Emotion Regulation Intervention to Sustain Physical Activity in Women and Men after a Major Cardiac Event

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Acknowledgements

eMotion Pilot

Study Team

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Background

Time spent in **moderate to vigorous physical activity (MVPA)** is critical to improve cardiovascular health

Cardiac rehabilitation

- Improves time spent in MVPA
- 58% do not maintain gains
- Gains are lost as early as 9 weeks

Symptoms of **depression** decrease time spent in MVPA and disrupt optimal recovery following a cardiac event

Physical Activity and Emotion Regulation

Effective use of **emotion regulation** is associated with **higher rates of MVPA**

MVPA improves mood and decreases the intensity of negative emotions that would prompt emotion regulation

Improving the strategies people are familiar with and the effective use of emotion regulation strategies **may mitigate or overcome the unpleasant aspects of exercise**

Emotion regulation training may support MVPA uptake and maintenance

Sigma Foundation Funded Study Aims

Aim 1: Evaluate early preliminary efficacy of the eMotion intervention to improve MVPA (primary outcome) and secondary outcomes of physical function and performance, symptom improvement, and health related quality of life among rural dwelling adults enrolled in cardiac rehabilitation after a first MI (n=24).

Aim 2: Evaluate the cognitive processes as intervention response variables (n=24).

Aim 3. Exploratory. Examine the relationships between emotion regulation and other cognitive processes and symptoms (threat and stress, attention and motivation [cognition, attention, motivation, and activation], awareness, and symptoms [depression, anxiety, pain, sleep, and fatigue]) among rural dwelling adults enrolled in cardiac rehabilitation after a first MI (n=24).

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eMotion Study Adjustments

COVID-19 related problems and solutions

Problems

Recruitment sites

- Closed for several months
- Fewer cardiac rehabilitation participants after re-opening
- Only essential staff allowed

COVID-19 transmission

- Unclear risk for participants and staff

Solutions

Recruitment

- Delayed initiation of recruitment
- Included additional major cardiac event survivors
- Develop fully remote screening and consent procedures

COVID-19 transmission

- Move to fully remote protocols

Adjusted Aims

Aim 1: **Evaluate early preliminary efficacy eMotion** for improving MVPA (primary outcome), symptom improvement (depression, anxiety, pain, sleep, and fatigue), and health-related quality of life (secondary outcomes) in adult cardiac event survivors enrolled in cardiac rehabilitation programs (n=40).

Aim 2: **Evaluate the cognitive processes** (cognitive reappraisal, emotion regulation strategy use, perceived cardiac threat and general stress, cognition, attention, motivation, and activation) as intervention response variables (n=40).

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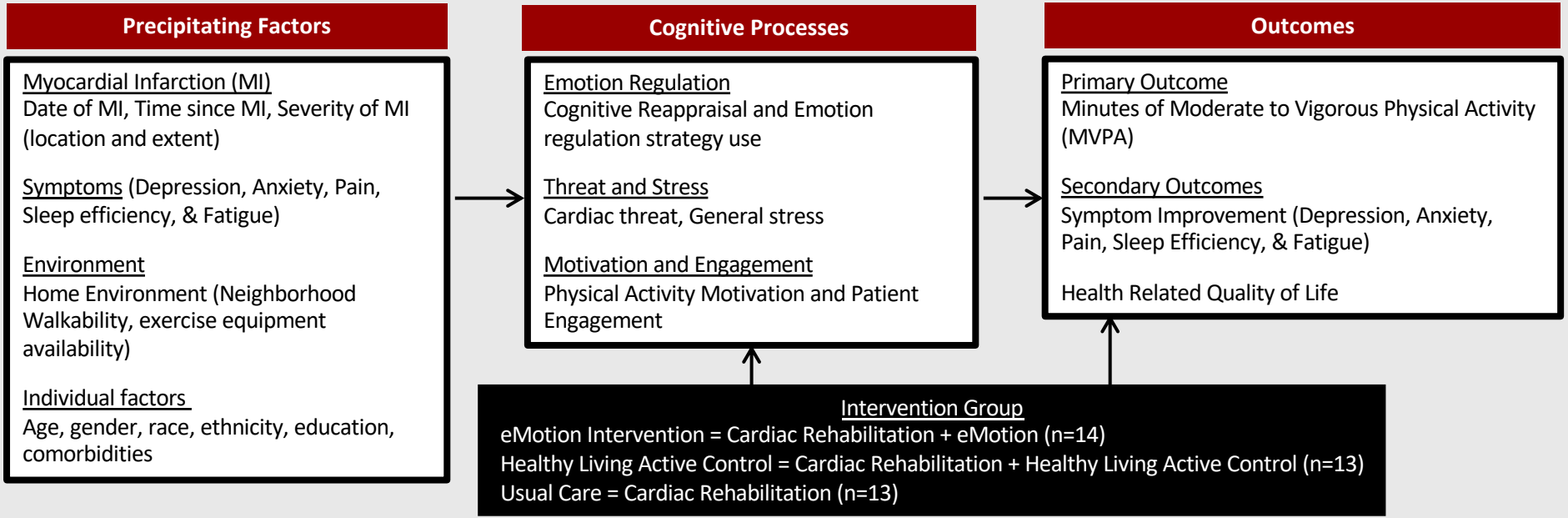
eMotion Conceptual Model



Covariates: Medications

Design

Study Design

- 3-arm randomized control trial stratified by gender
- Cardiac rehabilitation program site recruitment
- Administered surveys online, tasks by telehealth, mailed actigraphy

Inclusion Criteria

- Adults aged at least 21 years
- First myocardial infarction
- English speaking
- Living independently
- Symptoms of depression or anxiety

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Intervention Conditions

	eMotion Intervention (n= 12)	Healthy Living Active Control (n= 12)	Usual Care Group (n= 11)
Focus of content	Teaches patients recognize their emotions, balance emotional and physical wellbeing, and implement emotion regulation strategies effectively	Teaches patients about healthy living strategies, based on handouts from the American Heart Association	Complete usual cardiac rehabilitation without an additional intervention
Method of content delivery	Audiovisual content accessed on a mobile application based on weekly needs assessments	Audio content will be accessed online	
Length of Intervention	10 weeks	10 weeks	
Weekly Schedule	Day 1: Assessments will be completed, and content suggestions will be provided Day 7: Scheduled nurse video chat	Day 1: Content will be provided Day 7: Scheduled nurse video chat	

Measurements

Cognitive Factors - Emotion Regulation

Cognitive Reappraisal

- Measured with the objective computerized Emotion Regulation Task (EmReg) image response task
- Participants rate negative feelings in response to neutral images with a natural response and negative images under two conditions, natural response and emotion regulation response
- Internal consistency a > 0.80 and ICC > 0.68117
- ERT Pupil and fMRI responses indicate good concurrent validity

Emotion regulation strategy use

- Measured with the Emotion Regulation Profile-Revised.
- Scenario based survey which provides a subjective inventory of the emotion regulation strategies participants use

Measurements

Cognitive Factors – Threat and Stress

Threat - Perceptions of cardiac threat

- Measured with the Cardiac Threat Questionnaire

Stress - Perceived stress

- Measured with the 10-item Perceived Stress Scale

Measurements

Cognitive Factors – Motivation and Engagement

Motivation

- Measured with the Index of Self-Regulation
- Primarily assesses self-knowledge and motivation for physical activity

Engagement

- Measured with the CVD Patient Engagement Scale (investigator developed)

Measurements

Primary Outcome – Moderate to Vigorous Physical Activity (MVPA)

Minutes of time in MVPA

- Measured with ActiGraph GT9X Link accelerometer
- Participants complete 1-week of actigraph wear time on the non-dominant wrist
- Less prone to physical activity overestimations than commercially available monitors High sensitivity (70%) and specificity (93-100%) for measuring MVPA and is validated in individuals participating in cardiac rehabilitation programs

Measurements

Secondary Outcome – Symptoms

Depression and Anxiety

- Measured using the Depression, Anxiety, and Stress Scale (DASS-21)
- Sensitive to detecting sub-clinical psychological symptoms frequently experienced in post-MI patients

Pain

- Measured with the Brief Pain Inventory

Measurements

Secondary Outcome – Symptoms

Sleep efficiency

- Measured with ActiGraph GT9X Link accelerometer and sleep diary
- Participants complete 1-week of actigraph wear time on the non-dominant wrist
- Calculation based on the ratio of the total sleep time to time spent in bed
  - Sleep diary used for determining time in bed
  - Manual calculation of sleep time scored with observation of exponentially sharp increases or decreases in the level of activity counts per minute

Fatigue

- Measured using the Fatigue Severity Scale

Measurements

Secondary Outcomes – Health Related Quality of Life

Health Related Quality of Life

- Measured with a cardiac-specific measure - the Seattle Angina Questionnaire

Screening and Consent

Potential participants identified at cardiac rehabilitation clinics

Eligible patients identified and initially invited to participate in the study by care and research team members through phone and in-person recruitment

The research study team members then consented and enrolled the patients

Recruitment and Retention

Enrollment period 1/12/21 to 8/31/22

Consented participants: n = 40

Withdrawals: n = 12

- Too busy or overwhelmed to participate n = 7
- Lost to follow-up n = 3
- Hospitalized n = 1
- Disliked study measures n = 1

Demographic Characteristics

Characteristic	n (%)
Gender	
Woman	15 (41.7)
Man	21 (58.3)
Race and Ethnicity	
Black or African American	3 (8.3)
Hispanic or Latinx	1 (2.8)
White	32 (88.9)

Characteristic	n (%)
Educational Background	
Less than High School	1 (2.8)
High School Diploma or GED	9 (25.0)
Trade School	2 (5.6)
Two or fewer years of college	4 (11.1)
Associates Degree	3 (8.3)
Bachelor's Degree	8 (22.2)
Some Graduate School	3 (8.3)
Graduate Degree	4 (11.1)
Doctoral Degree	2 (5.6)

Results – Feasibility and Satisfaction

Remote delivery of intervention and measurement protocols successful

Participant satisfaction of intervention treatments

- eMotion - 100%
- Health Education - 86%

12-month data collection

- 70% agreed

Results - Data Collection Progress

Baseline: n = 40

3-months: n = 26

n = 3 potential remaining

6-months: n = 25

n = 4 potential remaining

12-months: n = 6

n = 17 potential remaining

eMotion Future

Additional funding secured to explore two additional aims

Aim 3: Examine long-term efficacy (12 month) of eMotion for improving MVPA (primary outcome) and symptom improvement (depression, anxiety, pain, sleep, and fatigue), and health-related quality of life (secondary outcomes) in adult cardiac event survivors enrolled in CRP (n=40).

Aim 4: Describe issues influencing feasibility of examining maintained efficacy (12 months) of eMotion for improving MVPA (primary outcome) and symptom improvement (depression, anxiety, pain, sleep, and fatigue), and health-related quality of life (secondary outcomes) in adult cardiac event survivors enrolled in CRP (n=40).

Clinical trial proposal submitted for R01 funding from the National Institutes of Nursing Research (November 2022).

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eMotion Program of Research Timeline

Activity by Year and Quarter	2021				2022				2023			
	1	2	3	4	1	2	3	4	1	2	3	4
Sample recruitment (n=40)												
Data collection baseline, 12-week, 20-week												
Data collection 52-weeks and medical record review												
Data safety monitoring committee orientation and review meetings												
Data cleaning, scoring, and analysis												
Report generation and submission												

Notes: **Red** = *eMotion* pilot **Black** = *eMotion* 12-month project extension