

Compassionate And Loving Mindset towards HEART health riSk (CALM HEARTS): A non-randomized pilot feasibility study for a parallel randomized controlled trial



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Introduction

Background:

- Self-regulation is required for engagement in health behaviours¹ but may be challenging for individuals coping with the difficult emotions that accompany a chronic disease risk^{2, 3}.
- Self-compassion has been positively associated with self-regulatory processes⁴.
- Self-compassion may promote adaptive responses, self-regulation, and engagement in health behaviours in response to a chronic disease risk.

Objectives:

Primary objective: Demonstrate the feasibility and acceptability of a self-compassion intervention for reducing behavioural risk factors targeted at women *at risk* for cardiovascular disease (CVD).

Secondary Objective: Observe mean changes in outcome measures for trends.

Methods

Participants and Procedures:

- 11 Women, aged 55-75 years at intermediate-to-high Framingham Disease risk, scoring below the mean in self-compassion, were recruited from the WARM Hearts cohort (ClinicalTrials.gov: NCT03938155).

The Intervention:

- Three, weekly, one-to-one meetings with a trained facilitator, held via phone call or Zoom video call. Home practice worksheets assigned between sessions.
- **Session A** (90 minutes): Participants reviewed their CVD risk profile, set a health behaviour goal (e.g., physical activity), and received self-compassion education (e.g., what is self-compassion).
- **Session B and C** (60 minutes): Participants discussed health behaviour goal progress and received self-compassion education (e.g., mindfulness and resistance; cultivating positive emotions).

Feasibility and Acceptability Outcomes:

- Recruitment, retention, adherence, intervention delivery, participant safety, acceptability.

Outcome Measures:

Measure	Items	Scale	Scale Range	Alpha (Baseline)	Alpha (Follow-Up)
Self-Compassion Scale ⁵	26	5-point Likert	1-5	.921	.810
MHQ* Health Anxiety Subscale ⁶	5	5-point Likert	1-5	.946	.928
Rosenberg Self-Esteem Scale ⁷	10	4-point Likert	0-30	.763	.915
Health-Promoting Behaviours ⁸	52	4-point Likert	1-4	.928	.966
International Physical Activity Questionnaire ⁹	9	Open response	-	-	-
Negative Affective Reactions to Health Risk ¹⁰	13	5-point Likert	1-5	.884	.907
MHQ* Illness Self-Blame Subscale ⁶	5	5-point Likert	1-5	.812	.970
State Rumination Scale ¹¹	3	5-point Likert	1-5	.767	.912

*Multidimensional Health Questionnaire

Analysis and Results

Analysis:

- Feasibility outcomes were compared to pre-specified standards. Safety and acceptability were assessed via open-ended survey responses.
- Mean changes in outcome measures were observed.

Results: Feasibility and Acceptability

Item	Standard	Result	Feasible?
Recruitment, Retention, Adherence			
Time for enrollment	2 weeks	1 week	Yes
Questionnaire completion	80% completion	97% completion	Yes
Participant drop-out	15-20% drop-out	0% drop-out	Yes
Intervention Delivery			
Home practice compliance	75% compliance	71% compliance	Needs addressing
Participant attendance	90-95% attendance	100% attendance	Yes
Resolution of technical issues	90-95% resolution	100% resolution	Yes
Completion of session slides	90-95% completion	82% completion	Needs addressing
Topics covered in session	90-95% of topics covered	97% of topics covered	Yes
Session completed in allotted time	90-95% timely completion	61% timely completion	Needs addressing
Instructor fidelity	80% fidelity	98% fidelity	Yes
Participant safety	100% safety	100% safety	Yes
Acceptability to participants	Observe and report	Acceptable to participants	Yes

Results: Exploratory Mean Changes

Outcome	Mean T1 (Baseline)	Mean T2 (Follow-Up)	Mean change (T1-T2)
Self-compassion	3.09	3.53	-0.44
Health anxiety	3.21	2.79	0.42
Self-esteem	19.60	21.50	-1.90
Health-promoting behaviours	2.53	2.78	-0.25
Physical Activity MET*minutes/week*	1198.70	2036.16	-837.46
Negative affect	1.94	1.57	0.36
Illness self-blame	9.45	8.09	1.36
State rumination	2.36	2.06	0.30

The **CALM HEARTS** Intervention should be **feasible and acceptable** with some modifications