Improving Quality of Life in COPD and Heart Failure: Unpacking a Successful Multicomponent Virtual Team Intervention

The ADAPT Randomized Clinical Trial

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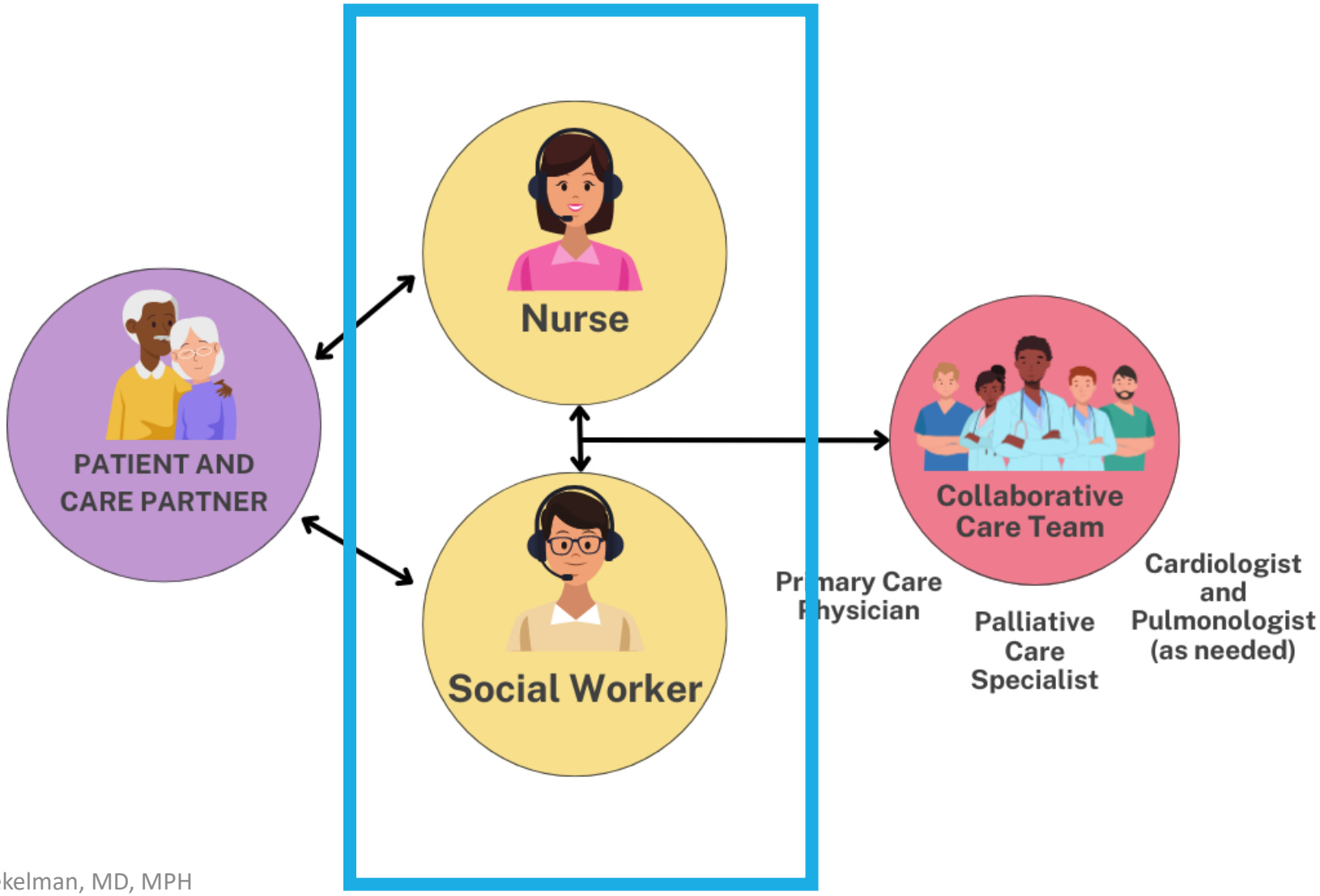
Background: Advancing Symptom Alleviation with Palliative Treatment (ADAPT)

COPD	HF	ILD

- Same symptoms persist despite disease focused therapies
- 50-60% clinically significant depression; anxiety also common
- Not enough palliative care specialists
- Palliative care approaches should be integrated into care before the end of life and be scalable

ADAPT Intervention: team, telecare (i.e., virtual)



Collaborative Care Team

- Weekly meetings
- Supervision
- Tests, consults, treatments

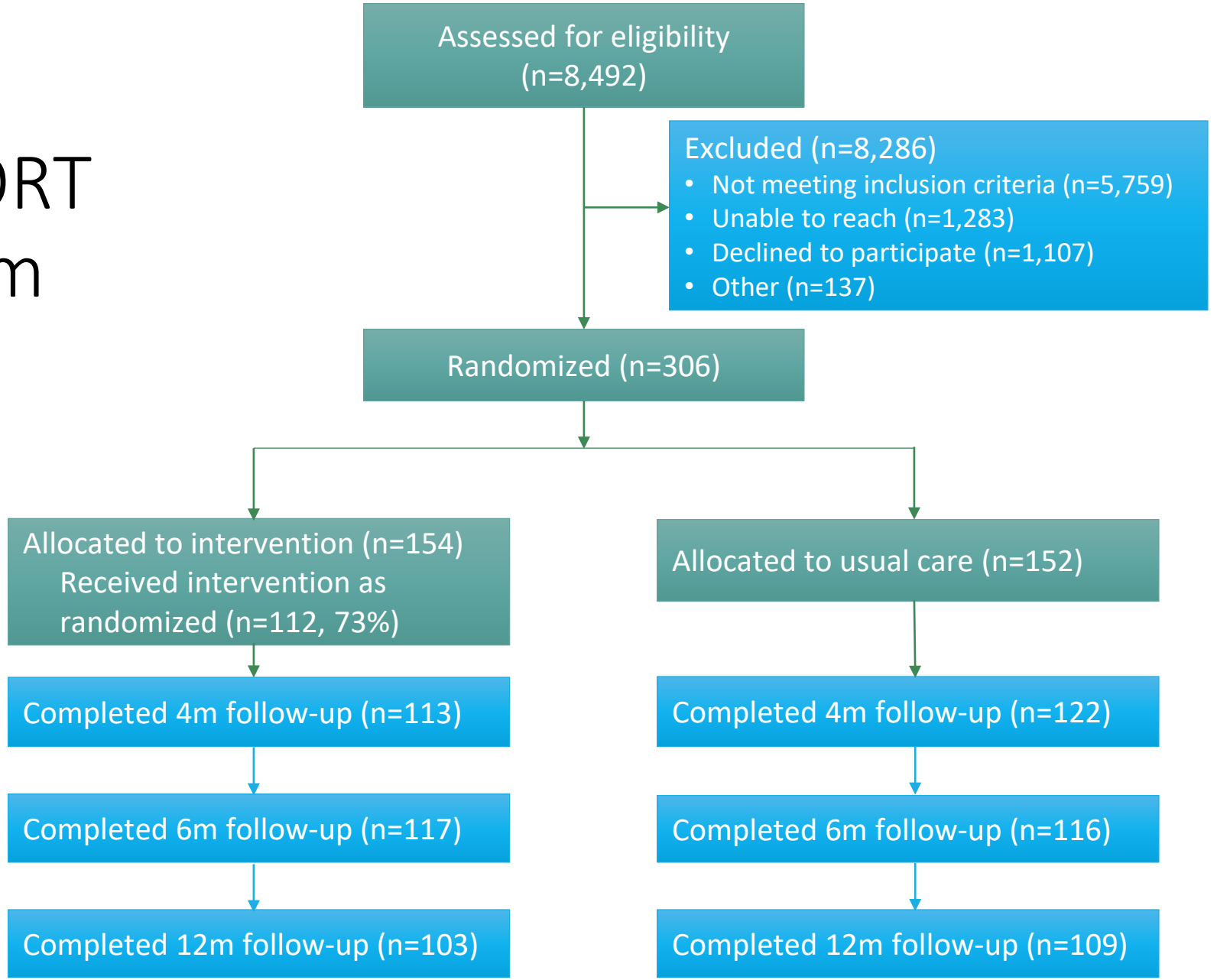
Aim and Study Design

- Determine the effect of ADAPT on quality of life, measured using the FACT-G (range, 0 to 108, MCID ≥4)
  - Primary outcome: difference between ADAPT and control in the change in FACT-G from baseline to 6 months
  - Secondary outcomes: disease-specific health status, depression, anxiety
- RCT: ADAPT vs usual care
- Study outcomes: baseline, 4, 6, and 12 months

Setting & Study Population

- Two VA Health Systems: Eastern Colorado, Puget Sound
- Patients with:
  - COPD, HF, or ILD
  - High risk of hospitalization or death (top 20^{th} percentile)
  - Low quality of life (FACT-G score ≤ 70)

ADAPT CONSORT Diagram



Demographics (n=306)

Male	90%
White	80%
Age, mean (SD)	68.9 (7.7)

Diseases, prior hospitalizations, mental health use

COPD only	177 (58%)
HF only	67 (22%)
COPD and HF	49 (16%)
ILD	13 (4%)

Comorbidities, mean (SD)	7.6 (2.3)
Hospitalized in prior 12 months	47%
2 or more hospitalizations	21%
Mental health specialists	Meds (28%), counseling (32%)

Selected Clinical Characteristics

COPD (n=226)	
Oxygen use	63%
GOLD III/IV COPD (among those with spirometry)	50%
Pulmonologist	61%

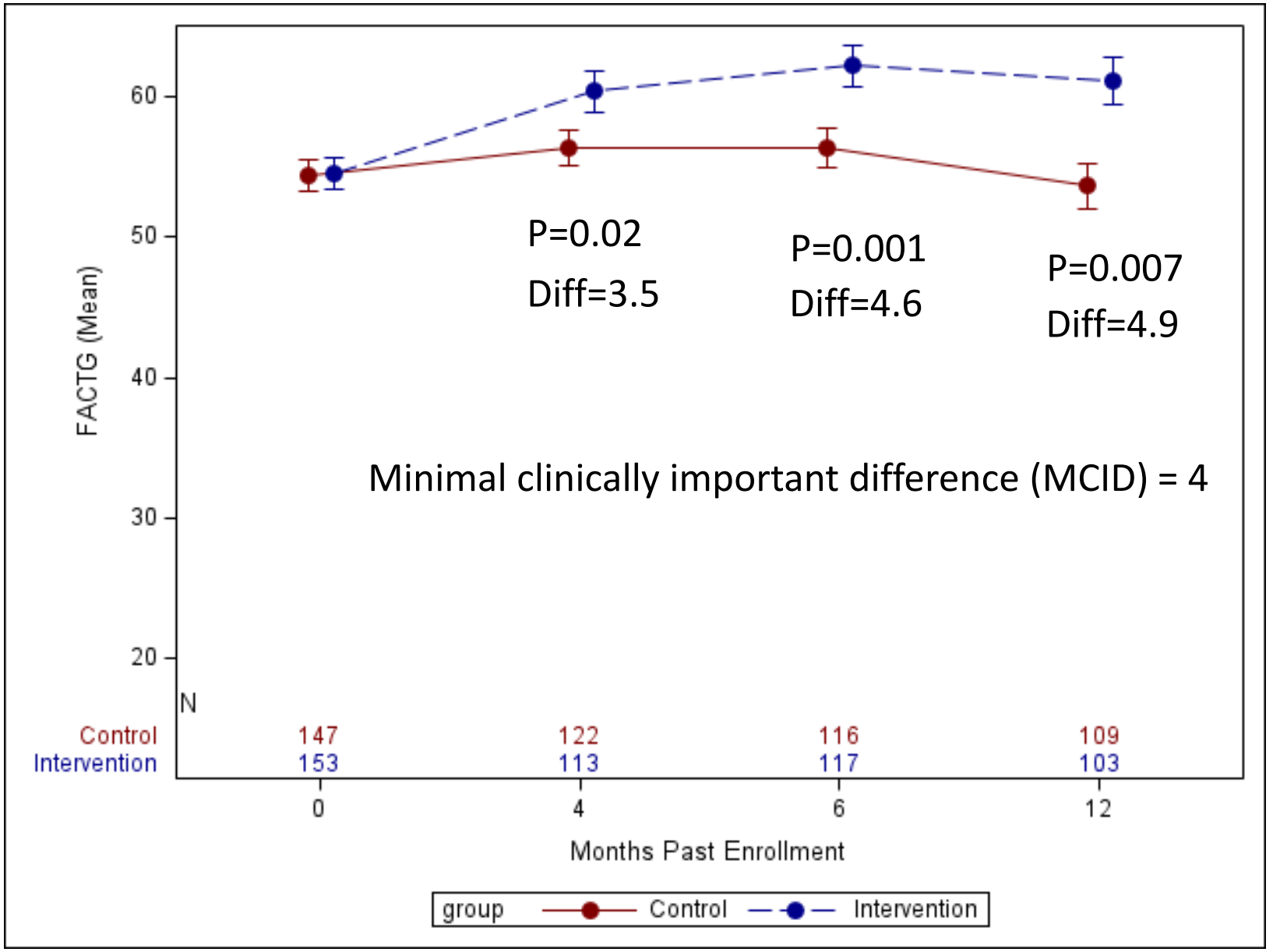
Heart Failure (n=116)	
Reduced EF	53%
Moderately/Severely reduced EF	25%
NYHA 3/4	62%
Cardiologist	75%

ADAPT intervention

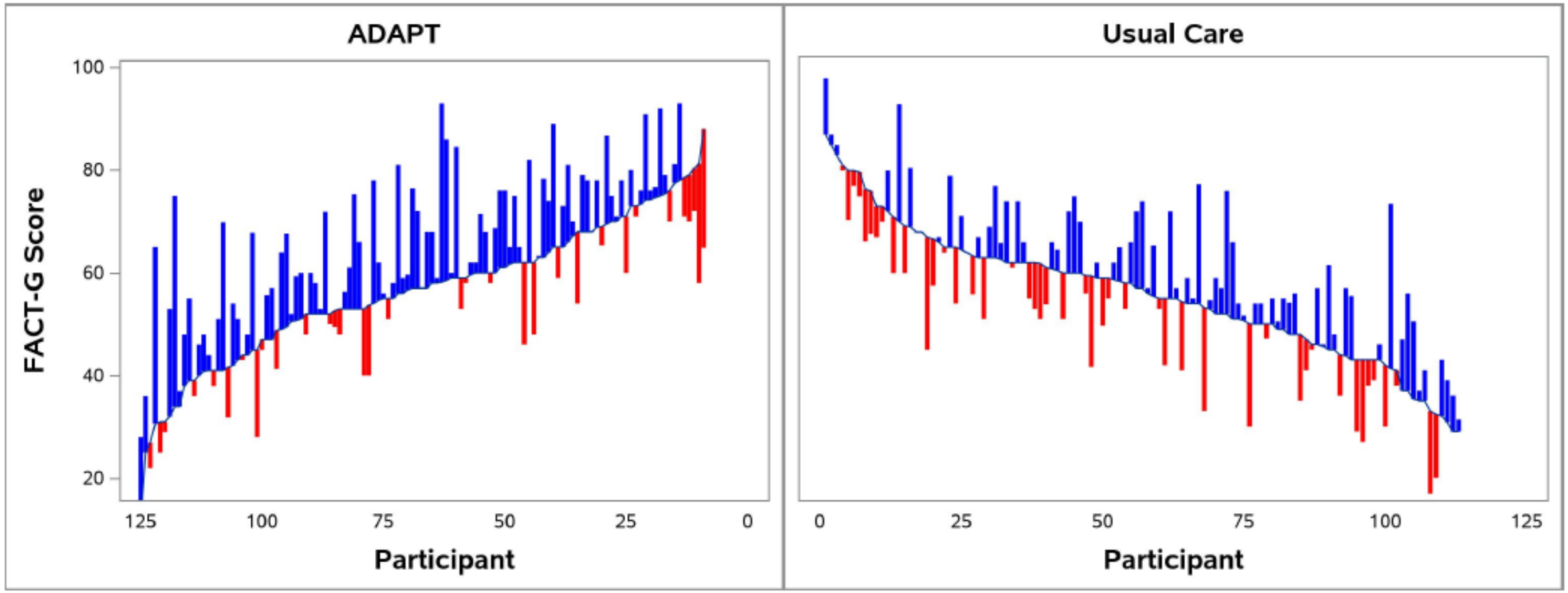
- 73% (112/154) received intervention as randomized
- 10.4 (SD 3.3) intervention visits per patient
  - Nurse: 8.6 (SD 2.9)
  - Social worker: 7.1 (SD 2.3)
- Intervention duration: 3.8 (SD 1.1) months
- Fidelity (intervention visits in 21 participants): 99.8% nurse; 98.5% social worker

Initial symptom targeted[g]	n=153
Shortness of breath	52 (34.0)
Pain	23 (15.0)
Sleep disturbance	23 (15.0)
Depression	22 (14.4)
Fatigue	22 (14.4)
Other symptom	16 (10.5)

Quality of Life Improved with the ADAPT Intervention



Baseline to 6-Month Change in FACT-G Score



ADAPT Improved Multiple Quality of Life Outcomes

Outcome	Difference (6 months)	MCID	Effect size (p-value)
Overall Quality of Life (FACT-G)	4.6	4	**0.41 (p=0.001)**
COPD health status (CCQ)	0.32	0.4	**0.41 (p=0.01)**
Heart failure health status (KCCQ-SF)	7.1	3.6 to 5	**0.44 (p=0.04)**
Depression (PHQ-8)	2.4	3	**-0.50 (p<0.001)**
Anxiety (GAD-7)	2.4	2-4	**-0.51 (p<0.001)**

MCID = minimal clinically important difference

Heterogeneity of treatment effect, hospitalizations, mortality

- No difference in intervention effect on HF vs COPD
- No differences in hospitalizations
  - not hospitalized (109, intervention; 119, control)
  - hospitalized once (24, intervention; 17, control)
  - twice or more (9 intervention, 9 control)
- At one year, 6/154 (3.9%) intervention and 5/152 (3.3%) usual care patients had died (p=0.76)

Limitations

- External validity
- Participants could not be blinded
- Lack of attention control

Conclusion

- A nurse and social worker palliative telecare team demonstrated early, persistent, clinically meaningful improvements in quality of life for high-risk outpatients with COPD, HF, and ILD.
- This virtual care model leveraged a team of nurses, social workers, and physicians across two large VA health systems to increase the reach of palliative care to common, serious non-cancer illnesses.

Research

JAMA | Original Investigation

Nurse and Social Worker Palliative Telecare Team and Quality of Life in Patients With COPD, Heart Failure, or Interstitial Lung Disease
The ADAPT Randomized Clinical Trial

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Pragmatic?

PRECIS-2

- Eligibility: included participants of any age, most medical morbidities; targeted those at high risk, poor quality of life
- Recruitment
- Setting: representative of VA health care settings
- Organization: nurse, social worker, team care; a multifaceted or “complex” intervention[1]
- Flexibility (delivery, adherence): flexibility allowed
- Outcome: patient reported
- Analysis: intent to treat, all available data

[1]Skivington K et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021 Sep 30;374:n2061. doi: 10.1136/bmj.n2061. PMID: 34593508.

Next steps

- Intervention effect on utilization, end of life outcomes
- Can this care model be useful in advanced liver or renal disease?
- Testing in community settings with community-based providers
  - NIH Stage III: focus on internal validity
  - NIH Stage IV: focus on external validity
- Examine strategies of implementation and adoption (NIH Stage V)

NIH Stage Model for Behavioral Intervention Development | Science Of Behavior Change

What's in the "black box" of ADAPT?

- Collaborative care team discussed each participant 3.7 times and made 7 recommendations per participant
  - Common recommendations: consults/referrals and adding medications
- 7-9 nurse and social work telephone sessions lasting 40-45 minutes on average over 3-4 months
- > 80% completion of nurse and social work sessions

TRAINING

8 hours of online training for nurse and social worker

CASELOAD

- Part time (0.5 FTE) nurse and social worker: 40-50 patients
- 20-25 sessions/week

Collaborative

NURSE AND SOCIAL WORKER SESSIONS

6-10 Nurse Sessions
6-10 Social Work Sessions
Session Length: 15-45 minutes

How can we implement ADAPT in new settings with community providers?

- Replicating Effective Programs (REP) Framework + Practical, Robust Implementation and Sustainability Model (PRISM)
  - **Pre-conditions phase:**
    - Explore site-specific barriers and facilitators to implementation (PRISM contextual domains)
  - **Pre-implementation phase**:
    - Form a working group of key informants (e.g. RN/SW who will deliver intervention, clinical leadership)
    - Refine intervention content, workflows, staff trainings for new setting
    - Co-create implementation strategies to fit the new setting
    - Select pragmatic outcomes that matter to key informants
  - **Implementation Phase:**
    - Pilot to evaluate if ADAPT is feasible, acceptable, and appropriate in new settings and if providers can deliver with fidelity

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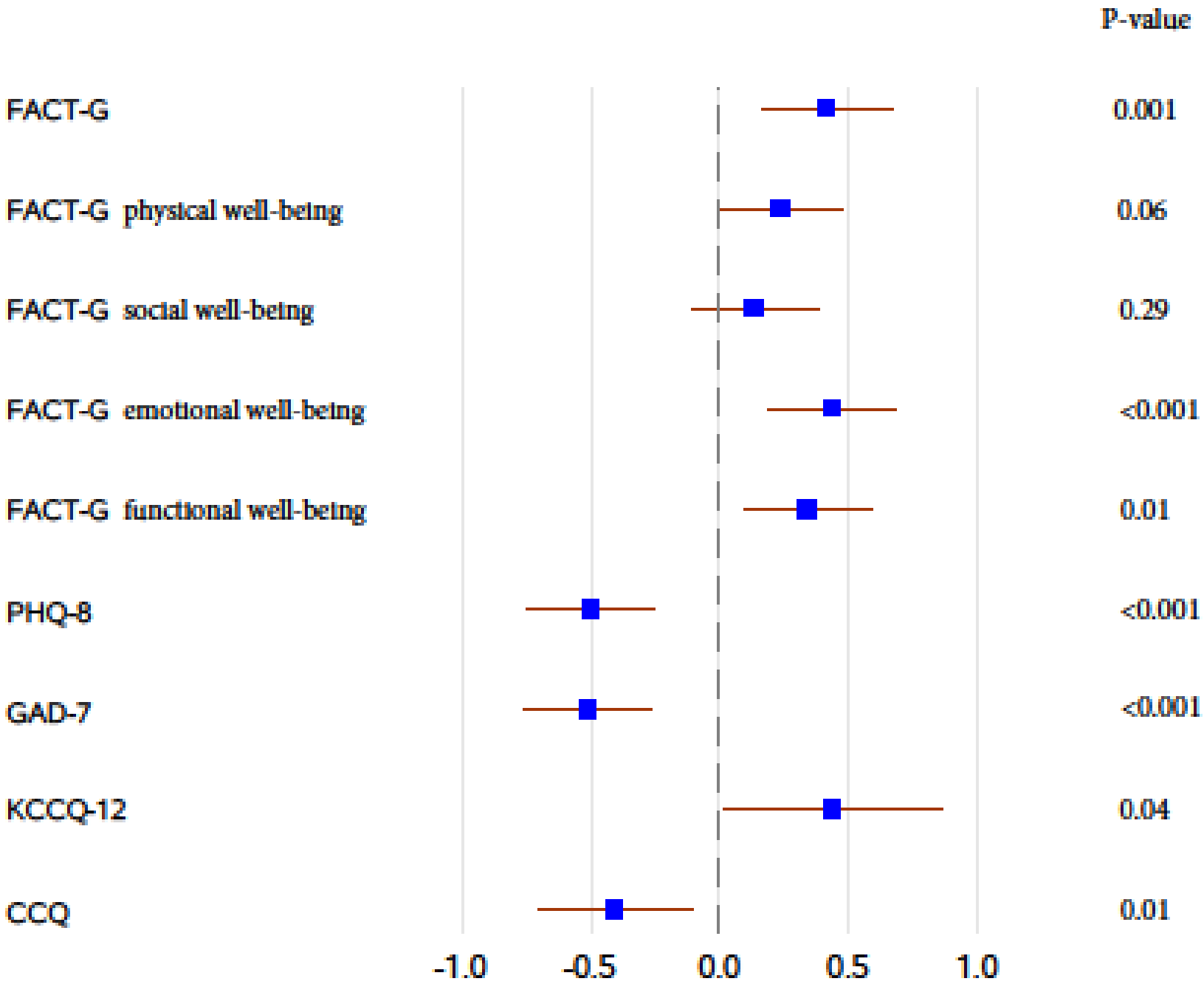
- Contributors: Marilyn Sloan, BS; Ed Hess, PhD; Brianna Moss, BS; Kelly Blanchard, LCSW; Brianne Morgan, RN; Michelle Upham, MA; Thomas Glorioso, MS; Anne Hines PhD; David Gaskin, BA; Jessica-Jean Casler, PhD; Madhura Gokhale, MS; Valerie Baldermann, BS; Lubin Deng, AB; Theresa Kulas, RN; Barbara Ciminelli, RN

Extra slides

Analysis

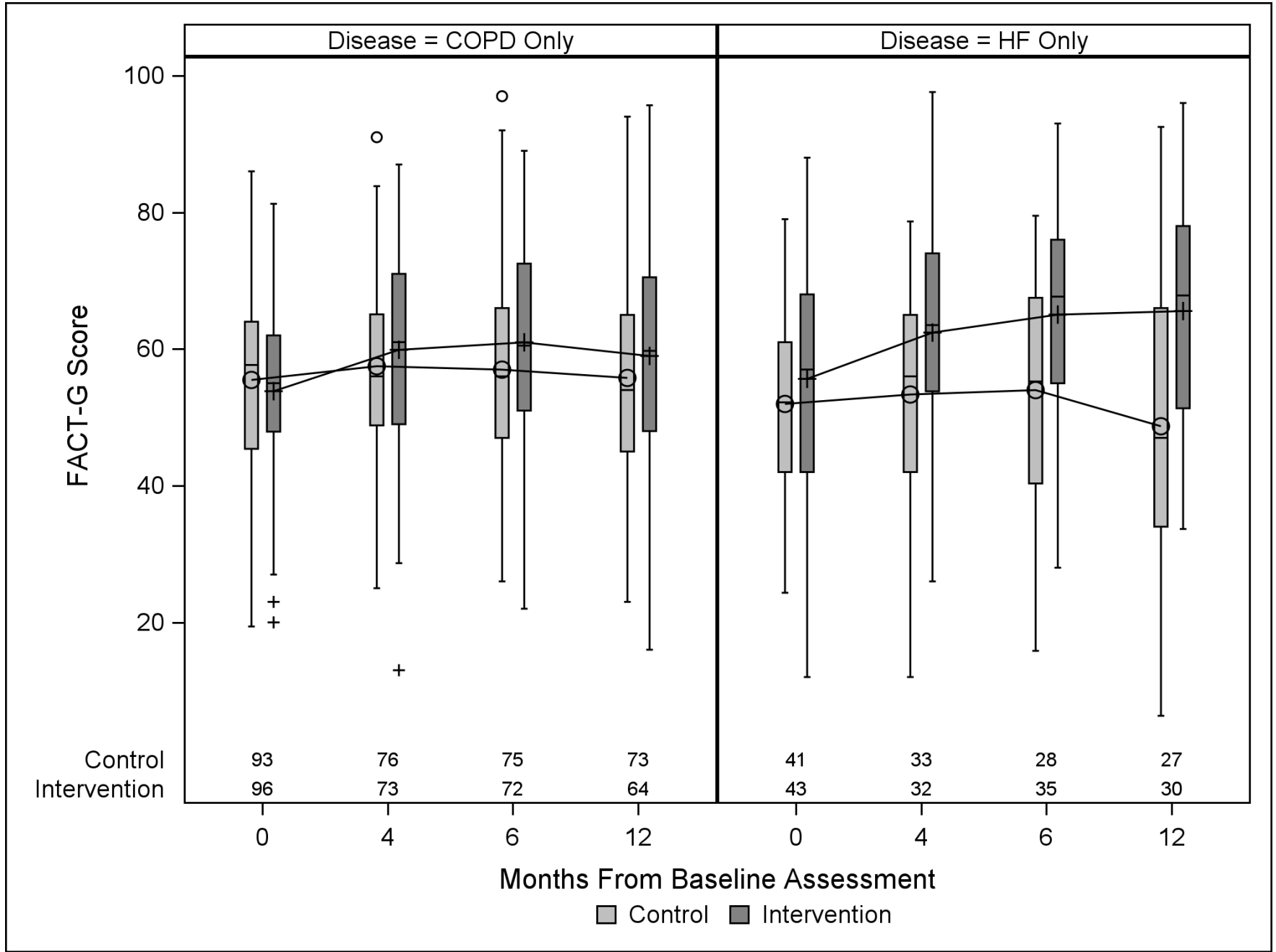
- Goal sample size 300
  - 85% power to detect an effect size of 0.4 (two-sided test, alpha=0.05).
  - This effect size reflects the minimal clinically important difference on the FACT-G of 4-6 points.
- Intent to treat
- Repeated measures analysis used maximum likelihood estimation for incomplete data with linear mixed models


P-value
FACT-G
0.001
FACT-G physical well-being
0.06
FACT-G social well-being
0.29
FACT-G emotional well-being
<0.001
FACT-G functional well-being
0.01
PHQ-8
<0.001
GAD-7
<0.001
KCCQ-12
0.04
CCQ
0.01
-1.0
-0.5
0.0
0.5
1.0

FACT-G Improved with ADAPT Intervention

ADAPT	Intervention	Control	Between-group Difference in Change From Baseline		
No. of months after baseline	Mean (SE)	Mean (SE)	Mean (SE) (95% CI)	*P* value	Effect size, Cohen *d* (95% CI)
0	52.9 (4.0)	52.7 (4.0)	0.2 (1.6)	0.89	0.01 (-0.21 to 0.24)
4	58.1 (4.0)	54.4 (4.0)	3.5 (1.5)	0.02	0.30 (0.05 to 0.55)
6	58.9 (4.0)	54.1 (4.0)	4.6 (1.4)	0.001	0.42 (0.16 to 0.66)
12	58.9 (4.1)	53.1 (4.1)	4.9 (1.8)	0.007	0.36 (0.10 to 0.62)

FACT-G Score Over Time by Disease



Nursing Sessions

- **Session 1:** Initial symptom assessment and rapport building
- **Session 2:** Activity goal setting
- **Session 3:** Healthcare navigation
- **Session 4:** Disease education
- **Session 5:** Goals of care
- **Session 6:** Close-out

Social Worker Sessions

- **Session 1:** Initial psychosocial assessment
- **Session 2:** Pacing yourself
- **Session 3:** Deep breathing and relaxation
- **Session 4:** Change in role and asking for/accepting help
- **Session 5:** Goals of care
- **Session 6:** Close-out