Dr. Benjamin Lebwohl

Application for Irving Institute/Clinical Trials Office (CTO) Pilot Funds

Principal Investigator: Benjamin Lebwohl, MD, MS

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Title

A Pilot Study to Test the Feasibility and Acceptability of Using Gluten Sensor Devices & Social Video-Based Discussion Tools to Promote a Gluten-Free Diet in Patients with Celiac Disease.

Goals

The purpose of this pilot study is to collect preliminary data for an NIH R01 grant application that will compare the effects of various novel interventions, alone and in combination, to promote a strict gluten-free diet (GFD) in teenagers and adults with celiac disease (CD).

This proposal brings together a multi-disciplinary team of Columbia University pediatric and adult clinicians, dietitians and nutrition educators, behavioral scientists, and technology design developers to understand the best ways to promote a GFD in CD patients while maximizing quality of life (QOL) and minimizing intestinal damage and long-term complications. Data from this pilot study will be used to conduct a larger randomized controlled trial to examine the effects of four interventions: 1) A GFD with a one-time dietitian session (standard of care), 2) standard of care in combination with a novel technology - a portable gluten sensor device, 3) standard of care in combination with a novel online social video-based discussion tool, and 4) standard of care in combination with both a portable gluten sensor device and an online social video-based discussion tool. Outcomes for this larger trial will be measures of QOL [1], depression [2] and anxiety [3], and adherence as measured by survey methods [4,5], levels of serum CD antibodies [6], stool gliadin peptide fragments [7], and mucosal healing status on follow-up biopsy [8].

We have two Specific Aims for the proposed pilot:

1. To assess the acceptability and feasibility of using portable gluten sensor devices to promote GFD adherence. *This dose finding aim will describe how CD patients use a portable gluten sensor device and the potential facilitators and barriers to promoting GFD adherence and QOL.*

2. To assess the acceptability and feasibility of using a social video-based

discussion tool to promote GFD adherence. *This aim will describe how CD patients engage with a social online video- based discussion tool and the potential facilitators and barriers to promoting GFD adherence and QOL.*

The sample for this pilot will be 40 teenagers and adults with biopsy confirmed CD recruited from the Celiac Center at Columbia University in New York City. Thirty participants will pilot test a portable gluten sensor device with its associated iPhone app for 3 months. Ten participants will pilot test an online social video-based discussion tool during the same 3 months. At baseline and 3-month follow-up, participants will complete measures of GFD adherence, QOL, symptoms, anxiety, and depression. Post-intervention we will collect in- depth data related to the feasibility and acceptability of the gluten sensor monitors and the social video-based discussion tool.

At the completion of the proposed pilot study, we will have preliminary data to inform development of interventions that will include gluten sensor monitoring and a social video-based discussion tool in the CD patient population. Our longer-term goals are to use this preliminary data for an NIH R01 application. These findings, in combination with a larger trial, have the potential for the development of a new standard of care in the management of patients with CD. These findings may inform a paradigm shift from traditional one-time dietitian sessions immediately following CD diagnosis to a more enhanced intervention that has the potential to improve adherence, QOL, and long-term health outcomes for patients with CD.