ACTIVE-GUT Study



Study Fact Sheet

Purpose

The purpose of this study is to examine how walking may influence the bacteria living in the gut of people with prediabetes.

Participants

We are looking to recruit people with Pre-Diabetes, aged 30 to 64, who are not actively engaged in a current exercise program.

Participation

Individuals participating in this study will be randomized into one of two groups:

- **Experimental:** Will complete a walking exercise intervention 3 times/week for 30-45 min/session for 8 weeks.
- **Control:** Will maintain regular physical activity levels for 8 weeks.

As part of participating in the study, over the 11-week time period people will be asked to:

- Attend 4 in-person study visits (varying between 10-20 minutes, see reverse)
 These take place at 1100 Washington Ave S in Minneapolis (close to public transportation and free parking)
- Complete 6 phone interviews about what you ate & drank the previous day.
- Wear an activity monitor during the course of the study (a Fitbit Inspire2 watch).

Each participating individual can choose to either keep their Fitbit Inspire 2 watch and \$25 OR choose to receive a total of up to \$100* for completing these study activities. (*See other side for details)

Voluntary

Participation is voluntary. To participate, people must provide written consent. Participants are free to withdraw from the study at any time.

COVID-19 Precautions

Your safety is important to us! We'll limit your time spent within 6 feet of our staff, and both staff and participants will wear masks and complete a COVID-screener prior to meeting in-person.

At the end of the study

At the end of the study, participants will be provided with their own study data, along with the overall results.

Funding

This research study is being conducted by Drs. Ryan Demmer & Mark Pereira at the University of Minnesota's School of Public Health with funding from the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health.

For more information

If you need more information or would like to participate in this study, call **612-655-2133** or send an email to activegut@umn.edu. You can also find more information, along with a link to our online screening survey, at our study website z.umn.edu/activegut.

Study Activities and Participant Compensation

The study is divided into two parts:

- **Part 1:** These **three weeks** serve to collect various aspects of the baseline data (i.e. your usual food intake, baseline measures of gut microbiome, fasting glucose, etc).
- **Part 2:** These **eight weeks** are considered the active part of the study. You will be randomly assigned to either the intervention or control group at the start of this part.

| | Visit (in-person visit duration) | Activities completed | Compensation amount*† |
|-----------------|--|--|-----------------------|
| Part 1: 3 weeks | Screener Visit (10-15 min) | Eligibility confirmedFitbit Inspire2 providedStool collection kit given to you | |
| | Home collection activities | 3 phone interviews where you tell interviewer everything you ate and drank the day before Stool collection Keep a 3-day food record | |
| | Baseline Visit (20 min) (~3 weeks after screener visit) | Weight measureBlood Pressure measureFasting Blood DrawSaliva collection | \$20* |
| | Randomization to one of the two study groups will follow the baseline visit. | | |
| Part 2: 8 weeks | Pre-Week 4 visit home activities: | · Stool collection | |
| | Week 4 visit (15-20 min) | Weight measure Blood Pressure measure Saliva collection Return stool collection to staff | \$40* |
| | Pre-Week 8 visit home activities | 3 phone interviews where you tell interviewer everything you ate and drank the day before (occurs during weeks 7 & 8) Stool collection (week 8) | |
| | Week 8 visit (20 min) | Weight measure Blood Pressure measure Fasting Blood Draw Saliva collection Return stool collection to staff | \$40* |
| | Total Amount Possible: | *Keep the Fitbit Inspire 2 plus \$25 OR Receive an \$100 Visa Card | |

[†]Additional Non-Monetary Compensation:

Upon request, you will be provided with a copy of your personal data, including a microbiome report, at the very end of the entire study (once all 100 participants have completed the study; ~Dec 2022).

For more information

If you need more information or would like to participate in this study, call **612-655-2133** or send an email to activegut@umn.edu.

You can also find more information, <u>along with a link to our online screening survey</u>, at our study website <u>z.umn.edu/activegut</u>.