What happens with the test results?

You will have access to the results. Based on the results you may be asked to participate in an **8-week treatment trial**.

What is the treatment trial?

We are testing **two** potential treatments which may help the vagus nerve function more normally. In one trial, participants receive a medication called pyridostigmine or an identical pill that contains no medication (placebo). The other trial involves a vagal nerve stimulator which is applied to the neck.

The schedule

The testing is spread out over several days, and arranged to accommodate your schedule. We try to do most of the questionnaires over the phone before the in person visits. Autonomic and breath testing is done on the first day. SmartPill is given on a different day and then you come back 5 days later to return the Smartpill recorder. If you enter the treatment trial, you will repeat the breath test and blood draw at 4-weeks and all the testing at 8-weeks.

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Am I eligible?

Most adults will be eligible. You don't have to have any particular symptoms to participate, but people with certain medical conditions (e.g. diabetes) or taking certain medications (e.g. antibiotics) may be excluded.

Will I be paid for my time?

Yes! You will receive \$200 for completing all the baseline testing. If you also complete the treatment trial you will receive an additional \$250.

How do I get more information?

We're here to answer your questions!

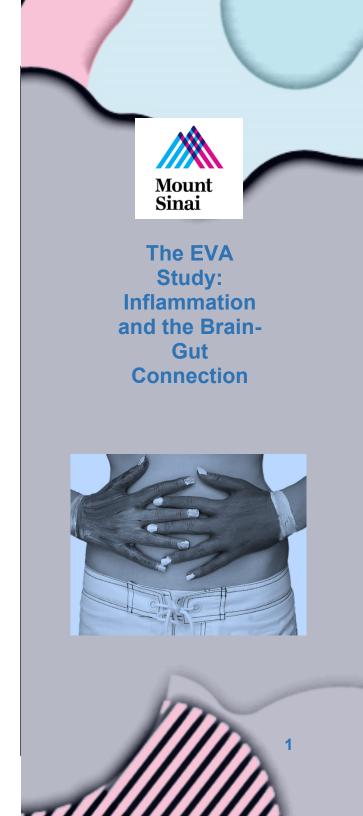
Feel free to give us a call at 212-241-0190 or you can email us at:

paired.project@mssm.edu



Effective Date: 10/4/2022 End Date:10/3/2023





The Gut-Brain **Axis**

The vagus nerve connects the brain to the GI system (stomach and



intestines). This allows the brain to control GI function, and the GI system to send information to the brain. This is sometimes referred to as the gut-brain axis.

The purpose of this research study is to learn more about what happens to GI function when the vagus nerve is not working properly. We think that this might result in GI slowing, overgrowth of intestinal bacteria, and signs of inflammation in the blood

What's involved?

You will speak with the study team to review your medical history and answer some questionnaires. You will also have the following testing. Scan the **QR codes** to see a video of what's involved.

The testing

1. Autonomic tests

These tests assess the function of your vagus nerve, and other similar nerves. This involves measuring the sweat output from your skin and measuring your heart rate and blood



pressure as you go from lying down to standing up and do breathing exercises.

2. Breath test

You will be tested for small intestinal bacterial overgrowth (SIBO). People with SIBO have more methane and hydrogen gasses in their breath. We collect breath samples and send them for analysis.



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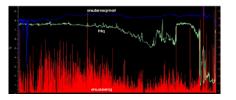


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3. SmartPill test

The SmartPill is swallowed and then travels through the entire GI tract measuring temperature, pH and pressure. The pill transmits this information to a recording device you keep nearby you.



4. Blood, urine, saliva and stool collection

You will be asked to provide urine and saliva samples, and some blood will be drawn. You will also be sent home with a kit and instructions to collect a stool sample and bring it back to the research team.