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ORIGINAL ARTICLE
Mobile apps

Effect of a pragmatic home-based mobile health exercise intervention after transcatheter aortic valve replacement: a randomized pilot trial

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Aims Impaired physical function is common in patients undergoing transcatheter aortic valve replacement (TAVR) and associated with worse outcomes. Participation in centre-based cardiac rehabilitation (CR) after cardiovascular procedures is sub-optimal. We aimed to test a home-based mobile health exercise intervention as an alternative or complementary approach.

Methods and results At five centres, after a run-in period, eligible individuals treated with TAVR were randomized 1:1 at their 1-month post-TAVR visit to an intervention group [activity monitor (AM) with personalized daily step goal and resistance exercises] or a control group for 6 weeks. Among 50 participants, average age was 76 years, 34% were female, average STS score was 2.9 ± 1.8, and 40% had Short Physical Performance Battery (SPPB) ≤9. Daily compliance with wearing the AM and performing exercises averaged 85–90%. In the intention to treat population, there was no evidence that the intervention improved the co-primary endpoints: daily steps +769 (95% CI -244 to +1783); SPPB +0.68 (-0.27 to 1.53); and Kansas City Cardiomyopathy Questionnaire -1.7 (-9.1 to 7.1). The intervention did improve secondary physical activity parameters, including moderate-to-intense daily active minutes ($P < 0.05$). In a pre-specified analysis including participants who did not participate in CR ($n = 30$), the intervention improved several measures of physical activity: +1730 (100–3360) daily steps; +66 (28–105) daily active minutes; +53 (27–80) moderate-to-intense active minutes; and -157 (-265 to -50) sedentary minutes.

Conclusion Among selected participants treated with TAVR, this study did not provide evidence that a pragmatic home-based mobile health exercise intervention improved daily steps, physical performance or QoL for the overall cohort. However, the intervention did improve several measures of daily activity, particularly among individuals not participating in CR.

Trial registry Clinicaltrials.gov NCT03270124.

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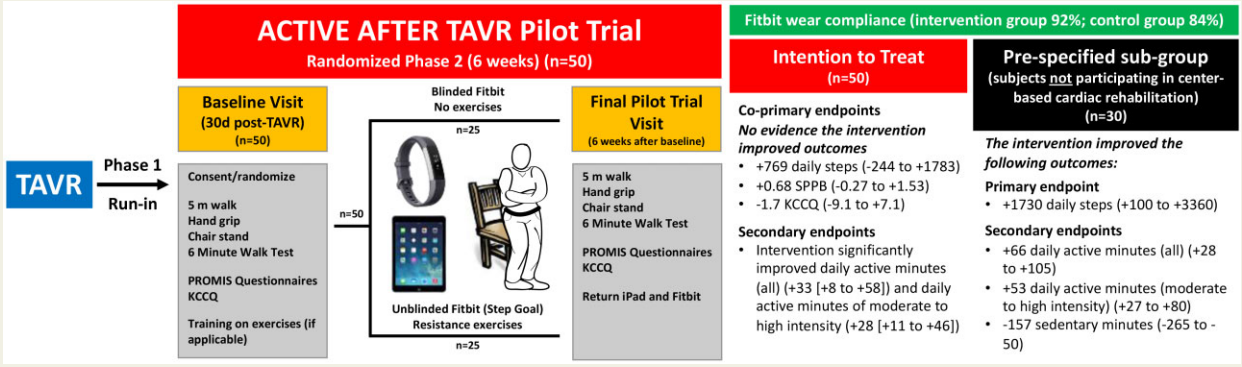
Graphical Abstract



Keywords Aortic stenosis • Transcatheter aortic valve replacement • Cardiac rehabilitation • Frailty • Accelerometer • Mobile health • Actigraphy

Lay abstract

Given the high prevalence and adverse effects of frailty in patients undergoing transcatheter aortic valve replacement (TAVR) and low participation rates in traditional centre-based cardiac rehabilitation (CR), there is a pressing need for alternative strategies to promote post-TAVR rehabilitation. After TAVR, a pragmatic home-based mobile health exercise intervention was successfully implemented and demonstrated high compliance and increased physical activity compared to control, particularly among patients who did not participate in CR. These randomized pilot data could be used to design and power more definitive studies on the optimal implementation and clinical efficacy of this type of intervention.

Introduction

Frailty is common in patients with aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR) and surgery and associated with poor post-procedural outcomes.[1,2] Those with improvements in physical function after TAVR have better subsequent outcomes.[3,4] Accordingly, beyond replacing the heart valve, there is growing recognition that targeting frailty and impaired physical function is important to optimize patient-centred outcomes.[5] A recent report on cardiac rehabilitation (CR) after valve surgery showed that although CR was associated with reduced rehospitalization and mortality in the first year after the surgery, participation rates were only 43%.[6] While the literature demonstrates similar associations between CR and reduced mortality among patients treated for coronary artery disease, rates of participation are even lower.[7,8] Participation in CR after TAVR has not been studied.

Given the logistical, financial, and other barriers to participation in traditional centre-based CR, there is interest in developing alternatives, including those that leverage expanding technological capabilities.[9] In the midst of the current COVID-19 pandemic participation in traditional CR is substantially lower, and alternatives have become increasingly important.[10] While usage rates of various devices (e.g. activity trackers, smartphones, tablets) continue to steadily increase among individuals of all ages, penetration of and familiarity with these devices are lower among older adults.[11,12] Accordingly, it is unclear whether mobile health alternatives to traditional CR are feasible and effective for older adults.

Our objective was to obtain pilot and feasibility data on a pragmatic home-based mobile health exercise intervention to increase daily activity and improve physical function and quality of life in older adults with AS undergoing TAVR. We examined compliance with mobile health devices and gathered data on the effects of an exercise intervention on multiple patient-centred parameters.

Methods

Study population

From August 2018 to February 2020, at five centres (listed in the Supplementary material online, *Methods*) in the USA, we enrolled patients into Phase 1 (roll-in, non-randomized) and Phase 2 (randomized) of the study (NCT03270124). All patients had severe AS and underwent TAVR with placement of a SAPIEN 3 transcatheter heart valve (Edwards Lifesciences). Exclusions included stroke during the procedure or prior to discharge, inability to walk, physical or neuropsychiatric limitations (e.g. cognitive impairment, blindness) that would prevent proficient use of the study tools, and discharge from the hospital to a skilled nursing or rehabilitation facility. The study was registered on clinicaltrials.gov prior to

any patient enrolment and all participants provided written informed consent.

Study design

An overview of the study design is shown in Supplementary material online, *Figure S1*. Eligible individuals signed informed consent prior to discharge from their TAVR procedure. They then underwent physical performance assessments and completed quality of life questionnaires (details provided in Supplementary material online, *Methods*). They received instruction on wearing and charging a commercially available activity monitor (Fitbit Alta HR, a wrist-worn device that tracks heart rate while worn) (showing only time of day during Phase 1), and using an iPad (which was provided to each participant with a data package to avoid reliance on iPad ownership and WiFi) including syncing activity data from the activity monitor and answering daily questions on a customized app.

Phase 1 (roll-in phase, non-randomized) extended from discharge to the 30-day post-TAVR clinical visit and included enough patients to allow for 50 to be randomized into Phase 2. At this clinical visit, Phase 1 participants again completed physical performance assessments and completed quality of life questionnaires (serving as baseline measurements if patients went on to Phase 2). Participants who were compliant with study instructions during Phase 1 (defined as wearing the activity monitor ≥10 waking hours a day ≥5 days a week and answering questions on the iPad app ≥5 days a week) were invited to participate in Phase 2. Participants continuing into Phase 2 were randomized 1:1 to an intervention or control group for a 6-week study period after which they returned to the study site for final assessments of physical performance and completion of quality of life questionnaires. Randomization was stratified by sex and 5-m walk time (≥7 vs. <7 s) at the 30-day post-TAVR visit. Because of the known survival benefit of traditional CR, we did not restrict enrolees from participation. With five participants yet to complete their final Phase 2 study visit, SARS-CoV-2 began to spread with subsequent recommendations restricting movement and social encounters. Accordingly, data for the final visits for these five participants were obtained through a combination of video conferencing, phone interview, and other adaptive means.

Study intervention

For the randomized Phase 2, all participants were given an iPad with a data package and app loaded to answer daily and weekly questions and an activity monitor with instructions to wear the device at all times. For the intervention group, the activity monitor displayed daily steps, time, distance moved, heart rate, and battery level (recharging required every 5–7 days). Participants were given a personalized daily step goal to meet that was 10% higher than their average daily step count at the end of Phase 1; they also received notification on the activity monitor when they met their daily step goal and received a vibration each hour at ten minutes to the hour to encourage at least 250 steps/h. They were also instructed to perform daily resistance exercises, including 5–10 chair sit-to-stand exercises (to strengthen lower extremities), 5–10 chair push-ups (to strengthen upper extremities), and 10 stress ball squeezes (to strengthen handgrip). The intervention group was encouraged to repeat this cycle of 3 exercises at least once and up to 5 times in a day for 6 out of 7 days per week. Reminders were sent via the iPad to complete the exercises each day and participants answered a daily question regarding whether they completed the exercises, including the number of cycles. For the control group, the activity monitor only displayed the time and gave no reminders or feedback and no instructions, reminders, or queries about exercise were given.

For all participants, the activity monitor was synced to the iPad on a regular basis via Bluetooth, which allowed the coordinating centre to track each participant using a dashboard to ensure the activity monitor was being worn, synced, appropriately charged, and that data were being captured appropriately. Regardless of study group, participants were contacted via phone 7 days and 3 weeks post-randomization when questions could be addressed. At other times, if and when problems were identified and regardless of study group, the site coordinator contacted the participant to address the problem. Wear compliance for the activity monitor was determined daily based on whether the participant wore the device during their waking hours for ≥10 h as recommended[13,14]; a recorded heart rate made it simple to determine when the participant was awake and when the device was worn. Only compliant days were considered in calculating any of the activity monitor-based activity data as recommended.[13,14] Compliance with exercises for those in the intervention group was determined by participant self-report through the iPad each day.

Study assessments and endpoints

The three co-primary endpoints were average daily steps, short physical performance battery (SPPB), and Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score. The SPPB is a 3-part test that assesses balance, gait speed, and chair sit-to-stand time.[15,16] The Kansas City Cardiomyopathy Questionnaire, a heart failure disease-specific health status measure, was used to assess health status and the overall summary score was evaluated.[17] The prespecified secondary endpoints included: daily active minutes, daily active minutes of moderate to high intensity, daily sedentary minutes, number of hours per day with ≥250 steps, gait speed, chair sit-to-stand time (for 5), balance score, 6-min walk distance, handgrip strength, PROMIS 10 global physical and mental health scores, and PROMIS computerized adaptive test scores for physical function, depression, fatigue, and dyspnoea.

Statistical analysis

Please refer to the Supplementary material online, *Methods*.

Results

Participants

Among 85 participants enrolled into Phase 1, 35 did not continue into Phase 2. Fourteen withdrew prior to completing Phase 1, 9 completed Phase 1 but were not compliant enough with study activities to be eligible for Phase 2, 10 completed Phase 1 and were eligible for Phase 2 but declined participation, and 2 were not enrolled in Phase 2 since we had already reached our randomization goal. Of the 50 enrolled in Phase 2, 25 were randomized to the control group and 25 to the intervention group; all 50 completed the randomized Phase 2 study period. Baseline characteristics for the Phase 2 participants are shown in *Table 1*. The average age was 76 years, 34% were female, average STS score 2.9 ± 1.8, 18% had slow gait speed (<0.8 m/s), 40% had an SPPB ≤9, 33% had a KCCQ <75, and 40% participated in CR during Phase 2.

Compliance

Daily compliance with wearing the activity monitor, defined as wearing the device for 10 or more waking hours, is shown for the whole randomized study population in *Figure 1A*. Wear compliance averaged ∼90% during the first two-thirds of the study period and remained ≥80% until the end. Over the study period, the average wear compliance was 92% ± 9.8% for intervention group and 83.5% ± 17.0% for control group ($P = 0.037$). For a majority of the days,

Table 1 Baseline characteristics

	Control ($n = 25$)	Intervention ($n = 25$)
Age, years	76 (9)	76 (7)
Female (%)	8 (32%)	9 (36%)
Non-white (%)	1 (4%)	1 (4%)
BMI	30.5 (5.2)	29.8 (7.3)
STS score	3.0 (1.9)	2.7 (1.6)
Diabetes	8 (32%)	7 (28%)
Prior MI	0 (0%)	2 (8%)
Atrial fibrillation	12 (48%)	7 (28%)
Prior stroke	3 (12%)	1 (4%)
Oxygen dependence	0 (0%)	2 (8%)
ESRD (dialysis)	0 (0%)	0 (0%)
Peripheral vascular disease	2 (8%)	5 (21%)
Liver disease	1 (4%)	1 (4%)
Active cancer	3 (12%)	5 (20%)
TAVR approach (% transfemoral)	25 (100%)	25 (100%)
NYHA III/IV class (from P1/P2 30d/baseline visit)	1 (4%)	1 (5%)
LVEF on echo from P1/P2 30d/baseline visit	58 (14)	61 (9)
Moderate-severe AR on echo from P1/P2 30d/baseline visit	0 (0%)	0 (0%)
Moderate-severe MR on echo from P1/P2 30d/baseline visit	2 (8%)	1 (4%)
Walking aid used (e.g. cane, walker)	3 (12%)	3 (12%)
Slow gait speed (<0.80 m/s) (%)	5 (20%)	4 (16%)
Weak handgrip (%)	5 (20%)	2 (8%)
SPPB <10 at Phase 2 baseline (%)	10 (40%)	10 (40%)
KCCQ <75 at Phase 2 baseline (%)	7 (29%)	9 (36%)
Cardiac rehab participation during Phase 1 (%)	4 (16%)	9 (36%)
Cardiac rehab participation during Phase 2 (%)	8 (32%)	12 (48%)

Data are expressed as % or mean (SD).

there was no significant difference in wear compliance between the intervention and control groups, except for Day 34 (96% vs. 74%, $P = 0.04$), 36 (100% vs. 68%, $P = 0.003$), and 41 (100% vs. 74%, $P = 0.05$) (*Figure 1B*). Compliance with daily exercise performance was only assessed in the intervention group and was consistently 85–90% throughout the intervention period (*Figure 1C*); the non-response rate to the daily exercise question averaged 7% across all participants and days. Overall activity monitor wear compliance and exercise compliance for the whole intervention period is shown in Supplementary material online, *Table S1*. Among all the participants in the intervention group, the daily step goal was met 52.6% of days (only compliant days were considered).

Primary endpoints

In the intention to treat population ($n = 50$), daily steps for each assigned group across the intervention period are shown in *Figure 2A*. The difference in daily steps between groups across the study period is shown in *Figure 2B*. At the end of the study period, those in the intervention group averaged a non-significantly greater number of daily steps (+769, 95% CI -244 to +1783, $P = 0.14$) compared to the control group. In both pre-specified sub-group analytic populations, defined as those who were compliant with study activities ($n = 46$) and those who did not participate in CR during the study period ($n = 30$), those in the intervention group had significantly more daily steps than the control group at the end of the study period (*Figure 2C–F*). Raw data on average steps per day for each assigned group during the first and last 5 compliant days of the study period and change between them are shown in Supplementary material online, *Table S2*. In the control group, average daily steps were 4065 (2350–7337) steps for the first 5 compliant days and 3821 (2191–5280) steps for the last 5 compliant days; average change in daily steps per participant in the control group was -3% (-25% to +17%) between the beginning and end of the study period. In the intervention group, average daily steps were 4748 (3413–7185) steps for the first 5 compliant days and 4930 (2560–6598) steps for the last 5 compliant days; average change in daily steps per participant in the intervention group was +10% (-30% to +29%) between the beginning and end of the study period.

At the final visit, those in the intervention group had a non-significantly higher SPPB (+0.68, 95% CI -0.27 to +1.53) compared to the control group (*Table 2*). These data are shown for the pre-specified sub-groups in Supplementary material online, *Table S3*. In the sub-group of participants who did not participate in CR, there was a significant interaction between baseline SPPB and group

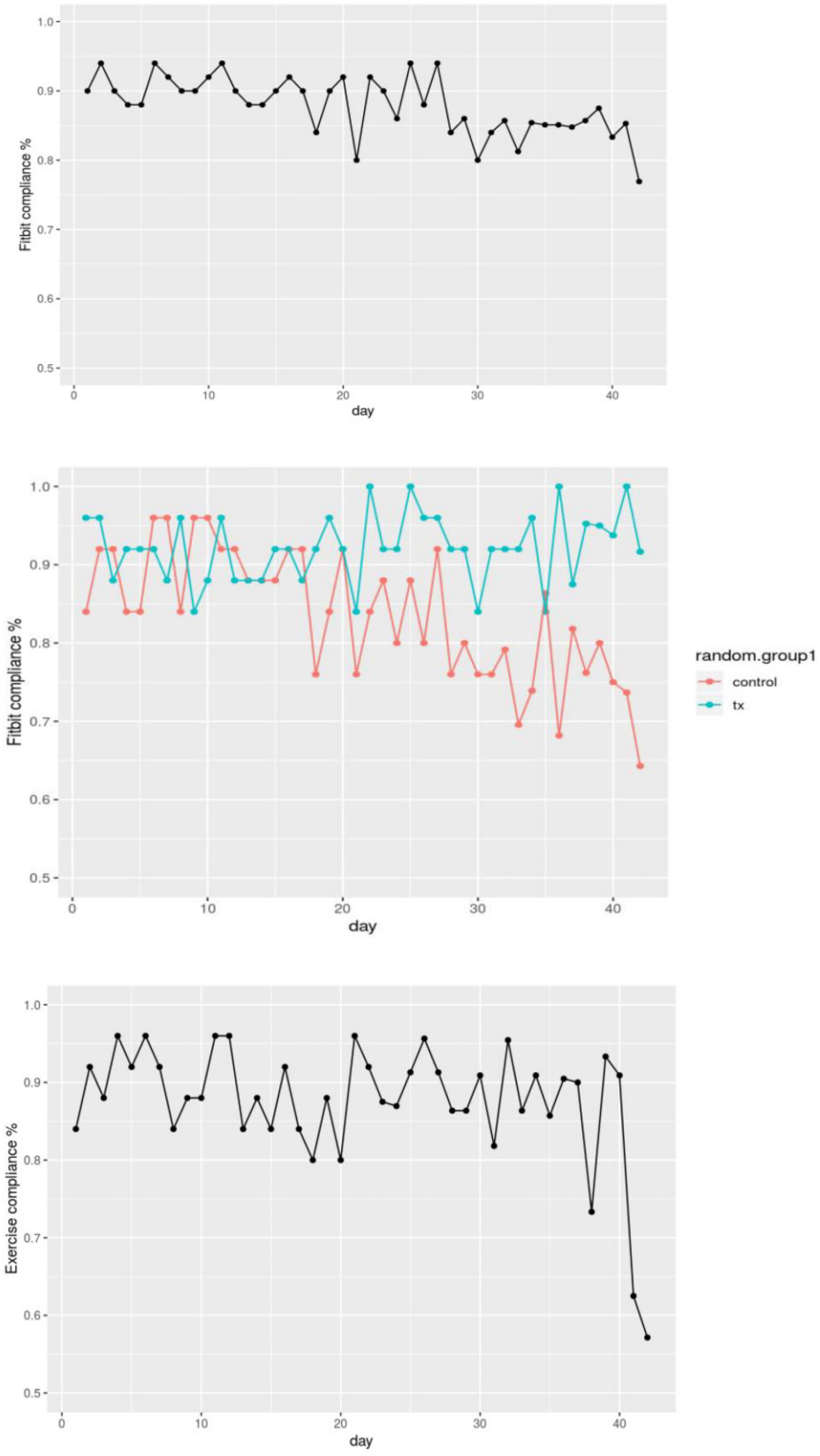


Figure 1 Activity monitor and exercise compliance during the intervention period. Compliance is reported by day throughout the study period for wearing the activity monitor among the whole population (*A*) and by assigned group (*B*); and for performance of daily exercises among the intervention group (*C*).

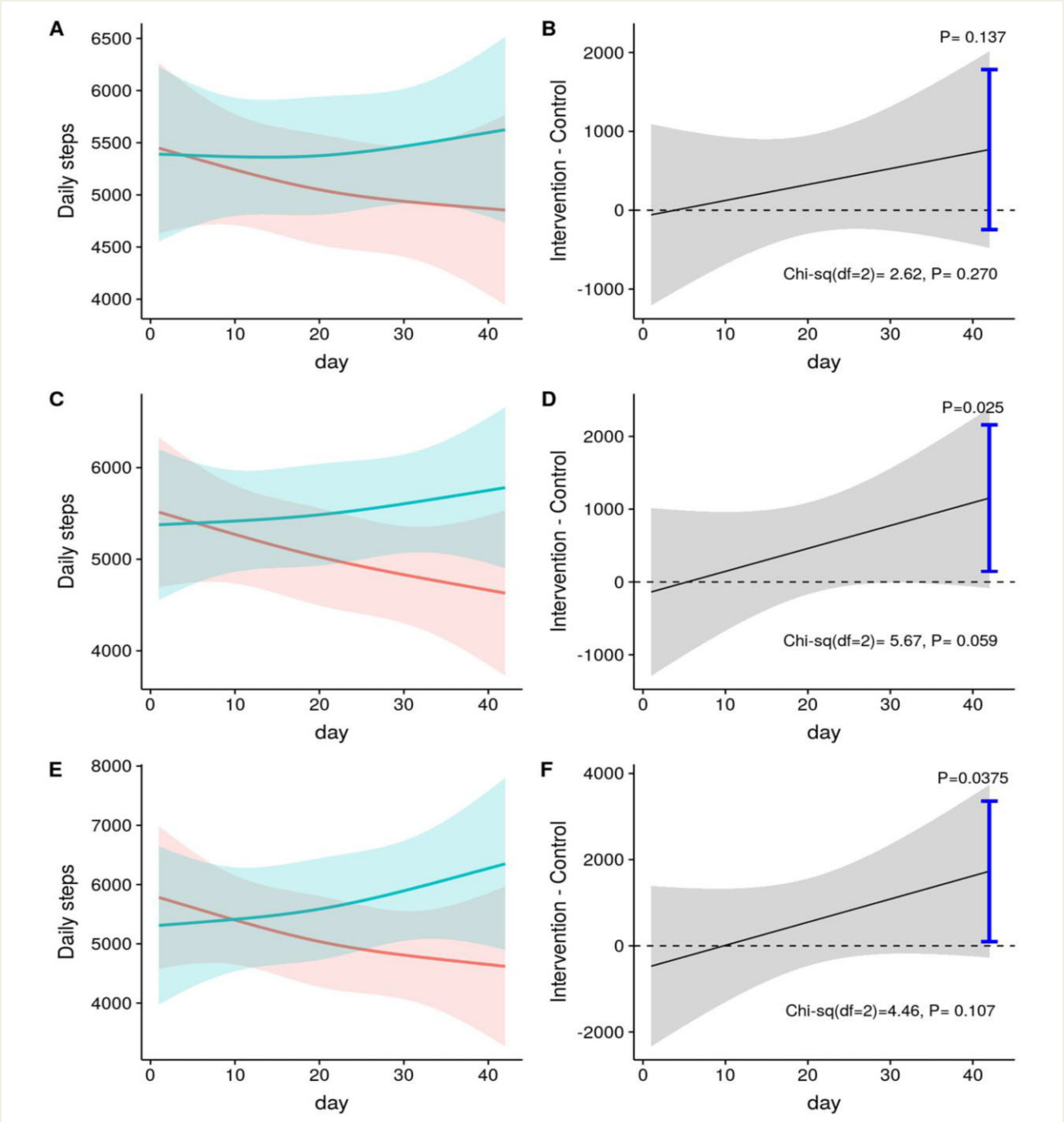


Figure 2 Daily steps. The left panels represent the model estimated daily steps by assigned group over the 6-week study period (green represents the intervention group; orange represents the control group) for the intention to treat population ($n = 50$) (*A*), compliant population ($n = 46$) (*C*), and participants who did not participate in cardiac rehabilitation during the study period ($n = 30$) (*E*). The shaded area represents the 95% confidence interval. Models were adjusted for age, sex, baseline gait speed, baseline steps, and, except for *E*, participation in cardiac rehabilitation. The right panels represent the difference in daily steps (intervention group – control group) for the intention to treat population (*B*), compliant population (*D*), and participants who did not participate in cardiac rehabilitation during the study period (*F*). The shaded area represents the 95% confidence interval adjusting for multiple comparisons. The blue line represents the individual 95% confidence interval that is not adjusted for multiplicity at Day 42.

Table 2 Co-primary and secondary endpoints in the intention to treat population

	n	Control	Treatment	Difference (treatment – control)
Co-primary endpoints				
SPPB baseline	50	10 (8, 11) 9.3 (2.0)	10 (8, 12) 9.6 (2.4)	
SPPB final visit	50	10 (8, 11) 9.1 (2.7)	11 (9, 12) 9.8 (2.9)	+0.68 (-0.27, 1.53)
KCCQ baseline	49	93 (73, 98) 85 (20)	81 (69, 95) 77 (19)	
KCCQ final visit	48	94 (81, 99) 82 (26)	87 (71, 97) 80 (21)	-1.7 (-9.1, 7.1)
Secondary endpoints				
Gait speed (m/s) baseline	50	1.1 (1.0, 1.3) 1.1 (0.3)	1.2 (0.9, 1.4) 1.2 (0.4)	
Gait speed (m/s) final visit	48	1.2 (1.0, 1.3) 1.2 (0.3)	1.2 (0.9, 14) 1.2 (0.3)	0.007 (-0.054, 0.166)
Chair sit-to-stand time (s) baseline	45	14.4 (12.3, 16.4) 15.3 (5.6)	12.8 (9.9, 14.4) 13.1 (4.5)	
Chair sit-to-stand time (s) final visit	42	13.8 (11.2, 17.4) 14.9 (4.9)	11.1 (9.1, 14.0) 11.5 (3.2)	-2.3 (-4.2, -0.3)
Balance score (0–4) baseline	50	4 (3, 4) 3.4 (0.8)	4 (3, 4) 3.5 (0.9)	
Balance score (0–4) final visit	50	4 (4, 4) 3.6 (1.0)	4 (3, 4) 3.4 (1.1)	-0.05 (-0.78, 0.08)
Six-min walk distance (m) baseline	47	357 (241, 427) 364 (250)	366 (235, 441) 334 (143)	
Six-min walk distance (m) final	45	366 (285, 481) 371 (132)	396 (261, 473) 374 (179)	+14 (-51, 77)
Handgrip strength baseline	49	25 (20, 35) 26.9 (12.7)	27 (21, 35) 27.4 (8.3)	
Handgrip strength final visit	44	28 (19, 32) 27.1 (11.8)	30 (21, 37) 28.2 (9.1)	-0.04 (-3.3, 2.9)
Global physical health (PROMIS 10) Bsl	50	51 (42, 58) 50.9 (10.1)	51 (42, 58) 50.0 (8.7)	
Global physical health (PROMIS 10) final	49	51 (42, 58) 51.4 (10.8)	48 (42, 59) 50.0 (10.0)	-0.4 (-4.9, 4.5)
Global mental health (PROMIS 10) Bsl	50	53 (46, 59) 53.2 (8.7)	53 (46, 59) 52.5 (7.5)	
Global mental health (PROMIS 10) final	49	53 (46, 59) 53.6 (9.4)	51 (45, 60) 52.4 (8.6)	-0.3 (-4.2, 3.8)
Physical function score (PROMIS CAT) Bsl	50	44 (37, 48) 42.9 (8.8)	44 (38, 49) 44.2 (7.9)	
Physical function score (PROMIS CAT) Fin	49	44 (40, 52) 45.3 (10.0)	45 (41, 51) 45.6 (7.3)	+0.3 (-3.2, 3.6)
Depression score (PROMIS CAT) Baseline	50	43 (34, 48) 42.4 (7.2)	46 (39, 50) 45.4 (8.8)	
Depression score (PROMIS CAT) Final	49	43 (39, 51) 44.4 (8.6)	46 (38, 52) 45.5 (9.3)	-1.5 (-5.1, 3.3)
Fatigue score (PROMIS CAT) Baseline	50	49 (42, 51) 45.6 (9.3)	45 (39, 51) 47.1 (11.5)	
Fatigue score (PROMIS CAT) Final	49	46 (38, 56) 46.3 (11.4)	46 (39, 54) 47.3 (10.0)	+0.1 (-5.4, 6.0)
Dyspnoea score (PROMIS CAT) Baseline	49	28 (24, 38) 33.1 (11.8)	29 (24, 34) 31.4 (9.2)	
Dyspnoea score (PROMIS CAT) Final	49	24 (23, 38) 32.2 (11.8)	30 (25, 39) 33.8 (11.1)	+0.9 (-4.4, 7.2)

For each assessment, data are shown for each group at the baseline and final visits as median (25th, 75th percentile) and mean (SD). The difference between the treatment and control groups at the final assessment is shown with the average difference (95% CI) based on a model adjusting for age, sex, baseline gait speed, cardiac rehabilitation participation and the baseline value of the variable of interest. This is based on bootstrap simulation.

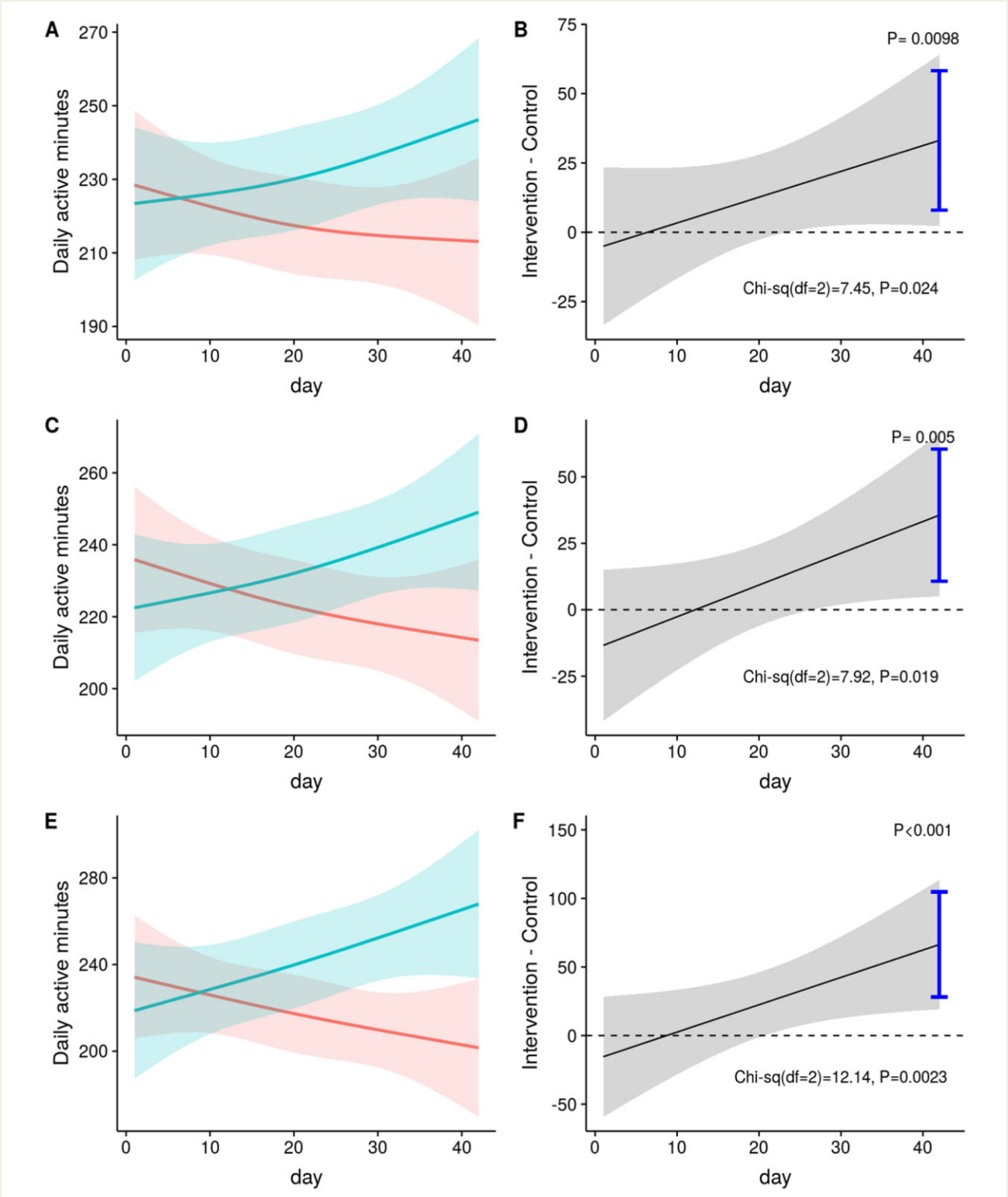


Figure 3 Daily active minutes. The left and right panels show data exactly as described in *Figure 2* except that daily active minutes are displayed in this figure.

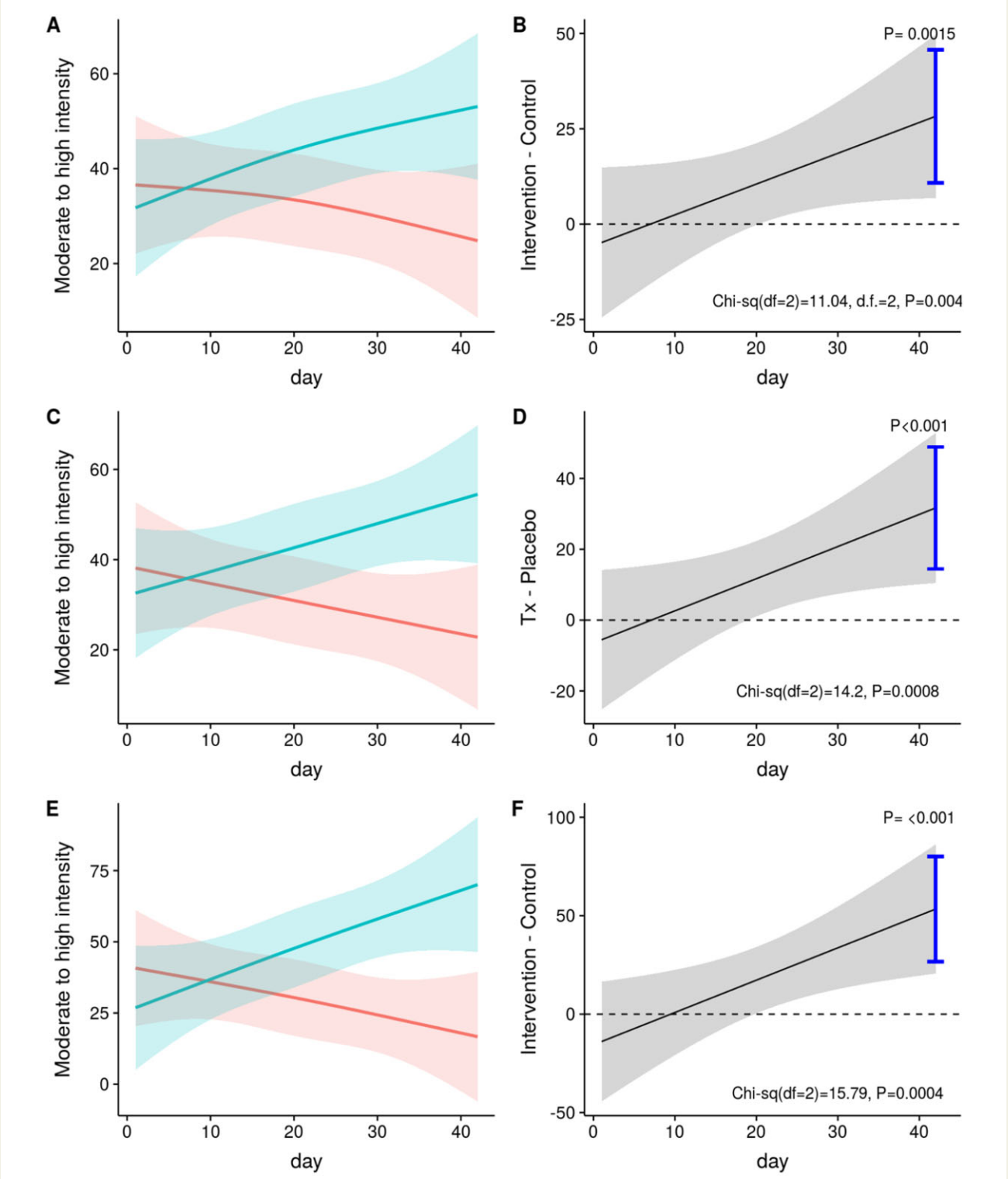


Figure 4 Daily active minutes of moderate to high intensity. The left and right panels show data exactly as described in *Figure 2* except that daily active minutes of moderate to high intensity are displayed in this figure.

assignment with respect to final SPPB (*P* for interaction = 0.04). Those with a lower SPPB at baseline had a higher SPPB at the final visit if they were in the intervention group, whereas those with a higher SPPB at baseline had a similar SPPB at the final visit regardless of group allocation (Supplementary material online, *Figure S2*). KCCQ overall summary scores at baseline and final visits for each assigned group are shown in *Table 2* and for the pre-specified sub-groups in Supplementary material online, *Table S3*. In all populations, there was no significant difference in the KCCQ score at the final visit between assigned groups. A comparison of those who did ($n = 20$) vs. did not ($n = 30$) participate in CR during Phase 2 is shown in Supplementary material online, *Table S4*.

Secondary endpoints—activity monitor

In the intention to treat population and both pre-specified sub-group populations, daily active minutes and daily active minutes of moderate to high intensity were significantly greater in the intervention group than the control group from approximately Day 20 through the end of the intervention period (*Figures 3* and *4*). In the intention to treat population, at the end of the study period, those in the intervention group averaged +33 (95% CI +8 to +58, $P = 0.01$) more daily active minutes and +28 (95% CI +11 to +46, $P = 0.002$) more daily active minutes of moderate to high intensity than the control group. In the sub-group that did not attend CR, at the end of the intervention period, those in the intervention group averaged +66 (95% CI +28 to +105, $P < 0.001$) more daily active minutes and +53 (95% CI +27 to +80, $P < 0.001$) more daily active minutes of moderate to high intensity than the control group.

Daily sedentary minutes were similar in both groups throughout the intervention period in the intention to treat population, but lower in the intervention group at the end of the study period (-157 daily sedentary minutes, 95% CI -265 to -50, $P < 0.001$) in the sub-group that did not attend CR (*Figure 5*). Also, in this sub-group, the number of hours per day with ≥250 steps tended to be higher at the end of the study period in the intervention group (+0.7 h, 95% CI -0.02 to +1.43, $P = 0.057$), but was similar between groups in the intention to treat population (*Figure 6*).

Raw data on these secondary measures of activity for each assigned group during the first and last 5 compliant days of the study period and change between them are shown in Supplementary material online, *Table S2*. In exploratory analyses to get insight regarding comparison of the in-home intervention compared to centre-based CR, physical activity parameters for the 13 participants in the intervention group who did not also participate in CR were compared to the 8 participants in the control group who did participate in CR. In very under-powered analyses, there were trends toward greater daily active minutes and greater moderate to high intensity daily active minutes at the end of the study period among those assigned to the home-based intervention (Supplementary material online, *Figure S3*).

Secondary endpoints

Physical performance and quality of life. At the final study assessment, compared to control, the intervention did not appear to improve most measures of physical performance or quality of life (*Table 2* for the intention to treat population and Supplementary material online, *Table S3* for the two pre-specified sub-groups). Within the intention to treat population, compared to control, the intervention group took 2.3 fewer seconds (95% CI 0.3–4.2) for five chair rises at the final study visit (*Table 2*).

Adverse events

Among the 50 participants in the randomized study, there were no falls recorded during the 6-week study period or any serious adverse events related to the study.

Discussion

After TAVR, a pragmatic home-based mobile health exercise intervention was successfully implemented and demonstrated high compliance and increased physical activity compared to control, particularly among patients who did not participate in traditional centre-based CR. Prior literature suggests patients are less mobile 1 year after TAVR than before.[18] With little prior experience with this type of intervention in this patient population, the findings of this pilot study provide insight into feasibility, compliance, and data on the effects of such an intervention on physical activity, physical performance, and quality of life. These data could be used to design and power more definitive studies on the clinical efficacy of this type of intervention.

We observed that daily compliance with wearing the activity monitor was quite high (85–90%), although it declined over time in the control group (to ∼75%) perhaps related to the lack of feedback from the device; the high compliance in both groups was likely influenced by a screening and consenting process that tended to select out individuals who were unlikely to comply. Importantly, these compliance data are robust as they are based entirely on heart rate recorded by the device. Compliance was also high (∼85–90%) with daily resistance exercises appropriate for older adults, although this could have been inflated as it was based on self-report.

There was compelling evidence indicating that the intervention was associated with greater daily physical activity. In the intention to treat population, at the end of the study period, there was a statistically greater number of daily active minutes and active minutes of moderate to high intensity in the intervention group. These differences were even more pronounced among those not participating in traditional CR in whom the intervention, compared to control, was associated with 1730 more daily steps, 66 more daily active minutes, 53 more moderate to high intensity daily active minutes, and 157 fewer sedentary minutes. Contextualizing these differences, for older women participating in the Women's Health Study every increase of 1000 steps/day was associated with a 15–20% reduction in the adjusted hazard of all-cause mortality and 30–60 min of moderate intensity activity is recommended each day.[14,19] In patients undergoing TAVR, prior work has shown that a higher level of habitual physical activity, assessed by self-report and not actigraphy, was associated with lower 1-year mortality, even after adjustment for frailty and several other factors associated with mortality.[18] On average, habitual physical activity was lower 1 year after TAVR than prior to the procedure. Accordingly, while the activity monitor definition of moderate to vigorous activity may be over-inclusive, the magnitude of

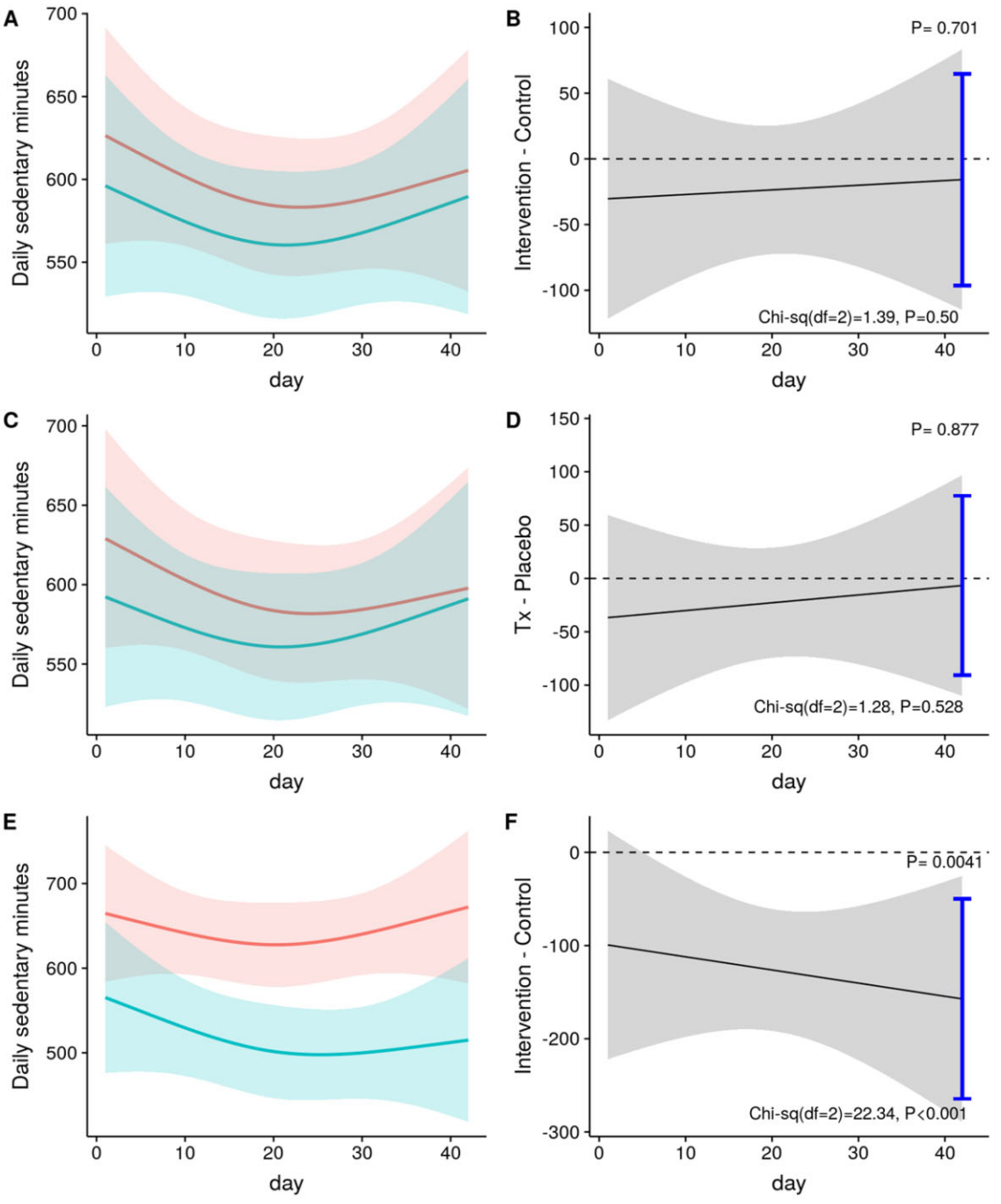


Figure 5 Daily sedentary minutes. The left and right panels show data exactly as described in *Figure 2* except that daily sedentary minutes are displayed in this figure.

difference between groups is substantial and may have important clinical consequences.

Except for a reduction in the chair sit-to-stand time, the intervention did not appear to have an effect on any physical performance or quality of life measures. This may have been due to the cohort enrolled and a ceiling effect for many of these measurements. Prior studies in higher risk patient cohorts have indicated that up to ~75% of patients undergoing TAVR are frail as measured by gait speed or SPPB.[1,20] In contrast, only 18% in this study had a slow gait speed and only 40% had an SPPB <10. With an average age of 76 years and STS score <3, our study population reflects a shift to lower risk and younger patients undergoing TAVR. Additionally, the KCCQ at Phase 2 baseline averaged 87.5 (out of 100), which is equivalent to NYHA functional class I and SPPB averaged 10 (out of 12). As such, in this population, there was relatively little room for improvement in physical performance and KCCQ from any intervention. Relevant to

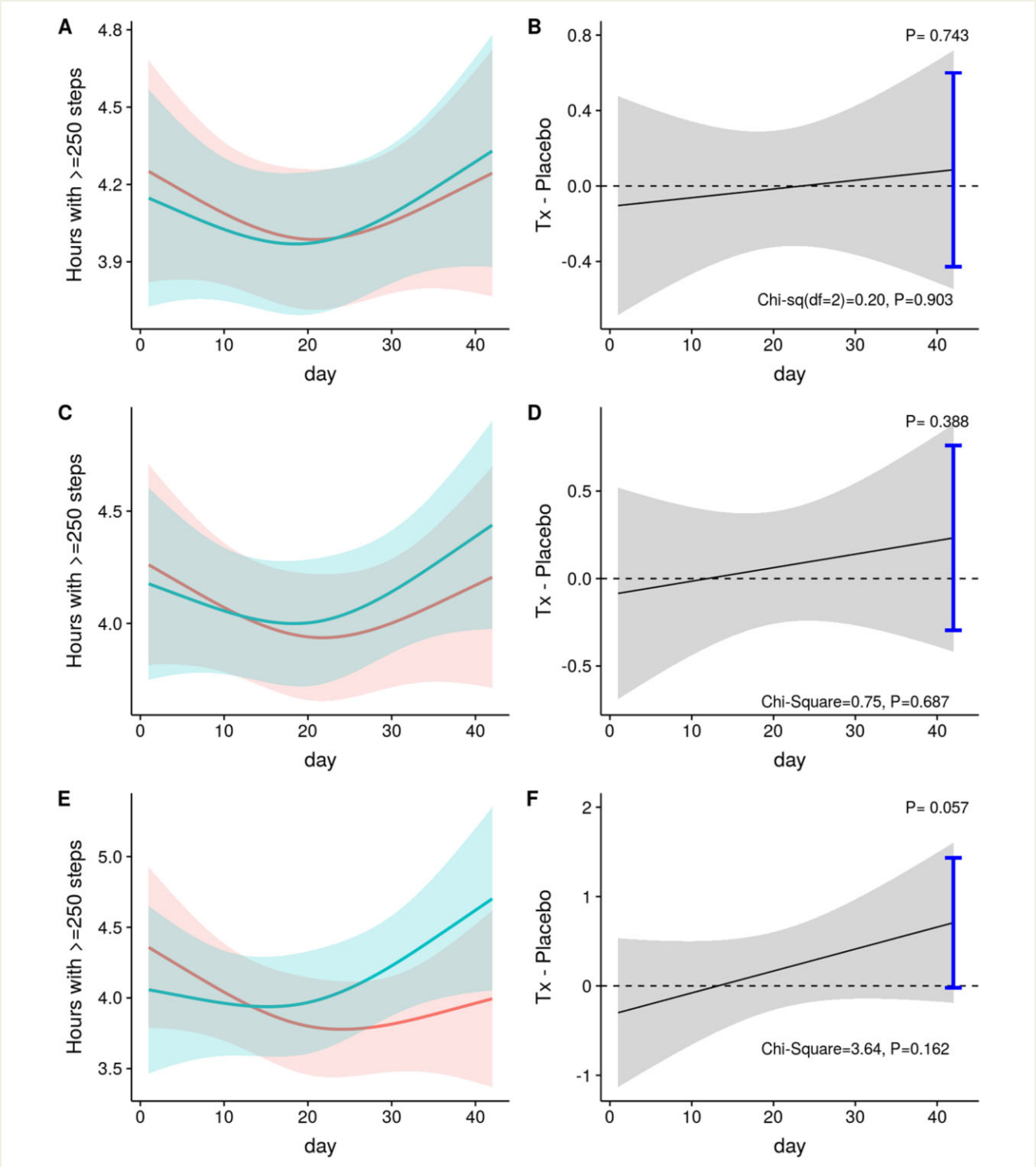


Figure 6 Daily number of hours with ≥250 steps. The left and right panels show data exactly as described in *Figure 2* except that daily hours with ≥250 steps are displayed in this figure.

this, among those not undergoing CR, an interaction analysis suggested that the intervention was associated with a higher SPPB (better physical performance) at the final visit when the starting SPPB was low (more impaired physical performance), but no difference when it started high.

Centre-based CR for individuals who have experienced a cardiovascular hospitalization or undergone a cardiovascular procedure is associated with improved survival and lower rates of rehospitalization.[6,7] Indeed, the magnitude of the benefit that comes from participation in CR exceeds many expensive drugs and procedures in

medicine. For example, a recent analysis of Medicare patients undergoing cardiac valve surgery showed that CR participation was associated with a 61% relative decrease and 4.2% absolute decrease in 1-year mortality risk and a 34% reduction in the relative risk of rehospitalization.[6] Despite this, many barriers to participation exist and only a minority attend.[6–8] This has spurred efforts to develop and test home-based or hybrid alternatives that could extend the benefits of CR to more individuals.[9] The core interventions of CR include exercise training to promote physical activity, dietary education to promote healthy eating, medication management to promote medication adherence, tobacco counselling to promote smoking cessation, and psychosocial assessment to promote stress management.[9,21] Prior studies have shown how particular components of CR are related to various outcomes, including an association between exercise training and lower all-cause mortality, but whether those findings apply to this older and more frail and inactive study population is not known.[22] Because our patient population is characterized by a high prevalence of physical inactivity and impaired physical function, our trial focused on testing an intervention to increase physical activity and muscle strength. Intriguingly, although home-based CR and centre-based CR may yield similar positive effects at the end of the intervention period, home-based CR may better facilitate long-term behaviour changes that yield more sustained improvements after the active intervention period is completed, but this requires further study.[23]

The scalability, generalizability, resource utilization, and costs of any alternative to traditional centre-based CR require careful consideration.[9] Complex interventions that may demonstrate effectiveness of home-based CR but that require multiple personnel to make home visits or regularly monitor patients remotely may be difficult to implement beyond the context of a clinical trial.[23,24] Interventions that target the most consequential behaviours in a manner that maximizes participant engagement and minimizes resources required are more likely to be effective and sustained over time.

Limitations

This was a pilot study with a limited number of participants and not powered to determine efficacy of the intervention. Because the control group knew their activity was being monitored, this may have influenced the activity habits of these individuals and blunted the difference in physical activity observed between groups. The lack of a progressive increase in the daily step goal for the intervention group could have yielded a ceiling effect for the influence of the intervention on physical activity. Due primarily to a lack of familiarity with the technological components of the study and a desire to avoid travelling a long distance for a research visit, many individuals were excluded which limits generalizability. While the run-in period was useful for a pilot study to filter out individuals who would not adhere to the study instructions, it could influence how generalizable the findings may be to an unselected post-TAVR population. Determination of exercise compliance was based on self-report alone. The resistance exercises may not have been challenging enough for many participants. Although comparisons were made between the tested in-home intervention and CR, our focus was more narrowly on physical activity and exercise, whereas key components of CR also include modifying risk factors, education, and counselling.

Conclusion

Among a selected group of participants treated with TAVR, compliance with a pragmatic home-based mobile health exercise intervention was high and associated with greater daily physical activity, particularly among participants who did not participate in traditional CR. While our study did not provide evidence that the exercise intervention improved physical performance or quality of life for the overall study cohort, it merits emphasis that the participants in this study were less frail than the general TAVR population with relatively high levels of physical function and quality of life at baseline. Whether a similar intervention targeting those not participating in traditional CR or more frail individuals may improve physical performance and quality of life requires further study. Beyond that, the clinical consequences (e.g. reduced mortality and rehospitalization) of any such improvements in those metrics by a home-based mobile health exercise intervention need to be examined. Given the dismal participation rates in traditional CR, which have been further reduced during a global pandemic, alternative approaches to CR are a pressing unmet need.

Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health*.

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Data availability

The data underlying this article are available in the article and in its online supplementary material.

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