Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Kitzman DW, Whellan DJ, Duncan P, et al. Physical rehabilitation for older patients hospitalized for heart failure. N Engl J Med. DOI: 10.1056/NEJMoa2026141

Supplementary Appendix

Provided to give additional information regarding the work of Kitzman et al in *Physical Rehabilitation for Older Patients Hospitalized for Heart Failure.*

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REHAB-HF Eligibility Criteria

Inclusion Criteria

- Age ≥ 60 years old
- In the hospital setting >24 hours for the management of ADHF, or diagnosed with ADHF after being hospitalized for another reason. ADHF will be confirmed by the study physician, and will be defined according to the Food and Drug Administration definition of hospitalized heart failure as a combination of symptoms, signs, and HF-specific medical treatments, and requires that all 4 of the following are met:
    1) At least **one** symptom of HF which has worsened from baseline:
        a. dyspnea at rest or with exertion;
        b. exertional fatigue;
        c. orthopnea;
        d. paroxysmal nocturnal dyspnea (PND)
    2) At least **two** of the following signs of HF:
        a. Pulmonary congestion or edema on exam (rales or crackles) or by chest xray;
        b. Elevated jugular venous pressure or central venous pressure ≥ 10 mm Hg;
        c. peripheral edema;
        d. wedge or left ventricular end diastolic pressure ≥15 mmHg;
        e. rapid weight gain (≥ 5 lbs.);
        f. Increased b-type natriuretic peptide (BNP) (≥100 pg/ml) or N-terminal prohormone BNP (≥220pg/ml)
    3) Change in medical treatment specifically targeting HF defined as change in dose or initiation of or augmentation of at least **one** of the following therapies:
        a. diuretics;
        b. vasodilators;
        c. inotropes (including digoxin if for HF);
        d. other neurohormonal modulating agents, including angiotensin converting enzyme inhibitors, angiotensin II receptor blockers, beta-blockers, aldosterone or direct renin inhibitors
    4) The primary cause of symptoms and signs is judged by the investigator to be due to HF
- Adequate clinical stability has been achieved in the judgment of the investigator to allow participation in study assessments and the intervention
- Prior to admission and HF decompensation, patient was independent with basic activities of daily living (ADLs) including the ability to ambulate independently (with or without the use of an assistive device)
- Able to walk 4 meters (with or without the use of an assistive device) at the time of enrollment
- Signed informed consent document indicating that the patient understands the purpose of and procedures required for the study and is willing to participate in the study

Exclusion Criteria

- Acute myocardial infarction (Note: given that cardiac biomarkers such as troponin are frequently elevated in HF patients, the diagnosis of acute myocardial infarction should be based on clinical diagnosis, not biomarkers alone)
- Planned discharge other than to home or a facility where the participant will live independently
- Already actively participating in formal, facility-based cardiac rehabilitation
- Prior cardiac transplantation or planned within the next 6 months
- Severe aortic valve stenosis
- Ventricular assist device or anticipated within the next 6 months
- Already engaging in regular moderate to vigorous exercise conditioning defined as > 30 minutes per day, ≥ twice per week consistently during the previous 6 weeks
- Terminal illness other than HF with life expectancy < 1 year
- Impairment from stroke, injury or other medical disorder that precludes participation in the intervention
- Dementia that precludes ability to participate in rehabilitation and follow study protocols
- Enrollment in a clinical trial not approved for co-enrollment
- Expected use of continuous intravenous inotropic therapy after discharge

- Implantable cardioverter defibrillator with heart rate limits < expected heart rates for exercise and unable to be reprogrammed
- Advanced chronic kidney disease defined as estimated glomerular filtration rate < 20 mL/min/1.73 m2 based upon the Modification of Diet in Renal Disease study equation, current ultrafiltration, or on chronic or intermittent dialysis or dialysis anticipated within the next 6 months
- High risk for non-adherence as determined by screening evaluation
- Inability or unwillingness to comply with the study requirements
- Anticipated hospital discharge before baseline study measures could be complete

Detailed Summary of the REHAB-HF Intervention

Introduction

The rehabilitation intervention was a novel, multi-domain, tailored, and progressive program specifically developed for patients hospitalized with ADHF. The Rehabilitation Intervention focused on 4 physical domains: strength, balance, mobility, and endurance, each designed to address deficits present in the ADHF population. The Rehabilitation Intervention was transitional and conducted in multiple phases and pathways including a one-on-one supervised Inpatient (hospital) and Outpatient (facility-based) phases (enrollment to 3-month follow-up), which was supplemented with a home exercise prescription, and a Maintenance phase (months 4-6).

Inpatient Intervention

The intervention began in the inpatient setting after randomization and was performed up to once per day for approximately 45 minutes each. Inpatient sessions focused on balance, mobility, and functional strength, and were exercises that could easily be administered in a hospital room by a physical therapist or exercise physiologist with minimal equipment. The relatively short length of the typical index hospitalization and need to accommodate other clinically-ordered diagnostic procedures and treatments limited the number of inpatient rehabilitation intervention sessions (**Table S5**).

Outpatient Intervention

Outpatient sessions began as soon as possible after discharge, up to 2 weeks post-discharge, and averaged 7-10 days. Outpatient sessions were conducted 3 days/week for 60 minutes each for a total of 12 weeks or 36 sessions. For very debilitated patients who were physically unable to get to the outpatient facility to start the intervention, home-based intervention sessions were provided, with the goal of strengthening and transitioning the patient to be able to attend the outpatient based setting (**Table S6**).

Rehabilitation Exercises and Progression

The initial exercise prescription was individualized for each participant based upon functional performance level (1-4, from lowest to highest) in each domain using the objective criteria shown in **Table S1**, and was progressed as patients improved in function. The relative time spent on each domain during the session was tailored to the participant's physical function impairments. Specifically, a participant with poor balance and functional mobility spent a greater proportion of time performing balance and mobility exercises in the early portions of the intervention. As balance and functional mobility improved, these comprised a smaller portion of the session and time spent on endurance was increased. Alternatively, participants with only modest impairments in balance and functional mobility at baseline spent most of the session performing endurance and strengthening exercises. Patients were continually challenged to improve physical function by advancing through a gradual progression of small increments from session to session. A key goal of the Rehabilitation Intervention was to safely increase endurance (walking time), which required balance, strength, and mobility training for safe ambulation. During all exercise, close supervision, including the use of a gait belt as needed, was provided by the interventionist to prevent injuries and falls.

Strengthening exercises included both functional strengthening exercises focusing on the lower extremities and general resistance exercises for major muscle groups of the upper and lower extremities. Functional strengthening exercises included: sit-to-stand from chair (or bed in the hospital setting), step-ups (front and side), calf raises, and body-weight squats. For the most impaired participants (level 1), this began with guarded stands, assisted step-ups on a 4-inch step, and seated toe raises, and hand-assisted squats at 15 degree flexion. These exercises progressed to (level 4) rapidly repeated stands with platform in front of chair, unassisted step-ups on an 8-10 inch step, standing toe raises on one leg, and unassisted squats >45 degree flexion. For general strengthening exercises, the most impaired participants (level 1) began with assistive or lightly resistive exercises. The interventionists matched the participant's ability to exercise major muscle groups of the upper and lower extremities and used Rate of Perceived Exertion (RPE) of Hard-Very Hard (15-16) to guide advancement. As participants progressed, strengthening exercises of the major muscle groups of the upper and lower extremities using resistance bands or free weights were incorporated. Functional strength

exercises of the lower extremities were prioritized as they directly translate to performance of activities of daily living and impact other domains such as balance and endurance.

Balance rehabilitation included both static and dynamic exercises. For the most unsteady participants (level 1), balance rehabilitation began with holding a shoulder-width stance for static balance and standing and reaching forward and backward 6 inches for dynamic balance. For static balance, these exercises progressed to holding an increasingly narrow base of support (feet together to semi-tandem stance to tandem stance to single leg stance) with eyes open and progressing to eyes closed. For dynamic balance, these exercises progressed to level 4 (standing with a staggered stance and reaching forward and backward 10 inches). Balance exercises were incorporated as this domain is often underappreciated or overlooked in traditional exercise training, and improvements in both static and dynamic balance could translate to safe ambulation.

Improving functional mobility was one of the primary goals of the rehabilitation intervention, particularly in participants with slower gait speeds (<1 meter/sec) and impaired dynamic balance. Accomplishing this involved rehabilitation exercises that combined balance activities with mobility, including dynamic start and stop and changing direction while walking. In addition, participants with a slow gait speed underwent accelerated gait exercises.

Endurance training for the most debilitated participants (level 1) began with repeated bouts of ambulation at usual speed with rest breaks as needed, with an initial goal of 5-10 minutes total duration, and at least 2 minutes continuous. The endurance training progressed to sustained walking for up to 40 minutes for the highest-functioning participants (level 4). Initially, heart rates of 20-30 bpm above resting were used to guide exercise intensity, along with RPE. Initially, RPE target was Light-Moderate (11-13) and as patients progressed, was increased to Moderate-Hard (13-15). Walking was the preferred mode of endurance exercise, however, endurance exercises utilizing other equipment (e.g. exercise bicycle) were incorporated into the endurance training to supplement walking, especially for especially impaired patients.

Adherence to the outpatient sessions was high (**Table S4**).

Home Exercise Prescription

Home exercise was initiated following a visit by study staff to evaluate the participant's home environment for safe participation in home exercises, including potential barriers to safe ambulation. Participants were instructed in low-intensity walking at their usual pace on non-intervention days, gradually increasing toward a goal of 30 minutes daily. Seated or standing strengthening exercises were also incorporated. The home exercise prescription was designed in part to help facilitate the transition to the independent, self-guided Maintenance Phase.

Maintenance Phase (Months 4-6)

A key goal which was addressed early and throughout the outpatient, facility-based intervention phase was to prepare the patient to transition to the independent Maintenance Phase. An individualized exercise prescription was developed by the intervention team using primarily walking-based and functional strength exercises that were safe to perform at home and required no special equipment. Preparations for this phase began early in the Rehabilitation Program and included: a) the home evaluation and home exercise described above; b) identifying community resources for ongoing physical activity and endurance training, such as YMCA Silver Sneakers, private fitness centers, and phase II and III cardiac/pulmonary rehabilitation programs; c) emphasizing the importance of continued regular exercise; d) identifying and addressing potential barriers; and e) engaging family or caregiver for ongoing support. The structured, supervised Outpatient Phase helped to instruct the patient on safe modes and settings for continuing exercise independently. Participants were contacted by phone every 4 weeks to encourage continued adherence to their maintenance phase exercise program and collect information on health status and clinical events. At 6 months, 83% of participants alive and in phone contact reported regular exercise (**Table S7**), suggesting that behavioral change, a requisite for long-term adherence, may have occurred.

Control Arm

Participants randomized to the control arm followed standard care as ordered by their individual, treating physician. To reduce the potential for bias from greater attention and surveillance in the rehabilitation intervention group, participants in the control group received at least bi-weekly contact from study personnel during the first 3 months following the index hospitalization. This contact was provided as a combination of telephone calls and specified study visits. Specifically, in-person contact was made with study visits at weeks 4 and 12 and with telephone calls at weeks 2, 6, 8, and 10. Further, contact was made within the first 2 weeks following discharge for the purposes of retention. Consistent with the rehabilitation intervention group, telephone contact was also made at weeks 16, 20, and 24 (Months 4, 5, and 6, respectively), matching the type and frequency of calls received by the intervention group during this phase. Information regarding symptoms, HF transitional management program use, medical compliance, activity level, rehabilitation received, medical resource utilization, and clinical events was collected at each of these encounters. Adherence to medication regimens and follow-up appointments was also encouraged. Participants in the control arm did not receive any specific rehabilitation recommendations or exercise prescription from study personnel. However, they were able to receive any physical or occupational therapy deemed appropriate by their usual clinical care providers, both during the hospitalization and as outpatients.

Provision of Usual Care

Participants in both arms received standard therapies as directed by their clinical providers, which included any of the following services: inpatient physical therapy, outpatient physical therapy, or cardiac, or pulmonary rehabilitation 6 weeks after discharge. All aspects of disease management, including medical therapy and HF management, were left to the discretion of the participant's treating physician and were specifically not addressed by the study protocol for either study arm. Clinical concerns raised by the participant and/or identified by study personnel were referred to the participant's health care provider(s) for further management.

Figure S1. Organizational structure of clinical hubs and satellite sites. There were 3 central hubs with up to 2 satellite sites each for increased recruitment and intervention capability.

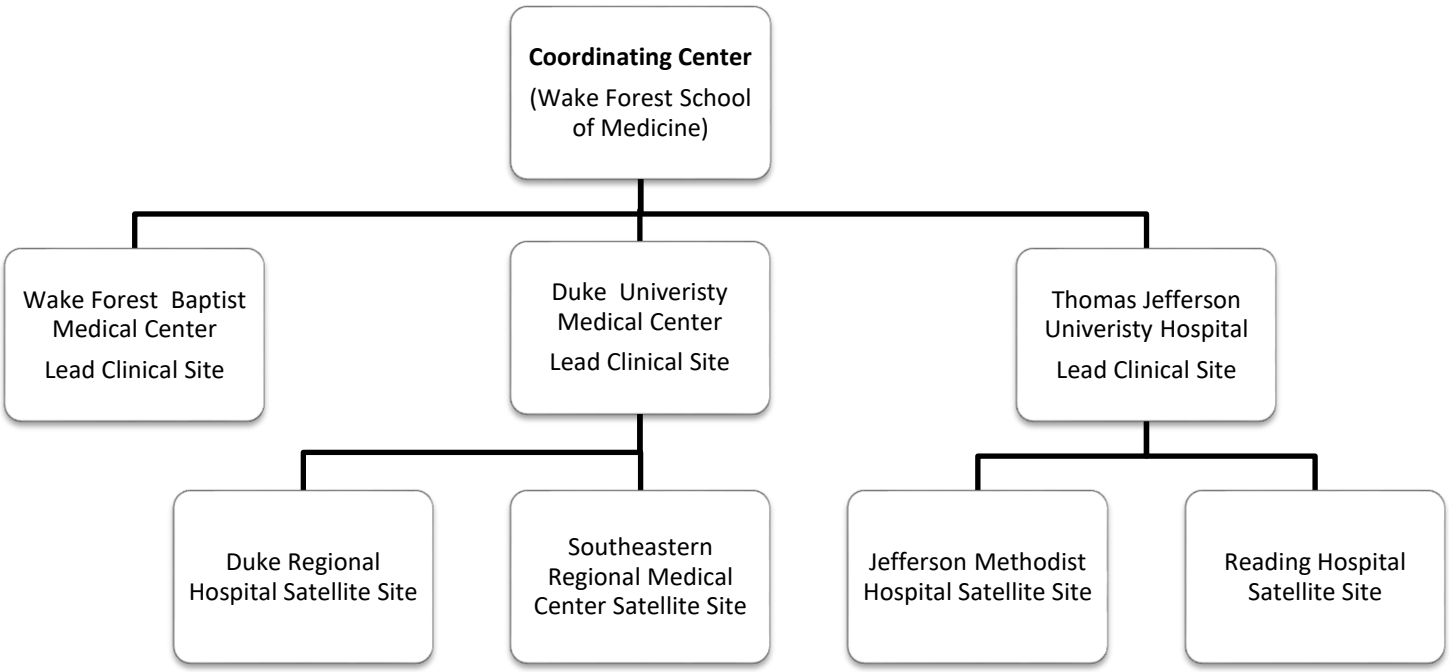

Figure S2: CONSORT Diagram for the Secondary Outcome (All-Cause Rehospitalizations at 6-month Follow-up)

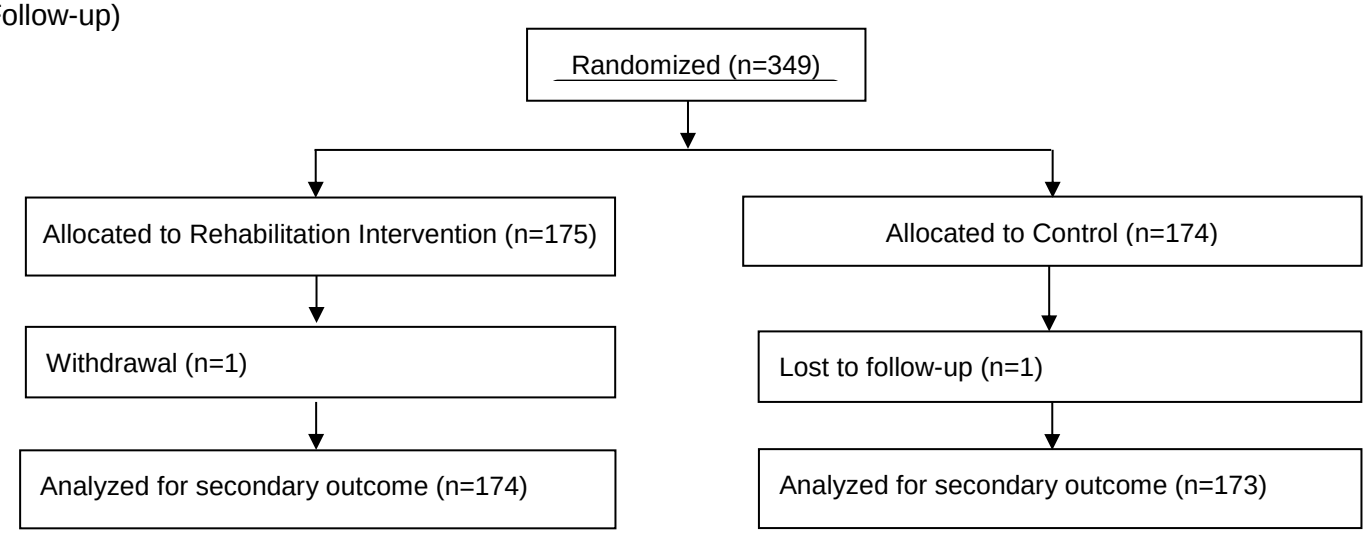

Figure S3. Disposition of all participants randomized to the Rehabilitation Intervention. Dashed line represents the average intervention attendance of all participants alive at 3-month follow-up.

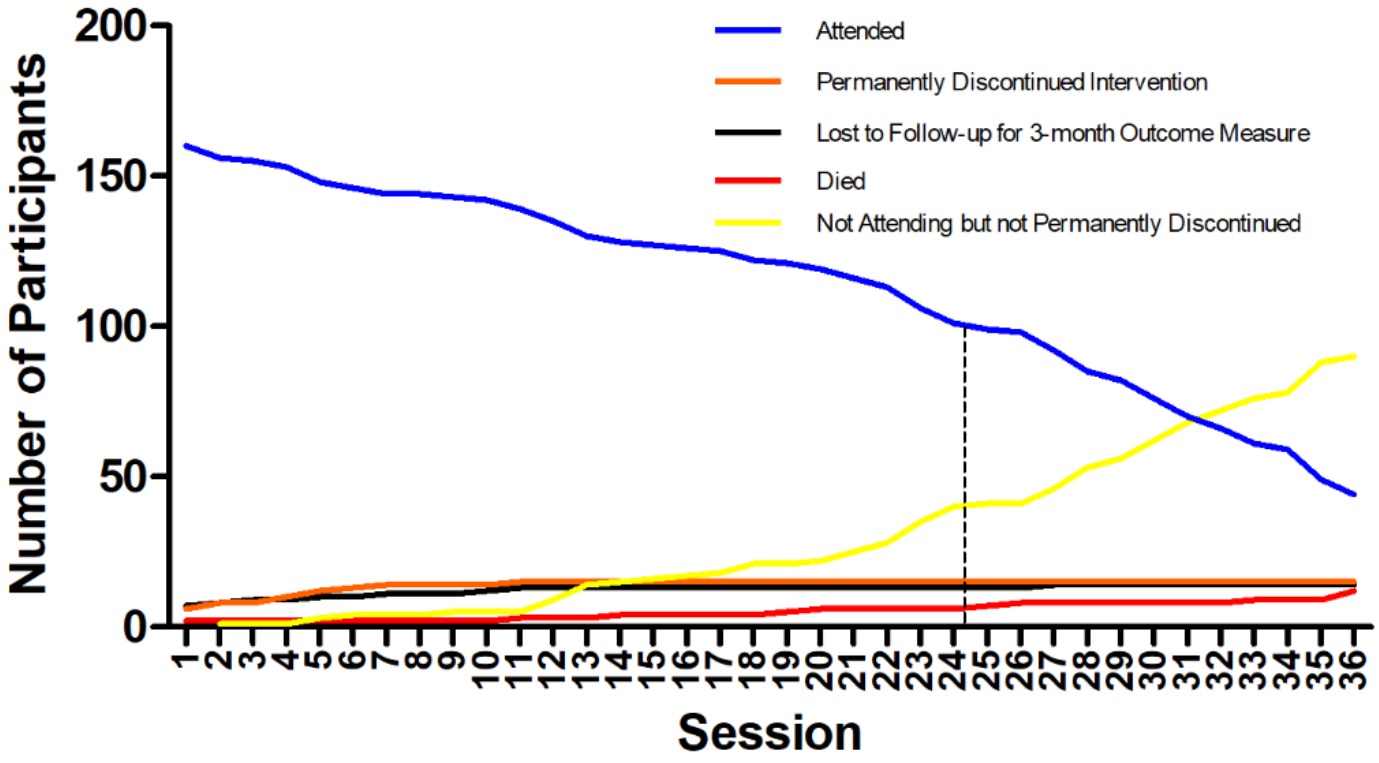

Figure S4. Short physical performance battery at baseline and 3-month follow-up. Clear bars show data for in the control group and black bars show data for the intervention group. Data shown as mean±standard error.

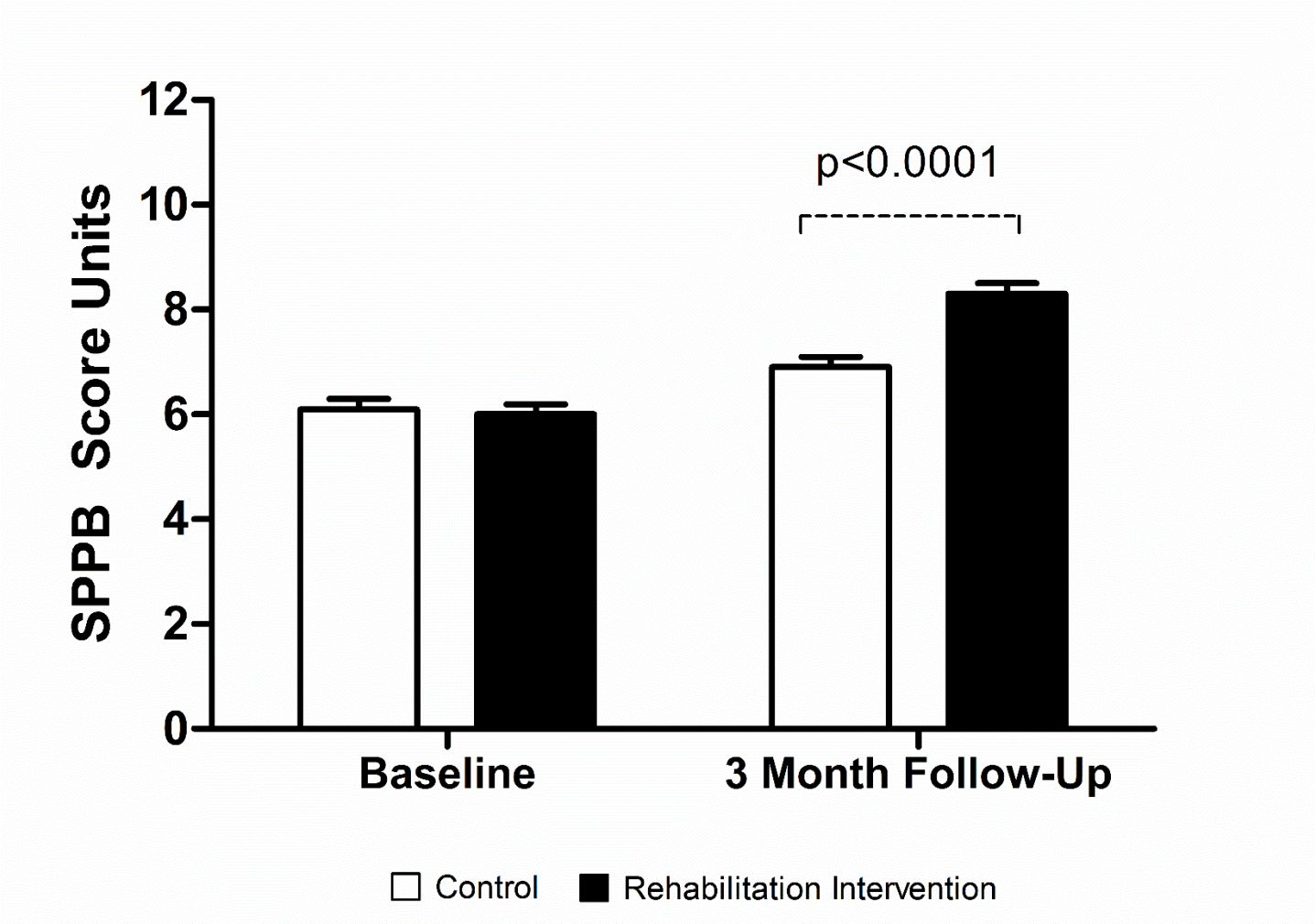

Figure S5. Additional Outcomes at Baseline and 3-month Follow-up. Six-minute walk distance, number of modified Fried Frailty Criteria, Kansas City Cardiomyopathy total score (disease specific quality of life), and Geriatric Depression Score in the control (clear bars) and intervention groups at baseline and at 3-month follow-up. Data shown as mean ± standard error.

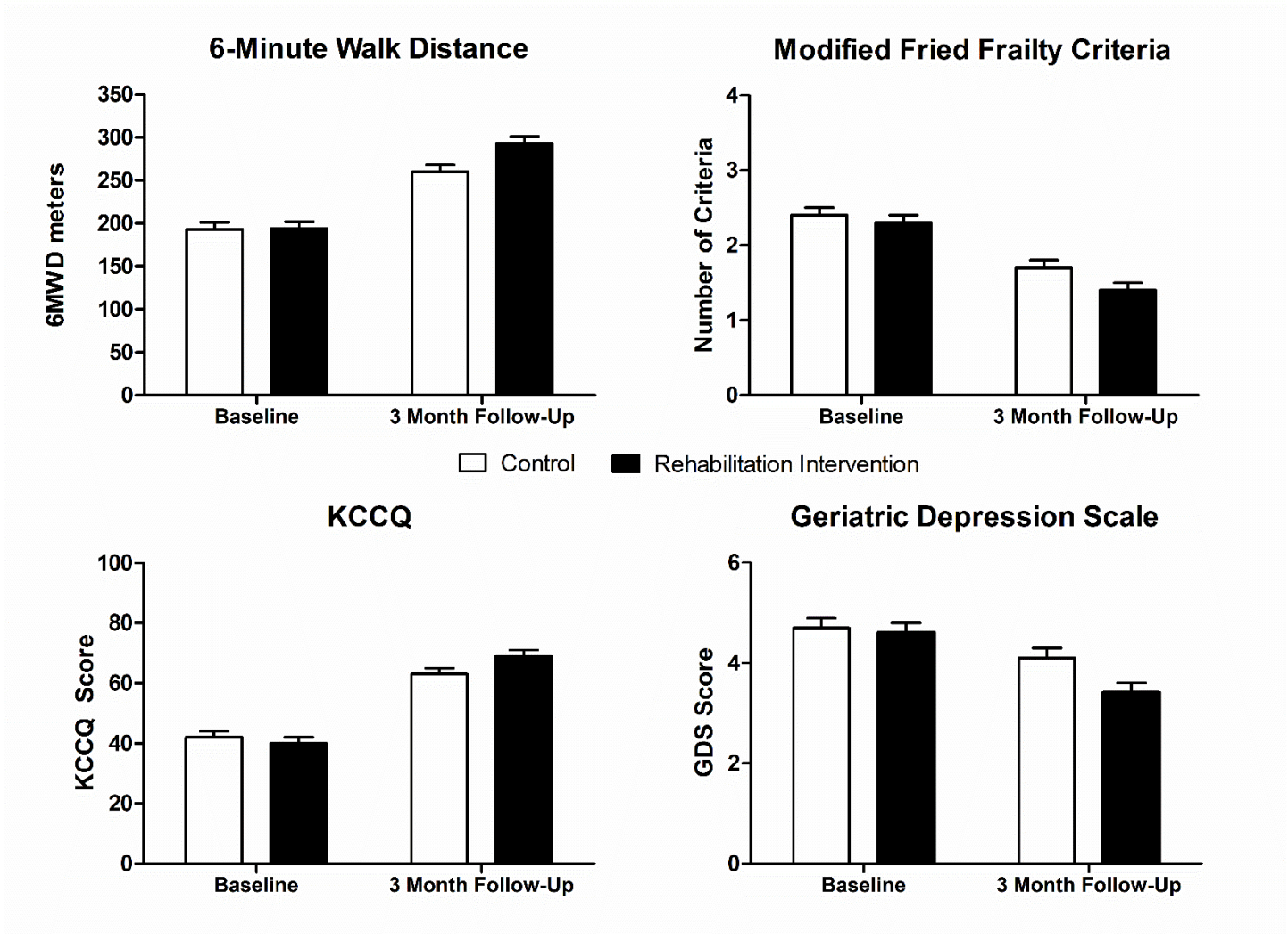

Table S1. REHAB-HF Rehabilitation Intervention Stratification Grid

	Level 1	Level 2	Level 3	Level 4
Strength: Rise from chair without hand support	Unable	At least once	5 times in > 15 but <60 sec.	5 times in ≤ 15 sec.
Balance: Standing	Unable with feet together for 10 sec.	With feet together for 10 sec.	Unsupported and reach forward 10 in.	On 1 leg for 10 sec.
Endurance: Continuous walking	< 2 minutes	≥ 2 but < 10 minutes	≥ 10 but < 20 minutes	≥ 20 minutes
Mobility: Gait speed	≤ 0.4 m/sec.	> 0.4 but ≤ 0.6 m/sec	> 0.6 but ≤ 1 m/sec.	> 1 m/sec.

Table S2. Detailed Reasons for Exclusion

	Number (%)
Number Meeting Exclusion Criteria	18815
Number (%) Primarily Excluded for:	
Acute MI	838 (4%)
Planned discharge other than to home or a facility where the participant will live independently	1521 (8%)
Already actively participating in formal, facility-based cardiac rehabilitation	155 (1%)
Prior cardiac transplantation or planned within the next 6 months	158 (1%)
Severe aortic valve stenosis	653 (3%)
Ventricular assist device or anticipated within the next 6 months	636 (3%)
Already engaging in regular moderate to vigorous exercise conditioning defined as > 30 minutes per day, ≥ twice per week consistently during the previous 6 weeks	103 (<1%)
Terminal illness other than HF with life expectancy < 1 year	224 (1%)
Impairment from stroke, injury or other medical disorder that precludes participation in the intervention.	1815 (10%)
Dementia	965 (5%)
Enrollment in a clinical trial not approved for co-enrollment	249 (1%)
Expected use of continuous intravenous inotropic therapy after discharge	288 (2%)
Implantable cardioverter defibrillator with heart rate limits < expected heart rates for exercise and unable to be reprogrammed	15 (<1%)
Advanced chronic kidney disease defined as estimated glomerular filtration rate < 20 ml/min/1.73m^2 based upon the Modification of Diet in Renal Disease study equation, current ultrafiltration, or on chronic or intermittent dialysis or dialysis anticipated with the next 6 months	2507 (13%)
High risk for non-adherence as determined by screening evaluation	558 (3%)
Inability or unwillingness to comply with the study requirements *****	2184 (12%)
Excessive distance precluding travel to exercise facility	5097 (27%)
Anticipated hospital discharge before baseline study measures could be completed	849 (5%)

Table S3. Additional Baseline Characteristics, Comorbidities, and Medications

Characteristics	Rehabilitation Intervention (N=175)	Control (N=174)
Current tobacco use	17 (10%)	19 (11%)
Current alcohol abuse	7 (4%)	5 (3%)
Patients with HF hospitalizations in previous 6 months	42 (24%)	47 (27%)
Comorbidities		
Chronic obstructive pulmonary disease	54 (31%)	44 (25%)
Chronic kidney disease	59 (34%)	58 (33%)
Stroke	26 (15%)	26 (15%)
Peripheral vascular disease	27 (15%)	13 (7%)
Arthritis, muscle/joint pain, or connective tissue disease	84 (48%)	70 (40%)
History of Cancer	42 (24%)	33 (19%)
Sleep apnea or sleep disordered breathing	68 (39%)	57 (33%)
Peptic ulcer disease	6 (3%)	5 (3%)
Liver disease or chronic hepatitis	6 (4%)	8 (5%)
Medications and Heart Failure Therapies (at discharge)		
Loop diuretic	162 (93%)	164 (95%)
Beta-blocker	138 (79%)	138 (80%)
Angiotensin-converting enzyme inhibitors	65 (37%)	66 (38%)
Angiotensin II receptor blockers	38 (22%)	37 (21%)
Aldosterone antagonist	29 (17%)	34 (20%)
Sacubitril/valsartan	1 (1%)	1 (1%)
Digoxin	8 (5%)	11 (6%)
Insulin	53 (30%)	45 (26%)
Oral diabetic agents	51 (29%)	34 (20%)
Metformin	34 (19%)	26 (15%)
Sulfonylureas	18 (10%)	19 (11%)
SGLT-2 inhibitor	1 (1%)	1 (1%)
GLP-1 agonist	1 (1%)	0 (0%)
DPP 4 inhibitor	6 (3%)	3 (2%)
Thiazolidinediones	2 (1%)	0 (0%)
Other oral diabetic agents	2 (1%)	0 (0%)
Antidepressants	37 (21%)	38 (22%)
SSRIs	21 (12%)	27 (16%)
SNRIs	9 (5%)	4 (2%)
TCAs	3 (2%)	3 (2%)
MAOIs	0 (0%)	0 (0%)
Mirtazapine	6 (3%)	3 (2%)
Other atypical antidepressants	10 (6%)	7 (4%)
Implantable cardioverter-defibrillator	33 (19%)	28 (16%)
Biventricular pacemaker	12 (7%)	13 (7%)

Data presented as N (%). Abbreviations: HF: heart failure; SGLT-2: sodium-glucose cotransporter-2; GLP-1: glucagon-like peptide-1; DPP-4: dipeptidyl peptidase-4; SSRI: selective serotonin reuptake inhibitor; SNRI: serotonin-norepinephrine reuptake inhibitor; TCA: tricyclic antidepressant; MAOI: monoamine oxidase inhibitor

Table S4. REHAB-HF Intervention Outpatient Sessions and Adherence

	Number of Patients	Average Intervention Sessions Attended	Adherence (% of 36 Sessions)	Adherence Adjusted for Medical Leave* (% of Scheduled Sessions)
All Intervention Patients	175	23.3±1.0	65±3%	76±3%
Intervention Patients Alive at 3-Month Follow-up	163	24.3±1.0	67±3%	78±3%
Intervention Patients with Primary Outcome	149	26.1±0.9	73±3%	80±2%

Data presented as mean±SE. *Adherence adjusted for medical leave excludes absences for acute illness, rehospitalization, and scheduled non-study medical appointments.

Table S5: REHAB-HF Intervention Sessions during Index Hospitalization

Number of Patients Receiving Inpatient Sessions (%)	Number of Sessions (mean±SE)
61 (35%)	107 (1.8±0.2)

Table S6: REHAB-HF Intervention Sessions Performed at Home to Enable Transition to Outpatient Facility-Based Outpatient Rehabilitation Intervention

Number of Patients Receiving Home Intervention (%)	Number of Sessions (mean±SE)
23 (13%)	130 (5.6±1.1)

Table S7. Exercise by Patient Report during Maintenance Phase Exercise in Rehabilitation Intervention Participants

	4 Months	5 Months	6 Months
Patients Randomized to Intervention	175	175	175
Patients Alive at Timepoint	161	156	154
Patients Alive with Successful Telephone Contact	123	125	137
Patients Reporting Exercise	101 (82%)	100 (80%)	114 (83%)
Days/Week of Exercise for Those Reporting Exercise	2.3±0.1	2.3±0.1	2.3±0.1

Data presented as N(%) or mean±SE.

Table S8. Usual Care Exercise Therapy Received in 6-month Follow-up by Treatment Group

	Rehabilitation Intervention (n=175)		Control (n=174)	
Type of Therapy	Number of Patients	Number of Sessions	Number of Patients	Number of Sessions
Physical Therapy or Occupational Therapy	36	340	56	643
Cardiac or Pulmonary Rehabilitation	5	78	18	410

Table S9. Causes of Death

Cause of Death	Rehabilitation Intervention	Control
Total Deaths	21	16
Cardiovascular	15	8
Heart Failure	10	6
Sudden Cardiac Death	5	1
Pulmonary Embolism	1	1
Stroke	3	1
Non-cardiovascular	6	8
Pulmonary	0	4
Renal	0	2
Malignancy	1	1
Trauma	1	0
Gastrointestinal	1	0

Table S10. Serious Adverse Events by Treatment Group

	Rehabilitation Intervention (N=175)		Control (N=174)	
Body System	**Number of Patients (%)**	**Total Events**	**Number of Patients (%)**	**Total Events**
Cardiovascular	79 (45%)	146	82 (47%)	155
Heart failure	60 (34%)	106	65 (37%)	116
Atrial flutter / fibrillation	7 (4%)	7	7 (4%)	8
Chest pain	11 (6%)	13	7 (4%)	8
Supraventricular tachycardia	4 (2%)	4	2 (1%)	2
Valve disease	3 (2%)	4	1 (1%)	1
Myocardial infarction	2 (1%)	2	4 (2%)	5
Cardiac arrest	0 (0%)	0	1 (1%)	1
Symptomatic bradycardia	1 (1%)	1	3 (2%)	3
Ventricular fibrillation	0 (0%)	0	0 (0%)	0
Ventricular tachycardia	2 (1%)	2	1 (1%)	1
Minor cardiovascular procedure	3 (2%)	3	7 (4%)	9
Sudden cardiac death	4 (2%)	4	1 (1%)	1
Respiratory, thoracic, and mediastinal disorders	10 (6%)	10	12 (7%)	16
Gastrointestinal disorders	16 (9%)	18	13 (7%)	13
Injury, poisoning, and procedural complications	10 (6%)	10	13 (7%)	14
Nervous system disorders	9 (5%)	10	8 (5%)	11
Infections and infestations	6 (3%)	7	10 (6%)	10
Musculoskeletal disorders	4 (2%)	4	4 (2%)	4
Vascular disorders	5 (3%)	7	6 (3%)	9
Renal and urinary disorders	6 (3%)	8	7 (4%)	8
Metabolism and nutrition disorders	7 (4%)	7	2 (1%)	3
Neoplasms, benign, malignant, and unspecified	4 (2%)	5	2 (1%)	3
Blood and lymphatic system disorders	2 (1%)	2	1 (1%)	1
Psychiatric disorders	0 (0%)	0	2 (1%)	2
Heptobiliary disorders	1 (1%)	1	1 (1%)	1
Reproductive disorders	1 (1%)	1	1 (1%)	0
Immune disorders	1 (1%)	1	0 (0%)	0
Eye disorders	1 (1%)	1	0 (0%)	0
Prescription drug overdose	0 (0%)	0	1 (1%)	1
Total Events	**106 (61%)**	**238**	**115 (66%)**	**251**

Table S11. Non-serious Adverse Events By Treatment Group

Adverse Event	Intervention	Control	All
Heart failure	8	7	15
Chest pain	7	4	11
Tachycardia	3	0	3
Bradycardia	2	0	2
Atrial fibrillation	1	1	2
Hypertension	5	0	5
Hypotension	2	0	2
Dyspnea	4	2	6
Weight Gain	3	0	3
Extremity swelling	0	1	1
Fatigue	2	0	2
Dizziness	10	2	12
Falls (self report)	94	112	206
Musculoskeletal	15	12	27
Infection	10	5	15
Planned procedures	7	4	11
Gastrointestinal	6	5	11
Procedural complication	3	4	7
Hypoglycemia	5	1	6
Renal	3	3	6
Nervous system	4	1	5
Hyperglycemia	4	0	4
Injury	2	1	3
Elevated INR	2	0	2
Headache	2	0	2
Hypokalemia	1	1	2
Hypovolemia	2	0	2
Nose Bleed	1	1	2
Neuropathy	1	1	2
Urinary	0	2	2
Vascular	0	2	2
Anemia	1	0	1
Chronic pulmonary disease exacerbation	0	1	1
Total	**210**	**173**	**383**

Data presented as number of events.