

# Brain Health & the Microbiome

*A Proof-of-Concept Study in Patients with Mild Cognitive Impairment*

*We are inviting 1) adults with early Alzheimer's disease (eAD), 2) adults with mild cognitive impairment (MCI), and 3) healthy adults to participate in this research study.*

*The main reason this study is being done is to learn more about if the gut microbiomes of people with eAD and MCI are altered following lifestyle changes in the hope that this will improve our understanding and, perhaps, future prevention and treatment efforts.*

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#### **Why you may want to participate in the study:**

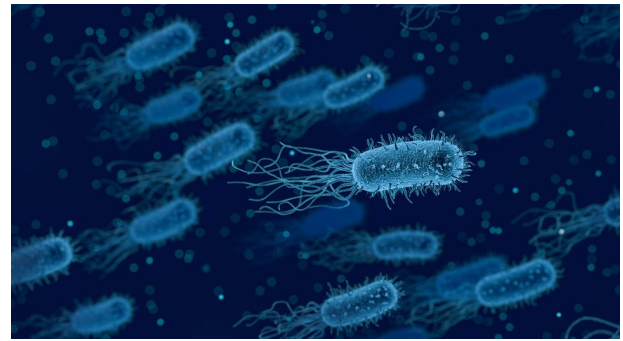
You will learn about your gut microbiome and receive 3 EzBiome reports with tailored recommendations for lifestyle changes, which may improve the health of your gut microbiome, at no cost to you. Information learned from the study may help people with eAD and MCI in the future.

#### **What does the study involve?**

**Gut Microbiome Analysis:** You will be asked to collect microbiome samples at home at baseline, 3 months, and 6 months (2 consecutive samples to be integrated into a single EzBiome report at each time point). You will receive your EzBiome reports and be advised to consider implementing the suggested lifestyle changes at each timepoint (baseline, 3 months, and 6 months). Any changes you make (either recommended in the EzBiome report or otherwise) while participating in the study will be your decision and be documented as part of the research study.

**Cognitive Measures:** You will be asked to complete an Activities of Daily Living (ADCS-ADL) survey, a cognitive function test (BOCA), a general health assessment (PROMIS-29), a dietary pattern assessment (DietID), and report your symptoms.

**Health History:** You will be asked about measures that are part of standard of care and are included in your medical records (such as markers of inflammation, e.g. CRP) if available.



#### **How long will the study last?**

We expect the duration of your participation in this study to be a little more than 6 months (no more than 8 months) from start to finish.

#### **Are there costs to participate?**

There are no costs to the participants.

#### **Are you eligible?**

If you are 50-90 years old with mild cognitive impairment, early Alzheimer's disease, or neither (to serve as a healthy control), you may be eligible for this study.

#### **Will you be paid for your participation?**

You will be compensated at each visit you complete (telehealth and/or in-person). Compensation will include \$30 for each time-point visit (baseline, 3 months, and 6 months), \$20 for each visit to discuss the EzBiome report and the recommended lifestyle changes, and \$50 at close out of your participation.

#### **Who are we and who is paying for the study?**

This study is run at the George Washington University School of Medicine and Health Sciences. This research is being funded/sponsored by the TMCity Foundation, a philanthropic organization.

#### **The principle investigator is:**

Leigh A. Frame, PhD, MHS (leighframe@gwu.edu)

#### **Who can you talk to if you have questions?**

**To learn more about this study, contact the study coordinator at [aalqalam@gwu.edu](mailto:aalqalam@gwu.edu) or 843-801-2008.**