time constraints, with our goal to assess feasibility and preliminary impact in this population. As a feasibility trial, this study is not powered to detect impact on our primary outcome, HbA1c; however, effect sizes from this study will be used to power a possible future full-scale trial of the NU-DSMP intervention, if the study deems it is feasible, acceptable, and preliminarily effective.

6) Framework

The superiority hypothesis testing framework will be used, testing whether exposure to the intervention results in better outcomes than exposure to the control arm. Comparisons will be presented as differences between arms in changes in outcomes from baseline to follow-up.

7) Statistical interim analyses and stopping guidance

a. Information in interim analyses specifying what interim analyses will be carried out and listing time points
    i. None planned
b. Any planned adjustment of the significance level due to interim analysis
    i. No
c. Details of guidelines for stopping the trial early
    i. None

8) **Timing of final analyses**

Analysis is planned to begin in June 2022 upon completion of all field data collection in May 2022, when the 12-week follow-up of all participants is done. Analysis to evaluate the durability of the intervention will commence after the end of 24 weeks of follow-up (August 2022).

7) **Timing of outcome assessments**

Research staff will administer surveys at baseline, 6 weeks, 12 weeks, and 24 weeks in both study arms. Data will be collected within a window period around each data collection time point of up to 1 month.

Section 4: Statistical Principles

1) Confidence intervals and P Values

a. **Level of statistical significance.** No significance testing will be conducted unless required by a journal. We will report 95% confidence intervals and exact p-values (or p<0.001).
b. **Description and rationale for any adjustment for multiplicity and, if so, detailing how the type I error is to be controlled.** The primary outcomes were established in the protocol, and thus no adjustments will be made for multiplicity.
c. **Confidence intervals to be reported.** 95% confidence intervals will be reported alongside exact p-values.

2) **Adherence and protocol deviations**

a. **Definition of exposure to the intervention and how this is assessed including extent of exposure:**
   Adherence to the intervention will be assessed through the following mechanisms:
   i. Case management: Attends at least the first case management session (out of 3)
   ii. Meals: Receives meals at least 50% of intervention weeks (>= 6 weeks of meals).
   iii. Groceries: Receives at least 1 grocery box
b. **Description of how adherence to the intervention will be presented** – Adherence to the intervention will be presented through a brief description in the narrative summarizing the percent of weekly engagement with meal deliveries (out of 12 weeks), % of grocery boxes received (out of 3 boxes), and % of food reported eaten, as well as % of case management sessions attended (out of 3).
c. **Protocol deviation.** The following are pre-defined minor protocol violations:

   i. Participants that for any reason are not seen within the visit window (up to 1 month later).

ii. Investigators miss giving a questionnaire or a section of the questionnaire to the participant.

The following are pre-defined major protocol violations:

i. Participants that are mistakenly enrolled in the study without meeting the inclusion criteria.

ii. Participants in the control arm receiving meals or groceries from Project Open Hand during the active intervention period (baseline to 3 months).

iii. Participants for whom informed consent was not obtained prior to any study-specific procedures.

iv. Lapse in study approval

The number (and percentage) of participants with major and minor protocol deviations will be summarized by arm with details of type of deviation provided. The participants that are included in the ITT analysis data set will be used as the denominator to calculate the percentages. No formal statistical testing will be undertaken.

3) Analysis populations.

a. **Intention-to-treat.** The primary analysis will be intent to treat (ITT). The ITT analysis will include all participants in both arms who were enrolled and completed all baseline assessments, regardless of if they received the intervention or not.
b. **Per protocol.** A secondary analysis will be per-protocol, including control participants with baseline and follow-up evaluations who did not have any major protocol violations, and intervention participants with baseline and follow-up evaluations who adhered to the intervention (i.e., attended at least the first case management session, received 1 out of 3 grocery boxes, and received home-delivered meals at least 50% of weeks in intervention period), and no major protocol violations.

<u>Section 5: Trial Population</u>

1) **Screening Data**

a. Participants will be recruited from Contra Costa Health Services (CCHS), a safety-net county health system serving low-income individuals in Contra Costa County in the San Francisco Bay Area.

Participants will be recruited via provider referral or via recruitment flyers and/or tabling in CCHS clinics. UCSF will screen patients either over the phone or in-person for eligibility based on study inclusion and exclusion criteria using the study recruitment script. The research team will obtain confirmation of diabetes diagnosis, HbA1c test date and result and lack of co-morbidity exclusions from CCHS.

A summary will be provided indicating the number of participants screened, number of participants eligible, number of participants not eligible and reason for non-eligibility, number of participants enrolled, number of participants not enrolled and the reason for non-enrollment, and the number of participants randomized to each arm.

2) **Eligibility** – summary of eligibility criteria

Inclusion Criteria:

1. Confirmed diagnosis of type 2 diabetes mellitus (T2DM) in the medical record
2. Most recent HbA1c (within 1 year) ≥ 7%
3. Receives primary care for diabetes from Contra Costa Health Services
4. Is a current member of Contra Costa Health Plan
5. Age ≥18 years
6. Has a point-of-care HbA1c test in the medical record in the last month; OR their doctor has an active order for an HbA1c test for the potential participant; OR the participant is eligible to have a test ordered as part of usual care
7. Speaks English or Spanish
8. Adequate cognitive and hearing capacity to complete study measures
9. Willing to participate in the online or telephone DSMP education, and if randomized to the intervention, to receive home-delivered meals and groceries
10. Has the ability to engage with simple reading materials (e.g. directions to join the education session by phone or Zoom) on their own or with the support of a family member or friend
11. Has access to a device (telephone, tablet, and/or computer) that can be used to receive remote DSMP education (possible via phone, computer or tablet) and complete study assessments (phone only; or tablet or computer with phone capabilities) (does not need to be participant's own device)

Exclusion Criteria:

1. Currently pregnant, currently breastfeeding, up to 6 months postpartum, or plans to become pregnant during the course of the study.
2. Has confirmed Type 1 DM
3. Has confirmed stage 5 chronic kidney disease, end stage renal disease or is on dialysis or expected to start dialysis in the next 6 months
4. Does not have the means to receive delivery of, store (e.g. refrigerator or freezer), and heat or prepare (e.g. microwave or stove) intervention food.
5. Has a food allergy, intolerance or preferred diet that POH cannot accommodate with meal delivery (e.g. vegan diet). POH can accommodate many but not all diet restrictions.
6. Does not live in Contra Costa County or plans to move out of the county in the next 6 months
7. Being a current POH client, past POH client who stopped services less than 6 months prior, or past or present participants in other POH medically tailored meals studies
8. Another household member is already enrolled in the NU-DSMP study

3) **Recruitment** – A CONSORT flow diagram will be used to summarize the number of participants who were:

a. Assessed for eligibility at screening
   i. Eligible at screening
   ii. Non eligible at screening, and reasons why were not eligible
b. Eligible and randomized
   i. Eligible and randomized
   ii. Eligible but non-randomized, and reason
c. Lost to follow up at 12 weeks, and reason
d. Lost to follow up at 24 weeks, and reason
e. Discontinued the intervention, and reason
f. Randomized and included in primary analysis
g. Randomized and excluded from the primary analysis, (if any), and reason.

4) **Withdrawal/follow-up**

Reasons and details of withdrawal at twelve and twenty-four weeks for both arms will be reported. This information will be summarized in the CONSORT flow diagram. In addition, the numbers of losses to follow up will be summarized by treatment arm.

5) **Baseline patient characteristics**.

a. **List of baseline characteristics to be summarized.** Sociodemographic and clinical characteristics at baseline overall and by study arm will be described. These

characteristics includes age, sex at birth, gender identity, household size, educational attainment, income, housing situation, relationship status, language(s) spoken, employment status, nutritional (household food insecurity, diet quality) mental health (depressive symptoms score, diabetes distress), behavioral (physical activity, diabetes medication adherence, diabetes self-efficacy, smoking and alcohol use), clinical outcomes at baseline (HbA1c, BMI), health-related quality of life and acute care utilization.

b. **Details of how baseline characteristics will be descriptively summarized**. Categorical variables will be presented as numbers and percentages. Continuous variables will be summarized by mean and SD for variables with normal distribution, and by median and IQR if data are skewed. Minimum and maximum values will also be presented for continuous data. Tests of statistical significance will not be performed for baseline characteristics.

Section 6: Analysis

1) **Outcome definitions**

Primary Outcome Measures:

1. Hemoglobin A1c. We will collect HbA1c from the medical record at twelve weeks and twenty-four weeks, The change in HbA1c levels (%) from baseline to twelve weeks by study arm will be reported.
2. Food security. Food insecurity will be measured with the 10-item adult module USDA Household Food Security Survey Module (HFSSM), validated in many populations. The score ranges from 0 to 10. Higher scores indicate higher severity of food insecurity. The change in the food insecurity scores from baseline to twelve weeks by study arms will be reported.

Secondary Outcome Measures:

1. Glucose control. The change in the proportion of participants with glucose control, defined as HbA1c <9%, from baseline to twelve weeks by study arms will be reported.
2. Low food security. Food security as a binary response will be assessed, identifying a participant having low or very low food security or food security (vs. food security or marginal

food secure) by study arm. The change in the proportion of participants having food security from baseline to twelve weeks by study arm will be reported.

3. Health-related quality of life (HRQL). Health-related quality of life will be measured using the Summary Index of Unhealthy Days collected via the CDC Healthy Days scale. This scale asks the number of days in the past 30 days the person felt physically or mentally unwell. The summary index then estimates the number of recent days when a person's physical and mental health was good (or better) and is calculated by subtracting the number of unhealthy days from 30 days. The change in healthy days from baseline to twelve weeks by study arm will be reported.
4. Fruit and vegetable consumption. Dietary information using the Dietary Screener Questionnaire (DSQ) will be collected. The DSQ obtains information on the frequency of consumption of fruits and vegetables. These responses are then converted to cup equivalents per day using a scoring algorithm based on the NHANES 24-hour recall. The change in fruit and vegetable consumption (servings/day) from baseline to twelve weeks by study arm will be reported.
5. Added sugar consumption. Dietary information using the Dietary Screener Questionnaire (DSQ) will be collected. The DSQ obtains information on the frequency of consumption of food items with added sugars. These responses are then converted to teaspoon equivalents per day using a scoring algorithm based on the NHANES 24-hour recall. Added sugars consumption (teaspoon equivalents per day) from baseline to twelve weeks by study arm will be reported.
6. Depressive symptoms. The 8-item Patient Health Questionnaire (PHQ-8) will be used to evaluate depressive symptoms. The PHQ-8 score ranges from 0 to 24, with higher scores indicating higher levels of depression. The change in PHQ-8 scores from baseline to twelve weeks by study arm will be reported.
7. Diabetes self-efficacy. The 8-item Diabetes Self-Efficacy scale will be used to assess confidence in one's ability to manage numerous self-care behaviors. The scores ranges from 8 to 40, with higher scores indicating more confidence in self-managing their diabetes. The changes in the scores from baseline to twelve weeks by study arm will be reported.

Other Pre-specified Outcome Measures:

1. Durability of HbA1c after intervention end. To evaluate durability of changes, if any, in HbA1c after the intervention ended, the change in HbA1c levels (%) from 12 weeks to 24 weeks by study arm will be reported.

2. Durability of glucose control after intervention end. To evaluate durability of changes, if any, in glycemic control after the intervention ended, the change in the percent of participants with HbA1c levels less than 9% from12 weeks to 24 weeks by study arm will be reported.
3. Durability of health-related quality of life after intervention end. To evaluate the durability of changes, if any, in health-related quality of life, the change in healthy days from 12 weeks to 24 weeks by study arm will be reported.

2) **Analysis methods**

a. **Preliminary/Descriptive analyses.** Frequency tables for all variables and measures of central tendency and variability for continuous variables will characterize the sample and be stratified by randomization arm to check for non-equivalence. If the two arms differ at baseline on any covariates, the Rubin causal model (e.g., propensity scores, double-robust estimation) will be used to obtain the desired marginal effect estimates under the counterfactual assumption of balanced arm. Although the computerized data collection protocol and the presence of an interviewer should minimize missing data, the analyst will examine patterns of non-response, and inspect distributions of mediating and outcome variables to identify outlying or unusual values and assess distributional characteristics. Validity and reliability of scale constructs via confirmatory factor analysis and internal consistency will be verified.

b. **Analyses for Aim 2 (Diabetes and other health and behavioral outcomes):** The intervention is intended to improve clinical and other health and behavioral outcomes suggested by our intervention model. Although we are not powered to detect changes in HbA1c, we will test the preliminary hypothesis that the NU-DSMP intervention will lead to improved (i.e., lower) mean HbA1c (primary outcome). For the primary analysis, an intent-to-treat analysis will be performed using the Stata mixed procedure assessing whether the intervention resulted in differentially improved changes from baseline to twelve weeks in the primary outcome. The model will specify mixed (i.e., fixed and random) effects, be estimated by maximum likelihood, use all the longitudinal data, and account for variability among and within and individuals using an exchangeable covariance structure. The fixed effects specified will be arm (intervention or control), visit (baseline or six months), and their interaction as a product term. The random effect will be individuals. The model is equivalent to a repeated-measures or differences-

indifferences model. The interaction term estimates the difference-in-differences. A fully fixed-effects model (with individuals as a fixed rather than random effect) and an analysis of covariance with the outcome at 12 weeks regressed on the outcome at baseline and arm will be examined as robustness checks.

Additional analyses will be done to a) check robustness if the two arms differ at baseline by controlling for the propensity score (or the covariates that were important in the propensity score); and b) adjust for medication use.

Similar analyses will be done for the secondary outcomes using mixed-effects linear or logistic models as appropriate. For primary and secondary outcomes, Box-Cox transformations will be used to correct for skewness if needed.

c. **Analyses for aim 3 (process evaluation).**
Quantitative process evaluation data (structured interview and administrative data) and qualitative data (interviews and weekly team meetings) will be analyzed separately and then compared to cross-validate findings and generate lessons learned. Qualitative data analysis will be performed using content coding procedures to identify key themes using Dedoose software. Emergent themes will be identified and coded inductively. Coding consensus will be considered when transcripts achieve ≥90 percent coder agreement.

3) Sensitivity analysis

a. No sensitivity analyses will be done beyond those described above.

4) Subgroup analysis

a. Additional models and statistical interactions (i.e., product terms) will be performed to identify characteristics of individuals who most benefitted from the intervention, such as biological sex, food insecurity, poor T2DM control (A1c ≥ 9), and insulin use.

5) Missing data

The study will use several strategies to account for and address missing data. Missing data will be categorized into missed individual questions and missed visits.

a. <u>Missed individual questions:</u> Multiple imputation will be used to address incomplete data under the weak assumption that incomplete data arise from a conditionally missing-at random mechanism (MAR) rather than the missing-completely-at-random process

assumed by ad hoc methods such as listwise deletion. Auxiliary variables will be included to help meet the MAR assumption and sensitivity analyses will be conducted with weighted multiple imputation to assess the MAR assumption. Information on percent of questions missing and imputed will be reported for each variable as appropriate in study manuscripts.

b. Missed visits: When a participant misses a visit, this will be noted in the study register, and no data will be imputed for this participant for that visit.

6) **Additional analyses**

a) **Durability of health benefits:** To assess whether any improvements in primary or secondary outcomes were sustained in the intervention arm, researchers will estimate effects of the intervention on outcomes measured at 24 weeks using the same statistical modeling techniques as the main outcomes measured at 12 weeks. Mixed models specifying two visit fixed effects will be used, one for differences between baseline and twelve weeks and one specifying differences between twelve and twenty-four weeks. The random effect will be individuals.

7) **Harms** Research will be conducted according to Good Clinical Practice guidelines, the U.S. Code of Federal Regulations (CFR) Title 21 CFR (Part 50 – Protection of Human Subjects and Part 56 – Institutional Review Boards), and the Declaration of Helsinki.

a) Data safety: Participant confidentiality will be prioritized following strict guidelines on privacy. For the proposed study, all data will be collected in private and be handled as confidentially as possible within the law. For interviews and medical record data collected as part of the study, participants will be assigned a unique study identification number, and the participant's name or other public identifiers (e.g., phone number, address) will not be included with any data. All consent and other material with personal identifiers (e.g., recruitment and follow-up tracking documents) will be kept separately from all data sources. The project manager will keep consent materials in a locked cabinet in a locked office and/or in a password protected file on an encrypted computer. Research assistants and support staff will be trained on procedures for maintaining privacy and will sign a pledge of confidentiality. All electronic records (computer, online, audio-recorder) will be password protected and encrypted to prohibit illicit access. When these procedures are followed, it is highly unlikely that any information revealed by participants during the study will be disclosed to the analyst or anyone outside the research team.

b) **Adverse events**. The PI will report all serious events and problems having to do with participant safety to UCSF's Human Research Protection Program within ten working days. All serious adverse events and events associated with the study participation will be reported in writing. Dr. Palar will annually provide a discussion of any problems noticed during the previous year of the study to the UCSF Human Research Protection Program during the annual review. Participants will be provided with information on how to contact the study staff to report serious adverse events and adverse events associated with study participation. Field staff will be trained to collect information about serious adverse events that will be sent to the study principal investigators. All serious adverse events related to the study, will be reported by arm. No formal statistical analysis will be done.

8) Statistical software

The following software systems will be used in the analysis: 1) Stata SE version 14 [College Station, TX: StataCorp LP]; Stat Transfer 14.

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Signature Page

Declaration

I have reviewed and agree to the Statistical Analysis Pan as presented in this document.

_____ __9/20/2021_____

Kartika Palar, Principal Investigator Date

_____ __9/20/2021_____

Edward A. Frongillo, Senior Statistician Date