Title: Barriers to Lifestyle Change in Irritable Bowel Syndrome

Summary:

The Data Studio Workshop brings together a biomedical investigator with a group of experts for an in-depth session to solicit advice about statistical and study design issues that arise while planning or conducting a research project. This week, the investigator(s) will discuss the following project with the group.

Irritable bowel syndrome (IBS) is a chronic condition that impacts approximately 6% of the population. Symptoms include intermittent abdominal pain associated with a change in bowel function or stool form. First-line treatment recommendations include diet and lifestyle modifications. This is a prospective survey study of IBS patients. The survey will be administered to patients in clinic as well as an internet survey. Typical IBS surveys have a response rate that ranges between 30% and 60% (median 35%). The race/ethnicity of study participants in prior IBS clinical trials and survey studies in IBS is typically 75% non-Hispanic White, 7% Black, 7% Latinx, 5% Asian, and 6% other. Similar studies do not exist; therefore, the effect size is not known to assist with sample size determination.

This study has two aims. The first aim is to understand barriers to various therapies including diet, sleep, mental health, herbal, and pharmaceutical therapies. The second aim is to compare the patient-perceived acceptability of different nonpharmacologic and pharmacologic interventions. Identifying barriers to treatment can help formulate strategies to improve adoption of lifestyle changes in the IBS population. Patients will be asked a series of questions regarding common therapies prescribed or recommended for IBS. The first question is a categorical (YES/NO). Patients who answer NO will be asked the same 14 questions regarding the reason why they gave that answer. For all patients in the study, we will collect demographic information (age, gender, ethnicity, language fluency, income, education), clinical variables (duration of disease, medical comorbidities), and treatment-specific response. The demographic and clinical variables will be assessed to determine if any of these factors are associated with any of the response categories.

Questions:

For this specific project, I need help with sample size determination and subsequent data analysis. More importantly, I'm interested in developing a long-term collaboration with a data scientist.

1. What is the sample size needed to adequately draw conclusions about barriers to therapy given the interconnection between race/ethnicity and socioeconomic factors?

2. Given the historically low representation of minorities in IBS trials, should we enrich the population by determining sample size by race or increasing the entire sample size to increase the number rather than the ratio?
3. We will perform descriptive analyses of the prevalence of the various barriers related to each therapy.
   
   (a) How would you suggest handling the data to determine association between REA and SES factors and individual barriers?
   
   (b) How would you handle the data in participants who answer that they experience multiple barriers to a particular therapy?
   
4. The individual therapies surveyed fall into categories of diet, lifestyle, complementary/alternative therapies (CAM), and medications. What is the best way to compare barriers to therapy quantitatively when using this qualitative survey?

**Zoom Meeting Information**

Join from PC, Mac, Linux, iOS or Android:
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