

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

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## Background

- Cardiovascular disease (CVD) is a leading cause of death for Canadian women (1).
- Physical activity helps to prevent CVD (2), but 85% of Canadians are inactive (3).
- Women who use self-compassion cope better with CVD risk and may do more physical activity (4).

The three components of self-compassion



Self-kindness



Mindfulness



Common Humanity

## Trial Design

- Two-armed optimization trial
- ClinicalTrials.gov, NCT05209373.

## Participants

- 96 participants will be enrolled in the trial.
- Aged 55+; female, high blood pressure (10); low self-report physical activity (11); safe to engage in physical activity

## 1:1 Randomization

- Individual intervention delivery
- Group intervention delivery (6-9 participants per group)

## Outcomes

Assessed pre- and post- intervention: physical activity (14); self-compassion (15); health promoting lifestyle (16); health anxiety and illness self-blame (17); health behaviour intentions (6); personal growth initiative (18).

## Analysis

2X3 Factorial Anova

**Primary:** Examine main effects of the group condition on physical activity across all levels of self-compassion.

**Secondary and tertiary:** Explore main and interaction effects between baseline self-compassion (low, moderate, high) and intervention condition (group or individual) on physical activity, behavioural outcomes, and psychological outcomes.

## Purpose

**To optimize an intervention which teaches women at risk for CVD to cope using self-compassion to adopt a physically active lifestyle.**

## Research Questions

- #1:** Is group intervention delivery comparably effective to individual delivery for increasing physical activity?
- #2:** Do participants with low, moderate, or high self-compassion benefit similarly from the intervention?
- #3:** Is one method of delivery (group or individual) better suited to women at low, moderate, or high self-compassion?

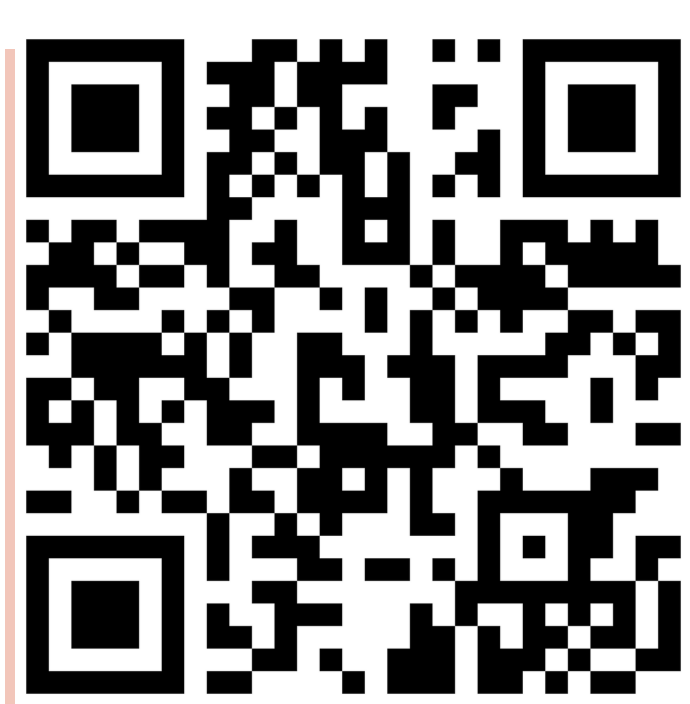
## Intervention Overview

Four, weekly one-hour sessions held on Zoom videoconferencing. Both conditions will be exposed to identical intervention content.

### Week

### Activities

- | Week | Activities  |
|------|---|
| 1    | <ul style="list-style-type: none"><li>• Discussion of CVD risk factors &amp; Canada's 24-hour Movement Guidelines + physical activity goal setting</li></ul>  |
| 2    | <ul style="list-style-type: none"><li>• Introduction to self-compassion &amp; applying the three components of self-compassion to CVD risk</li><li>• <i>Home practice: self-compassionate writing activity</i></li></ul>  |
| 3    | <ul style="list-style-type: none"><li>• Using the Yin and Yang of self-compassion to cope with difficult emotions and increase physical activity. Using mindfulness to overcome resistance and accept suffering</li><li>• <i>Home practice: self-compassionate writing and 5-10 minutes daily mindfulness</i></li></ul> |
| 4    | <ul style="list-style-type: none"><li>• 3-step method for applying mindfulness and self-compassion to difficult emotions. Using self-compassion to cultivate positive emotions</li><li>• <i>Home practice: savouring and gratitude journaling</i></li></ul>   |



Scan here for reference list

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