Farming for Life - Health Impact of Organic Vegetable Prescriptions for Adults Living With or at Risk of Type 2 Diabetes

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03940300	RECRUITING	MAY 7, 2019	JUNE 16, 2021

STUDY DESCRIPTION

Brief Summary

Farming for Life aims to determine the health impacts of providing weekly "prescriptions" of fresh organic vegetables to adults living with or at risk of type 2 diabetes. Over 4 years, up to 400 adults diagnosed with or at high risk of developing type 2 diabetes will be engaged for 3 months each, and receive weekly doses of locally-grown organic vegetable prescriptions. The end-points for comparison will be changes in blood pressure, weight, waist circumference, glycemic control [defined as Time in Range (TIR) (70-140mg/dl)] using continuous glucose monitoring (CGM), and HbA1c levels (a measure of long-term blood glucose level control) after 3 months compared to baseline measurements. Additional assessments will be made on the impact of the organic vegetable prescriptions on food security. At an optional Visit 13, offered 6 months after Visit 1, an additional health screening will be conducted. Prevalence and risk of type 2 diabetes in the US is disproportionately high among low income and minority groups and is exasperated by high levels of food insecurity. The investigators hypothesize that improving access to fresh organic vegetables will result in measurable health outcomes for adults with type 2 diabetes and those at risk of developing the condition. This represents a promising and potentially cost-effective strategy for improving diabetes outcomes at a population level, particularly among low income, minority populations with type 2 diabetes.

Condition or Disease: Diabetes Mellitus, Type 2
Food Supply
Poverty
Minority Health
Obesity

Intervention/treatment: Dietary Supplement: Fresh organic vegetables

Phase: N/A

DETAILED DESCRIPTION

Farming for Life will recruit adults with or at high risk of developing type 2 diabetes (non-insulin treated). Because diabetes rates are disproportionately high in low income and minority populations, the investigators expect that many participants will be members of these groups. After obtaining written consent, participants will receive 10 weekly free "prescriptions" of fresh organic vegetables sourced from local growers. Health measurements will be conducted by trained clinical staff at baseline and upon completion of the intervention period.

The total duration for the program is approximately 4 years, in which up to 400 participants may be engaged. Program visits will take place at vegetable distribution centers and clinical locations (SDRI or other clinical sites). SDRI will ensure provision of appropriately trained clinical staff and equipment to obtain accurate clinical measurements.

Potential participants will be recruited via bilingual outreach materials. Up to 440 individuals will be enrolled for an anticipated 400 individuals completing the program (8% anticipated dropout rate). A subset of approximately 120 participants will use CGM.

Eligible and consented participants in this program will be asked to complete 12 visits, with an optional 13th visit. Over the course of these visits, participants will collect 10 weekly organic vegetable prescriptions that are signed by a qualified medical practitioner, as well as complete health screenings and questionnaires during the first and last visits. For those using CGM, data will be collected by study staff at an additional Visit 3b, concluding the first 14 days of participation, and at Visit 12, concluding the final 14 days of participation. At each prescription pick-up visit, each participant will receive a week's "dose" of organic vegetables. The outcome data will be collected at Visit 1 after obtaining informed consent and at Visit 12 after the completion of 10 weeks of prescriptions. Additionally, participants will be invited to submit via cell phone, photographs of meals featuring their prescribed organic vegetables. At an optional Visit 13, offered 6 months after Visit 1, an additional health screening will be conducted.

Participants may receive nutrition education in the form of printed material featuring organic vegetable recipes and nutrition guidance offered at vegetable collection sites. Recipes will be sourced from the American Diabetes Association Diabetes Food Hub website (www.diabetesfoodhub.org). Aside from the weekly supply of organic vegetables allocated by prescription, health measurements, and printed nutrition education materials, there will be no compensation nor other incentives for program participants.

The Unity Shoppe in Santa Barbara (http://www.unityshoppe.org/) hosted Farming for Life in a pilot and will be a storage and distribution site. If necessary, additional appropriately-equipped, Independent Review Board (IRB) approved sites may be used. Visits 1, 12, and 13 will occur at SDRI and, if necessary, additional appropriately-equipped, IRB approved clinical sites.

The organic vegetables for this program will primarily be sourced and purchased wholesale from two or more farms within 100 miles of the vegetable distribution location/s. Organic vegetables received for prescription distribution will be coded and tracked through an inventory system.

Visit 1 begins with screening and enrollment via the initiation of the informed consent process. Participant eligibility will be confirmed following review of the inclusion and exclusion criteria by program staff. Each participant will be provided with oral and written information (English and/or Spanish, as appropriate) describing the nature and duration of the program. Prior to initiation of program-related procedures, the participant will sign and date the written informed consent and authorization form, authorizing the use and disclosure of the participant's protected health information (PHI). The participant will also sign the California Experimental Subject's Bill of Rights.

Once enrolled via informed consent, participants will first complete questionnaires on diabetes management, food security and health. Then participant height, weight, blood pressure and waist circumference will be measured. HbA1c level will be measured via finger-stick. A subset of up to 120 participants will then be trained to wear CGM sensors under supervision of staff. Participants will be informed that the CGM data will be blinded during each CGM session. The CGM data for each participant who may wear a CGM sensor will be summarized using software which produces both a statistical and graphic display of data. Participants will then receive a prescription for 10 weeks of organic vegetables. Finally, participants will be invited to share photographs of and recipes for meals they prepare with their prescribed organic vegetables.

Visits 2-11 will all follow the same format and will include the fulfillment of weekly prescriptions. The types and quantities of organic vegetables distributed to each participant will be tracked. For those using CGM, during visit 3 the CGM sensor will be removed, and during visit 10 a CGM sensor will be inserted.

During Visit 12, clinical measurements will be taken and recorded as in Visit 1. For those using CGM, the CGM sensor will be removed and data will be downloaded from the recorder. After these measurements, participants will complete questionnaires on diet, food security, and health as they did in Visit 1. Participants will also complete an Exit Questionnaire to gauge satisfaction with and experience participating in the program.

At an optional Visit 13, offered 6 months after Visit 1, an additional health screening will be conducted.

STUDY DESIGN

Study Type:	Interventional
Estimated Enrollment :	440 participants
Intervention Model :	Single Group Assignment
Masking:	None (Open Label) ()
Primary Purpose:	Treatment
Official Title:	Farming for Life - a Program to Prescribe Fresh Organic Vegetables for Adults Living With or at Risk of Type 2 Diabetes.

Actual Study Start Date:	January 2019
Estimated Primary Completion Date:	December 2023
Estimated Study Completion Date:	May 2024

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Adults with or risk for Type 2 Diabetes All adult individuals with (non-insulin treated) or at risk for type 2 diabetes are in the treatment group and will receive prescriptions of fresh organic vegetables on a weekly basis for 10 weeks.	Dietary Supplement: Fresh organic vegetables Individual participation in this program will take 12 weeks, from screening and enrollment through evaluation. Once enrolled, visits will occur on a weekly basis to ensure that participants receive each week's "dose" of fresh organic vegetables. At an optional Visit 13, offered 6 months after Visit 1, an additional health screening will be conducted.

OUTCOME MEASURES

Primary Outcome Measures:
1. Improve cardio-metabolic health in adults with (non-insulin treated) type 2 diabetes or at risk for type 2 diabetes as measured by blood pressure. [Time Frame: 12 weeks]
Cardio-metabolic health is described by lower blood pressure (systolic and diastolic pressure, mmHg).
2. Improve cardio-metabolic health in adults with (non-insulin treated) type 2 diabetes or at risk for type 2 diabetes as measured by body mass index. [Time Frame: 12 weeks]
Cardio-metabolic health is described by lower body mass index (kg/m2).
3. Improve cardio-metabolic health in adults with (non-insulin treated) type 2 diabetes or at risk for type 2 diabetes as measured by waist circumference . [Time Frame: 12 weeks]
Cardio-metabolic health is described by decreased waist circumference (cm).
4. Improve cardio-metabolic health in adults with (non-insulin treated) type 2 diabetes or at risk for type 2 diabetes as measured by hemoglobin A1c. [Time Frame: 12 weeks]
Cardio-metabolic health is described by decreased hemoglobin A1c (%).

Secondary Outcome Measures:
1. Improve food security for adults with or at risk for type 2 diabetes assessed by U.S. Household Food Security Survey Module: Six-item short form [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Food security or insecurity assessed by a six-item short form developed by the Economic Research Service, United States Department of Agriculture (USDA), September 2012. Questionnaire consists of 6 questions regarding food security or insecurity, and the choices for answers are "often true", "sometimes true", "never true", and "don't know or refused". There are no better or worse values.
2. Improve glycemic control measured by continuous glucose monitoring (CGM) [Time Frame: Visit 1, Week 1 to Visit 3, Week 3 and Visit 10, Week 10 to Visit 12, Week 12]
Time in Range defined as blood glucose, 70 - 140 mg/dL, over 2 weeks [percentage of glucose readings, or hours per day] will be measured by continuous glucose monitoring (CGM) in a sub-set of participants.

Other Outcome Measures:
1. Acculturation measured by the Brief Acculturation Scale for Hispanics (BASH) [Time Frame: Visit 1, Week 1]
BASH is a participant reported questionnaire to measure acculturation. Responses are scored as 1 = only Spanish, 2 = Spanish more than English, 3 = Spanish and English equally, 4 = English more than Spanish, and 5 = only English. Items are summed and divided by the number of items. Low acculturation is less than or equal to 3.0, and high acculturation is greater than or equal to 3.0.
2. Socio-demographics assessed by questionnaire [Time Frame: Visit 1, Week 1]
Socio-demographics measured by questionnaire - including age, gender, self-identified race/ethnicity, contact information, number in household, insurance status, insurance type and payer, country of birth, and occupation.
3. Concurrent medications assessed by visual inspection [Time Frame: Visit 1, Week 1]
Medications currently being taken will be documented by visual inspection of medication containers
4. General health measured by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program questions regarding general health measured by a 4 point scale (1 poor, 2 fair, 3 good, 4 excellent)
5. Food consumption behavior measured by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program questions regarding food consumption behavior measured by a 4 point scale (1 strongly disagree, 2 disagree, 3 agree, 4 strongly agree)
6. Factors influencing food consumption measured by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program questions regarding factors influencing food consumption measured by a 4 point scale (1 not important at all, 2 a little important, 3 important, 4 extremely important)
7. Sleep evaluation by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program Likhert scale to answer the question, "How would you rate your sleep over the course of the past 7 days?," from worst sleep to best sleep
8. Mood evaluation by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program Likhert scale to answer the question, "How would you rate your mood over the course of the past 7 days?," from worst mood to best mood
9. Pain evaluation by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program Likhert scale to answer the question, "How would you rate your level of pain over course of the past 7 days?," from worst pain to no pain
10. Physical activity evaluation by questionnaire [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Pre and post program questionnaire about daily physical activity
11. Total daily tortilla consumption evaluation [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
The number of flour and/or corn tortillas consumed daily for the past 30 days is estimated
12. Daily sugar-sweetened beverage consumption evaluation [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
Daily sugary drink consumption is measured by the 2 questions in the Sugar Sweetened Beverages module of the Behavioral Risk Factor Surveillance System Questionnaire (BRFSS) from the Centers for Disease Control.
13. Number of times per week eating meals prepared away from home [Time Frame: Visit 1, Week 1 and Visit 12, Week 12]
National Health and Nutrition Examination Survey (NHANES) 2017-2018 question asked - During the past 7 days, how many meals did you get that were prepared away from home in places such as restaurants, fast food places, food stands, grocery stores, or from vending machines?

14. Participant experience with the program evaluated by questionnaire [Time Frame: Visit 12, Week 12]
Questionnaire regarding participant's experience with the study program consists of 9 questions. Participants are asked general questions about the program's impact on health, difficulties in participating, ease of participating, what should be changed, what should be kept, vegetable consumption, and would friends or relatives be interested in this program.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Adults ≥ 18 years of age at Visit 1
2. Self-reported diagnosis of type 2 diabetes OR self-reported as at high risk for developing type 2 diabetes
3. Based on program staff's judgment, subject must have a good understanding, ability, and willingness to adhere to the protocol

Exclusion Criteria:
1. Currently taking insulin as treatment for diabetes
2. Pregnant
3. Any active clinically significant disease or disorder, which in the investigator's opinion could interfere with the participation in the trial
4. Mental incapacity, psychiatric disorder, unwillingness or language barriers precluding comprehension of program activities and informed consent
5. Participation in other trials involving medication or device within 1 month prior to Farming for Life enrollment
6. Known or suspected abuse of alcohol, narcotics, or illicit drugs

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CONTACTS AND LOCATIONS

Contacts

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Locations

United States, California	Sansum Diabetes Research Institute	Santa Barbara

Sponsors and Collaborators

Sansum Diabetes Research Institute

United States Department of Agriculture (USDA)

Investigator

Principal Investigator :	David Kerr, M.D.	Sansum Diabetes Research Institute

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MORE INFORMATION

Responsible Party :	Sansum Diabetes Research Institute
ClinicalTrials.gov Identifier :	NCT03940300
Other Study ID Numbers :	2018-01793
First Posted :	May 7, 2019
Last Update Posted :	June 16, 2021
Last Verified :	June 2021
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Sansum Diabetes Research Institute:	*Diabetes Mellitus, Type 2* *food insecurity* *food prescriptions minority* *low-income*
Additional relevant MeSH terms :	*Diabetes Mellitus* *Diabetes Mellitus, Type 2*