DGIM Project Summary

Name of Project:
Walnuts to Achieve Lasting NUTrition to prevent Diabetes (WALNUT-Diabetes)

PI and primary contact:
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Research question(s):
Aim 1: Determine a) feasibility for recruitment and retention into a randomized controlled trial of daily walnut supplementation, and b) acceptability and adherence to the intervention containing 28g of walnuts daily, compared with usual care in individuals with prediabetes.

Aim 2: Determine preliminary efficacy of the walnut intervention vs. usual care on change in a) fasting glucose, HbA1c and lipid levels, b) dietary quality score and c) BCAA and AAA levels. These estimates of efficacy will inform the sample size for a larger future randomized controlled trial.

Brief Background/Significance:
Prediabetes is a precursor of type 2 diabetes and an independent risk factor for cardiovascular disease, and currently affects one-quarter of the population of the United States. Individuals of overweight or obese BMI are at particular high risk for incident diabetes. A major modifiable risk factor for type 2 diabetes is poor dietary quality, and improvement of dietary quality can effectively delay and even prevent type 2 diabetes. Interventions to improve dietary quality thus far, however, rely on short-term intensive clinically designed meals replacing the entire diet which have poor sustainability. Persistent improvements to daily dietary patterns are often difficult without directed guidance, and overall dietary quality in the United States remains poor. A practical, daily dietary intervention to improve dietary quality and prevent diabetes in those at high risk remains unknown. Our goal is to implement a daily walnut supplement to improve dietary quality and surrogate markers for diabetes in patients with prediabetes as a tool for future type 2 diabetes prevention.

Inclusion Criteria:
1. Male or female between 18-65 years of age at baseline living in the San Francisco Bay area.
2. BMI>25 m/kg^2 (or >23 m/kg^2 for individuals of Asian or South Asian ethnicity)
3. Documentation of prediabetes diagnosis as evidenced by the following criteria:
    a. A fasting glucose 100-125 mg/dL, or a HbA1c measurement of 5.7-6.4%, OR a diagnosis of “prediabetes” or “impaired fasting glucose” in the past 6 months, identified through an electronic medical record query from patients at UCSF and through outside recruitment in the surrounding community
    b. We will confirm eligibility of potential participants by repeating fasting capillary blood glucose measurements at the baseline visit to ensure that they have prediabetes
4. Written informed consent and ability for subject to comply with the requirements of the study.

Exclusion Criteria:
1. Pregnant or breastfeeding women at enrollment.
2. Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the patient or the quality of the data, such as diverticulosis or diverticulitis.
3. Tree or peanut allergies

4. Unwilling to consume a daily walnut supplement.
5. Diagnosis of diabetes
6. On glucose lowering medications
7. Dietician-managed dietary intake, or personal or medical dietary restrictions that do not allow consumption of walnuts
8. Malabsorptive conditions including intestinal bypass surgery, pancreatitis, inflammatory bowel disease

All subjects should be maintained on the same medications throughout the entire study period, as medically feasible, with no introduction of new glucose-lowering therapies.

Method of contact/recruitment (be specific):

1. "Dear Doctor" letter soliciting referrals of patients who are overweight or obese and with prediabetes.
2. Flyers at Mt. Zion and Parnassus

Benefits/burden for participants (clearly identify potential for harm):

As this is a feasibility and acceptability study, there are no direct benefits, however participants may improve their overall diet quality as a result of walnut consumption. Potentia harm: A daily walnut supplement has a low risk to produce GI distress and weight gain. In rare instances, there may be an allergic reaction to the walnut supplement.

Any benefits or burden to DGIM practitioners?

There are no direct benefits or burdens for DGIM practitioners

Timeline for recruitment (projected start and stop dates)

Start recruitment: 1/1/18 End recruitment: 4/1/18
End study: 6/31/18

Funding source:
UCSF Nutrition Obesity Research Center (NORC) pilot award, supported by NIDDK

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)
None at this time, however there will be a possibility for secondary analyses after the trial is complete.

Do you agree to notify us when recruitment is completed?
Yes

Date form completed: 11/28/17