A Positive Psychology-Motivational Interviewing Intervention to Promote Adherence in Heart Failure: Design and Methods of a Randomized, Controlled Clinical Trial

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BACKGROUND

- Patients with heart failure (HF) frequently struggle to adhere to important health behaviors, such as physical activity, a low sodium diet, and medications.
- Psychological factors, such as motivation and well-being, may influence adherence to health behaviors in HF.
- Motivational interviewing (MI) is an established counseling strategy that is associated with mild improvements in health behavior adherence in HF; however, it may not be enough to improve downstream health outcomes in this patient group.
- Positive psychology (PP) interventions improve well-being and engagement in health behaviors. A combined PP-MI intervention has the potential to powerfully improve health behavior adherence in HF but has received limited study.
- We are performing a randomized, controlled clinical trial to examine the efficacy of a 12-week, phone- and text message-delivered, PP-MI intervention in adults with HF and suboptimal health behavior adherence.

OBJECTIVES

Primary Aim:

- To examine the efficacy of the PP-MI intervention on health behavior adherence (composite of overall activity [accelerometer], sodium intake [urine sodium], and medication adherence [electronic pill bottle]) at 12, 24, and 48 weeks, compared to an MI-based educational condition.

Secondary Aims:

- To examine the PP-MI intervention's impact on psychological outcomes, health-related quality of life, HF symptoms, and function.
- To explore the intervention's impact on markers of cardiovascular health, major adverse cardiac events, HF hospitalizations, and mortality.

METHODS

Participants:

- Adults with New York Heart Association (NYHA) class I, II, or III HF and suboptimal adherence to health behaviors, as measured by the Medical Outcomes Study Specific Adherence Scale (MOS-SAS).
- Exclusion criteria: cognitive impairment, severe medical illness, inability to participate in physical activity, language/literacy barriers, inability to receive text messages.
- Participants are randomized to receive a PP-MI or MI-based educational intervention.

PP-MI Intervention:

- Participants engage in weekly phone sessions with a study trainer for 12 weeks.
- During phone sessions, the study trainer reviews the previous week's PP exercise and progress towards health behavior goals, assigns a new PP exercise for the upcoming week, introduces a new MI topic, and helps participants set one or more health behavior goals for the week.
- Participants receive twice weekly text messages for 24 weeks.
  Weeks 1-12: Fixed messages related to the PP and MI topics from that week
  Weeks 12-24: Interactive messages focused on continued PP skill use and health behavior goal setting

Session	Positive Psychology		Motivational Interviewing	
	Construct	*PP Exercise*	*Health Behavior*	*Topics Covered*
1	Gratitude	Gratitude for Positive Events	Physical Activity	Monitoring activity
2		Expressing Gratitude		Setting a SMART activity goal
3		Capitalizing on Positive Events		Problem-solving barriers
4		Gratitude in Daily Life		Finding new routes
5	Strengths	Recalling a Past Success		Using resources
6		Using Personal Strengths, Part 1		Managing slips
7		Using Personal Strengths, Part 2	Low-Sodium Diet	Monitoring sodium intake
8		Strengths in Daily Life		Setting a SMART diet goal
9	Meaning	Enjoyable & Meaningful Activities		Barriers to and resources for a low-sodium diet
10		Performing Acts of Kindness	Medication Adherence	Monitoring medications
11		The "Good Life"		Setting a SMART medication goal
12		Meaning in Daily Life		Barriers to and resources for medication adherence
13	Planning for the Future			

MI-based Educational Control Condition:

- Participants complete weekly calls with a study trainer and assignments between sessions.
- Phone sessions focus on providing education about HF, physical activity, diet, and medications, and the study trainer uses MI-based tools to help participants identify areas for health behavior improvement and set relevant health behavior goals.

Analysis Plan:

- Main analyses: Repeated measures, mixed effects regression with an unstructured covariance matrix. We will also include as covariates in the model sex, race/ethnicity, recruitment site, Charlson Comorbidity Index, New York Heart Association (NYHA) class, and their interactions with time.
- Sensitivity analyses: We will add interaction terms (i.e., sex*group*time, race*group*time, NYHA class*group*time, reduced ejection fraction*group*time) to determine whether sex, race/ethnicity, NYHA class, or ejection fraction (EF) category moderates the effects of the intervention on adherence.
- Assuming N=280, with 15% dropout, and an effect size of d=0.45, we will have 92% power to detect between-group differences on composite health behavior adherence (primary outcome).

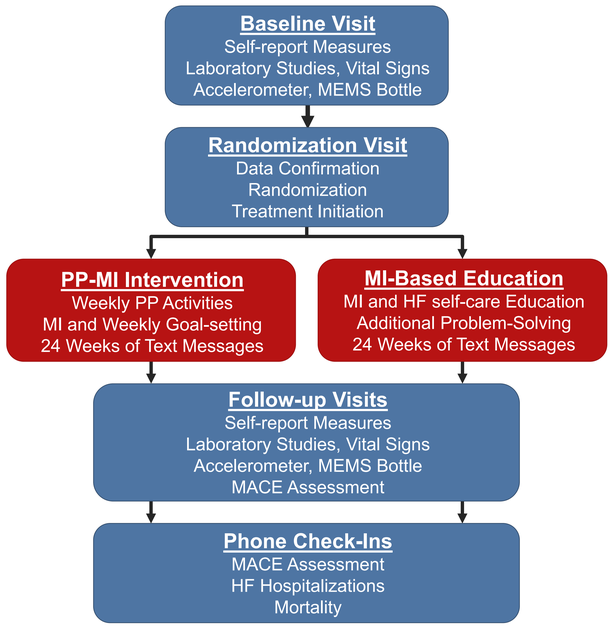
STUDY OUTCOME ASSESSMENTS

Study Outcomes

Type of Outcome	Outcomes
Aim #1 Outcomes	
Health Behavior Adherence	Composite of overall physical activity, sodium intake (urine sodium), and medication adherence (Medication Event Monitoring System [MEMS])*
Physical Activity	Overall activity (steps/day), moderate to vigorous physical activity (minutes/day), sedentary time (minutes/day)
Sodium Intake	Urine sodium, Scored Sodium Questionnaire
Medication Adherence	MEMS, Questionnaire
Aim #2 Outcomes	
Psychological Outcomes	Positive affect (PANAS), optimism (LOT-R), depression (HADS-D), anxiety (HADS-A), self-efficacy (GSES), locus of control (MHLC)
Functional outcomes	Physical function (PROMIS PF-20), health-related quality of life (SF-12), HF-specific quality of life (KCCQ), HF symptoms (KCCQ)
Aim #3 Outcomes	
Markers of Cardiac Health	Blood pressure, body mass index, LDL and HDL cholesterol, triglycerides, fasting glucose, 6-minute walk test
Cardiac outcomes	Major adverse cardiac events (MACE), HF-related hospitalizations, all-cause hospitalizations, mortality

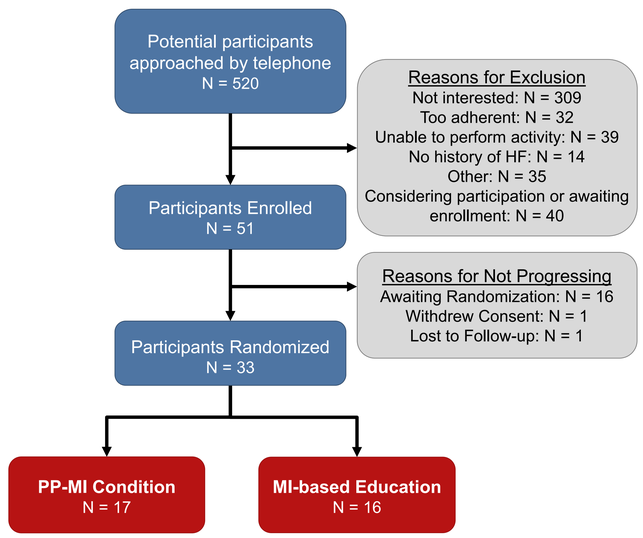
* Primary outcome. This composite score will be created by combining the component z-scores for each measure. The component z-scores will be calculated by subtracting the baseline mean and dividing by the baseline standard deviation.

Study Procedures



BASELINE CHARACTERISTICS

CONSORT Diagram



Baseline Characteristics

Characteristic	Group	
	PP-MI (N=17)	MI Education (N=16)
Sociodemographic		
Age in years (M [SD])	67.4 (11.7)	66.9 (14.6)
Female gender	7 (41)	7 (44)
Non-Hispanic White	16 (94)	14
Medical characteristics		
NYHA Class		
NYHA class I	7 (41)	7 (44)
NYHA class II	6 (35)	6 (38)
NYHA class III	3 (18)	4 (25)
Left ventricular ejection fraction (M [SD])	56.4 (10.4)	50.5 (14.5)
Medical comorbidities		
Coronary artery disease	6 (35)	6 (38)
Type 2 diabetes	8 (47)	2 (13)
Hyperlipidemia	14 (82)	14 (88)
Hypertension	13 (76)	12 (75)
Age-adjusted Charlson Score (M [SD])	5.1 (1.6)	4.7 (2.2)
Baseline Outcome Measures		
Physical activity (steps/day)	2791 (826)	3840 (1476)
Sodium excretion (mmol/L)	69.6 (31.6)	87.7 (49.3)
Medication Adherence (MEMS; % of days with correct number of bottle openings)	97.5 (5.0)	95.9 (10.9)
Positive affect (PANAS)	33.8 (5.8)	33.9 (7.9)
Depression (HADS-D)	4.0 (4.1)	5.3 (4.2)
Physical Function (PROMIS PF-20)	85.2 (10.7)	82.7 (11.2)
Mental HRQoL (SF-12 MCS)	48.9 (12.5)	50.8 (12.0)
Physical HRQoL (SF-12 PCS)	43.5 (9.5)	42.4 (9.3)

CONCLUSIONS

This randomized, controlled trial will provide important information regarding the effects of this 12-week, telephone-delivered, PP-MI intervention on important health behavior, psychological, and functional outcomes. If effective, we will examine the intervention's effects in a larger trial that is well-powered to detect differences in cardiovascular health outcomes. If effective, this intervention has the potential to improve both health behavior adherence and cardiovascular outcomes in a group of patients at high risk for hospitalization and mortality.

Grant support: This work was supported by the National Heart, Lung, and Blood Institute (grant R01-HL155301). Study visits completed in the Translational and Clinical Research Center were supported by Catalyst grant 1UL1TR001102.