

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 Prediabetes, aged 30 to 64, who are not taking medication to control blood sugar or actively exercising more than 15 min per day (or ~100 minutes per week). If you think you may have prediabetes but are unsure, our staff can determine if you meet the criteria with a simple blood test.

Participation

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

- **Experimental:** Will complete a walking exercise intervention 3x/wk for 30-45 min/session for 8 weeks. The walking can be done at times and locations convenient for you.
- **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 other side for details). *These take place at 1100 Washington Ave S in Minneapolis (close to public transportation and free parking)*
- Provide two fasting blood draws.
- Collect three stool samples at home (much easier than you think!).
- 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 <u>activegut@umn.edu</u>. 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>.

Study Activities and Participant Compensation

The study is divided into two parts:

Part 1: Duration=3 weeks. During these three weeks we will collect important baseline information (e.g., your usual food intake, a baseline stool sample, fasting glucose, height/weight).

Part 2: Duration=8 weeks. 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 part 2.

	Visit (in-person visit duration)	Activities completed	Compensation amount* [†]
Part 1: Weeks 1 – 3	Day 1:	Eligibility confirmed	
	Screener Visit (10-15 min)	Fitbit Inspire2 provided	
		 Stool collection kit given to you 	
	Weeks 1-2:	· 3 phone interviews where you tell interviewer	
	Home collection activities	everything you ate and drank the day before	
		 Keep a 3-day food record 	
	Week 3:	Home stool collection	
	Home collection activities		
	End of week 3:	Return stool collection to staff	\$20*
	In-person baseline visit (20 min)	Weight measure	
		Blood Pressure measure	
		 Fasting Blood Draw 	
		Saliva collection	
	Randomization to one of the two study groups will follow the baseline visit.		
	Pre-Week 7 visit home activities:	Stool collection	

Part 2: Weeks 4 – 11	Pre-Week 7 visit home activities:	Stool collection	
	Week 7 visit (15-20 min)	• Weight measure	\$40*
		Blood Pressure measure	
		Saliva collection	
		Return stool collection to staff	
		· 3 phone interviews where you tell interviewer	
	Pre-Week 11 visit home activities	everything you ate and drank the day before	
		(occurs during weeks 7 & 8)	
		 Stool collection (week 8) 	
	Week 11 visit (20 min)	 Weight measure 	\$40*
		Blood Pressure measure	
		 Fasting Blood Draw 	
		 Saliva collection 	
		Return stool collection to staff	
	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).

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