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CLINICAL INVESTIGATION

Home-Based Rehabilitation After Transcatheter Aortic Valve Replacement (REHAB-TAVR): A Pilot Randomized Controlled Trial

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Keywords: randomized controlled trial | rehabilitation | transcatheter aortic valve replacement

ABSTRACT

Background: The benefit of early cardiac rehabilitation after transcatheter aortic valve replacement (TAVR) is not well established. This pilot study evaluated the feasibility and short-term effects of a home-based exercise program, with or without cognitive-behavioral intervention (CBI).

Methods: We randomized 51 patients (mean age, 83.9 years; 19 women) to a home-based exercise program with CBI (Group A; $n=18$) or without CBI (Group B; $n=15$), or telephone-based education control (Group C; $n=18$). The exercise program focusing on balance, flexibility, strength, and endurance began within 7 days post-discharge and was delivered once weekly by a physical therapist for 8 weeks. CBI included discussions on exercise benefits and barriers, goal setting, detailed exercise planning, and a weekly cash adherence incentive. The primary outcome was a disability score (range: 0–22; higher scores indicate greater disability) at 8 weeks. Secondary outcomes included the Short Physical Performance Battery (SPPB) (range: 0–12; higher scores indicate better function), self-efficacy, and outcome expectation scores. Feasibility outcomes included adherence and drop-out rates.

Results: Fifteen participants (83.3%) in Group A, 10 (58.8%) in Group B, and 10 (52.6%) in Group C completed ≥ 5 of the eight assigned weekly sessions ($p=0.196$). Two participants in each group were lost to follow-up. At 8 weeks, the home-based exercise groups (Group A and B combined) demonstrated lower disability scores (mean [SE]: 2.6 [0.3] vs. 4.5 [0.5]; $p=0.042$) and higher SPPB scores (9.5 [0.6] vs. 6.5 [0.8]; $p=0.003$) compared with the education group (Group C). Group A had lower disability scores than Group B (2.1 [0.4] vs. 3.4 [0.5]; $p=0.047$), with no differences in self-efficacy and outcome expectation scores.

Ms. Rapley is currently at Eli Lilly. This work was performed when Drs. Percy and Kaneko were at Brigham and Women's Hospital, Boston, MA.

Conclusions: An early, home-based, multi-domain exercise program appears feasible and may prevent disability and improve physical function in older adults after TAVR. Adding CBI, including a modest cash incentive, showed trends toward improved adherence and reduced disability.
Trial Registration: NCT02805309

1 | Background

Despite the minimally invasive nature of transcatheter aortic valve replacement (TAVR), functional recovery trajectories vary considerably among older adults [1, 2]. A prospective cohort study revealed that most functional status changes occur within the first 3 months post-TAVR, with minimal changes thereafter [1]. This suggests that early rehabilitation may be crucial for achieving long-term improvements in physical function and quality of life in these patients.

The clinical benefits of cardiac rehabilitation after heart valve surgery are less well established compared to those for coronary artery disease and heart failure [3]. Cardiac rehabilitation, typically based on aerobic exercise, has shown reductions in all-cause or cardiovascular mortality, hospitalizations, and improvements in quality of life for patients with coronary heart disease [4] and heart failure [5]. However, participation in cardiac rehabilitation remains suboptimal due to various barriers, including individual factors (e.g., advanced age, comorbidities), socioeconomic challenges (e.g., costs, low income), logistical issues (e.g., transportation, scheduling conflicts), and psychosocial factors (e.g., lack of social support) [6]. These barriers are particularly problematic among patients undergoing TAVR, many of whom have frailty, mobility limitations, cognitive impairment, and depression [1, 2], which further impede participation. A multi-domain exercise program that targets balance, flexibility, strength, and endurance may improve functional status and quality of life in these patients, as demonstrated in a single-arm pilot study of TAVR patients [7]. Similar programs have proven effective in improving physical function among older patients with acute decompensated heart failure [8]. Additionally, home-based rehabilitation [9, 10] or cognitive behavioral interventions (CBI) [11–13] may overcome barriers and further enhance the benefits of exercise [14].

In this pilot randomized controlled trial (RCT), we aimed to examine the short-term effects of a home-based exercise program, with or without CBI, versus an attention-control educational intervention on physical function and disability in older adults discharged home following TAVR. We tested two hypotheses: (1) home-based exercise would improve physical function and reduce disability more effectively than education, and (2) home-based exercise with CBI would benefit more compared with home-based exercise without CBI. Additionally, we evaluated the feasibility of enrollment, intervention delivery, and outcome assessments to inform the design of a definitive RCT.

2 | Materials and Methods

This RCT (NCT02805309) was performed at Beth Israel Deaconess Medical Center and Brigham and Women's Hospital in Boston, Massachusetts. The Institutional Review Board at each participating institution approved this study, and written informed consent was obtained from all participants. The study protocol is available in Supporting Information 1.

2.1 | Enrollment and Randomization

The enrollment began in August 2017 and concluded in May 2020 due to the onset of the Coronavirus Disease 2019 (COVID-19) pandemic. Patients were eligible if they were 65 years or older, had undergone TAVR, lived within 20 miles of the recruiting site, and planned for home discharge. Exclusion criteria included: (1) stroke or other medical conditions preventing participation in home-based exercise; (2) Mini-Mental State Examination (MMSE) score < 15; (3) concurrent enrollment in another clinical trial; or (4) lack of medical clearance from the patient's clinician. Patients were disenrolled if their clinical condition changed or if they were discharged to a skilled nursing facility. Participants were randomized using a computer-generated 1:1:1 allocation to one of three groups: Group A (home-based exercise with CBI); Group B (home-based exercise without CBI); or Group C (attention-control educational intervention).

2.2 | Interventions

The interventions began within 14 days of hospital discharge. Participants in Group A were scheduled to receive eight supervised exercise sessions (40 min/session) and eight CBI sessions (20 min/session) at their home over 8 weeks. The exercise program was an individualized, progressive, multi-domain program that targeted balance, flexibility, strength, and endurance. The program was delivered twice a week for the first and second weeks, once a week for the third and fourth weeks, and once in the sixth week and the eighth week. Exercises were adopted from the National Institute of Aging *Go4Life* exercise guide [15]. Physical therapists at Hebrew Rehabilitation Center in Boston, Massachusetts, adapted exercises to the participants' needs and home environment. Based on individual progress, physical therapists assigned more challenging exercises. In addition to exercise, physical therapists delivered CBI to correct negative beliefs, increase self-efficacy, and enhance positive outcome expectations of exercise based on the literature [16–18]. The CBI included discussions about the benefits of exercise and barriers, setting personal goals, creating detailed exercise plans, self-monitoring progress, and maintaining an exercise diary. Participants received a $10 gift card each week if they recorded in their diary that they exercised for 30 min daily on five or more days. Participants in Group B received the same home exercise program (40 min/session) without CBI. Since maintaining an exercise diary was part of CBI, participants in Group B were instructed to exercise independently; however, their adherence was not tracked. Participants in Group C were scheduled to

Summary

- Key points
  - Older adults frequently experience functional decline following transcatheter aortic valve replacement (TAVR); however, the feasibility and potential benefits of structured cardiac rehabilitation after TAVR remain uncertain.
  - This pilot randomized controlled trial found that an early, home-based, multi-domain exercise program is feasible, and may result in lower disability scores and better physical function compared with an education control in older adults after TAVR.
  - Incorporating cognitive behavioral interventions, including a modest cash incentive for adherence, into home-based exercise showed trends toward improved adherence and reduced disability compared with exercise alone.
- Why Does This Paper Matter?
  - These findings offer critical insights for designing a larger, definitive randomized controlled trial to assess the efficacy of post-TAVR rehabilitation interventions.

receive a 30-min phone call weekly during which a study clinician or a physical therapist provided general information about exercise and diet from the *Go4Life* webpage [19] without specific instructions other than walking 30 min daily or as tolerated. All participants received post-procedure instructions at hospital discharge, and decisions regarding home care referrals for physical therapy were left to the clinical team. If participants in Group A or B received physical therapy outside the study ($n = 2$), the study intervention was withheld until the outside physical therapy concluded. The study intervention resumed as long as the total duration of physical therapy did not exceed 8 weeks.

2.3 | Baseline Assessment

Trained research assistants collected the following characteristics in the hospital after TAVR: age, sex, self-reported race and ethnicity (White, Black, Asian, Hispanic, other), left ventricular ejection fraction (%), body mass index (kg/m^2), Mini Nutritional Assessment-Short Form (range: 0–14 points; ≤11: at risk for malnutrition) [20], and a 50-item deficit-accumulation frailty index from a comprehensive geriatric assessment (non-frail: <0.15, pre-frail: 0.15 to <0.25, frail: ≥0.25) [1].

2.4 | Outcomes

The outcome assessment was conducted in the hospital after TAVR (baseline) and at home after 4 and 8 weeks of the intervention by a trained research assistant and a physical therapist who were blinded to the treatment assignment. Our primary outcome was the Late Life Function and Disability Instrument-Computer Adaptive Test (LLFDI-CAT) activity limitation score and participation restriction score, which were self-reported measures of physical function and disability (0–100 points; higher scores indicate better function or low disability) [21]. During our study period, the LLFDI-CAT software, developed in 2008 for an older Windows operating system, became incompatible with our institution's upgraded operating system, preventing us from obtaining follow-up LLFDI-CAT scores. Consequently, we adopted an alternative primary outcome measure: a self-reported composite disability score. This score (range: 0–22 points) represents the total number of tasks across seven activities of daily living (ADL), seven instrumental activities of daily living (IADL), and eight Rosow–Breslau [22] and Nagi physical tasks [23] for which assistance from another person is needed. It has previously been used to assess functional status recovery following TAVR [1].

Secondary and exploratory outcomes included: (1) the Short Physical Performance Battery (SPPB), a composite lower extremity physical function score based on gait speed (meter/s), five-chair stands (seconds), and balance (seconds) in side-by-side, semi-tandem, and full-tandem positions (range: 0–12 points; higher scores indicate better physical function) [24]; (2) 2-min walk distance (feet); (3) dominant hand grip strength (kg); (4) MMSE score (0–30; higher scores indicate better cognition); (5) New York Heart Association (NYHA) class (class 1–4; higher classes indicate severe symptoms); (6) self-efficacy scale for exercise (0–90 points; higher scores indicate higher self-efficacy) [25]; and (7) outcome expectation scale for exercise (1–5 points: higher scores indicate stronger expectation) [26]. Adverse events were obtained by the interventionists and outcome assessors using a standardized checklist. Serious adverse events were defined as any adverse events that result in death, life-threatening experiences, hospitalization or prolonged hospitalization, persistent or significant disability or incapacity.

As measures of feasibility, we assessed the number of patients who signed the consent form per month; the proportion of the screened patients who were randomized; the number of planned intervention sessions delivered; the proportion of patients lost to follow-up; and the missingness of outcome measures during the follow-up period.

2.5 | Statistical Analysis

We estimated that a sample size of 60 participants would yield at least 80% power to detect a 10-point effect size in the LLFDI-CAT score (equivalent to 1 standard deviation [SD] [27, 28]) at a 5% significance level, assuming a within-individual correlation of 0.40 and a dropout rate of 20%. Due to postoperative complications (e.g., stroke) that prevented participation in home-based exercise or changes in discharge plans (e.g., discharge to a skilled nursing facility), some participants were disenrolled and excluded from the analysis after informed consent ($n = 10$) or randomization ($n = 3$). Baseline characteristics across treatment groups were compared using analysis of variance and chi-square tests. We also compared baseline characteristics between participants whose outcomes were missing and those with complete outcome data.

Before conducting the outcome analysis, we assessed the correlation between the LLFDI-CAT score and the disability score at baseline. Least-square means and standard errors (SE) were estimated using linear mixed-effects models, including treatment, time indicators (4 and 8 weeks), and treatment-by-time

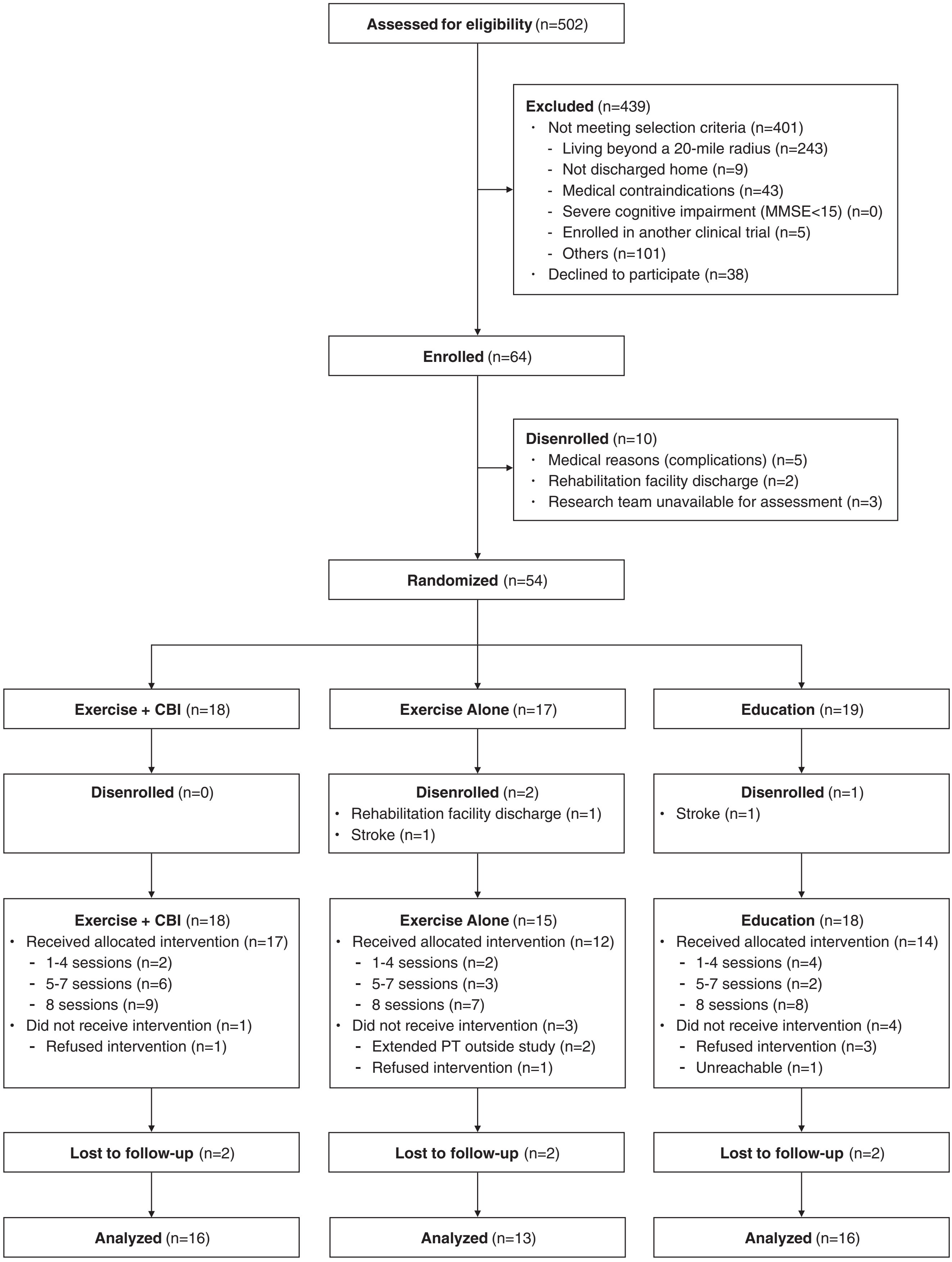

FIGURE 1 | CONSORT diagram. CBI, cognitive behavioral interventions.

TABLE 1 | Baseline characteristics[a].

Characteristics	Group A: exercise + CBI ($n=18$)	Group B: exercise alone ($n=15$)	Group C: education ($n=18$)	p
Age, years, mean (SD)	85.1 (9.1)	84.9 (5.1)	82.8 (8.0)	0.610
Female	9 (50.0)	1 (6.7)	9 (50.0)	0.011
White race	18 (100)	15 (100)	17 (94.4)	1.000
NYHA class III–IV	8 (44.4)	9 (64.3)	6 (40.0)	0.458
LVEF, %, mean (SD)	60.6 (9.4)	57.0 (8.1)	56.1 (15.6)	0.482
BMI, kg/m^2, mean (SD)	27.5 (6.4)	27.9 (4.8)	30.6 (6.3)	0.241
MNA-SF score ≤ 11	8 (44.4)	4 (26.7)	6 (33.3)	0.583
MMSE score, mean (SD)	25.8 (3.0)	25.8 (3.0)	25.4 (4.0)	0.902
Depression	3 (16.7)	2 (13.3)	2 (11.1)	1.000
ADL dependence	1 (5.6)	2 (13.3)	1 (5.6)	0.669
IADL dependence	6 (33.3)	7 (46.7)	9 (50.0)	0.601
Grip strength (kg)[b], mean (SD)	20.9 (13.2)	26.4 (16.6)	18.2 (8.2)	0.332
Gait speed (m/s), mean (SD)	0.73 (0.29)	0.65 (0.25)	0.58 (0.23)	0.263
Frailty index (range: 0–1), mean (SD)	0.20 (0.09)	0.23 (0.09)	0.24 (0.08)	0.370

Abbreviations: ADL, activities of daily living; BMI, body mass index; CBI, cognitive behavioral intervention; IADL, instrumental activities of daily living; LVEF, left ventricular ejection fraction; MMSE, mini-mental state examination; MNA-SF, mini nutritional assessment-short form; NYHA, New York heart association; SD, standard deviation.
[a]Data were presented in n (%) unless specified otherwise.
[b]Grip strength was not measured in 17 patients.

interactions with a random intercept. We adjusted for sex, as it did not achieve balance post-randomization. To test our hypotheses, we conducted two comparisons: (1) between the combined home-based exercise groups (Groups A and B combined) and the attention-control educational intervention (Group C), and (2) between home-based exercise with CBI (Group A) and without CBI (Group B) at 8 weeks. In a secondary analysis, we adjusted each model for the baseline value of the outcome measure. Analyzes were conducted using Stata 15, and a two-sided p-value less than 0.05 was considered statistically significant.

3 | Results

Out of 502 patients screened, we enrolled 64 patients (12.7%), averaging 2.1 patients per month, and randomized 54 patients (10.8%) (Figure 1). After disenrolling 13 patients due to postoperative complications or changes in discharge plans before the intervention, our analysis included 51 participants: 18 in Group A (home-based exercise with CBI); 15 in Group B (home-based exercise without CBI); and 18 in Group C (attention-control educational intervention). The treatment groups had a similar mean age (mean [SD] for Groups A, B, and C: 85.1 [9.1], 84.9 [5.1], 82.8 [8.0]; $p=0.610$), but more men were assigned to Group B (9 [50.0%], 14 [93.3%], 9 [50.0%]; $p=0.011$) (Table 1). There were no statistically significant differences in other characteristics, including NYHA class III or IV (8 [44.4%], 9 [64.3%], 6 [40.0%]; $p=0.458$), malnutrition risk (8 [44.4%], 4 [26.7%], 6 [33.3%]; $p=0.583$), gait speed (mean [SD]: 0.73 [0.29], 0.65 [0.25], 0.58 [0.23]; $p=0.263$), and the frailty index (mean [SD]: 0.20 [0.09], 0.23 [0.09], 0.24 [0.08]; $p=0.370$), consistent with pre-frailty.

3.1 | Adherence and Feasibility

Fifteen participants (83.3%) in Group A, 10 (58.8%) in Group B, and 10 (52.6%) in Group C completed at least five of the eight assigned intervention sessions ($p=0.196$). At baseline, SPPB or grip strength could not be measured in 22 participants due to post-procedural activity restrictions in the hospital. Two participants in each treatment group were lost to follow-up and did not complete any outcome assessments. Participants with missing outcome data had slower gait speeds and higher frailty index scores at baseline compared with those with complete data (Table S1 of Supporting Information 2).

3.2 | Effect of Home-Based Exercise Versus Education

At baseline, the disability score was moderate-to-highly correlated with LLFDI-CAT activity domain score (−0.76) and participation domain score (−0.65), supporting its validity (Figure S1 of Supporting Information 2). Over the 8-week period, the exercise groups showed no increase in the mean disability score, while the attention-control education group experienced a worsening disability at 4 weeks (mean [SE] for Group A and B vs. Group C: 2.8 [0.8] vs. 5.0 [0.6]; $p=0.012$) and 8 weeks (mean

TABLE 2 | Effect of exercise, with and without cognitive behavioral intervention, and education on study outcomes[a].

	Group A: exercise + CBI		Group B: exercise alone		Group A + B: exercise combined		Group C: education		p for group-by-time	
Outcome	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	AB vs. C	A vs. B
Disability score (range: 0–22)										
Baseline	18	2.8 (0.4)	15	3.1 (0.5)	33	2.9 (0.3)	18	3.8 (0.5)		
4 Weeks	13	2.5 (0.4)	13	3.1 (0.5)	26	2.8 (0.3)	13	5.0 (0.6)	0.012	0.498
8 Weeks	14	2.1 (0.4)	9	3.4 (0.5)	23	2.6 (0.3)	13	4.5 (0.5)	0.042	0.047
SPPB score (range: 0–12)										
Baseline	13	5.9 (0.7)	10	4.5 (0.8)	23	5.2 (0.5)	11	5.3 (0.7)		
4 Weeks	12	8.7 (0.7)	10	9.0 (0.8)	22	8.9 (0.5)	12	7.5 (0.7)	0.106	0.092
8 Weeks	10	9.7 (0.8)	7	9.3 (0.9)	17	9.5 (0.6)	9	6.5 (0.8)	0.003	0.346
2-min walk distance (feet)										
Baseline	8	313.9 (27.2)	6	279.0 (31.1)	14	296.7 (20.5)	5	244.6 (32.8)		
4 Weeks	12	304.4 (23.9)	10	311.7 (26.9)	22	308.3 (17.8)	11	278.4 (26.1)	0.579	0.277
8 Weeks	10	333.0 (25.4)	7	357.4 (29.5)	17	345.4 (19.3)	7	282.8 (29.4)	0.767	0.162
Grip strength (kg)										
Baseline	12	21.8 (2.9)	9	23.7 (3.4)	21	22.6 (2.2)	13	19.5 (2.8)		
4 Weeks	12	25.2 (2.9)	10	24.2 (3.4)	22	24.8 (2.2)	11	24.0 (3.1)	0.580	0.585
8 Weeks	10	23.0 (3.1)	7	22.8 (3.9)	17	22.9 (2.4)	8	24.1 (3.5)	0.365	0.720
MMSE score (range: 0–30)										
Baseline	17	25.8 (0.8)	15	25.8 (0.8)	32	25.9 (0.5)	17	25.4 (0.8)		
4 Weeks	12	26.3 (0.9)	10	26.9 (0.9)	22	26.7 (0.6)	11	26.7 (0.9)	0.585	0.623
8 Weeks	12	26.7 (0.9)	7	28.4 (1.1)	19	27.4 (0.7)	10	27.7 (0.9)	0.468	0.228
NYHA class (range: 1–4)										
Baseline	18	2.4 (0.2)	15	2.6 (0.2)	33	2.5 (0.1)	18	2.2 (0.2)		
4 Weeks	8	1.4 (0.2)	10	1.6 (0.2)	18	1.5 (0.2)	11	2.1 (0.2)	0.003	0.943
8 Weeks	7	1.7 (0.2)	7	1.8 (0.2)	14	1.8 (0.2)	9	1.6 (0.2)	0.819	0.830
Self-efficacy score (range: 0–90)										
Baseline	18	50.5 (5.8)	15	54.5 (6.2)	33	52.6 (4.2)	18	53.6 (5.7)		
4 Weeks	12	62.6 (6.9)	10	60.9 (7.4)	22	62.2 (5.0)	13	50.1 (6.5)	0.151	0.588
8 Weeks	12	66.2 (6.9)	7	59.6 (8.7)	19	64.2 (5.4)	12	51.1 (6.8)	0.138	0.369
Outcome expectation score (range: 9–45)										
Baseline	18	19.0 (1.3)	15	19.2 (1.5)	33	18.9 (1.0)	18	18.2 (1.4)		

(Continues)

TABLE 2 | (Continued)

Outcome	Group A: exercise + CBI		Group B: exercise alone		Group A + B: exercise combined		Group C: education		*p* for group-by-time	
	n	**Mean (SE)**	***n***	**Mean (SE)**	***n***	**Mean (SE)**	***n***	**Mean (SE)**	**AB vs. C**	**A vs. B**
4 Weeks	11	17.0 (1.5)	10	19.3 (1.7)	21	17.9 (1.2)	13	15.3 (1.5)	0.262	0.272
8 Weeks	12	16.8 (1.5)	7	16.6 (1.9)	19	16.6 (1.2)	12	15.7 (1.6)	0.887	0.828

Abbreviations: MMSE, mini-mental state examination; NYHA, New York heart association; SE, standard error; SPPB, short physical performance battery.
[a]Least-square means were estimated from linear mixed-effects models, adjusting for sex.

[SE]: 2.6 [0.3] vs. 4.5 [0.5]; $p = 0.042$) (Table 2 and Figure 2). The exercise groups also had a higher mean SPPB score than the attention-control education group at 8 weeks (mean [SE]: 9.5 [0.6] vs. 6.5 [0.8]; $p = 0.003$) and a lower mean NYHA class score at 4 weeks (mean [SE]: 1.5 [0.2] vs. 2.1 [0.2]; $p = 0.003$). Other secondary outcomes, including 2-min walk distance, grip strength, MMSE score, self-efficacy score, and outcome expectation score, did not differ significantly between the exercise groups and the attention-control education group. The treatment group-by-time interactions were statistically significant for SPPB and NYHA class after adjusting for the baseline value of each outcome (Table S2 of Supporting Information 2).

3.3 | Effect of CBI as an Adjunct to Home-Based Exercise

Among participants who were assigned to home-based exercise, Group A had a lower mean disability score than Group B at 8 weeks (mean [SE]: 2.1 [0.4] vs. 3.4 [0.5]; $p = 0.047$) (Table 2). There were no statistically significant differences in other secondary outcomes, including self-efficacy and outcome expectation scores, between Group A and Group B. When the baseline value of each outcome was adjusted for, none of the treatment group-by-time interactions were statistically significant (Figure 2).

3.4 | Adverse Events

There was a total of 59 adverse events from 51 participants, with the most common adverse events being musculoskeletal pain (13 events), followed by chest pain (7 events), fatigue (6 events), dizziness (5 events), and falls (3 events) (Table S3 of Supporting Information 2). However, serious adverse events were infrequent (7 events). No participants died during the 8-week follow-up.

4 | Discussion

In this pilot RCT, we showed that an 8-week home-based, multi-domain exercise program initiated shortly after discharge was both feasible and more effective than education alone in preventing post-hospitalization disability and improving physical function in older adults following TAVR. The home-based nature of our program addresses common logistical barriers, such as transportation challenges and scheduling conflicts, making it more accessible for this high-risk population. However, the added benefit of including CBI into the home-based exercise program, in terms of improving self-efficacy, outcome expectations, and adherence, remains uncertain.

A 2021 Cochrane review of 6 RCTs found that cardiac rehabilitation after open or transcatheter valve surgery moderately improved exercise capacity but had uncertain effects on mental and physical health-related quality of life [3]. The RCTs enrolled 12 [29] to 147 patients [30] (only two studies [30, 31] enrolled more than 100 patients), with a mean age ranging from 31 [31] to 82 years [32]. The cardiac rehabilitation program varied widely across RCTs: components included combined aerobic and resistance [30–34] or aerobic exercises only [29], starting 4–11 weeks [29, 30, 32–34] post-surgery except for one study [31], with frequencies from 1 to 3 [29–33] or 7 sessions [32] per week, over durations of 4–12 weeks [29–34], delivered at both home and hospital [30, 31, 34] or hospital only [29, 32, 33]. Patient-centered quality-of-life outcomes were examined only in two studies [30, 33]. A single-arm pilot study evaluated a 12-week home-based cardiac rehabilitation program in 41 patients who underwent TAVR [7]. The intervention consisted of personalized plans targeting strength, aerobic, and balance exercises, supervised remotely by nurses through weekly telephone calls, with no involvement of physical therapists. Significant improvements were observed in the self-reported Duke Activity Status Index score and the SF-36 Physical Function score. However, this study was limited by a lack of a comparison group, large drop-out rates (only 14 of 41 patients completed both pre- and post-intervention surveys and 5 completed 6-min walk test post-intervention).

In this pilot RCT of 54 patients (mean age, 83.9 years) discharged home after TAVR, we evaluated an early, home-based, multi-domain exercise program focused on balance, flexibility, strength, and endurance. Our program differed from typical cardiac rehabilitation in that it was initiated within 14 days of discharge, compared to the usual 4–11 weeks, and was tailored to each patient's baseline physical abilities. Findings showed no increase in disability scores and a greater improvement in SPPB scores in the exercise groups compared with the education group. These findings are consistent with the REHAB-HF trial [8], which similarly showed benefits of a multi-domain rehabilitation program in older patients (mean age, 73 years) with acute decompensated heart failure. The REHAB-HF intervention began in the hospital, transitioned to 36 outpatient sessions supplemented with home-based exercises in the first 3 months, and concluded with an independent maintenance phase for

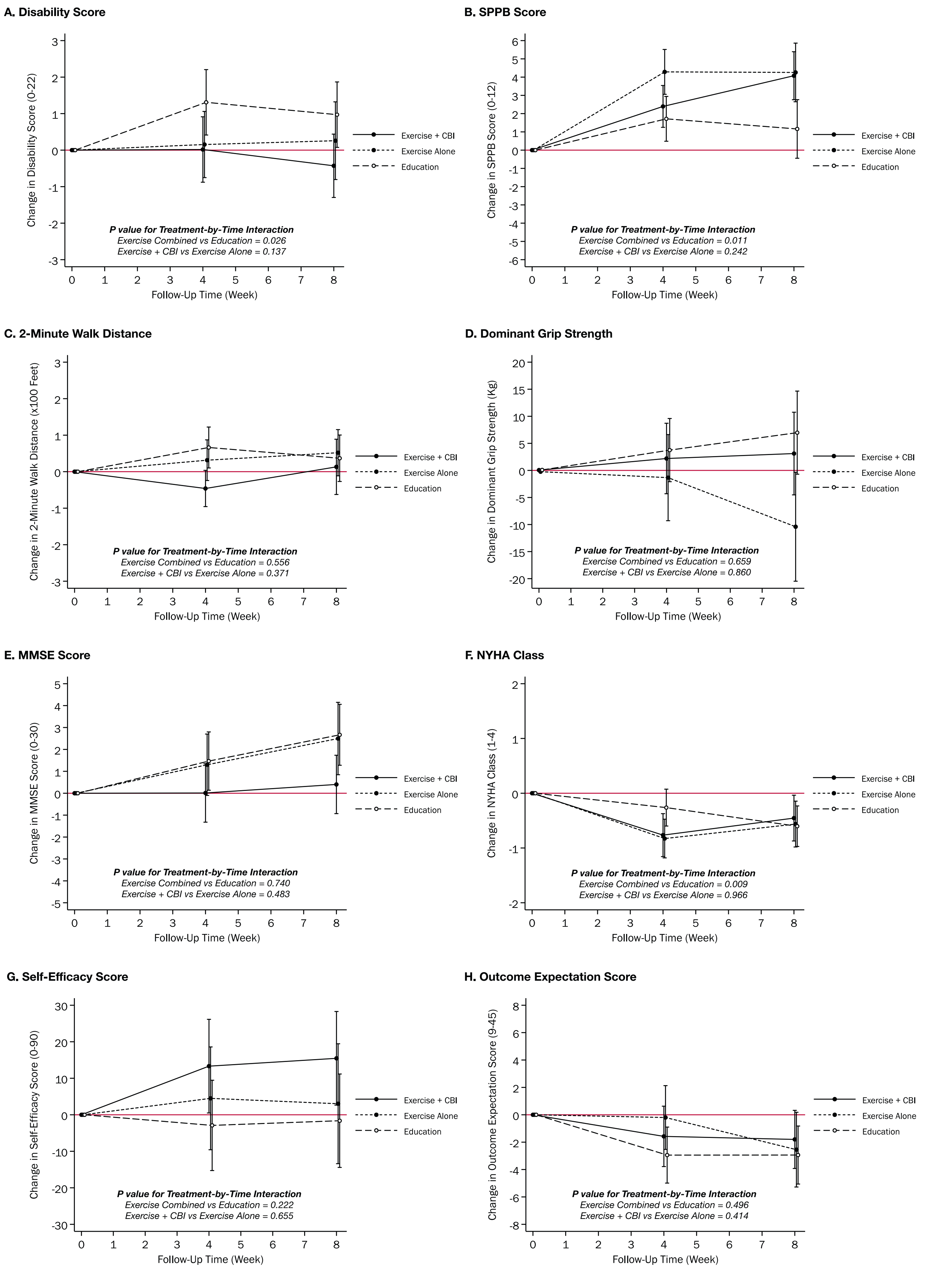

FIGURE 2 | Legend on next page.

FIGURE 2 | Effect of exercise, with and without cognitive behavioral intervention, and education on changes in study outcomes[a]. CBI, cognitive behavioral interventions; NYHA, New York heart association; SPPB, short physical performance battery. [a]Least-square means were estimated from linear mixed-effects models, adjusting for sex. The vertical line indicates the 95% confidence interval.

TABLE 3 | Challenges and strategies for designing a randomized controlled trial of a home-based exercise intervention after transcatheter aortic valve replacement.

Design	Challenges	Strategies
Enrollment	• Distance from the site was the most common reason for exclusion. • Racial and ethnic diversity was lacking. • Patients did not have sufficient time to think about participation and provide written informed consent before hospital discharge. • Patients were unwilling to be assigned to the education group. • Disenrollment after informed consent due to medical complications or change in discharge location was common.	• Multiple enrollment sites and involvement of multiple physical therapists working at different sites can cover broader geographical areas and diverse populations. • Screening, enrollment, and baseline assessment should take place in the ambulatory setting before the procedure. • The proportion of home discharge should be considered in sample size estimation.
Baseline assessment	• Baseline assessment was conducted in the hospital post-procedure. • Physical performance tests were often impractical or did not accurately represent the preoperative baseline due to the limitations imposed by postoperative precautions.	• Baseline assessment should be performed before the procedure for accurate assessment of preoperative physical performance and health status.
Interventions	• Less than 50% of participants received all planned intervention due to high treatment burden and interruptions by medical illnesses, physical therapy outside of the study, and personal events. • The fidelity of cognitive behavioral interventions delivered by physical therapists might have been variable.	• The intervention schedule needs to be flexible to balance the overall treatment burden and adherence to the study intervention. • Ongoing training of the study physical therapists in cognitive behavioral interventions is needed.
Outcome assessment	• Physical performance tests are not patient centered. • Some physical performance tests are difficult to standardize in the participant's home environment. • Loss to follow-up is common and likely informative (e.g., sicker patients are more likely to drop out).	• Patient-centered outcomes (e.g., quality of life, home time) can complement physical performance measures. • Patient-reported outcomes or remote monitoring technologies may overcome challenges in in-person physical performance measurements.

the subsequent 3 months. In contrast, our program was less intensive (8 sessions over 8 weeks), entirely home-based, and incorporated CBIs (in Group A). Despite these differences, both programs emphasized early initiation, multi-domain exercises, and personalization based on baseline physical abilities. This shared focus underscores the critical importance of early, tailored, multi-domain rehabilitation in facilitating recovery following TAVR.

We evaluated the effect of several CBI strategies to support the home-based exercise program, including discussing exercise benefits and barriers, setting personal goals, developing detailed exercise plans, weekly progress reviews, and rewarding adherence with gift cards, equivalent to a modest amount of cash incentive. Typically, financial incentives are not part of cognitive behavioral strategies, which focus on fostering self-motivation for behavior change. However, in our study, the gift card serves as a small immediate reward to reinforce adherence and as a token of recognition, rather than financial incentives. These strategies aimed to boost self-efficacy and positive outcome expectations for exercise [16–18]. However, the evidence is mixed for the clinical benefits of adding CBI to exercise. CBI strategies may improve adherence to exercise interventions [12, 13] and reduce fear of falling and activity avoidance in older adults [11]. In our study, although Group A showed trends toward better adherence (83.3% in Group A and 58.8% in Group B completed at least 5 of the 8 assigned sessions) and lower disability scores at 8 weeks, these comparisons were limited by insufficient statistical power and the greater loss of follow-up at 8 weeks in Group B. Self-efficacy and outcome expectations were not different between Groups A and B.

Several challenges emerged during our study (Table 3), including limited geographical reach, insufficient diversity, difficulties in pre-procedure enrollment, and adherence issues due to high treatment burdens and medical interruptions in this population. Additionally, missing baseline physical performance assessments were unavoidable in some patients due to post-procedural activity restrictions. To address these, we propose expanding sites, enrolling pre-procedure, using flexible intervention schedules, providing ongoing training for physical therapists in CBI, and incorporating patient-centered outcomes, patient-reported measures, and remote monitoring technologies to supplement in-person physical performance assessments. These strategies may inform the design of a definitive RCT for a home-based exercise program.

4.1 | Limitations

First, the small sample size of our study limits the ability to draw definitive conclusions regarding the benefits and potential harms of the program. Second, the predominance of White participants discharged home after TAVR from two Boston-based academic medical centers and the use of geriatric-specialized physical therapists at an academic rehabilitation center may limit the generalizability of our results to more diverse populations and clinical settings. The efficacy of the home-based exercise program may vary when delivered by the community-based interventionists. Moreover, since most participants in our study were pre-frail, the efficacy for patients with more severe frailty remains unclear. Third, CBI employed in our study included a modest financial incentive. Although the monetary value was small, we were unable to evaluate the effect of CBI without a financial reward. Fourth, clinicians making phone calls were aware of the study question, and routine home care referrals for physical therapy were uncommon (only 2 patients received physical therapy through home care agencies outside the study). As a result, the weekly telephone-based education with a clinician in Group C can be considered an "enhanced usual care", potentially diminishing the observed effect size. Fifth, we had to replace our original primary outcome, LLFDI-CAT scores, with a previously used disability score due to software compatibility issues. However, the disability score was moderate-to-highly correlated with LLFDI-CAT scores. Sixth, physical performance measurement in the immediate postoperative setting posed challenges, resulting in missing data, and loss to follow-up likely introduced selection bias. Seventh, we did not adjust for multiple comparisons, which increases the risk of type 1 error. Lastly, our data may not reflect current TAVR practices, where patients are discharged home more quickly than during the study period.

4.2 | Conclusions

Our pilot RCT demonstrates that an early, home-based, multidomain exercise program is feasible and shows promise for reducing post-hospitalization disability and improving physical function in older adults after TAVR. Although incorporating CBI into home-based exercise showed trends toward better adherence and lower disability than exercise alone, these benefits were not conclusive. Addressing challenges like diversity, enrollment timing, and intervention burden will be essential in designing a larger, definitive RCT to confirm these preliminary findings.

Author Contributions

Dae Hyun Kim: study concept and design. **Faith-Anne Rapley, Heather Margulis, Kimberly Guibone, Edward Percy, Dae Hyun Kim:** acquisition of subjects and data. **Sandra M. Shi, Faith-Anne Rapley, Kuan-Yuan Wang, Heather Margulis, Roger J. Laham, Kimberly Guibone, Edward Percy, Tsuyoshi Kaneko, Dae Hyun Kim:** analysis and interpretation of data. **Sandra M. Shi, Yuan Wang, Dae Hyun Kim:** drafting of manuscript. **Sandra M. Shi, Yuan Wang, Roger J. Laham, Kimberly Guibone, Edward Percy, Tsuyoshi Kaneko, Dae Hyun Kim:** critical review of the manuscript for important intellectual content. **Dae Hyun Kim:** statistical analysis. **Dae Hyun Kim:** obtained funding. **Dae Hyun Kim:** administrative, technical, or material support. **Dae Hyun Kim:** supervision.

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The authors have nothing to report.

Conflicts of Interest

Kimberly Guibone is an educational consultant to Abbott Laboratories and Medtronic Inc. The other authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.