

**Title:** Internet-based stress management program for patients with cardiovascular disease: piloting a Sequential Multiple Assignment Randomized Trial (SMART)

**Authors:** \*Lambert S, Grover S, Laizner A, McCusker J, Moodie E, Kayser J, Vallis M, Pilote L, Da Costa D, Belzile E, Firth W, Lowensteyn I, Ibberson C, de Raad M.

**Background:** Online stress management interventions for individuals with cardiovascular diseases (CVDs) show promise, yet up to 60% of individuals do not respond. We used an innovative trial design, the Sequential multiple assignment randomized trial (SMART), to develop an adaptive online stress management intervention.

**Objective:** Evaluate the feasibility, acceptability, and clinical significance of an adaptive online stress management intervention.

**Methods:** 60 patients with CVDs were randomized to a 6-week self-directed, online stress management program or the same intervention plus weekly lay telephone coaching. At 6 weeks, intervention response was assessed, and those who did not improve were re-randomized to either continue their initial program or motivational interviewing (MI) for 6 weeks. Changes in stress were calculated to examine clinical significance. Feasibility (e.g., consent and refusal rates) and acceptability (e.g., attrition and adherence rates) were also collected.

**Results:** We enrolled about 1 patient per week, with 16% refusal; enrolment ratio 44 men: 56 women. Missing data: < 3% at baseline; none at follow-up for primary outcomes. Attrition rates: higher among non responders (39%) vs responders (4%). Intervention adherence rates and satisfaction were higher in the groups receiving lay coach support vs self-directed. Magnitude and direction of effect sizes, comparing all combination of supports were generally in the expected direction, exceeding our clinical significance threshold of effect size = 0.20.

**Conclusion:** A larger trial would be both feasible and acceptable to patients. Attention to retention of non-responder groups, and characteristics of interventionists need to be considered.