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The Impact of a Wearable Activity Tracker and Structured Feedback Program on Physical Activity in Hemodialysis Patients: The Step4Life Pilot Randomized Controlled Trial

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Supplementary Material

Supplementary File (PDF)

Figure S1: Average daily steps taken per week and stratified by group (Fitbit plus feedback and Fitbit alone) (n = 46 participants who completed 12-week intervention).

Figure S2: Average steps taken per day stratified by randomized group (Fitbit plus feedback and Fitbit alone) at baseline, 4 weeks, 8 weeks, and 12 weeks (per-protocol analysis, 46 participants).

Figure S3: Average steps taken per day stratified by randomized group (Fitbit plus Feedback and Fitbit alone) at baseline, 4 weeks, 8 weeks, and 12 weeks (55 participants: multiple imputation for missing values).

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Data Sharing: Anonymized individual patient data and study documents can be requested from the corresponding author (r3malhotra@health.ucsd.edu).

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Abstract

Rationale & Objective: People with end-stage kidney disease (ESKD) have very low physical activity, and the degree of inactivity is strongly associated with morbidity and mortality. We assessed the feasibility and effectiveness of a 12-week intervention coupling a wearable activity tracker (FitBit) and structured feedback coaching versus wearable activity tracker alone on changes in physical activity in hemodialysis patients.

Study Design: Randomized controlled trial.

Setting & Participants: 55 participants with ESKD receiving hemodialysis who were able to walk with or without assistive devices recruited from a single academic hemodialysis unit between January 2019 and April 2020.

Interventions: All participants wore a Fitbit Charge 2 tracker for a minimum of 12 weeks. Participants were randomly assigned 1:1 to a wearable activity tracker plus a structured feedback intervention versus the wearable activity tracker alone. The structured feedback group was counseled weekly on steps achieved after randomization.

Outcome: The outcome was step count, and the main parameter of interest was the absolute change in daily step count, averaged per week, from baseline to completion of 12 weeks intervention. In the intention-to-treat analysis, mixed-effect linear regression analysis was used to evaluate change in daily step count from baseline to 12-weeks in both arms.

Results: Out of 55 participants, 46 participants completed the 12-week intervention (23 per arm). The mean age was 62 (± 14 SD) years; 44% were Black, and 36% were Hispanic. At baseline, step count (structured feedback intervention: 3,704 [1,594] vs wearable activity tracker alone: 3,808 [1,890]) and other participant characteristics were balanced between the arms. We observed a larger change in daily step count in the structured feedback arm at 12 weeks relative to use of the wearable activity tracker alone arm (Δ 920 [± 580 SD] versus Δ 281 [± 186 SD] steps; between-group difference Δ 639 [± 538 SD] steps; P <0.05).

Limitations: Single-center study and small sample size.

Conclusion: This pilot randomized controlled trial demonstrated that structured feedback coupled with a wearable activity tracker led to a greater daily step count that was sustained over 12 weeks relative to a wearable activity tracker alone. Future studies are required to determine longer-term sustainability of the intervention and potential health benefits in hemodialysis patients.

Funding: Grants from industry (Satellite Healthcare) and government (National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK).

Trial Registration: Registered at ClinicalTrials.gov with study number NCT05241171.

PLAIN-LANGUAGE SUMMARY

Patients receiving hemodialysis are known to have less physical activity. A sedentary lifestyle is associated with excess illness and death among those on dialysis. We performed a pilot randomized control trial to evaluate the effect of a structured feedback intervention coupled with a wearable activity tracking device to promote physical activity in patients receiving hemodialysis as compared with simply wearing an activity tracker. We found that implementation of a behavior feedback intervention to improve physical activity level is feasible and leads to a greater daily step count, which was sustained over 12 weeks, as compared with simply wearing an activity tracker without the accompanying intervention.

Physical activity is an important modifiable behavior that is known to impact morbidity and mortality.[1] Persons with advanced kidney disease, and especially those with end-stage kidney disease who are receiving maintenance hemodialysis (HD), are frequently deconditioned with decreased muscle mass, and they often have comorbidities such as anemia, malnutrition, and depression.[2] Patients receiving HD are known to have lower levels of physical activity as compared with the general population.[3] Several observational studies have also demonstrated that lower physical activity is associated with mortality in patients receiving HD.[4,5]

There has been growing experience with digital technology and intervention delivery modalities to capture and promote physical activity in chronic disease conditions.[6,7] However, little is known about using these interventions specifically in patients receiving HD.[3,8] Although digital technology can accurately measure step counts in patients receiving

HD,[3] it is not known whether it can be used as a tool to promote changes in physical activity. Moreover, the effect of behavior feedback interventions in patients receiving HD has been understudied.

We tested a weekly structured feedback intervention guided by a wearable activity tracker versus a wearable activity tracker alone to determine whether it would be feasible and would promote physical activity, and whether any observed changes in physical activity would be sustained for 12 weeks in patients receiving HD. We conducted a 12-week, unmasked, randomized, controlled pilot trial to determine the feasibility and effectiveness of providing structured feedback instructions along with a wearable activity tracker for improving physical activity levels in patients receiving HD as compared with the wearable activity tracker alone. We hypothesized that, equipped with activity data, sequentially informing the participants quantitatively about their levels of physical activity relative to other patients receiving HD would promote greater physical activity in this high-risk population.[8,9]

Methods

This was a 12-week, 2-arm, randomized, controlled pilot trial conducted in a single academic outpatient HD facility. The institutional review board at the University of California–San Diego approved the study (IRB 171917), and the trial was registered with Clinicaltrials.gov under identifier NCT05241171. Written informed consent was obtained from all participants.

Study Population

Fifty-five participants receiving maintenance HD thrice weekly between January 2019 and April 2020 provided consent to participate. The inclusion criteria included (1) HD for ≥3 months, (2) age ≥18 years, and (3) ability to walk with or without assistive devices. Participants who were wheelchair bound, with unstable clinical conditions (eg, acute infections, heart failure NYHA class 4 and/or unstable angina), had been hospitalized within 3 months before enrollment for non-access-related reasons, or had clinically recognized severe cognitive impairment including dementia or psychosis were excluded.

Randomization

All participants were provided a Fitbit Charge 2 (Fitbit, Inc) wearable activity tracker for 7 days before randomization and were asked to wear the device on their wrist (the side opposite to their vascular access) to measure their baseline physical activity. The participants were then randomized by an independent researcher in a 1:1 ratio to either the wearable activity tracker plus structured feedback (intervention) arm or the wearable activity tracker alone (comparator) arm; the randomization used a computer-generated random number sequence with permuted block randomization with block size of 2. The independent researcher was not involved in the conduct of clinical trial. Demographics, clinical and laboratory data, usage of medication, and dialysis parameters were collected from the electronic health record at time of study enrollment.

Measurements

The participants were instructed to wear the wearable activity tracker on their nonaccess arm during all hours, other than during bathing, for the 12-week study duration. A Fitbit user account was created and the wearable activity tracker configured for each participant. Every 3–5 days a member of the study team charged the wearable activity tracker while the participant was receiving HD within the dialysis unit; also at that time, the wearable tracker data was synchronized to Fitabase (Small Steps Labs), a commercially available research platform for aggregating and processing data from connected users in real time.[10] In this way, the study could check both battery life and continued tracking while the participant was undergoing a medical procedure where walking was not feasible. The Fitabase daily totals for steps were downloaded at the end of the study. Data from any day was considered valid when the pedometer was worn ≥10 hours.[11] Irrespective of their randomized arm, all participants received training on understanding the step-count data and feedback that the wearable activity tracker provided as well as how to use behavior tools available on the Fitbit website and app, including self-monitoring logs, message boards and other social tools, and reward badges. Each participant also received a printed intervention booklet that reinforced these instructions, which summarized the importance of physical activity for health and provided guidance for troubleshooting the wearable activity tracker.

Intervention

Participants who were randomized to the structured feedback intervention arm received face-to-face goal-setting counseling in the dialysis facility along with feedback graphs and charts to visualize their progress. The first feedback counseling session took place 1 week after baseline. Each week, a health care professional (nephrologists RM, SR, or UK) led the goal-setting process and reviewed the data, including progression of steps, with the participants during their dialysis session. The individualized goal-setting focused on increasing the daily and weekly step goals (generally a 10% increase in step count from baseline). However, the participants were also encouraged to set realistic, appropriate initial goals. Data from the baseline visit was used to facilitate the conversation about current activity levels and goals for the subsequent week. During this process, the participants were asked to establish personal moderate to vigorous physical activity and step goals and complete a goal-setting sheet that listed these goals, an action plan for achieving the goals (eg, 30-minute brisk walk on nondialysis day), anticipated barriers (eg, feeling tired after dialysis session), and a plan to address these barriers. The face-to-face goal-setting process took approximately 15–20 minutes once per week. To confirm that the participants fully understood the feedback suggestions, they were asked to explain how they had performed in the last few days. Participants in a self-managed comparator group did not receive any feedback on their activity level from the study team.

We also collected data on the participants' usage of the Fitbit app, website, and pedometer using self-reported questionnaires.[12] Responses were made on 8-point Likert scales. Responses were rated by the participants as more than once per day, once per day, 4–6 times per week, 2–3 times per week, once per week, 2–3 times per month, once a month or less, and never. The participants were asked to fill out the questionnaire with the help of a member of the study team at the 12-week visit.

Primary Outcome

The outcome was step count, and the main parameter of interest was the absolute change in daily step count, averaged per week, from baseline to completion of the 12-week intervention. We also evaluated the percentage change in the number of daily steps per week between the baseline visit and the 12-week study visit across the 2 arms in companion analyses.

Statistical Analysis

To plan for each arm, we estimated that to achieve >80% power to observe a mean difference in step count of at least 15% higher in the structured feedback arm compared with the wearable activity tracker–only arm[13,14] with 10% attrition rate, we would need 25 participants per arm (total n = 50). Continuous variables were expressed as the mean (± SD) or median (IQR). Categorical variables are expressed as absolute (n) and relative (%) frequency. Mixed-effect linear regression analysis was used to evaluate the absolute change in daily step count, averaged per week, from baseline to 12 weeks in both arms.

To investigate the intervention effect across time, we also compared changes in average daily step count, averaged per week, from baseline to week 4 and week 8. The main analyses were intention-to-treat analyses.

In secondary analyses we evaluated the per-protocol analyses among those who completed the trial, and we also evaluated the effect of the structured feedback intervention after using multiple imputation for missing data. We evaluated interaction (subgroups) analysis in participants with a complete set of step count data over the 12-week period according to age (≤65, >65 years), sex (male, female), race or ethnicity (Black, Hispanic, others), diabetes (yes/no), hypertension (yes/no), heart disease (yes/no), anemia (<10 mg/dL, ≥10 mg/dL), and serum albumin (<3.5 mg/dL, ≥3.5 mg/dL). These subgroups were not selected a priori, and post hoc analysis was performed; they were selected as they are known to effect physical activity. Statistical analyses were conducted using SPSS (IBM SPSS Statistics for Windows, Version 24.0; IBM Corp.), SAS software (SAS Institute), and Stata 9.3 (Stata Corporation). $P < 0.05$ was considered statistically significant for all analyses.

Results

Between January 2019 and April 2020, we approached 66 potentially eligible people receiving maintenance HD to reach our target recruitment goal of 50 HD participants. As some individuals were in the run-in week when we reached 50 patients, we ended up enrolling and randomizing 55 participants: 28 in the structured feedback group and 27 in the comparator group. Nine participants did not complete the 12-week intervention (5 participants in the structured feedback group and 4 participants in comparator group): 1 underwent transplantation, 1 transferred to a different HD unit, 1 refused to participate after signing the informed consent, 4 were hospitalized, and 2 died (Fig 1).

At baseline, the participants had a mean age of 62 ± 14 years, 28 (51%) were men, 24 (44%) were Black, and 20 (36%) were Hispanic. The prevalence of hypertension was 80% (n = 44), and 62% (n = 34) had diabetes. The mean dialysis vintage was 4.7 ± 2.4 years.

On average, the participants recorded 3,755 ± 1,730 mean (SD) steps per day in the week before randomization. The baseline demographics, clinical and laboratory characteristics, and number of steps were well balanced by randomization arm (Table 1).

In the 46 participants who completed the 12-week intervention, there was no significant difference in adherence to wearing the activity tracker between the structured feedback and comparator groups (P = 0.21). Adherence to the use of the pedometer appeared to peak at week 3 in the structured feedback group, dropped slightly to approximately 93% using it for ≥10 hours per day by week 5, and then modestly declined during the remainder of the 12-week intervention (Fig 2). Overall, adherence remained >90% across the 12-week intervention in the structured feedback group. Trends were similar overall in the comparator group although adherence was consistently approximately 3% lower.

Figure 3 shows the primary outcome (absolute change in step count) stratified by treatment arm. In the intention-to-treat analysis (n = 55), the participants in the intervention group experienced a statistically significantly greater increase in daily step count from baseline to week 12 compared with the participants in the comparator group (920 ± 580 vs 281 ± 186; between-group difference Δ 639 [± 538 SD] steps; P < 0.05). The magnitude of change in step count differences appeared most pronounced in the first 4 weeks (wearable activity tracker plus structured feedback: Δ 1,126 [± 517 SD] versus wearable activity tracker alone Δ 494 [± 281 SD) steps; between-group difference Δ 632 [± 523 SD] steps; P < 0.001) and modestly decayed thereafter yet remained statistically significantly different across the arms throughout the end of the intervention (Fig 3; Table 2). In the per-protocol analysis (n = 46 participants) and multiple imputation analysis (n = 55 participants) we found similar results to those in the intention-to treat analysis (Figs S1–S3).

The structured feedback intervention increased the average daily step count versus the comparator group in all subgroups we evaluated. However, the effect of the intervention was more pronounced in the younger participants (age ≤65) for total step count. The intervention also appeared more effective in those without known heart disease or severe anemia, and in those with higher serum albumin concentrations (Fig 4).

There were 2 reported falls in the intervention arm and 1 fall in the comparator arm. Findings from end-of-study questionnaires at 12-week are summarized in Figure 5. The majority of participants (n = 32, 69%) reported never using the Fitbit app or website, whereas 22% (n = 10) used it at least once per week.

Discussion

In this single-center, randomized, controlled pilot trial conducted in participants receiving maintenance HD, coupling a wearable pedometer with weekly structured feedback with goal-setting versus using a wearable activity tracker alone was associated with an increased step count over the 12-week duration. This change occurred rapidly over the first 4 weeks and appeared sustained over the 12-week study. The magnitude of differences in steps was large across the arms, both in terms of their potential impact on downstream clinical changes and in statistical significance. These data demonstrate the feasibility of using a wearable

activity tracker to increase physical activity when patients are away from the HD unit, and the feasibility of a structured feedback intervention to increase physical activity in patients receiving HD.

In our study, the mean daily steps of the participants receiving HD (3,755 steps/day) were lower than the reported daily steps in other chronic conditions, including chronic obstructive pulmonary disease (5,804 steps/day), heart failure (5,191 steps/day), and cancer (5,103 steps/day).[15–17] Thus, this finding confirms that patients receiving HD are often extremely sedentary, perhaps even more so than patients with other severe chronic health conditions.

Several prior studies have demonstrated the utility of using wearable pedometers to monitor physical activity and encourage increases in physical activity in populations living with a variety of chronic health conditions.[6,7,15–17] Within nephrology, investigators have evaluated the feasibility of using wearable pedometers to objectively measure physical activity in patients with both earlier stages of chronic kidney disease and in patients receiving HD.[3,8] Although there is widespread interest in intervention delivery modalities, studies evaluating behavior modification incorporating feedback to wearable technology are in their infancy in HD populations.[8,9,18] In a study of 29 patients receiving HD, Williams et al[19] reported no difference in the number of steps between a feedback group (n = 15) and a control group (n = 14) (5,365 ± 2,765 vs 5,211 ± 2,010, respectively) over 5 weeks.

In contrast, Sheshadri et al[9] reported a significant increase in average daily steps by 2,256 (95% CI, 978–3,537) in their feedback group as compared with their control group over 3 months, a time horizon similar to our study. Unfortunately, these differences were not maintained beyond 3 months. Our findings are in concordance with Sheshardri et al where we also showed improvement in average daily steps over a 12-week period. There were some differences in study design between the 2 studies. We required continuous wearing of a wrist-based wearable activity tracker; Sheshadri et al used a waist-worn pedometer during waking hours only. Our step data was synchronized directly to Fitabase whereas step count data were recorded manually on daily basis in other study. Also, we provided face-to-face structured feedback versus the telephonic counseling used by Sheshadri et al.

Our findings demonstrate that a face-to-face feedback intervention is feasible and can meaningfully increase step count in patients receiving HD. The 639 additional steps in the intervention arm were around 17% more steps per day than observed in the comparator arm. This may have important downstream health implications: changes of this magnitude have been associated with standardized risk reductions of approximately 3% to 4% in cardiovascular events and 4% to 6% in mortality in other populations.[20,21] Whether the intervention tested here could translate into reductions in cardiovascular disease and mortality in patients receiving HD is an exciting possibility but needs to be validated in future studies.

We also observed increases in step counts in our comparator group relative to their baseline step count, especially in the first 4 weeks after enrollment. The wearable pedometer, access to the online apps, websites to monitor step count, and education to motivate greater physical activity were given to both groups at baseline, which may explain this finding.

This finding further emphasizes the need of new multimodal approaches to increase long-term adherence to physical activity interventions in patients receiving HD, which would include feedback, individualized graphs of progress, motivational and educational content, and similar tools. The addition of integrated health coaching in dialysis units might further facilitate and sustain physical activity and improve fitness.

The 12-week feedback intervention appeared to be effective in increasing step count in all subgroups. However, when evaluated for absolute change in daily steps, the results in mean steps were more modest in the oldest participants and those who had a higher degree of comorbidity. The results were more similar when evaluated as a percentage change in step count, as these subgroups had lower step counts at baseline.

This finding has significant clinical and research implications. Though many physicians recognize the importance of physical activity, some may mistakenly believe that older participants with higher comorbidity burden may not be interested in or capable of benefiting from physical activity interventions. Our findings are reassuring that the multimodel intervention approach improved step count across the spectrum of patients receiving HD we evaluated, which supports broad inclusion criteria in future physical activity trials in the HD population. We believe it is likely that even modest improvements in physical activity may translate to health benefits, even in the oldest patients and in those with the greatest comorbidity, because this population will bear the highest absolute risk of adverse health outcomes.

Our study has many strengths including its design as a randomized controlled trial and use of a reliable and valid technology to capture step count data. The study also included patients who ambulated with an assistive device, which is common in patients receiving HD. We had high recruitment rates, which was possible due to frequent clinician engagement and social networks between patients in our academic dialysis facility.

The study has also important limitations. First, the study evaluated participants from a single academic HD center, and the sample size was small (n = 55). The study duration was only 12 weeks, so we lack data on long-term adherence or downstream health consequences. Not all participants who were approached consented to participate, and 9 dropped out before completion; however, our study findings were similar between intention-to-treat and per-protocol analyses. We lacked data on neurocognition, which may influence the effectiveness of behavioral feedback intervention. Weekly regular interaction and charging of the device may itself induce awareness and feedback above and beyond the tested intervention. We conducted this study in a region with temperate ambient weather conditions throughout year, which may affect its generalizability to other regions or its effectiveness in other climates. Finally, we assessed steps per day rather than intensity of physical activity.

In conclusion, in this single-center randomized pilot clinical trial we demonstrate that coupling a wearable activity tracker with a structured feedback intervention is feasible and results in an increase in daily step count, which was sustained for 12 weeks among participants receiving HD. Future studies should focus on evaluating the impact of this intervention on longer-term sustainability and on downstream health changes. Future studies

are also needed on self-efficacy behavior interventions to promote long-term adherence of physical activity interventions in patients receiving HD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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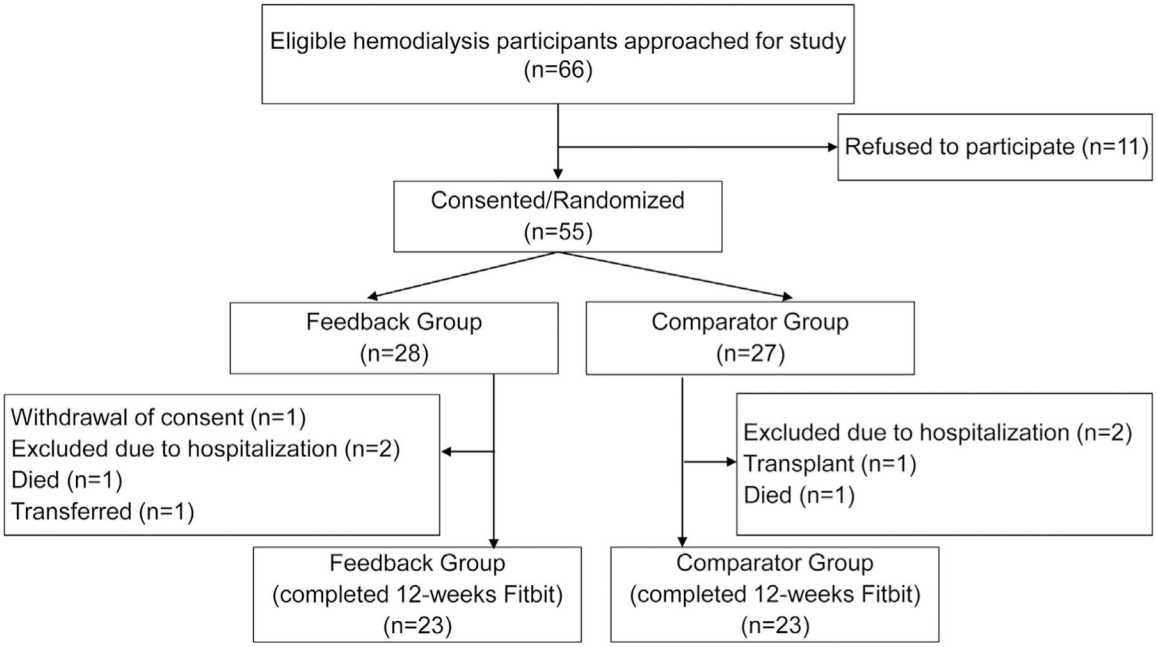

Figure 1.
Flowchart of the study enrollment and randomization.

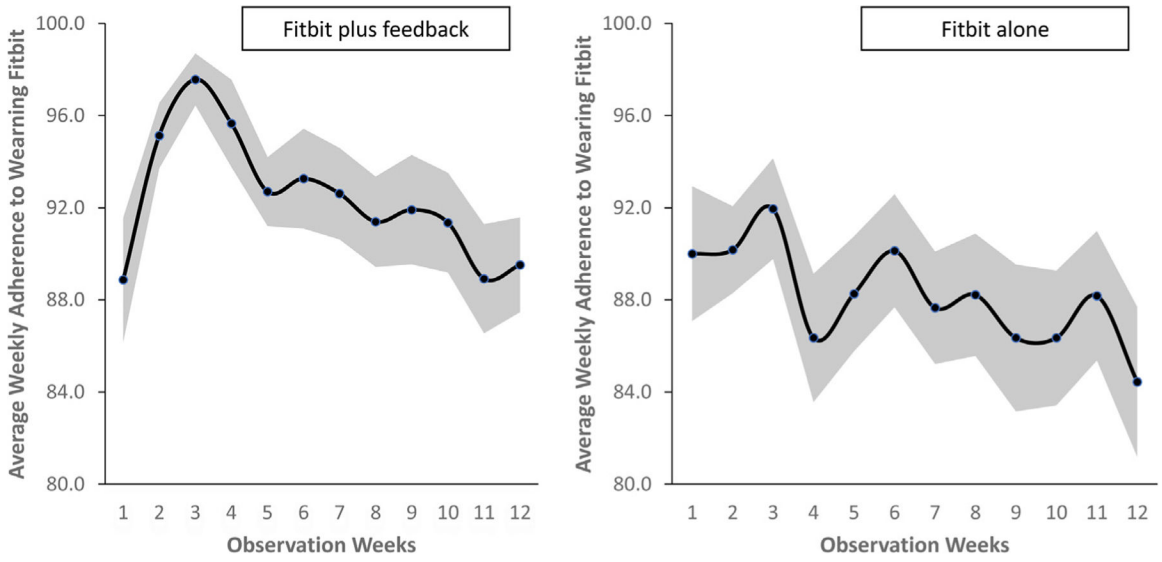

Figure 2.

Weekly percent adherence to wearing the Fitbit, averaged (standard error) across study participants who completed 12-week intervention (n = 46), and stratified by groups (Fitbit plus feedback [n = 23] and Fitbit alone [n = 23]). We defined a valid day as ≥10 hours of wear per day.

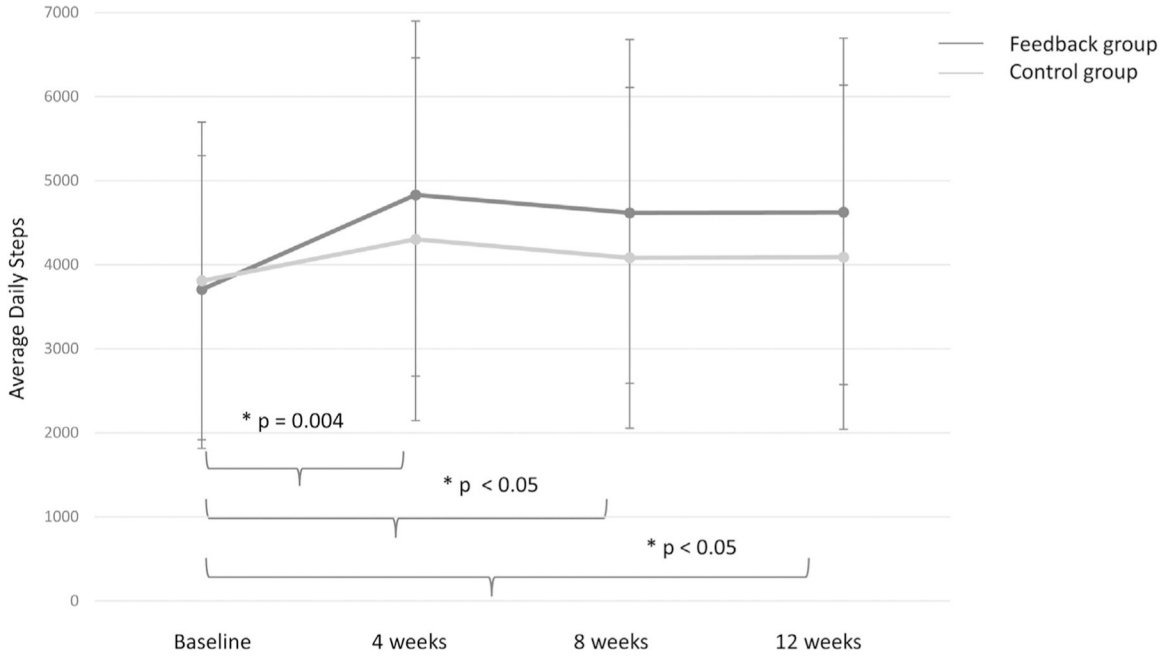

Figure 3.

Average steps taken per day stratified by randomized group (Fitbit plus feedback and Fitbit alone) at baseline, 4 weeks, 8 weeks, and 12 weeks (intention-to-treat analysis, 55 participants). The error bar represents SD. *Indicates differences between group for change in steps.

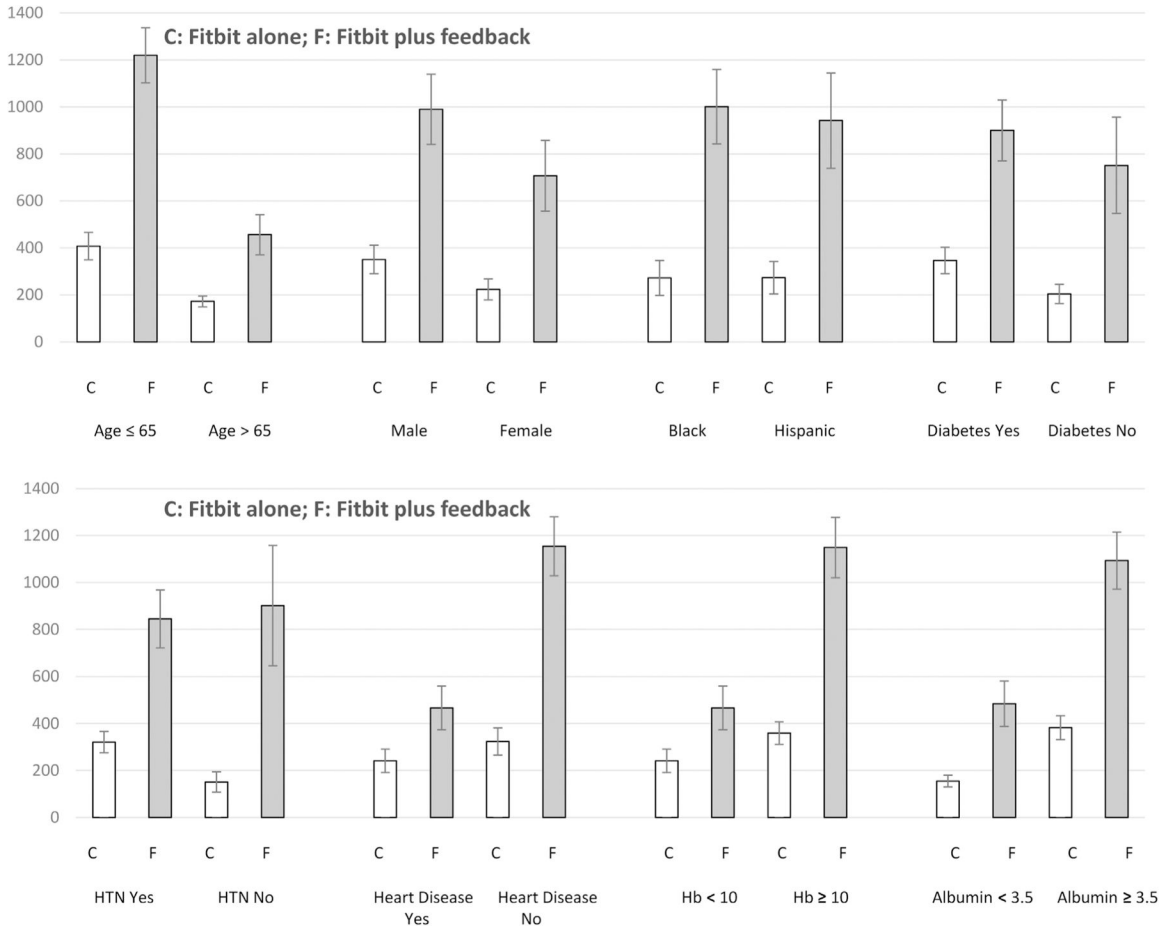

Figure 4.

Change in steps to the feedback Fitbit intervention by participant characteristics who completed 12-week intervention (n = 46). The error bar represents standard error. *P* value for interaction: age and Hb < 0.001; heart disease 0.005; albumin = 0.001. Abbreviations: Hb, hemoglobin; HTN, hypertension.

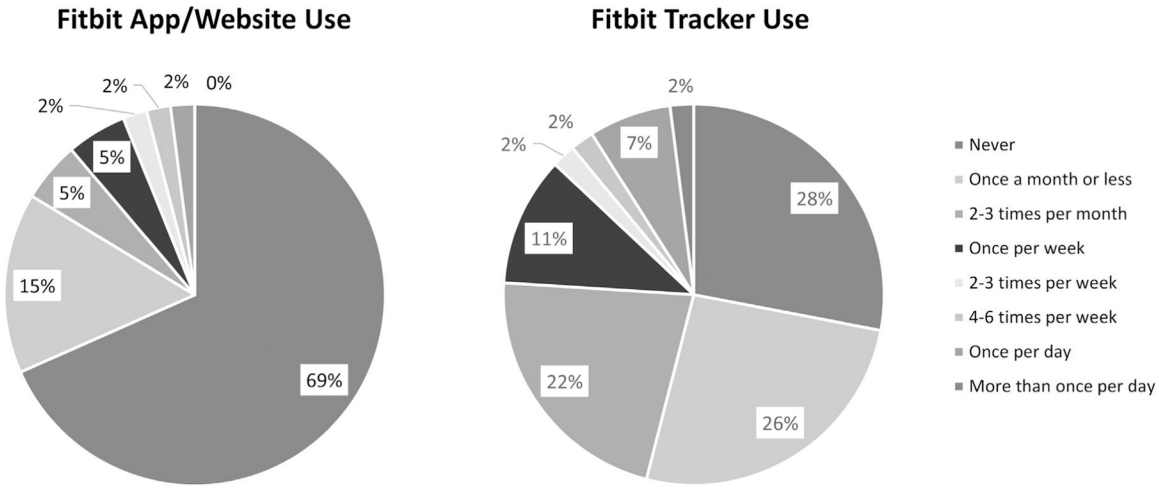

Figure 5.
Fitbit monitoring questionnaire.

Table 1.

Clinical Characteristics of Study Participants at Baseline

Variables	Feedback Group n = 28	Control Group n = 27
Age, y	62 ± 13	61 ± 14
Sex, male	15 (54%)	13 (48%)
Race/ethnicity		
Black	12 (43%)	12 (44%)
Hispanic	9 (32%)	11 (40%)
BMI, kg/m^2	30 ± 8	31 ± 9
Education, at least high school graduate	8 (29%)	10 (37%)
Employment, part-time/fulltime	2 (7%)	2 (7%)
Diabetes	18 (64%)	16 (59%)
Hypertension	23 (82%)	21 (78%)
History of heart disease	14 (50%)	13 (48%)
Cause of ESRD		
Diabetes	13 (47%)	12 (44%)
Hypertension	11 (39%)	10 (37%)
Other	4 (14%)	5 (19%)
Depression	6 (26%)	5 (22%)
Treatment-related Parameters		
Dialysis shift (M-W-F)	18 (64%)	16 (59%)
Dialysis vintage, y	4.6 ± 2.1	4.9 ± 2.7
Vascular access, AV fistula	18 (64%)	16 (59%)
Hemodialysis treatment time, min	242 ± 23	236 ± 26
Intradialytic weight gain, kg	2.7 ± 1.4	2.5 ± 1.6
eKt/V	1.6 (0.3)	1.5 (0.2)
Pre-SBP, mm Hg	152 ± 16	149 ± 15
Post-SBP, mm Hg	140 ± 20	139 ± 15
Pre-DBP, mm Hg	72 ± 15	76 ± 9
Post-DBP, mm Hg	68 ± 12	72 ± 11
Laboratory-related Parameters		
Hemoglobin, g/dL	10.3 ± 1.2	10.5 ± 1.2
Albumin, g/dL	3.6 ± 0.3	3.6 ± 0.3
Sodium, mg/dL	138 ± 3	139 ± 4
Potassium, mg/dL	4.9 ± 0.5	5.0 ± 0.6
Calcium, mg/dL	9.3 ± 0.6	9.3 ± 0.7
Phosphorous, mg/dL	5.5 ± 1.8	5.6 ± 1.7
Activity Parameters		
Steps	3,704 ± 1,594	3,808 ± 1,890
Sedentary (<5,000 steps/d)	21 (75%)	23 (85%)

Variables	Feedback Group n = 28	Control Group n = 27
Use of assisted device (cane/walker)	4 (14%)	5 (19%)

Values for continuous variables given as mean ± SD; for categorical variables as count (percentage). Abbreviations: AV, arteriovenous; BMI, body mass index; DBP, diastolic blood pressure; ESRD, end-stage renal disease; F, Friday; M, Monday;

Table 2.

Baseline to 4-Week, 8-Week, and 12-Week Changes in Step Count in Hemodialysis Patients Receiving Weekly Feedback Versus Controls

	Feedback Group				Control Group				Between-Group Difference	Between-Group *P* Value
	Baseline	Time Point	Absolute Change	Percent Change	Baseline	Time Point	Absolute Change	Percent Change		
4-week time point										
Average steps/d	3,704 ± 1,594	4,830 ± 2,068	1,126 ± 517	30 ± 7	3,808 ± 1,890	4,302 ± 2,159	494 ± 281	13 ± 4	632 ± 523	<0.001
8-week time point										
Average steps/d	3,704 ± 1,594	4,617 ± 2,068	913 ± 520	25 ± 7	3,808 ± 1,890	4,083 ± 2,028	275 ± 167	7 ± 3	638 ± 502	<0.05
12-week time point										
Average steps/d	3,704 ± 1,594	4,624 ± 2,072	920 ± 580	25 ± 7	3,808 ± 1,890	4,089 ± 2,049	281 ± 186	7 ± 3	639 ± 538	<0.05

Values are given as mean ± SD.