Blended Collaborative Care for Treating Heart Failure and Co-Morbid Depression: 12-Month Primary Outcomes from the

Hopeful Heart TRIAL

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NIH National Heart, Lung, and Blood Institute

Presenter Disclosure Information

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- Speakers bureau / honoraria / advisory board / ownership interest: None

Heart Failure

- 6,600,000 Americans affected
- Annually:
  - 650,000 new cases
  - 330,000 deaths (1-in-9 U.S. deaths)
- #1 Medicare diagnosis hospitalization
- Mortality essentially unchanged since ’95

2019 AHA Heart and Stroke Statistical Update

Depression and Heart Failure

- 40-70% of hospitalized HF patients
- Associated with:
  - ↓ Health-related quality of life (HRQoL)
  - ↓ Adherence with evidence-based care
  - ↑ Mortality, readmissions, health care costs
- Generally unrecognized and untreated
- Few depression treatment trials

Angermann CE. *Curr Heart Fail Rep*. 2018; 15:398

Collaborative Care for Post-CABG Depression

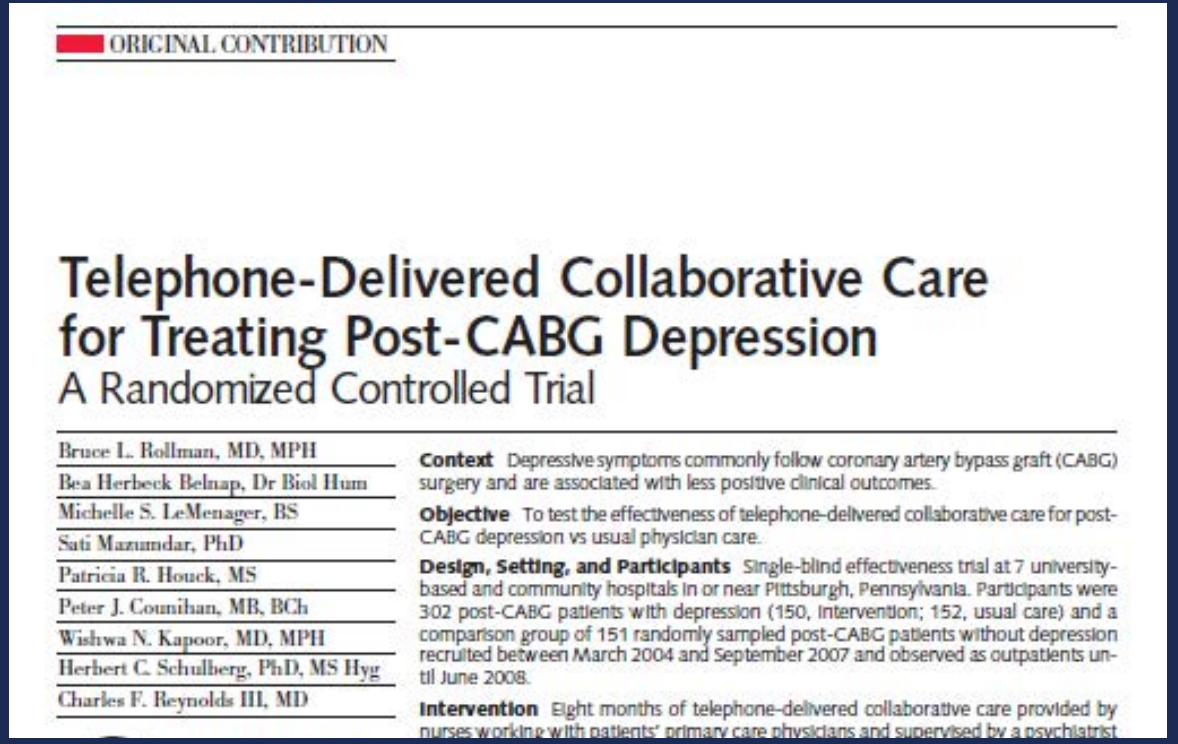
Bypassing the Blues Trial (2003-2009)

Improved:

- HRQoL (primary outcome)
- Physical functioning

Reduced:

- Mood symptoms
- Pain
- Health care costs (-$9,889 less per QALY)



ORIGINAL CONTRIBUTION

Telephone-Delivered Collaborative Care for Treating Post-CABG Depression

A Randomized Controlled Trial

Bruce L. Rollman, MD, MPH
Bea Herbeck Belnap, Dr Biol Hum
Michelle S. LeMenager, BS
Sati Mazumdar, PhD
Patricia R. Houck, MS
Peter J. Counihan, MB, BCh
Wishwa N. Kapoor, MD, MPH
Herbert C. Schulberg, PhD, MS Hyg
Charles F. Reynolds III, MD

Context Depressive symptoms commonly follow coronary artery bypass graft (CABG) surgery and are associated with less positive clinical outcomes.

Objective To test the effectiveness of telephone-delivered collaborative care for post-CABG depression vs usual physician care.

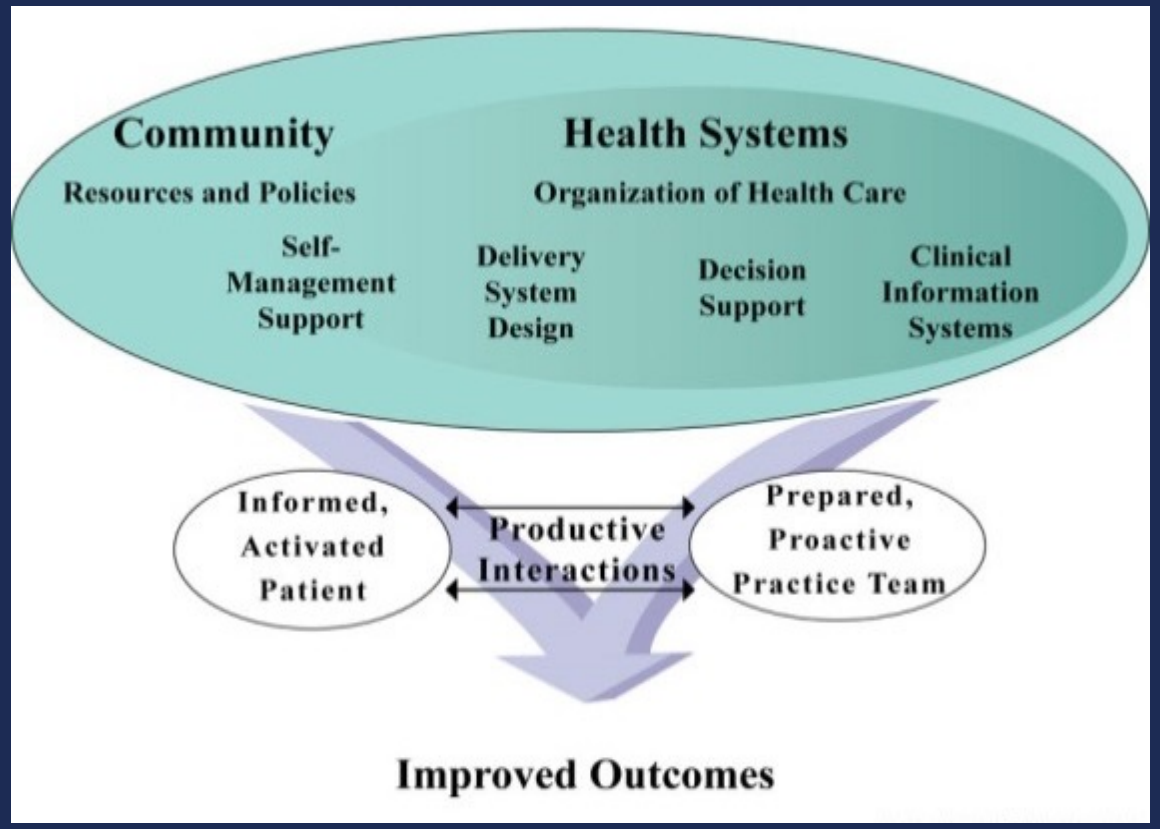
Design, Setting, and Participants Single-blind effectiveness trial at 7 university-based and community hospitals in or near Pittsburgh, Pennsylvania. Participants were 302 post-CABG patients with depression (150, intervention; 152, usual care) and a comparison group of 151 randomly sampled post-CABG patients without depression recruited between March 2004 and September 2007 and observed as outpatients until June 2008.

Intervention Eight months of telephone-delivered collaborative care provided by nurses working with patients' primary care physicians and supervised by a psychiatrist

Rollman BL, et al. *JAMA*. 2009; 302:2095
Donohue J, et al. *Gen Hosp Psych*. 2014; 36:453

Chronic Care Model

- Linked to primary care
- Team approach
- Care managers
- Registries
- Proactive
- Guideline-based care



Katon WJ, et al. *Gen Hosp Psych*. 2010; 32:456

What if we apply Collaborative Care for Depression to Heart Failure?

ORIGINAL CONTRIBUTION

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Intervention Eight months of telephone-delivered collaborative care provided by nurses working with patients' primary care physicians and supervised by a psychiatrist and primary care physician from this study.

Main Outcome Measures Mental health–related quality of life (HRQL) measured by the Short Form-36 Mental Component Summary (SF-36 MCS) at 8-month follow-up; secondary outcome measures included assessment of mood symptoms (Hamilton Rating Scale for Depression [HRS-D]), physical HRQL (SF-36 PCS), and functional status (Duke Activity Status Index [DASI]); and hospital readmissions.

Results The intervention patients reported greater improvements in mental HRQL (all $P \leq .02$) (SF-36 MCS: Δ, 3.2 points; 95% confidence interval [CI], 0.5-6.0), physical functioning (DASI: Δ, 4.6 points; 95% CI, 1.9-7.3), and mood symptoms (HRS-D: Δ, 3.1 points; 95% CI, 1.3-4.9); and were more likely to report a 50% or greater decline in HRS-D score from baseline (50.0% vs 29.6%; number needed to treat, 4.9 [95% CI, 3.2-10.4]) than usual care patients ($P < .001$). Men with depression were particularly likely to benefit from the intervention (SF-36 MCS: Δ, 5.7 points; 95% CI, 2.2-9.2; $P = .001$). However, the mean HRQL and physical functioning of intervention patients did not reach that of the nondepressed comparison group.

Conclusion Compared with usual care, telephone-delivered collaborative care for treatment of post-CABG depression resulted in improved HRQL, physical functioning, and mood symptoms at 8-month follow-up.

Trial Registration clinicaltrials.gov Identifier: NCT00091962

JAMA. 2009;302(19):2095-2103 www.jama.com

CORONARY ARTERY BYPASS graft (CABG) surgery is one of the most common and costly medical procedures performed in the United States.[1] Its main indications are the relief of angina and improvement in quality of life.[2] Yet as many as half of post-CABG patients report depressive symptoms in the perioperative period,[3] are more likely to experience a decreased health-related quality of life (HRQL) and functional status,[4] continued chest pains,[3,5] and increased rates of rehospitalization and death following CABG surgery independent of cardiac status, medical comorbidity, or the extent of surgery.[7-11]

Although the mechanism whereby depression affects post-CABG outcomes remains unknown,[12] widely generalizable strategies to detect and effectively treat post-CABG depression are of great interest. Several treatment trials for depression have been conducted in cardiac populations, but most achieved less than anticipated benefits with regard to reducing mood symptoms[13-19] or cardiovascular morbidity.[13-16,19,20] Moreover, none used the proven effective collaborative care approach[21] recently recommended by a National Institutes of Health expert consensus panel.[22]

Unlike earlier interventions that used a single antidepressant,[13,15,17,18] counseling modality,[20] or antidepressant in combination with counseling for treating cardiac patients with depression,[14,19] collaborative care emphasizes a flexible real-world treatment package that involves active follow-up by a nonphysician care manager who adheres to evidence-based

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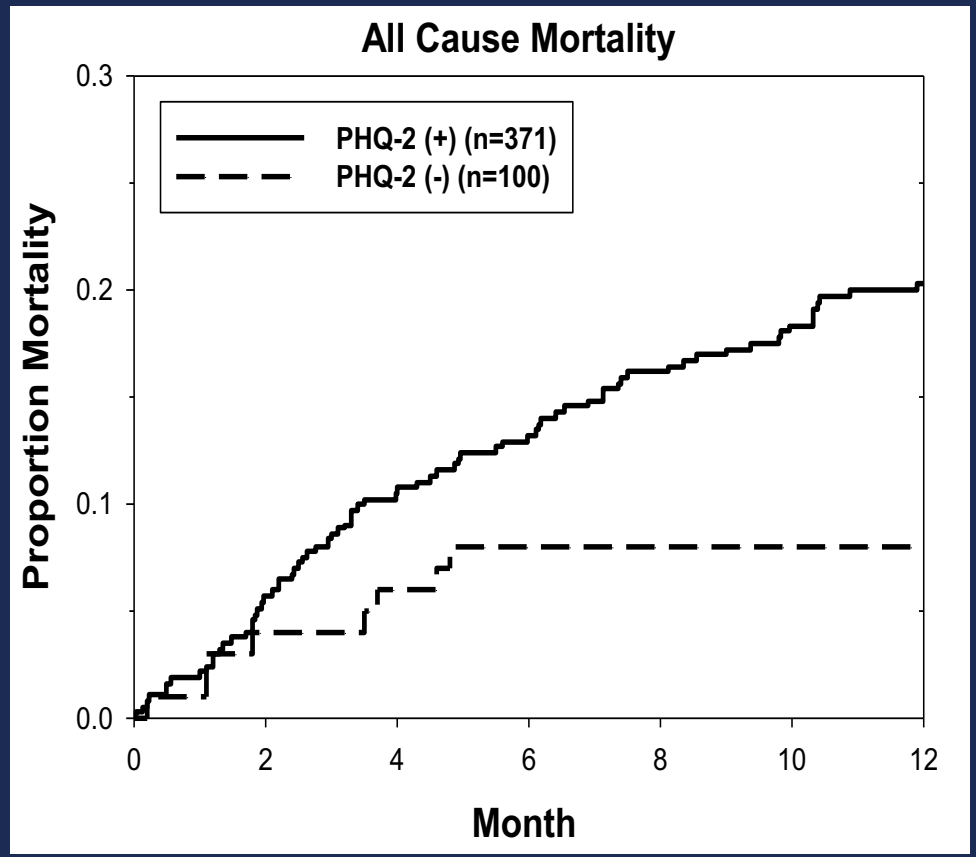

Rollman BL, et al. *J. Cardiac Fail.* 2012; 18:238

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Hopeful Heart Trial

Specific Aims

At 12-months follow-up, can "blended" CC for depression and HF:

Increase:

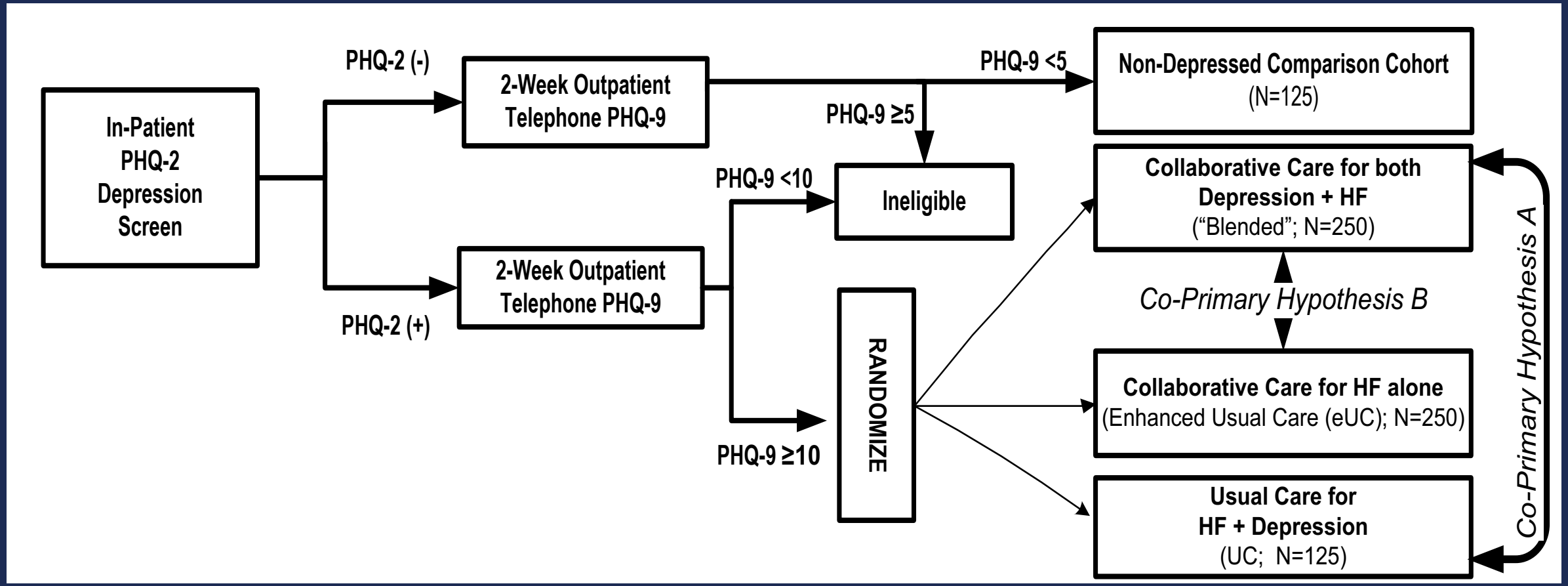
- Mental HRQoL (SF-12 MCS – primary outcome)
- Physical functioning (SF-12 PCS, KCCQ-12)
- Adherence with guideline-recommended care

Decrease:

- Mood symptoms (PROMIS Depression)
- Health care utilization (rehospitalization)
- Health care costs ($)

Hopeful Heart Trial

Study Design



Eligibility Criteria

- Ejection fraction (EF) ≤ 45%
- Medically stable
- Consent for PHQ-2 screen
- No substance abuse / dementia
- Discharged home
- At 2-wk f/u:
  If PHQ-2 (+) then PHQ-9 ≥10
  If PHQ-2 (-) then PHQ-9 ≤5 (control)

Screening Summary

4/14-10/17

Inpatients Approached	11,992
PHQ-2 Completed	7,866 (66%)
PHQ-2 (+) Screen	3,644 (46%)
Protocol-Elig./Consented	2,966 (81%)
PHQ-9 Completed (2-wk f/u)	1,890 (64%)
PHQ-9 ≥10	671 (36%)
Randomized	629 (94%) †

† 127 Non-depressed control patients enrolled (PHQ-2 (-) / PHQ-9 <5)

Sociodemographics

	Depressed (N=629)	**Non-Depressed** (N=127)	**P**
Age (SD)	64 (13)	66 (13)	0.11
Male	57%	54%	0.64
White	75%	61%	0.01
Married	42%	44%	0.86
>High School	51%	62%	0.02
Working	12%	19%	0.03

Medical Characteristics

	Depressed (N=629)	**Non-Depressed** (N=127)	**P**
Ejection fraction (SD)	28% (9)	28% (8)	0.98
Hypertension	86%	85%	0.78
Diabetes	52%	46%	0.22
Myocardial infarction	45%	40%	0.28
ACE-I/ARB	57%	57%	0.96
Beta-Blocker	85%	89%	0.27

Mood, HRQoL, and Function

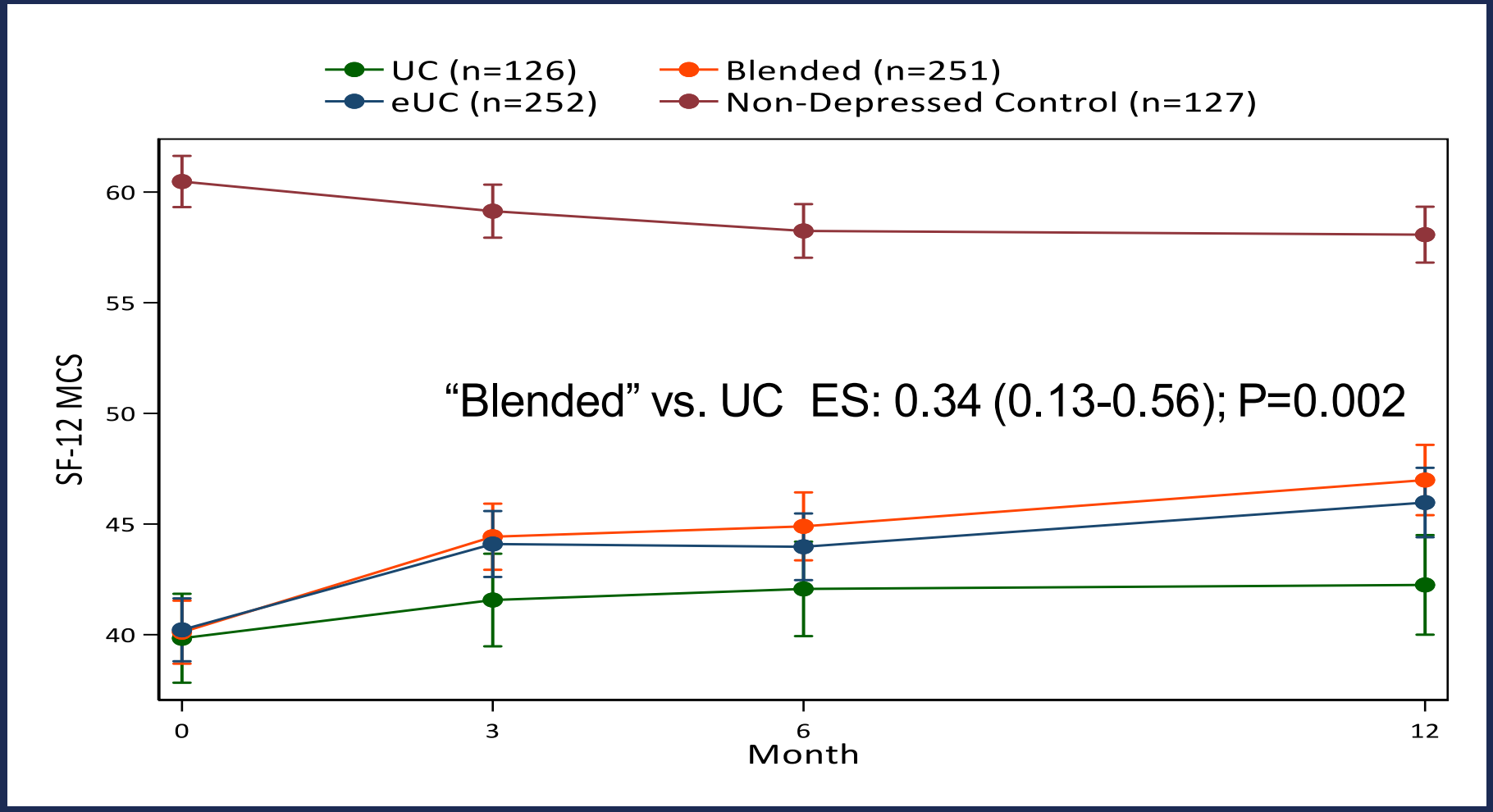
	Depressed (N=629)	**Non-Depressed** (N=127)	**P**
PHQ-9 (SD)	14.1 (3.6)	2.0 (1.2)	<0.0001
PROMIS-D (SD)	60.2 (8.0)	41.8 (5.5)	<0.0001
SF-12 MCS (SD)	40.1 (11.0)	60.5 (4.9)	<0.0001
SF-12 PCS (SD)	29.4 (9.7)	38.4 (11.2)	<0.0001
KCCQ-12 (SD)	29.4 (9.7)	38.4 (11.2)	<0.0001
NYHA Class III/IV	66%	42%	0.001

12-Month Interventions

- Patient informed of randomization status
- Care manager telephones at regular intervals to:
  - Assess current care (symptoms, meds, wt, BP)
    Promote adherence
    Recommend adjustments in medications
  - Monitor treatment response
- Separate weekly team meetings:
  - *"Blended"*: Psychiatrist, cardiologist, internist, nurses
  - *eUC*: Cardiologist, internist, nurses
- Nurses send treatment recs. to patients & PCPs

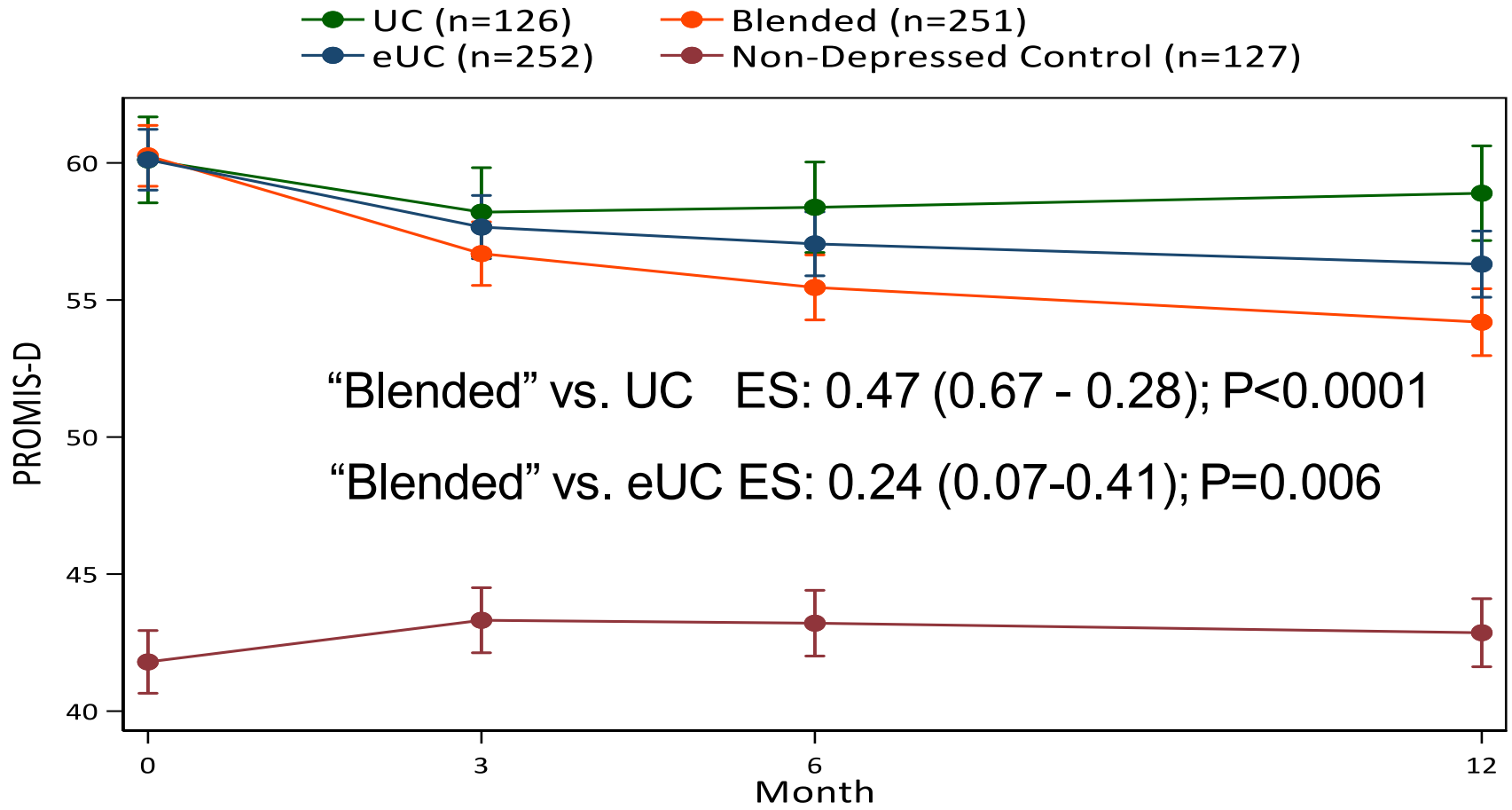
Mental Health-Related Quality of Life

(SF-12 MCS: Primary Outcome)

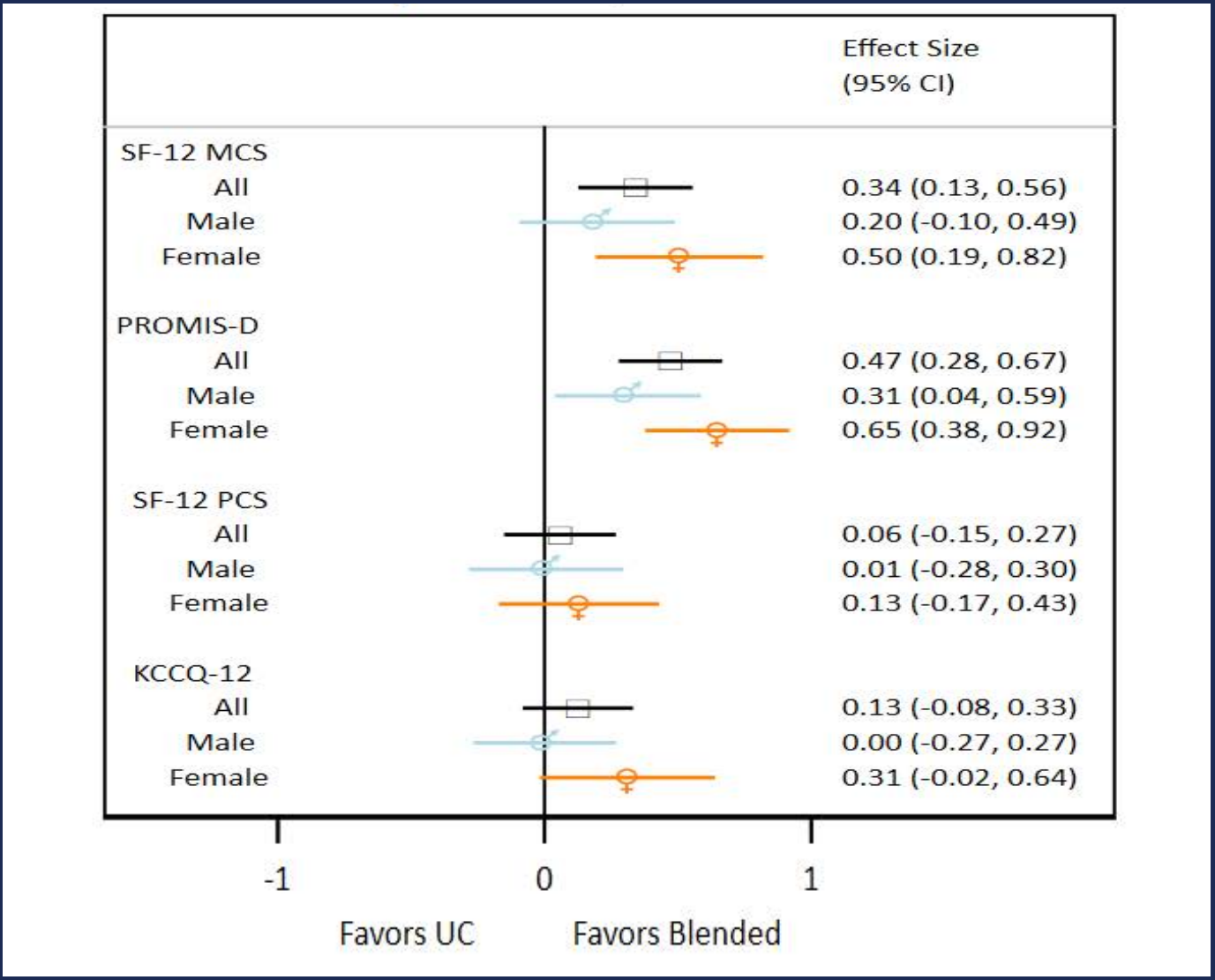


Mood Symptoms

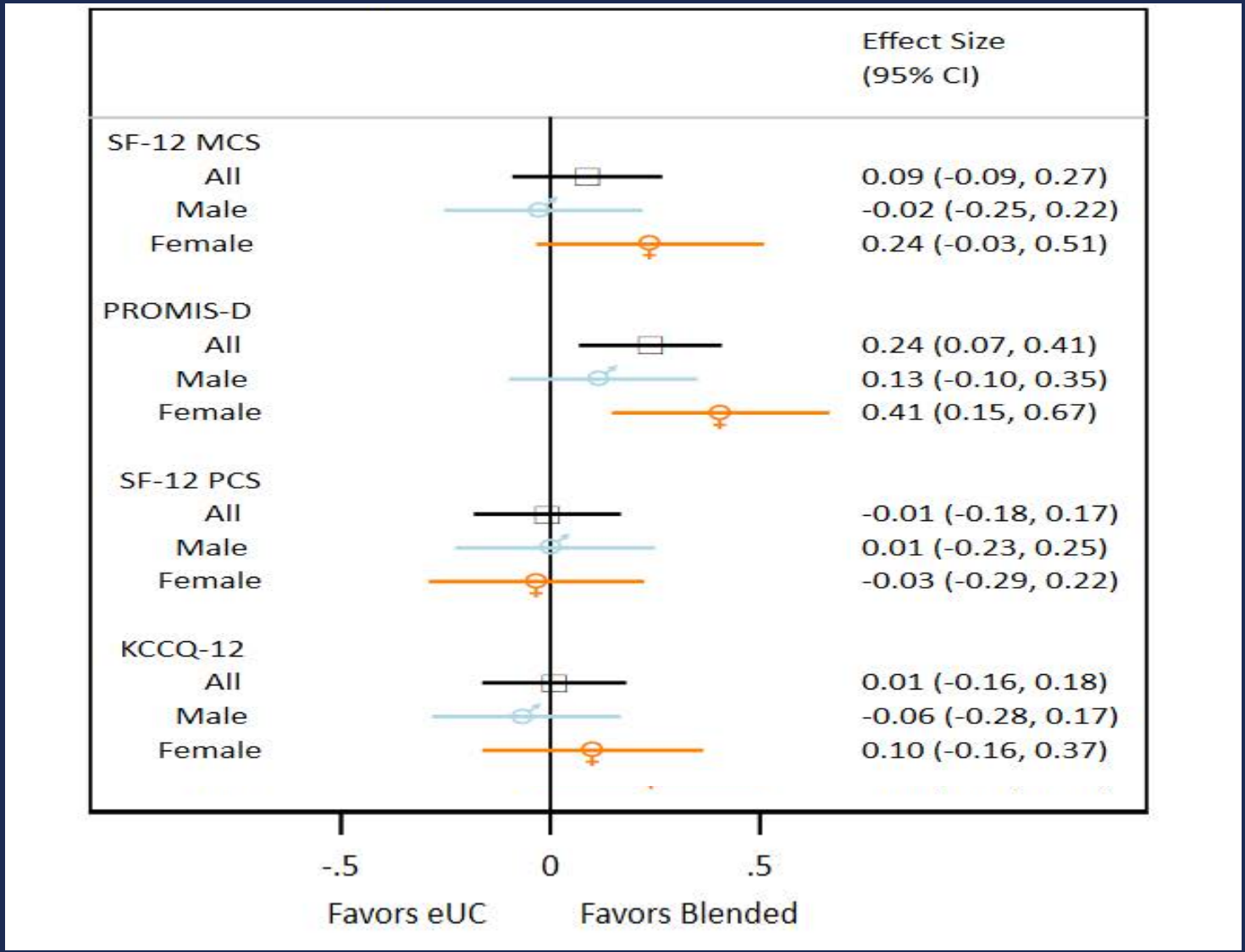
(PROMIS Depression)



“Blended” vs. Usual Care (UC)

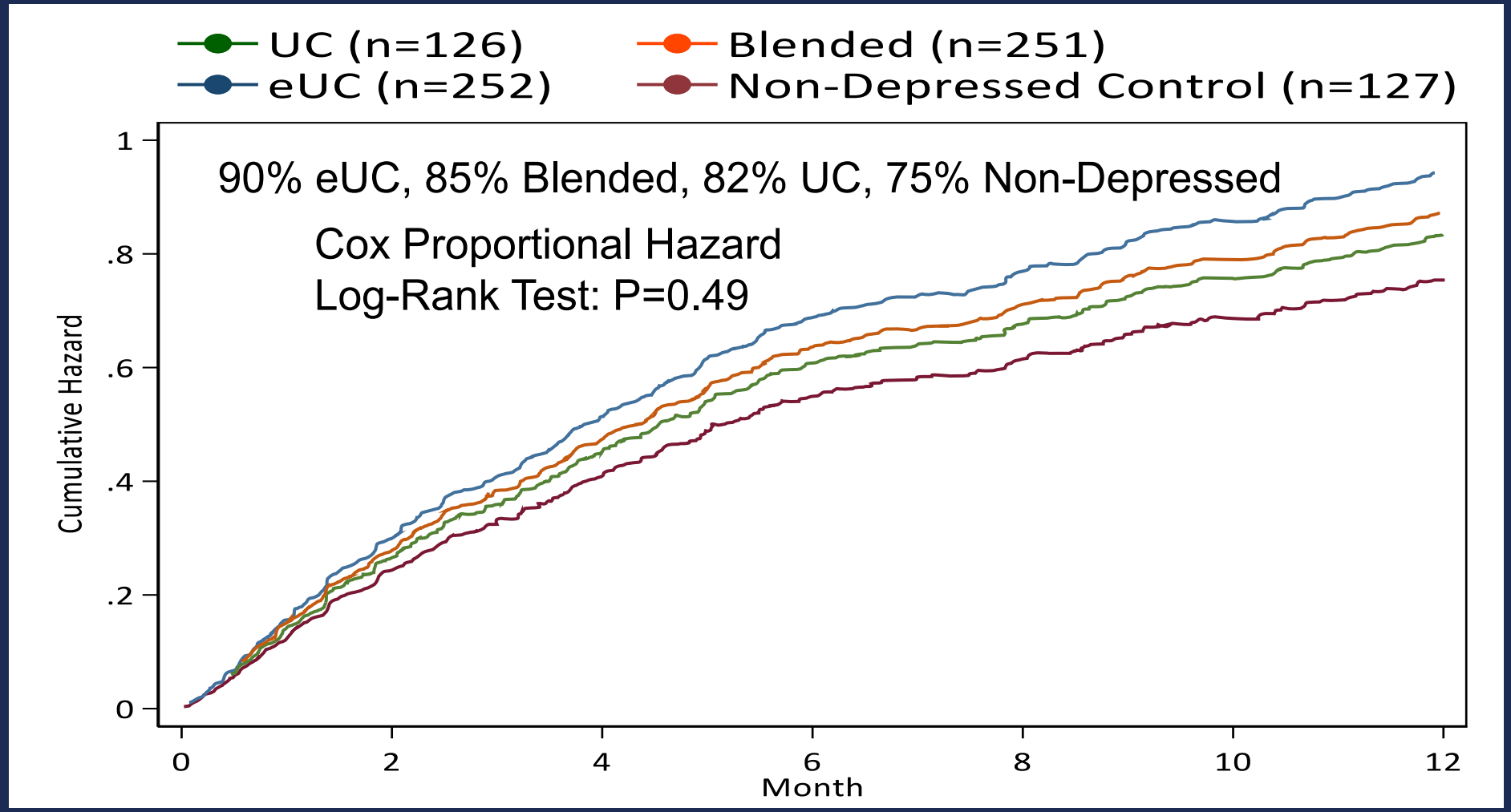


“Blended” vs. Enhanced Usual Care (eUC)



12-Month All-Cause Readmissions

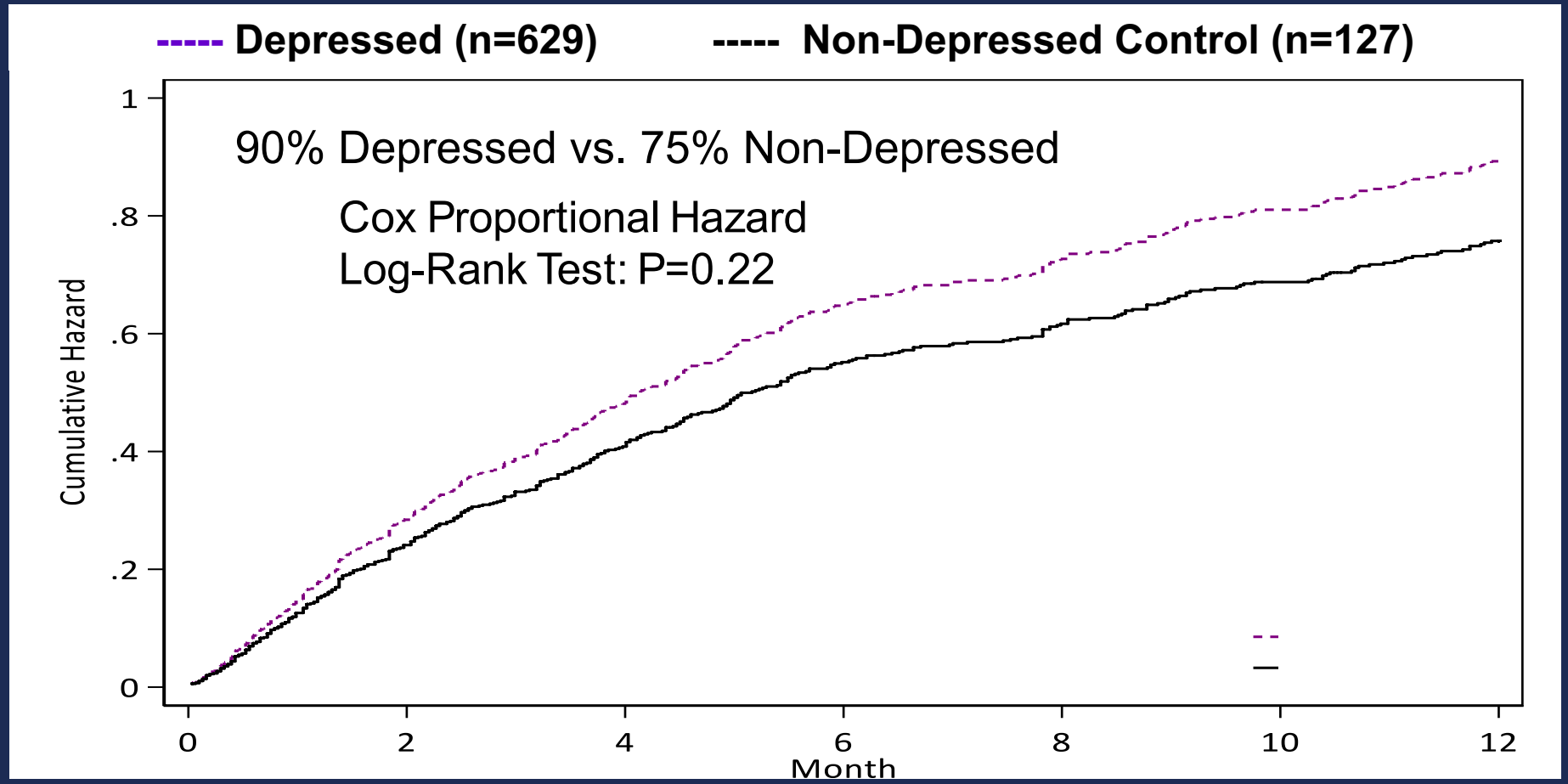
Depressed-Randomized & Non-Depressed Control



All Cox models adjusted for: hospital recruitment site, gender, time point, treatment assignment

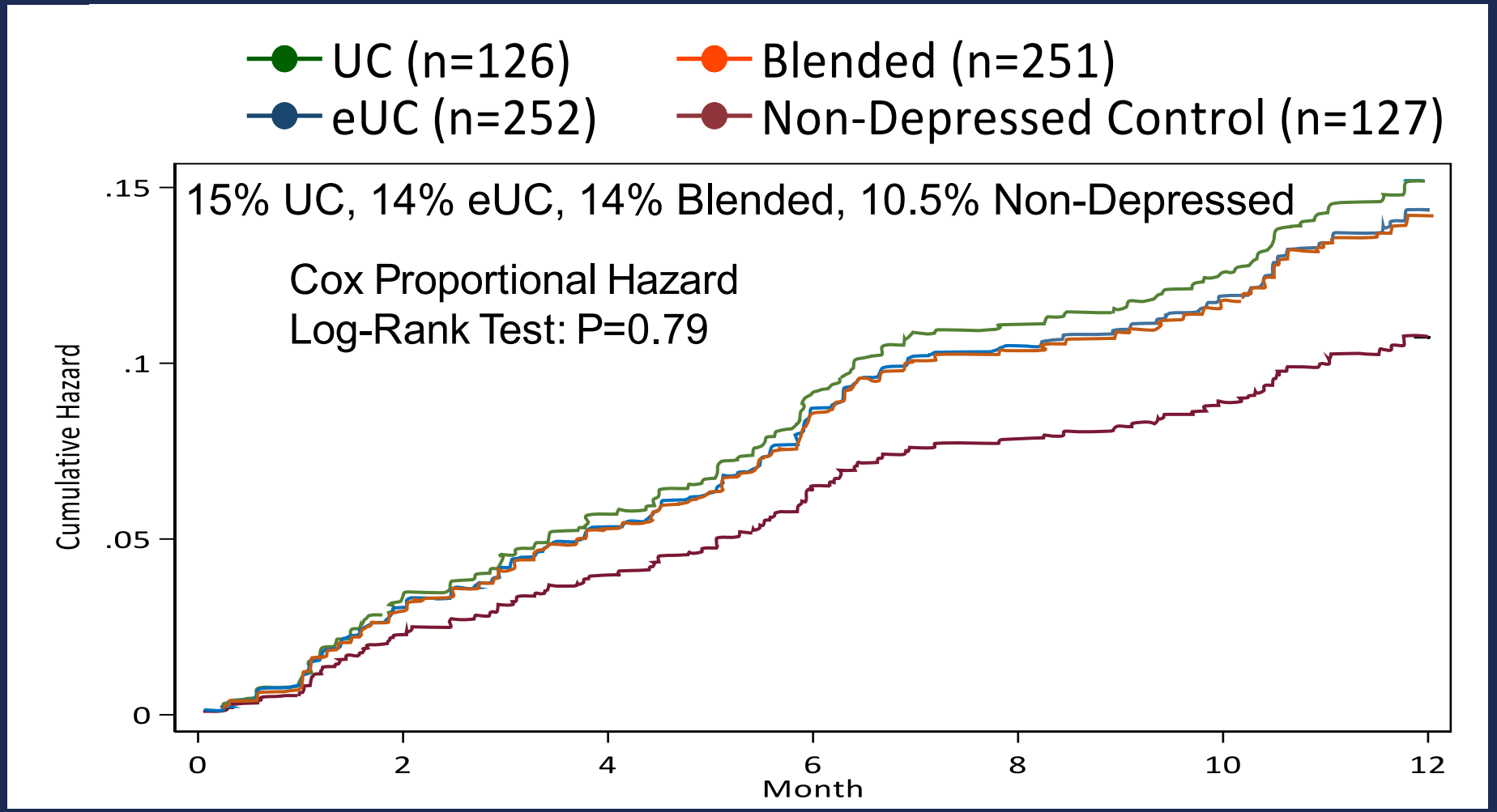
12-Month All-Cause Readmissions

Depressed vs. Non-Depressed Control



12-Month All-Cause Mortality

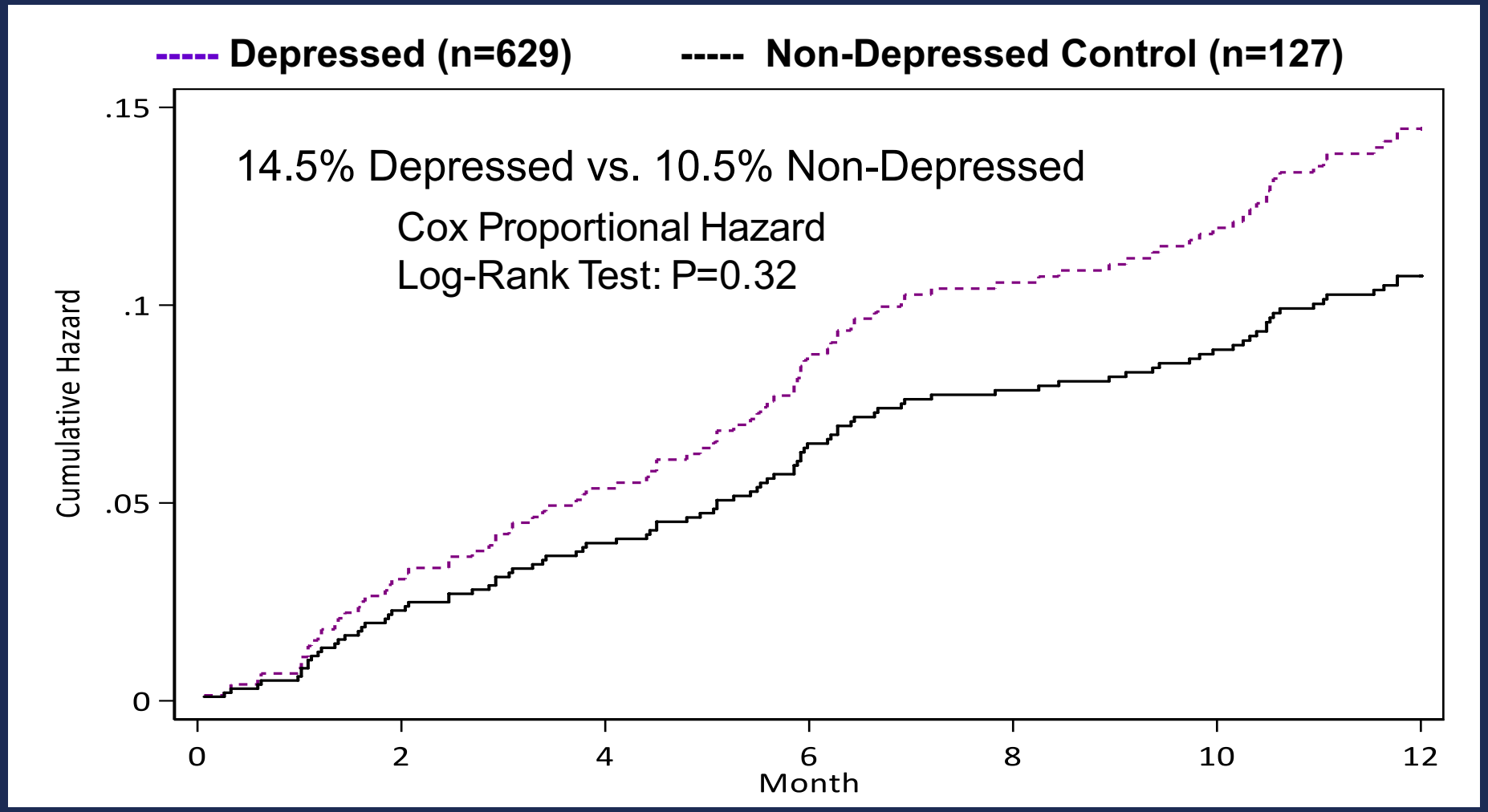
Depressed-Randomized & Non-Depressed Control



98 Deaths by 12-month follow-up (13%; 98/756)

12-Month All-Cause Mortality

Depressed vs. Non-Depressed Control



Limitations

Single-site

HIPAA

Medical nurses

Still to analyze:

- Mortality and readmissions causes
- Processes measures of care
- New vs. recurrent depression
- Recovery from depression vs. no change
- Insurance claims data
- Cost-effectiveness

Conclusions

1) Depression is highly co-mobid with HF & associated with worse self-reported function and HRQoL.
2) “Blended” collaborative care for depression and HF *improves* mHRQoL and mood sx. *more than* UC.
3) “Blended” collaborative care *reduces* mood symptoms *more than* collaborative care for HF-alone (eUC).
4) Depression and HF care did not reduce the incidence of readmission or mortality over either control group.
5) More effective treatments for depression are needed.

www.hopefulheart.pitt.edu

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PITT HOME | FIND PEOPLE

Blended Collaborative Care for Heart Failure and Co-Morbid Depression

Hopeful Heart Trial

UNDERSTANDING HEART FAILURE | FEELING DOWN | PEOPLE | STUDY MATERIALS | PUBLICATIONS & PRESENTATIONS | CONTACT US

Hopeful Heart

Our National Heart Lung and Blood Institute-funded study aims to examine new ways to:

- **Treat mood and cardiac symptoms together**
- **Reduce hospital readmissions; and**
- **Increase chances to live a longer life**

This website is intended as a resource for people living with heart failure and for people who care for someone with heart failure. We want you to know you are not alone and there is a lot of information available.

ABOUT HOPEFUL HEART

While new heart failure treatment guidelines advocate routine screening for depression, this recommendation is unlikely to be widely adopted without trial evidence that depression care improves outcomes and efficient methods to provide it.This study aims to examine if treating depression and heart failure together is more effective at improving health-related quality of life than treating heart failure alone. Read more about our trial here.

Hopeful Heart TRIAL