DGIM Project Summary
A Pilot Study of the Effects of Diet and Behavioral Interventions on Health in Diabetics

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Research question: Currently, controversy surrounds what the ideal diet should be for individuals with Type II diabetes. The goal of this research is to help create a stronger evidence base for dietary recommendations for individuals with Type II diabetes, as well as test whether we can improve long-term compliance. To do so, we will be running a pilot clinical trial, which will test two different diets (the American Diabetes Association diet versus a lower carbohydrate diet) in conjunction with a toolkit of psychological techniques for improving compliance. We are interested in diabetes-related outcomes such as HbA1c as well as other outcomes such as quality of life, mood, fatigue, weight, and general health.

Brief Background/Significance: Type II diabetes is a very costly and increasingly prevalent disease. While research has made advances in treatments, many do not effectively prevent complications. For example, newer data show that tight blood glucose control using medication can lead to adverse health effects in Type II diabetics. Consequently, some argue that other approaches, such as diet, should be used. However, there is no clear consensus around what the ideal diet should be for Type II diabetics. The ultimate goal of this research program is to improve the health of individuals with Type II diabetes using more rigorous, evidence-based recommendations.

Inclusion/exclusion criteria:
Inclusion criteria: Type II diabetes, 18 years or older, BMI 25 or above
Exclusion criteria: Condition that will make it difficult for participation such as cancer or severe autoimmune disorders. Current use of insulin. Immediate plans to start new or increase current diabetic medications. History of or planned weight loss surgery. Pregnant or planning to get pregnant in the year. Unable or unwilling to do home glucose monitoring

Method of contact/recruitment: At DGIM we would like to have business cards about the study made available as well as to advertise the study using flyers (such as in the 1st and 2nd floor bathrooms). If DGIM staff is interested, we would appreciate them mentioning the study to their patients who have Type II diabetes and are overweight. Interested participants go to SucceedStudy.org to find out more about the study and to see if they are eligible.

Benefits/burden for participants: Participants may benefit from individual attention in the 15 classes where they will be taught a diet and a psychological toolkit for reducing their stress and stress-induced eating. We will be asking them to change their eating habits, which can take considerable effort and therefore be a burden. While we do not expect adverse effects, we will have participants monitor their blood glucose, with oversight by study staff, to prevent hypoglycemic episodes. Some minor side effects can occur such as constipation.

Timeline for recruitment: We will be recruiting from September-mid November, 2012.

Funding source: Bowes Fund

Potential for DGIM collaborators? Possibly. Please contact us.

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

Date form completed: September 18, 2012