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

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BACKGROUND

- Stress is a major factor in CVD onset and progression
- Stress management programs reduce patient mortality, morbidity and related risk factors. However:
  - ✓ Reviews have yet to reach conclusions about which components of programs work, and for whom;
  - ✓ Existing programs have encountered barriers related to cost, access, and lack of anonymity, with attendance rates estimated at 30%.
- The Internet offers a more cost effective and scalable delivery vehicle
- However, online interventions must address adherence issues and adapt interventions to patient needs, particularly among those unresponsive to initial intervention

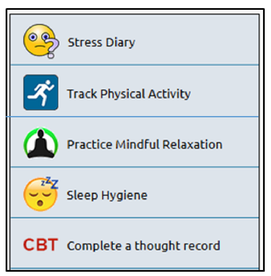
OBJECTIVES

- To examine the feasibility, acceptability and clinical significance of an adaptive, online stress management intervention based on a stepped-care approach for patients with CVDs

THE INTERVENTION

THE WEBSITE

- All participants received instructions on registering for and using the *My Health CheckUp* stress management website.
- Website components:
  - ✓ 5 essential modules (see image below): each with an information and skills practice component
  - ✓ Weekly self-assessments: to identify problem areas
  - ✓ Summary reports: to observe patterns and progress



COACHING

- Participants randomised to the first stage "website + coach" arm received short weekly telephone calls from a trained, lay coach. Coaches used scripted agendas to support participants by:
  - ✓ Helping to identify which modules to use based on needs
  - ✓ Providing information and guidance on how to use the modules
  - ✓ Helping with goal setting related to the modules
- Coaches used a positive and encouraging attitude but were specifically instructed to avoid providing counselling

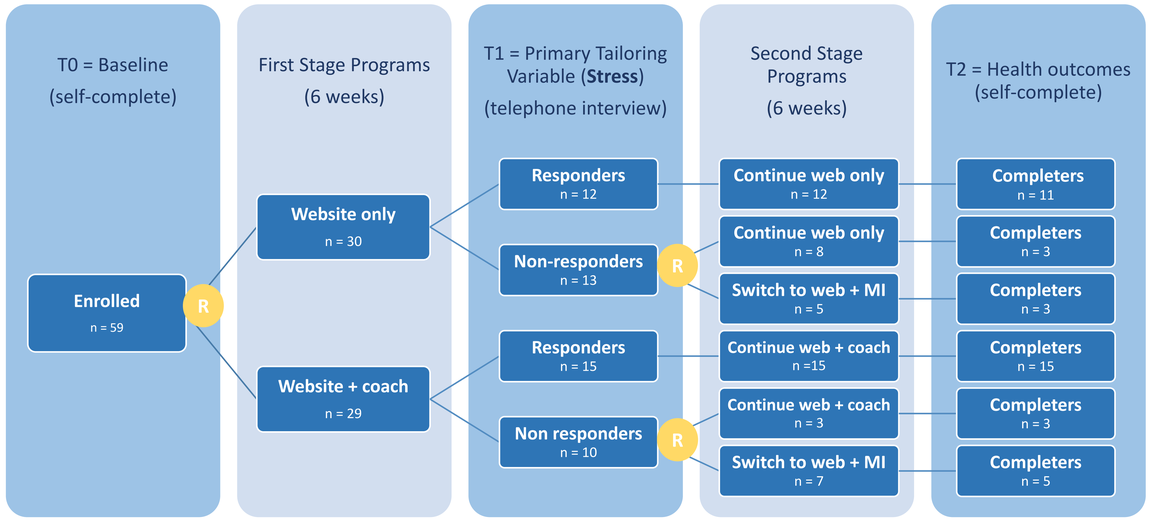
MOTIVATIONAL INTERVIEWING (MI)

- Participants randomised to the second stage "website + MI" arm received longer (30-45 mins) weekly telephone-based MI sessions delivered by an experienced, professional MI practitioner
- Goals of the sessions were to increase patient motivation and confidence in using the website, through four basic MI processes: engaging, focusing, evoking and planning.

METHODS

DESIGN

- The Sequential Multiple Assignment Randomization Trial (SMART) design is an innovative, experimental design for developing and evaluating adaptive interventions. We piloted a multi-center SMART with two intervention stages



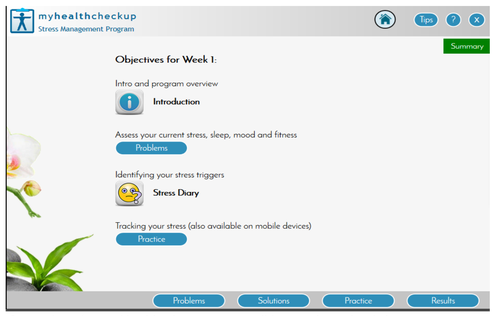
The aim was to have a minimum of n = 4 in each final "completers" cell. Final numbers are reported in figure above

ELIGIBILITY CRITERIA

- physician-confirmed diagnosis of CVD
- 3 months or more since diagnosis or most recent CV event
- moderate stress (DASS score of ≥18)
- ≥ 18 years old
- did not previously participate in a stress management program
- has regular access to a computer with internet and email
- not currently hospitalized or living in long-term care
- no cognitive impairment, severe stress (DASS score ≥ 34), suicidal intent, or concurrent psychological treatment

RECRUITMENT AND FOLLOW-UP

- Four participating clinical sites (three in Montreal, one in Halifax)
  - ✓ Clinicians introduced study to patients during appointments
  - ✓ Invitation letters were mailed
- Also, local community organizations were invited to inform their members:
  - ✓ Posters and pamphlets
  - ✓ Dissemination through social media, email newsletters and websites
- A research assistant (RA) completed study eligibility screening interview with interested patients
- Those eligible were directed to an online consent form and the baseline questionnaire hosted on SimpleSurvey.
- Consenting patients who completed the baseline were enrolled and randomized (first stage)
- At 6 weeks, the RA completed T1 assessment and re-randomised non-responders.
- At 12 weeks, participants completed follow-up on Simple Survey.



Screenshot of a weekly objectives page accessible to registered website users

OUTCOMES	MEASURES
Primary	
Stress	DASS Stress Subscale
Quality of life	SF-12
Secondary	
Anxiety	DASS Anxiety Subscale
Depression	DASS Depression Subscale
Self-efficacy	Self-Efficacy for Management of Chronic Disease
Appraisal	Cognitive Appraisal of Health Scale
Coping	Brief COPE
Physical activity	IPAQ
Satisfaction	CSQ-8

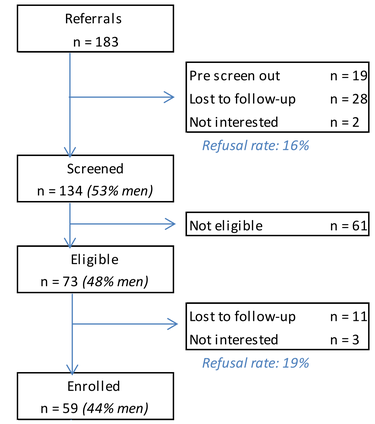
List of primary and secondary outcomes included in the T0 and T2 questionnaires. The DASS Stress Subscale was administered over the phone at T1.

RESULTS

FEASIBILITY

CONSENT, REFUSAL RATES AND REACH

Recruitment was conducted over approximately 40 weeks (1.5 enrolled per week)



MISSING DATA

- All primary outcomes computed
- 15% of the self-efficacy scales could not be computed due to missing data
- All COPE subscales missing data (range 5-13%)

ACCEPTABILITY

ATTRITION

- Overall attrition: 19 drop outs or lost to follow-up/ 59 enrolled = 32%
  - ✓ Among responders: 1/27 = 4%
  - ✓ Among non-responders: 9/23 = 39%

ADHERENCE

- High adherence was defined as participants had to have used the module practice component on at least 3 separate occasions. Using this definition:
  - ✓ 23% in the website only group completed at least one website module
  - ✓ 79% in the website + coach group completed at least one website module

SATISFACTION

- 47% in the website only group were satisfied with the intervention and study
- 74% in the website + coach group were satisfied with the intervention and study

Participants indicated that more technical support with website navigation was needed, and that study questionnaires were long.

CLINICAL SIGNIFICANCE

- 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.
- Benefits of coaching on primary outcomes were observed at the first stage; these were sustained in the second stage.
- The addition of the MI component in the second stage seems to show benefit only for non-responders who were in the website only group during the first stages

NEXT STEPS

A larger trial would be both feasible and acceptable to patients.

- Additional partner clinics for recruitment should be identified
- Longer, secondary outcome measurement instruments could be reduced
- Retention measures for non-responder groups should be considered
- Improvements to website navigation will increase satisfaction and adherence
- Improving transition for patients moving from the website + coach arm to the website + MI arm is being explored

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