

**Title:** Protocol for Compassionate And Loving Mindset towards HEART health riSk (CALM HEARTS 2): A randomized optimization trial

**Authors:** \*Sasha M. Kullman, Brittany N. Semenchuk, PhD Candidate, Todd A. Duhamel, PhD Shaelyn M. Strachan, PhD

**Background:** Cardiovascular disease (CVD) is a leading cause of death for Canadian women. Physical activity helps to prevent CVD, but 85% of Canadians are inactive. Difficult emotions about CVD risk may hinder attempts to become active. Research specific to women's CVD prevention is needed. Empowering women to cope with difficult emotions about their CVD risk may help them become more active.

Self-compassion (SC) is a kind way of relating to oneself. People who use SC cope better with health risks. The purpose of this protocol is to optimize an intervention which teaches women to cope with their CVD risk using SC to adopt an active lifestyle.

**Objectives:** We previously conducted an individually delivered SC intervention for 11 women with CVD risk that successfully increased physical activity. However, individual delivery was inefficient. We will now determine if group delivery is comparably effective for improving physical activity and secondary outcomes. Furthermore, only women low on SC were enrolled in our past trial. We will now determine if women higher in SC can also benefit.

**Methods:** We will conduct a randomized optimization trial for 96 women aged 55-75 years with high blood pressure and low physical activity. Participants will be assigned to receive the intervention in small groups or individually. The intervention will provide all participants with 1 session to discuss CVD risk and physical activity goals, and 3 sessions of SC training.

Self-reported physical activity (main outcome), health behaviours, SC, and emotions will be measured pre- and post-intervention. This trial will determine how best to deliver the intervention before it is tested on a larger scale. ClinicalTrials.gov, registration pending.