An Innovative Physical Function Intervention for Older Patients Hospitalized for Acute Decompensated Heart Failure

Dalane W. Kitzman, MD
Wake Forest School of Medicine

AMERICAN COLLEGE of CARDIOLOGY

An Innovative Physical Function Intervention for Older Patients Hospitalized for Acute Decompensated Heart Failure

Dalane W. Kitzman, MD

David J. Whellan, MD, Pamela Duncan, PhD, PT, Amy M. Pastva, PhD, PT, Robert J. Mentz, MD, Gordon R. Reeves, MD, Benjamin Nelson, MS, Haiying Chen, PhD, Bharathi Upadhya, MD, Shelby D. Reed, PhD, Mark A. Espeland, PhD, Leigh Hewston, PhD, and Christopher O'Connor, MD

Background and Rationale

- Acute decompensated heart failure (ADHF) is the most frequent hospital discharge diagnosis in older persons
- Poor quality of life, frequent rehospitalization, high mortality, loss of independence, nursing home admission
- Most intervention trials have been neutral
- Suggests outcomes may be driven partly by mechanisms that have been overlooked

Reeves et al, Am Heart J 2017; PMID: 28267466

Contribution of Physical Dysfunction to Poor Outcomes in Older ADHF Patients

- Pilot study showed marked impairments in all domains of physical function: balance, mobility, strength, endurance. >90% were frail/pre-frail.
- However, physical dysfunction is generally not addressed in ADHF clinical care pathways.
- Hospitalized ADHF patients were excluded from most prior exercise / rehab trials, and from reimbursement for traditional cardiac rehab by CMS policy "due to lack of evidence and potential for harm."
- Subjecting frail older patients to traditional endurance training can be ineffective and result in increased injuries and falls.

Reeves et, Am J Cardiol 2016, PMID: 27156830

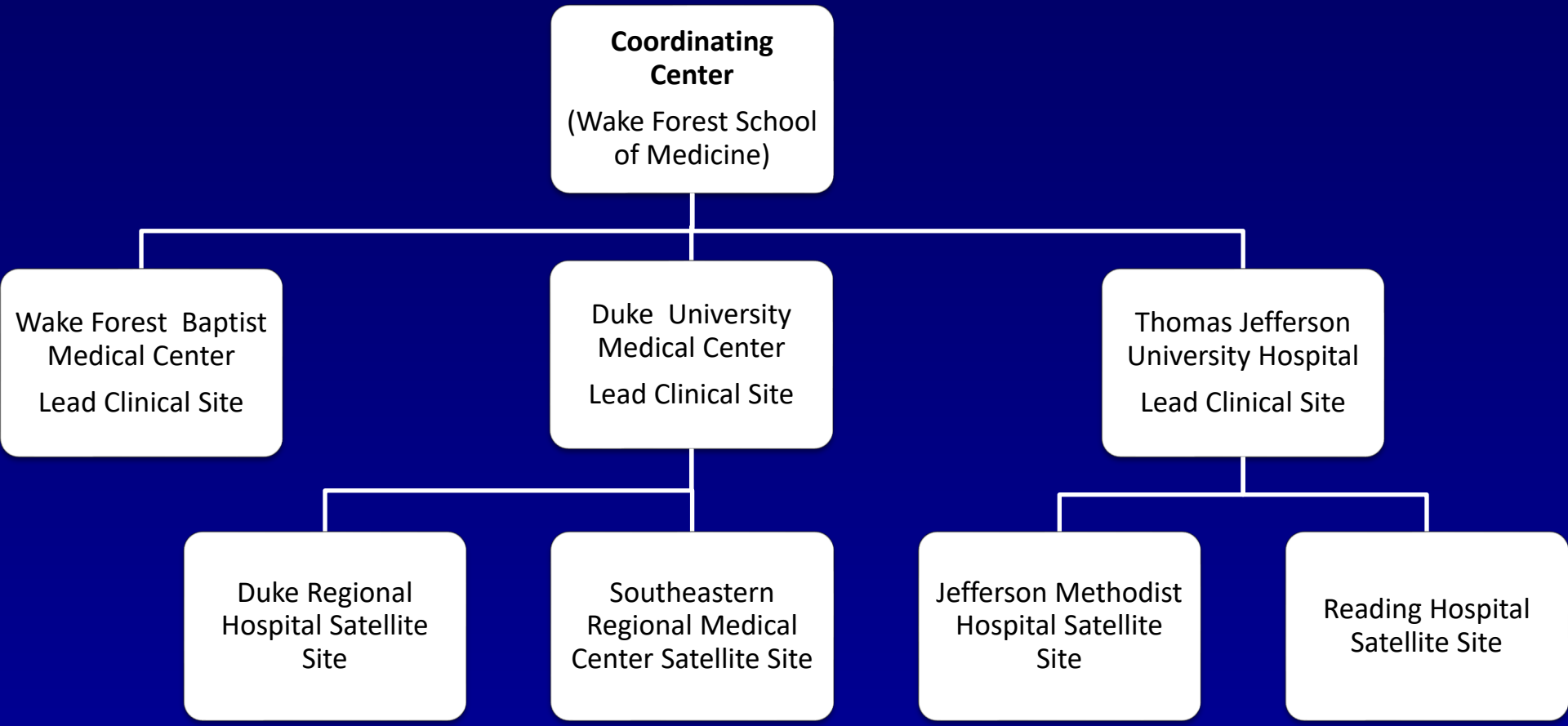
REHAB-HF Study Hypothesis

In frail, older patients hospitalized for ADHF, an innovative, early, transitional, tailored, progressive, multi-domain rehabilitation intervention that begins during hospitalization and continues for 3 months following discharge will improve physical function and reduce rehospitalizations

Organizational Structure:

-Clinical hubs with satellite sites

-4/7 sites were community hospitals



Kitzman et al NEJM 2021

REHAB-HF Inclusion Criteria

Inclusion Criteria:

- Adequate clinical stability to allow participation in study assessments and intervention
- Independent with basic ADLs and ambulation prior to admission
- Able to walk 4 m at enrollment (assistive device allowed)

Exclusion Criteria:

- Acute MI, LVAD, planned surgery
- Planned discharge to skilled nursing facility
- Life expectancy < 1 year
- Impairment from stroke, dementia, or other medical disorder that precluded participation
- Severe CKD (eGFR< 20) or dialysis

Reeves et, Am Heart J 2017, PMID: 28267466

Innovative REHAB-HF intervention

- Designed specifically for older, **frail** patients hospitalized with ADHF
- Conducted 1:1 by a trained therapist
- Used a 16-cell grid with 4 performance levels for each of the 4 domains of physical function to i**ndividualize** the program to accommodate all levels of disability
- Specific exercises to progressively build in each domain
- Corrected balance, mobility, strength before endurance

Pastva et al, Contemporary Clinical Trials 2018, PMID: 29079391

REHAB-HF 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.**

Pastva et al, Am Heart J 2017

Innovative REHAB-HF intervention

- Began in hospital or as soon as possible thereafter
- Transitioned from hospital to outpatient facility to home
- Outpatient 3 times / week for 12 weeks
- Home exercise on non-facility days began after a home visit and evaluation of built environment
- After 12 weeks, transitioned to self-directed, home based

Pastva et al, Contemporary Clinical Trials 2018, PMID: 29079391

Attention Control Group

- Standard, usual care ordered by the participant's treating physician, which could include routine physical therapy or cardiac / pulmonary rehab
- Bi-weekly contact with study staff for first 3 months
- Monthly telephone calls (same as rehabilitation group) in final 3 months

Reeves et, Am Heart J 2017, PMID: 28267466

REHAB-HF Outcomes

- Primary outcome: Short physical performance battery (SPPB)
  - Well-accepted measure of physical function in older persons
  - Clinically meaningful: predicts clinical outcomes; responds to interventions; associated with improved clinical outcomes
  - Assessed by blinded observer
- Secondary outcome: All-cause rehospitalizations

Reeves et, Am Heart J 2017, PMID: 28267466

Baseline Characteristics of the Trial Population

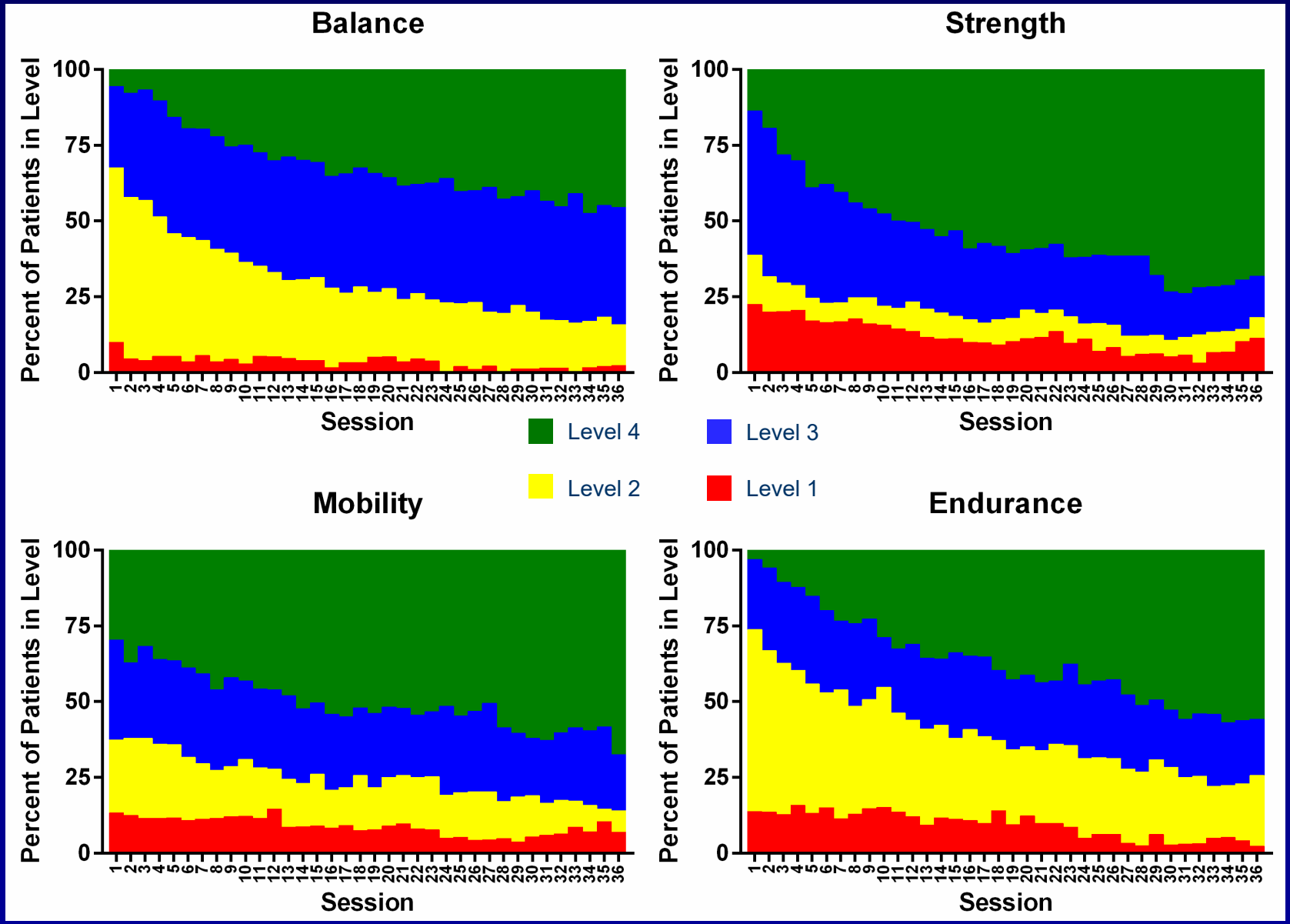
Baseline Characteristics	Rehabilitation Intervention (N=175)	Control (N=174)
Age (mean +/-SD)	73.1±8.5	72.2±7.7
Female	49%	56%
Non-white	46%	52%
BMI (kg/m^2)	32.9±8.2	33.0±8.9
Ejection fraction ≥45%	53%	53%
NYHA Class		
II or III	76%	72%
IV	23%	29%
N-terminal proBNP, pg/mL (n=117), median (IQR)	2527 (1395-4858)	3615 (1874-8637)
B-type natriuretic peptide, pg/mL (n=204), median (IQR)	595 (259-1292)	645 (381-1072)
Days Hospitalized at Index Hospitalization, median (IQR)	4 (3-7)	5 (3-7)
Previous Hospitalizations in previous 6 months	43%	46%
Total Comorbidities	5.4 ± 2.0	5.0 ± 1.9
Geriatric Conditions		
Frail or Pre-Frail (by Fried Criteria)	97%	97%
Depression (by EMR documentation)	17%	19%
Dementia or cognitive impairment (by EMR documentation)	3%	2%
Urinary incontinence	13%	15%
Patients with falls in previous 3 months	16%	14%

Kitzman et al NEJM 2021

Retention, Adherence, Safety

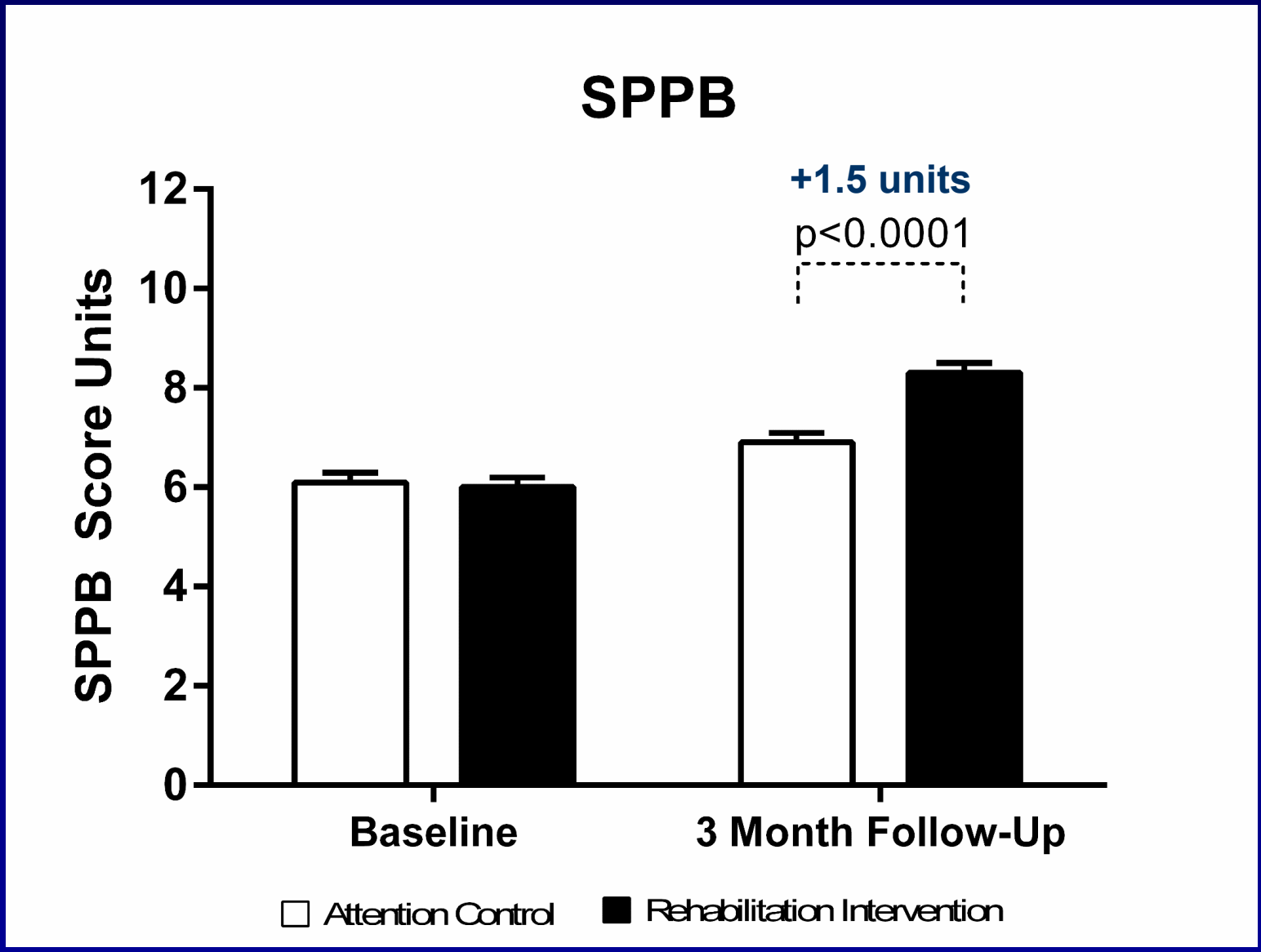
- Intervention retention: 82%
- Medical event-corrected adherence: 78%
- Retention for the secondary outcome: 99.4%
- At 6 months, 83% of intervention patients reported regular home exercise
- Safety: 3 serious adverse events possibly related to the intervention, all self-limited

Intervention Progression



Kitzman et al NEJM 2021

Primary Outcome: SPPB at 3-Month Follow-up



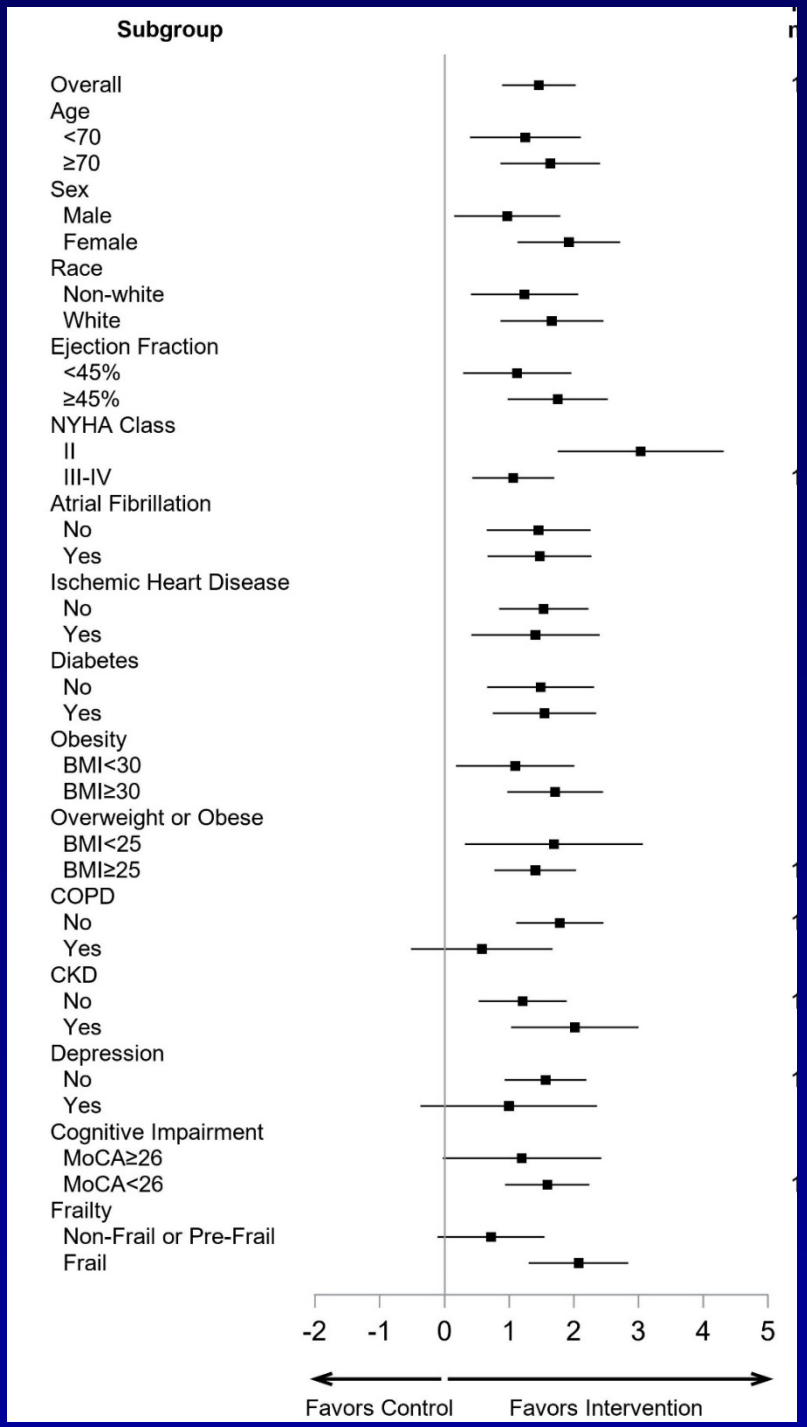
Clinically meaningful change is 0.5 units

Kitzman et al NEJM 2021

Forest plot of effect sizes and 95% CI for SPPB

- Relatively uniform results for the intervention among pre-specified subgroups

Kitzman et al NEJM 2021

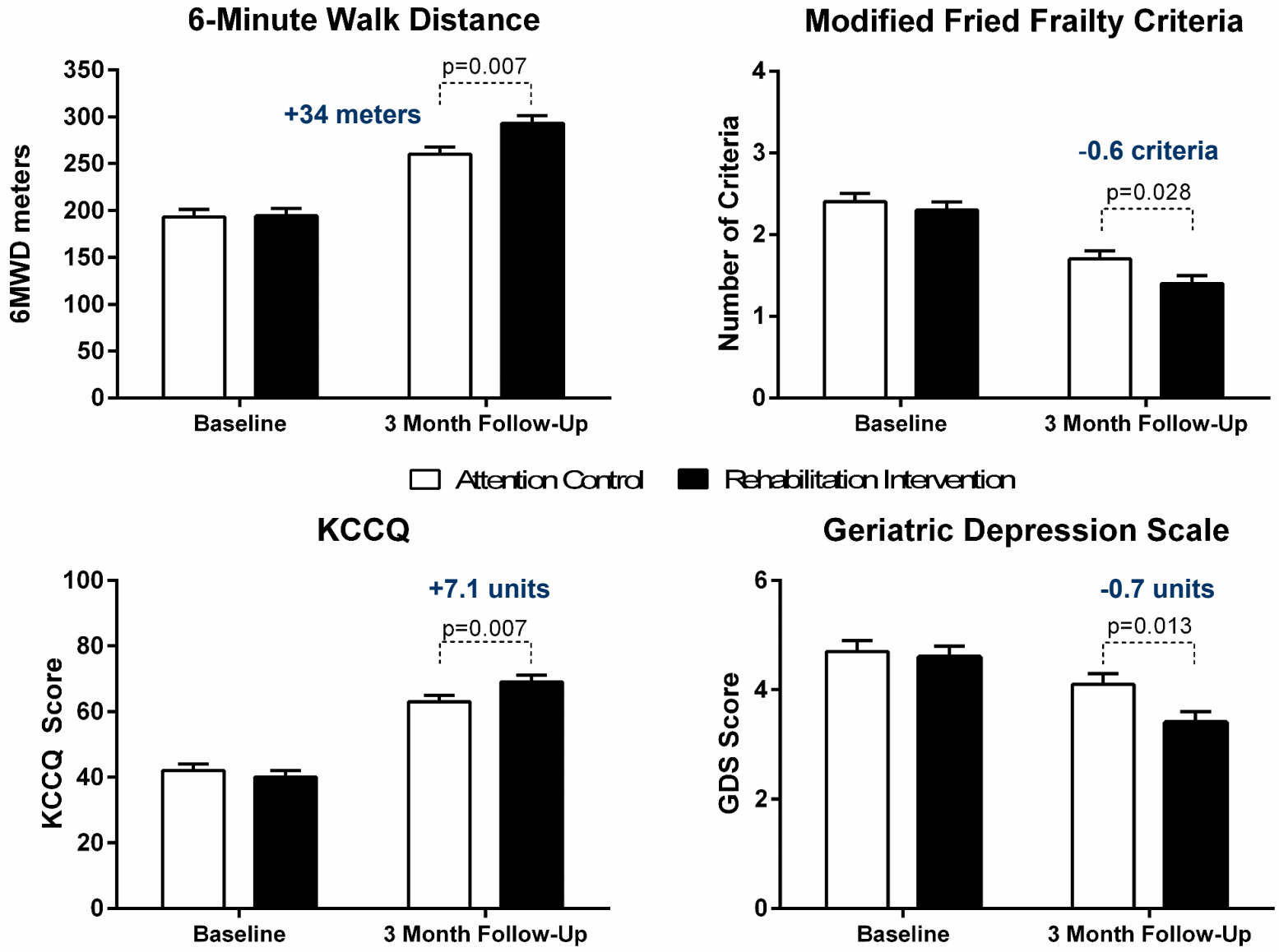


The REHAB-HF intervention was robust despite substantial cross-over treatment in the Attention Control Arm

- 43% of the Attention Control arm received usual care therapies (PT, Cardiac / Pulmonary rehab)
- In post-hoc analyses, when the patients were compared to Rehab Intervention, effect sizes were even larger for SPPB and KCCQ (+1.9 units and +8 units, respectively)
- Thus, the novel REHAB-HF Intervention appeared to provide large benefit even on top of usual care physical rehab treatments

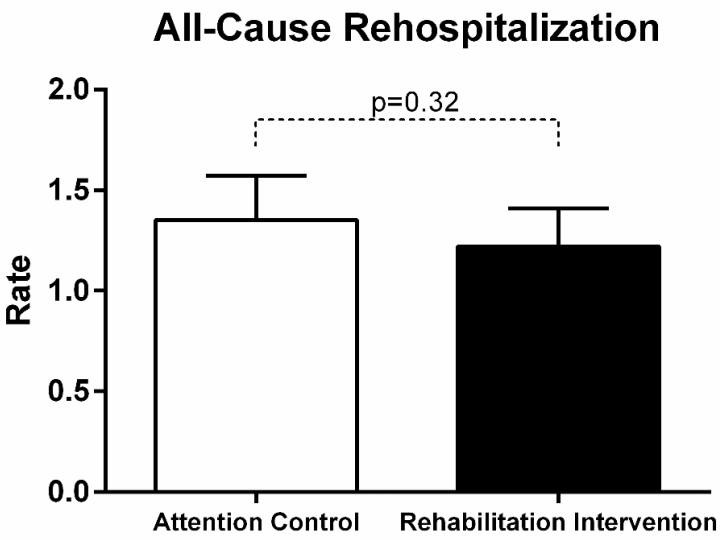
Kitzman et al NEJM 2021

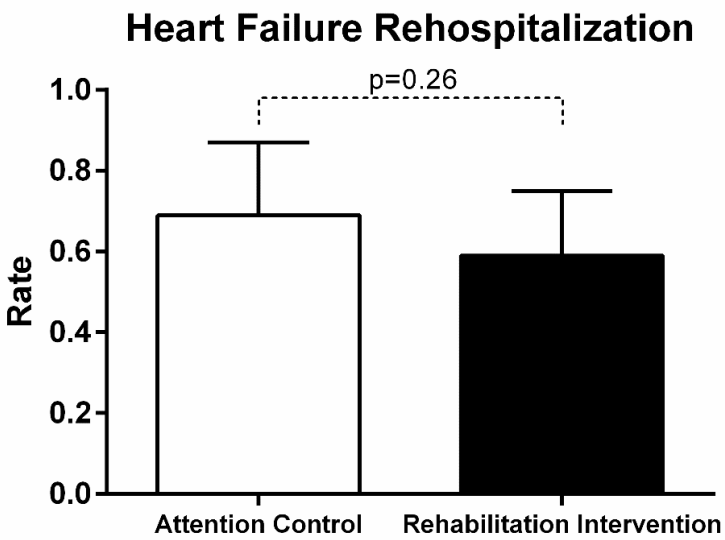
Other REHAB-HF 3-Month Outcomes



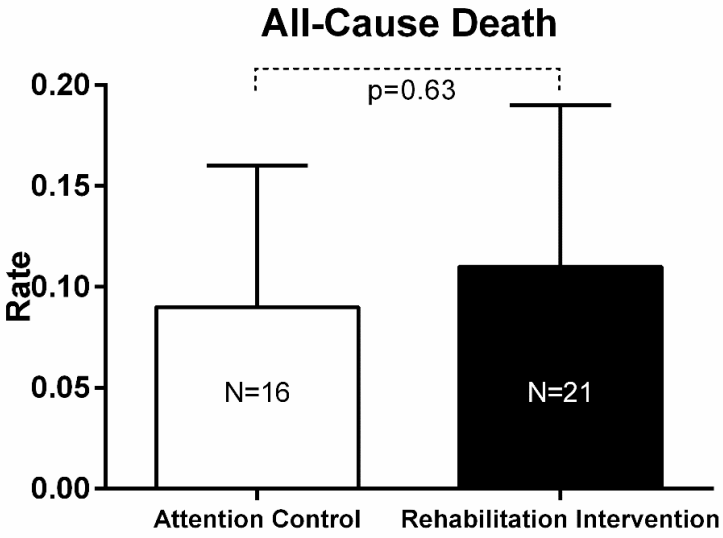
Kitzman et al NEJM 2021

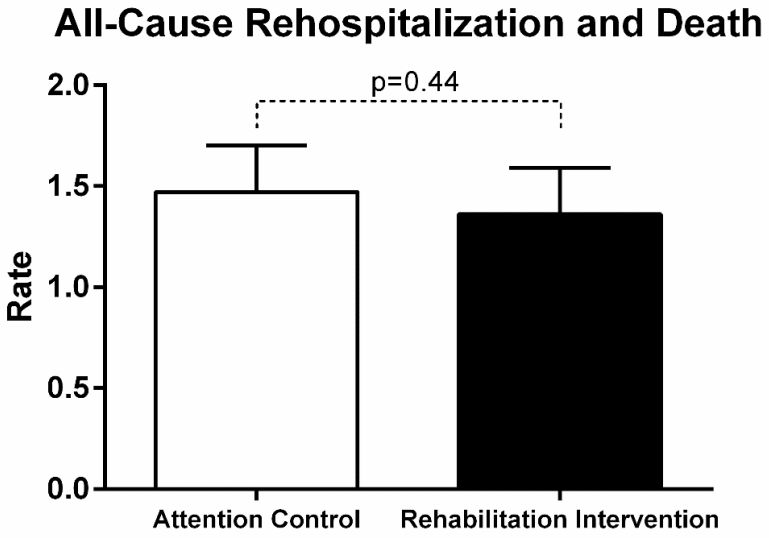
REHAB-HF 6-Month Outcomes





Attention Control Rehabilitation Intervention





Kitzman et al NEJM 2021

Summary of REHAB-HF Results

- Diverse, older population with high comorbidity burden
- Markedly impaired physical function and quality of life, and high rates of depression and frailty
- Intervention was feasible in both tertiary care and community hospital settings
- Excellent retention and intervention adherence

Summary of REHAB-HF Results

- The innovative intervention produced a large, significant improvement in SPPB that was relatively uniform across pre-specified subgroups
- Large improvements in 6-minute walk distance, quality-of-life, Fried Frailty score, and depression
- High rate of clinical events:
  - 1.17 rehospitalizations per patient over 6 months
  - 31% of patients had multiple hospitalizations
  - >10% died
- No statistically significant differences in rehospitalizations or death

National Institute on Aging grant: R01AG045551