

Invitation to Join a Study to Test the Utility of an Innovative Device in Reversing Metabolic Syndrome

What is the proposed study?

Prior studies found that employer wellness programs addressing manifest chronic diseases yield cost savings, but programs that target health risks broadly do not. A logical next question is whether a narrowly focused wellness program that selectively targets higher risks can be at least cost neutral, and a high-risk precondition of great interest is metabolic syndrome.

Impeto (<http://www.impeto-medical.com/>) has developed an FDA-cleared, non-invasive device to detect early stage pre-diabetes/metabolic syndrome by measuring the function of an individual's sweat glands. Even in early stages of insulin resistance, the device can detect subtle changes in the sympathetic nerves that regulate those glands. Studies have shown that slight improvement in metabolic control can reverse the nerve damage well before you get changes in body weight. The device therefore can be used to create a feedback loop for participants in an employer program for pre-diabetes/metabolic syndrome, and help participants generate a mental image of how lifestyle changes improve their metabolism.

RAND Health, the company's research partner is planning a project to test whether using the device in a metabolic program (1) improves program engagement and (2) health outcomes. The company is currently seeking one or more employers that are willing to participate in the study.

What will you need to do if you participate as an employer?

- The company's research partner will work with you to screen employees for pre-diabetes or metabolic syndrome
- You either have an existing or will establish a new program to address pre-diabetes or metabolic syndrome, like the CDC's Diabetes Prevention Program
- The project will need about 300 to 500 employees with pre-diabetes or metabolic syndrome, ideally located at different sites
- After initial screening, participating employees will repeat the non-invasive test during a 12-month follow-up period
- You will grant the company's research partner access to data about participating employees and comparison employees about their demographics, employer program participation, metabolic syndrome and other biometrics both before and after the intervention (the use of the device); the data will be shared in a de-identified manner; no individuals can be identified based on the information given to the research partner

Why will you benefit by participating in the pilot study?

- You get to participate in cutting edge research that tests a next-generation workplace wellness model
- You and participating employees can potentially benefit from reversal of metabolic syndrome and thus better health and lower cost
- You will get access to the study results, a briefing on the findings, and recognition in publications if you are want to be identified

- The company will cover the cost of the research and provide the device for free during the study period
- There is no obligation to keep using the device after the study is over

Where you can find more information about the pilot study?

We believe it is a great opportunity to test this innovative approach to reverse metabolic syndrome and improve employee health. If you are interested, please contact Hangsheng Liu, hliu@rand.org, 617-338-2059 x8638. Thank you.