

Title:

BOOST-HEALTH Trial

Investigators and Institutions:

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Description of the Study

Rationale: Type 2 diabetes (T2D) is characterized by chronic hyperglycemia. Individuals with T2D also display reduced cardiorespiratory fitness, which is a strong predictor for premature mortality and T2D-related complications. Aerobic training (AT) enhances cardiorespiratory fitness and is considered a cornerstone in the management and treatment of T2D. Emerging data suggest that AT combined with blood flow restriction (AT+BFR) training, could potentially enhance cardiorespiratory fitness faster than typical AT in healthy individuals. However, the feasibility of AT+BFR in individuals with T2D and its impact on cardiorespiratory fitness have yet to be determined.

The BOOST-HEALTH Trial is a multi-site randomized controlled pilot trial evaluating a 6-week supervised aerobic exercise program for adults living with Type 2 Diabetes. The study is examining whether low-intensity treadmill walking, with or without blood flow restriction, is feasible and may help improve cardiorespiratory fitness and glucose-related outcomes.

Participants will be randomized to either standard aerobic training or aerobic training combined with blood flow restriction. Both groups will complete supervised treadmill walking at a low-to-moderate intensity based on their individual fitness level.

Funding Source: Diabetes Canada

Project Start Date: February 2025

Project End Date: December 2027

Inclusion Criteria/Eligibility:

Eligible participants are adults aged 19 - 64 who are currently living with Type 2 Diabetes, have an HbA1c between 5.7% and 9.0%, and are not currently meeting physical activity guidelines.

Individuals interested in participating will complete an initial screening process with the research team to confirm eligibility and ensure the study is safe and appropriate for them. Individuals may not be eligible if they have certain medical conditions or medications that

would make exercise or blood flow restriction unsafe, including unstable diabetes medications, cardiovascular or red blood cell conditions affecting safe exercise participation, and musculoskeletal issues preventing exercise.

Participation Details:

We are recruiting 20 participants at the University of Guelph site, as part of a larger 60-participant multi-site study across Canada.

Participants will complete a 6-week supervised treadmill walking program. The study will collect information related to feasibility, including recruitment, enrollment, adherence, and retention. Secondary and exploratory outcomes include cardiorespiratory fitness, continuous glucose monitoring outcomes, quality of life, sedentary behaviour, sleep, and dietary intake.

Interested individuals can contact the research team directly by email or phone to learn more and complete an initial screening.

Participant Safety and Privacy:

All participants will complete an informed consent process before taking part in the study. Consent will be reviewed with research staff in a private setting, and participants will have the opportunity to ask questions before deciding whether to participate.

Participant data will be de-identified using a unique study code. Any information linking participant names to study codes will be stored separately and securely. Study data will be entered into REDCap, a secure web-based research data platform, and only approved study personnel will have access to the data. Written records will be stored in locked cabinets in restricted-access research spaces.

Ethics Approval: University of Guelph REB #2035

Website URL:

<https://hplguelph.weebly.com/ongoing-research-projects.html>

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