Group-Based Exercise in CKD Stage 3b to 4: A Randomized Clinical Trial

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Rationale & Objective: We aimed to test interventions to improve physical activity in persons with advanced chronic kidney disease not yet receiving dialysis.

Study Design: Randomized controlled trial with parallel-group design.

Setting & Participants: We embedded a pragmatic referral to exercise programming in high-volume kidney clinics servicing diverse populations in San Jose, CA, and Atlanta, GA. We recruited 56 participants with estimated glomerular filtration rates < 45 mL/min/1.73 m^2.

Interventions: We randomly assigned participants to a mobile health (mHealth) group—wearable activity trackers and fitness professional counseling, or an Exercise is Medicine intervention framework (EIM) group—mHealth components plus twice-weekly small-group directed exercise sessions customized to persons with kidney disease. We performed assessments at baseline, 8 weeks at the end of active intervention, and 16 weeks after passive follow-up and used multilevel mixed models to assess between-group differences.

Outcomes: Activity tracker total daily step count.

Results: Of 56 participants, 86% belonged to a racial/ethnic minority group; randomly assigned groups were well balanced on baseline step count. In intention-to-treat analyses, the EIM and mHealth groups both experienced declines in daily step counts, but there was an attenuated reduction in light intensity physical activity (standard error 0.2 [5.8] vs −8.5 [5.4] min/d; P = 0.08) in the EIM compared with the mHealth group at 8 weeks. In as-treated analyses, total daily step count, distance covered, and light and moderate-vigorous activity minutes per day improved in the EIM group and declined in the mHealth group at 8 weeks (standard error +335 [506] vs −884 [340] steps per day; P = 0.05; P < 0.05 for secondary measures), but group differences faded at 16 weeks. There were no differences in quality-of-life and mental health measures during the study.

Limitations: Small sample size, limited duration of study, assessment of intermediate outcomes (steps per day).

Conclusions: A clinic-integrated referral to small-group exercise sessions is feasible, safe, and moderately effective in improving physical activity in an underserved population with high comorbid conditions.

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Visual Abstract included

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Physical activity is associated with improved cardiovascular health, physical function, quality of life, transplant outcomes, and survival in persons with chronic kidney disease (CKD).[1-6] However, at the time of dialysis initiation, 44% cannot walk 1 block and 56% cannot climb 12 stairs.[7] Further, after starting dialysis, only 13% of elderly persons maintain functional status in the first year.[8]

Exercise interventions in persons with CKD have been primarily limited to the subpopulation who are receiving dialysis. In a meta-analysis of 41 exercise intervention trials targeted to patients with kidney disease, 6 enrolled patients with CKD not yet receiving dialysis.[9] An intervention at earlier stages of CKD could mitigate the near-doubling of risk for mortality seen in the first 120 days of initiation[10-12] and engage patients before frequent medical interactions with centers and hospitals.[13]

Given the dearth of studies in patients with advanced CKD, the type of programming most effective and acceptable to this population—and thus amenable to wider implementation at scale—is unclear. Group-based exercise training has a track record in multiple chronic conditions.[14,15] In the most prominent and now widely scaled example, lifestyle coaching paired with exercise sessions in the Diabetes Prevention Program reduced diabetes incidence by 58% in high-risk persons.[16] Wearable technology-enabled interventions are also gaining prominence; 1 systematic review of 28 studies noted a 24% increase in daily step count and 27% increase in moderate to vigorous physical activity with wearable activity tracker–related interventions.[17] However, a study of persons with peripheral vascular disease investigating the effect of telephone coaching and wearable technology found no improvement over 9 months compared with usual care, suggesting the importance of additional on-site interventions.[18]

We sought to test the feasibility, acceptability, and effectiveness of integrating, through clinical referral, a technology-enabled group-based exercise program in persons with advanced CKD not yet receiving dialysis. Working in 2 diverse clinical populations and using the American College of Sports Medicine Exercise Is Medicine (EIM) intervention framework,[19,20] we randomly assigned

PLAIN-LANGUAGE SUMMARY

Exercise is associated with longer life spans in patients with advanced kidney disease, but minimal programming exists to support patients even as they are dealing with complex medical transitions to dialysis and often experiencing loss in physical function in the process. We wanted to create a sustainable academic-community partnership in clinics servicing diverse populations to provide technology-enabled group exercise programming for patients with advanced kidney disease. Despite challenges in recruitment, we were able to create such an infrastructure, and among the people who engaged with the customized programming, we saw improvements in physical activity as measured by step counts. Implementing research projects such as ours will be key to increasing the reach and scale of much-needed exercise programming for patients with kidney disease.

persons to a wearable activity tracker and physical activity counseling (mobile health [mHealth] group) versus the more intensive intervention of mHealth augmented by in-person small-group training sessions led by an EIM fitness professional (EIM group). In addition to assessing recruitment, adherence, and safety, we evaluated the preliminary effectiveness of the interventions on: (1) objectively measured steps (through wearable activity tracker), (2) physical function measures (6-minute walk test and handgrip strength), and (3) self-reported mental health.

METHODS

The study protocol is published[21] and registered on clinicaltrials.gov (NCT03311763). Briefly, we recruited participants from 2 high-volume nephrology clinics at Emory University (Atlanta, GA; 1,200 patient encounters per month) and Stanford University/Santa Clara Valley Medical Center (San Jose, CA; 950 patient encounters per month). The 2 study sites serve largely minority populations (African American in Atlanta and Asian and Hispanic in San Jose). Clinics administered a screening questionnaire to assess patients' interest in improving physical activity in the waiting room, and thereafter, study research coordinators assessed eligibility based on prespecified inclusion/exclusion criteria (Table S1). The study received institutional review board (IRB) approval from all participating centers (Stanford IRB approval number: 43198) and Emory University (IRB number: IRB00099894).

Upon obtaining informed consent, we used a random number generator to a priori assign treatment group to 28 participant identification numbers at each site. We assigned participant identification numbers sequentially in the order by which study coordinators obtained consent. After we obtained consent, we first completed baseline assessment and then disclosed the assigned treatment to the participant.

Intervention

At baseline, we provided all participants with the wearable Garmin Vivofit 3 activity tracker, a tutorial on device use, and a free custom smartphone application for data syncing (IOS or Android). The application, developed as part of the EIM framework, allows for participants to track their step count and enables the study staff to remotely monitor participants' physical activity.

Trained fitness professionals counseled participants randomly assigned to the mHealth group in a 30-minute face-to-face session.[22] The counseling session used brief-action planning, a self-management support technique grounded in motivational interviewing and behavior change strategies (goal setting, identify preferences and barriers, problem solving, stages of change, and self-monitoring).[23] Fitness professionals encouraged integration of moderate physical activity throughout the week to achieve 100 to 150 minutes per week, primarily through walking for leisure and transportation or other preferred activities. The fitness professional performed weekly short (5-minute) interactions by telephone or text messaging to support, check on progress, and answer questions as needed for the 8-week intervention period.

Participants randomly assigned to the EIM group underwent the same counseling sessions and additionally were enrolled in an 8-week exercise program with twice-weekly 1-hour sessions led by the EIM fitness professionals and offered at community centers or facility grounds available near (<5 km) the nephrology clinic. Sessions were held for up to 8 participants and included a progressive training plan including aerobic conditioning, resistance, flexibility, stability, and balance training, slowly progressing toward 50 minutes of light to moderate physical activity per session. Blood pressure cuffs and glucometers were available for participants who experienced symptoms related to hypotension or hypoglycemia before, during, or after the class. After 8 weeks of intervention, the group-based exercise sessions were discontinued and participants were encouraged to accumulate moderate physical activity throughout the week on their own during the 8-week passive follow-up period.

Study Measures

We undertook study assessments at 3 time points: baseline, 8 weeks (at the end of exercise sessions for the EIM group), and 16 weeks. We obtained the following questionnaires at each study visit: Center for Epidemiological Studies-Depression questionnaire,[24] 12-Item Short-Form Health Survey,[25] Exercise Confidence Survey,[26,27] Brief Resilience Scale,[28] and International Physical Activity Questionnaire.[29] We additionally obtained body composition and functional fitness at each study visit using a standardized protocol[30]; height,

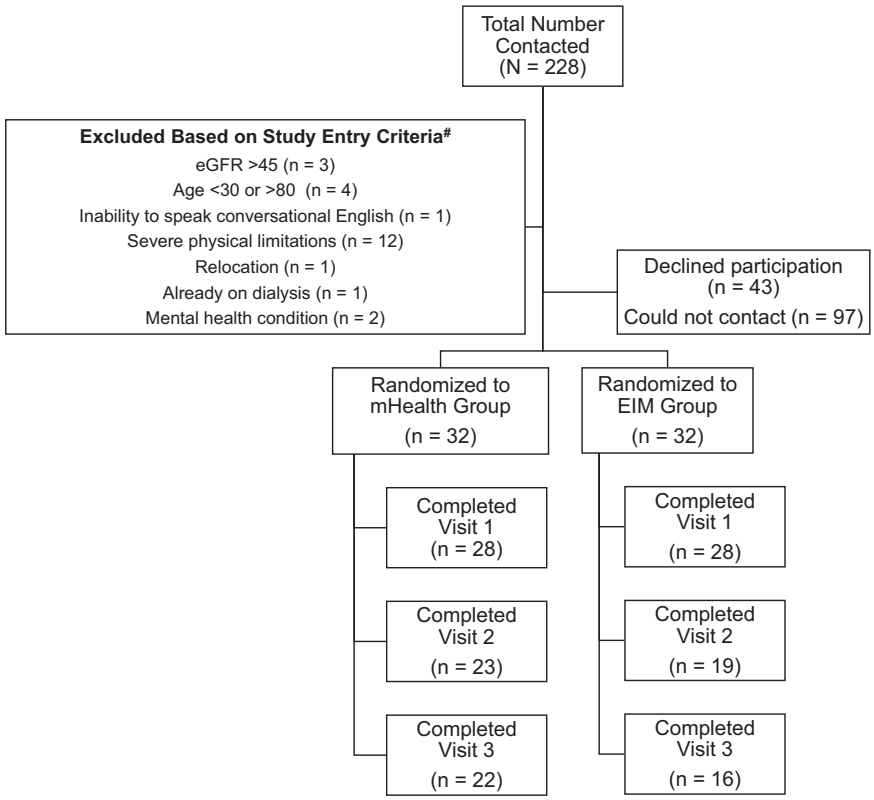

Figure 1. Study participant enrollment flowchart. Abbreviations: eGFR, estimated glomerular filtration rate; EIM, Exercise Is Medicine; mHealth, mobile health.

weight, Quételet (body mass) index, waist circumference, blood pressure at rest, 6-minute walk test,[31] and grip strength with a digital dynamometer (Takei 5401; Takei Scientific Instruments, Inc).

We also obtained an exit survey, and for participants in the EIM group, we additionally documented hospitalizations and session-related adverse events. The wearable activity tracker captured daily step count (primary outcome), distance traveled, and minutes of light and moderate to vigorous physical activity per day. This device was highly ranked in terms of validity, behavior change features, and data integration feasibility in a recent review of consumer-oriented wearable activity measurement devices for use in health care settings.[32,33] Furthermore, that this device has a 1-year battery life and is waterproof greatly enhances the likelihood of adequate wear time (see Item S1 for details on wearable activity tracker assessments).

Statistical Analysis

To compare the distribution of baseline characteristics after randomization to the mHealth and EIM groups, we used χ^2 test, Fisher exact test, 2-sample *t* test, and Wilcoxon rank sum test, as appropriate. We used multilevel mixed models with the restricted maximum likelihood approach to analyze the outcomes measured at 8 and 16 weeks and handle missing data. For each outcome measure, the model accounted for the intervention, time since intervention (baseline, 8 weeks, and 16 weeks), study site, and intervention-by-time interaction. The intervention-by-time interaction, which reflects the relative difference in change in the parameters over time, was the primary parameter for testing of difference between groups. We modeled dependent variables using fixed effects and incorporated individual level as the random effects to account for the correlation of outcomes measured over time. We report adjusted means and standard errors for each outcome. We conducted intention-to-treat and as-treated analyses, for which the "as-treated" EIM group was defined as participants attending at least 1 EIM session, and participants who did not attend any EIM sessions were assigned to the mHealth group.

Analyses were conducted using SAS, version 9.4 (SAS Institute). Results presented fulfill the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized-controlled trials.[34]

RESULTS

Participant Enrollment and Characteristics

Figure 1 outlines participant enrollment; 56 participants enrolled in the study (28 at Stanford and 28 at Emory).

Table 1 demonstrates participant characteristics by study group, which did not differ by age, sex, race, ethnicity, smoking status, comorbid conditions, cause of CKD, and baseline daily step total. Most participants (86%) belonged to a racial or ethnic minority group and 30% had diabetes as cause of CKD. Randomization was well balanced by characteristics listed in Table 1. The groups were well balanced at baseline by physical function measures of the 6-minute walk test and handgrip strength (Table S2).

Feasibility Assessment: Adherence and Safety

A larger number of participants in the EIM group (16 [57%]) compared with the mHealth group (7 [25%]) missed at least 1 study assessment session. Of the 16 EIM group participants missing a measurement, 11 (69%) also did not come to any exercise sessions. Adherence to wearable activity tracker use was similar in both groups: 3 participants (11%) in the EIM and 4 (14%) in the mHealth group did not log any wearable activity tracker data.

Table 2 compares participants who did and did not attend offered sessions. Participants who did not attend exercise sessions (N = 11 [39%]) were more likely to have been hospitalized during the study (46% vs 24% of participants, respectively). Among participants who attended at least 1 session, median for attendance was 10 (25th percentile, 7; 75th percentile, 12) sessions. During a single exercise session, 1 participant had elevated blood pressure at the time of arrival, which precluded their participation in that session. No other study-related adverse events were recorded.

Effectiveness Assessment: Physical Activity

In the intention-to-treat analyses, adjusted mean step counts and distance traveled decreased in both the EIM group and mHealth group at 8 and 16 weeks, without differences in mean change in step count in the groups over time (Standard Error [SE] −217.6 [610.4] vs −730.9 [568.1] steps per day; P = 0.25; and −1,217.1 [624.4] vs −946.1 [576.9] steps per day; P = 0.84) comparing 8 and 16 weeks with baseline in the EIM versus mHealth groups, respectively (Fig 2A and B). In as-treated analyses, the EIM group experienced an improvement at 8 weeks and had a smaller decrease at 16 weeks compared with the mHealth group, which continued to decline over time (SE +334.6 [506.0] vs −883.8 [339.6] steps per day; P = 0.05, and +381.8 [923.7] vs −1,362.9 [644.3] steps per day; P = 0.39, comparing 8 and 16 weeks with baseline in the EIM vs mHealth groups, respectively). A similar pattern emerged for distance traveled (Fig 2C and D).

For intensity of physical activity, in the intention-to-treat analyses, light physical activity levels declined over time in both groups, but to a lesser degree in the EIM group at 8 weeks (Fig 3; 0.2 [5.8] vs −8.5 [5.4]; P = 0.08, and ≤6.3 [6.0] vs ≤9.7 [5.5] minutes per day; P = 0.69 comparing 8 and 16 weeks with baseline in the EIM vs mHealth groups, respectively). In the as-treated analyses, mirroring the step count data, light physical activity levels improved at 8 weeks and had a smaller decrease at 16 weeks in the EIM compared with the mHealth group, which experienced a continuous decline (4.5 [7.0] vs ≤8.8 [4.7]; P = 0.02, and 1.6 [7.0] vs ≤13.0 [4.9] minutes per day; P = 0.20 comparing 8 and 16 weeks to baseline in the EIM vs mHealth groups, respectively). Moderate to vigorous physical activity levels improved slightly in the EIM group compared with the mHealth group both at 8 and 16 weeks in the intention-to-treat and as-treated analyses.

Effectiveness Assessment: Physical Function Measures, Blood Pressure, and Anthropometrics

Table S2 delineates physical function, blood pressure, and anthropometric measurements in the 2 groups. Mean overall results for all study participants at baseline are as follows: 405.8 (standard deviation [SD], 117.4) m in the 6-minute walk test, 25.4 (SD, 11.7) kg handgrip strength, 41.4 (SD, 5.8) Physical Component Summary scores on the 12-Item Short-Form Health Survey, 37.5 (SD, 64.7) minutes per day in moderate and vigorous physical activity, 17.2 (SD, 20.3) minutes per day in walking time, and 6.9 (SD, 3.4) hours per day in sedentary time measured by International Physical Activity Questionnaire. In as-treated analyses, systolic blood pressure decreased modestly in the EIM compared with the mHealth group at 8 weeks (P = 0.06). None of these assessments differed by group at baseline or 8 or 16 weeks.

Effectiveness Assessment: Self-reported Mental Health and Exercise Self-Efficacy

Table 3 delineates the results of mental health and exercise self-efficacy questionnaires of study participants in the 2 study groups. Similar to physical function measures, the measures did not differ by group at baseline or over the study period.

Intervention Feedback

A total of 26 participants returned exit surveys on the components of the program. All agreed that fitness professionals communicated simply and empathetically; 1 participant found the wearable activity tracker difficult to use and unhelpful. Most (92%) found the consent and recruitment to be well integrated within the clinical setting. Although 81% of participants wished for more engagement from their clinical team in exercise intervention, 42% reported that their clinical team commented on participation during visits. Dieticians were the most common recommendation to be added to the next iteration of the program. Participants who came to more than 1 class listed anticipated or experienced improvement in other areas on life, overall health and well-being, blood glucose control, and mental health as motivators for continued participation. Item S2 provides videos of patient testimonials from 2 EIM group participants.

Table 1. Trial Participant Characteristics at Baseline

	Intervention (N = 28)	Control (N = 28)
Age, y	56.2 (12.3)	58.1 (9.9)
Female sex	16 (57.1%)	15 (53.6%)
Hispanic	4 (14.3%)	5 (17.9%)
Race		
Asian	5 (17.9%)	5 (17.9%)
Black	14 (50.0%)	13 (46.4%)
White	4 (14.3%)	4 (14.3%)
Other	5 (17.9%)	6 (21.4%)
Smoking status		
Current smoker	2 (7.1%)	0 (0.0%)
Never smoker	15 (53.6%)	13 (46.4%)
Smoked in past	11 (39.3%)	15 (53.6%)
Cause of chronic kidney disease		
Diabetes	10 (35.7%)	7 (25.0%)
Glomerulonephritis	2 (7.1%)	6 (21.4%)
Hypertension or vascular disease	6 (21.4%)	5 (17.9%)
Other/unknown	10 (35.7%)	10 (35.7%)
Diabetes	15 (53.6%)	14 (50.0%)
Congestive heart failure	4 (14.3%)	5 (17.9%)
Cancer	3 (10.7%)	3 (10.7%)
Cardiovascular disease	8 (28.6%)	4 (14.3%)
Referred to dialysis education	8 (28.6%)	7 (25.0%)
Referred for dialysis access placement	3 (10.7%)	5 (17.9%)
Dialysis access placed	2 (7.1%)	4 (14.3%)
No. of home medications	11.2 (4.9)	10.4 (4.4)
eGFR, mL/min/1.73 m^2	30.4 (9.8)	31.1 (12.3)

Note: Data presented as mean (standard deviation) and number (percent)
Abbreviation: eGFR, estimated glomerular filtration rate.

Table 2. Comparison of Persons Randomly Assigned to EIM Group on Attendance to Group Exercise Classes

	Attended Exercise Session (N = 17)	Did Not Attend Exercise Session (N = 11)
Age, y	59 (53, 61)	64 (48, 70)
Female sex	9 (52.9%)	7 (63.6%)
Hispanic	3 (17.7%)	1 (9.1%)
Race		
Asian	3 (17.7%)	2 (18.2%)
Black	8 (47.1%)	6 (54.6%)
White	2 (11.8%)	2 (18.2%)
Other	4 (23.5%)	1 (9.1%)
No. of comorbid conditions	1 (1, 1)	1 (0, 2)
No. of medications	11 (8, 14)	12 (5, 16)
Hospitalized during study	4 (23.5%)	5 (45.5%)
Initiated dialysis during study	2 (11.8%)	1 (9.1%)
Mean eGFR, mL/min/1.73 m^2	30.6 (7.9)	30.1 (12.7)
Exercise confidence: sticking to it	4.2 (3.7, 4.9)	4.8 (3.8, 5.0)
Exercise confidence: making time for exercise	4.5 (4.0, 5.0)	4.8 (3.8, 5.0)
SF-12 Physical Component Summary score	40.9 (37.7, 45.4)	42.2 (38.0, 43.4)
SF-12 Mental Component Summary score	47.6 (38.1, 50.2)	47.7 (43.2, 52.6)
Distance from exercise session, miles	11 (6, 19)	13 (7, 21)

Note: Data presented as median (25th, 75th percentile), or N (%) due to small sample sizes, unless otherwise noted to be mean (SD).
Abbreviations: eGFR, estimated glomerular filtration rate; EIM, Exercise Is Medicine; SF-12, 12-Item Short-Form Health Survey.

DISCUSSION

We successfully integrated recruitment, physical activity assessment, and group-based exercise interventions into diverse clinical settings servicing largely patients of racial and ethnic minority descent with advanced CKD. At baseline, participants were generally inactive with poor aerobic capacity and strength. The intervention was safe, and retention in group programming was high among patients who came to at least 1 session. We observed modest improvements or an attenuated reduction in physical activity levels when fitness counseling and wearable device provision were coupled with CKD-customized small-group exercise sessions in persons who participated in at least 1 session, compared with participants receiving counseling and wearable activity trackers alone.

We delivered our intervention in high-volume clinical settings servicing minority patients. However, after screening 228 participants who all expressed initial interest in increasing physical activity levels, only a quarter reached the first study visit, indicating that a small select subset of this patient population is able to commit to participation in formal exercise programming. Among other CKD exercise intervention studies of equal duration and intensity, between 10% and 30% of patients who were screened proceeded to randomization.[35-37] Our low-cost low-intensity recruitment may nonetheless provide benefits justifying its retention. Integrating physical activity screening—known as the "physical activity vital sign"—in clinical visits improves physical activity awareness and counseling in patients and providers respectively.[33,38-40]

However, our data demonstrating safety of the intervention and weak signal for any variation in formal physical function assessments over time can inform a further even more pragmatic iteration of our protocols. For example, modified verbal consent documented digitally—increasingly accepted in pragmatic clinical trials[41,42]—and mail delivery of the wearable activity tracker could decrease the burden of in-person study-related interactions and facilitate a focus on the exercise programming.

Unlike in other group-exercise programming studies, in which adherence typically decreases over time, we observed an "all-in" or "none" phenomenon.[13,43-45] Participants randomly assigned to but not arriving at a

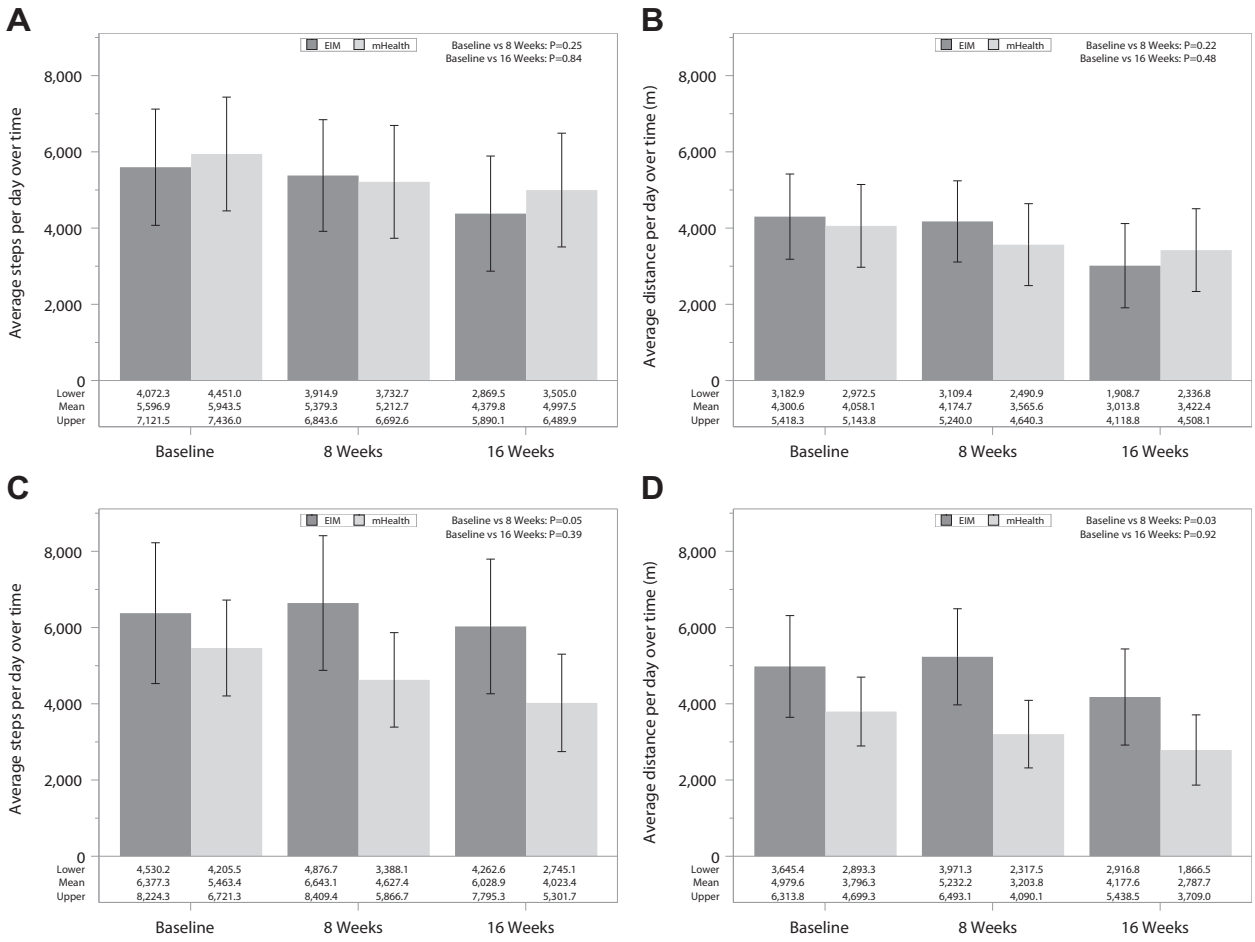

Figure 2. Overall physical activity assessment over time in the intervention.* (A) Adjusted means for step counts per day over time in intention-to-treat analyses (N = 28 for Exercise Is Medicine [EIM] and N = 28 for mobile health [mHealth]). Differences in EIM versus mHealth as follows: −217.6 (standard errors [SE] 610.4) versus −730.9 (SE 568.1) steps comparing 8 weeks with baseline, P = 0.25, and −1,217.1 (SE 624.4) versus −946.1 [SE 576.9] steps, P = 0.84, comparing 16 weeks to baseline. (B) Adjusted means for distance (meters) per day over time in intention-to-treat analyses. Differences in EIM versus mHealth as follows: −126.0 (SE 490.5) versus −492.6 (SE 457.8) m comparing 8 weeks with baseline, P = 0.22, and −1,286.9 (SE 502.2) versus −635.7 (SE 464.7) m, P = 0.48 comparing 16 weeks with baseline. (C) Adjusted means for step counts per day over time in as-treated analyses (N = 16 for EIM and N = 30 for mHealth). Differences in EIM versus mHealth as follows: +334.6 (SE 506.0) versus −883.8 (SE 339.6) steps, P = 0.05 comparing 8 weeks with baseline, and +381.8 (SE 923.7) versus −1,362.9 (SE 644.3) steps, P = 0.39, comparing 16 weeks with baseline. (D) Adjusted means for distance (meters) per day over time in in as-treated analyses. Differences in EIM versus mHealth as follows: +374.5 (SE 358.6) versus −619.6 (SE 240.7) m, P = 0.03, comparing 8 weeks with baseline, and −865.5 (SE 734.4) versus 957.8 (SE 513.3) m, P = 0.92, comparing 16 weeks with baseline. *In the intention-to-treat analysis, sample sizes were 20, 24, and 21 in the EIM group and 23, 24, and 23 in the mHealth group at the baseline, 8-week, and 16-week assessments. In the as-treated analysis, sample sizes were 13, 16, and 16 in the EIM group and 30, 32, and 28 in the mHealth group at the baseline, 8-week, and 16-week assessments, respectively.

single offered session had similar demographic and clinical characteristics and exercise self-efficacy scores, but higher rates of hospitalizations, compared with regular attendees. Numerous postdischarge exercise rehabilitation programs exist for patients with heart failure,[46,47] acute myocardial infarction,[48] and chronic obstructive pulmonary disease[49] to serve as secondary prevention measures. No such tailored programs exist to support possible physical setbacks and re-focus on lifestyle interventions for persons with CKD but are justified in the context of nationwide data reporting high rates of hospitalizations.[50] A third of our participants were hospitalized, further supporting the need for future programming to specifically accommodate postdischarge exercise rehabilitation.[51] In addition, we observed lower drop out in the mHealth group, implying that a lower intensity intervention may be more acceptable to patients receiving dialysis.

Despite the challenges in recruitment and attendance of the exercise sessions, small sample size, and highly comorbid patient population, we observed a modest effect of our intervention. In a similar intervention delivered to

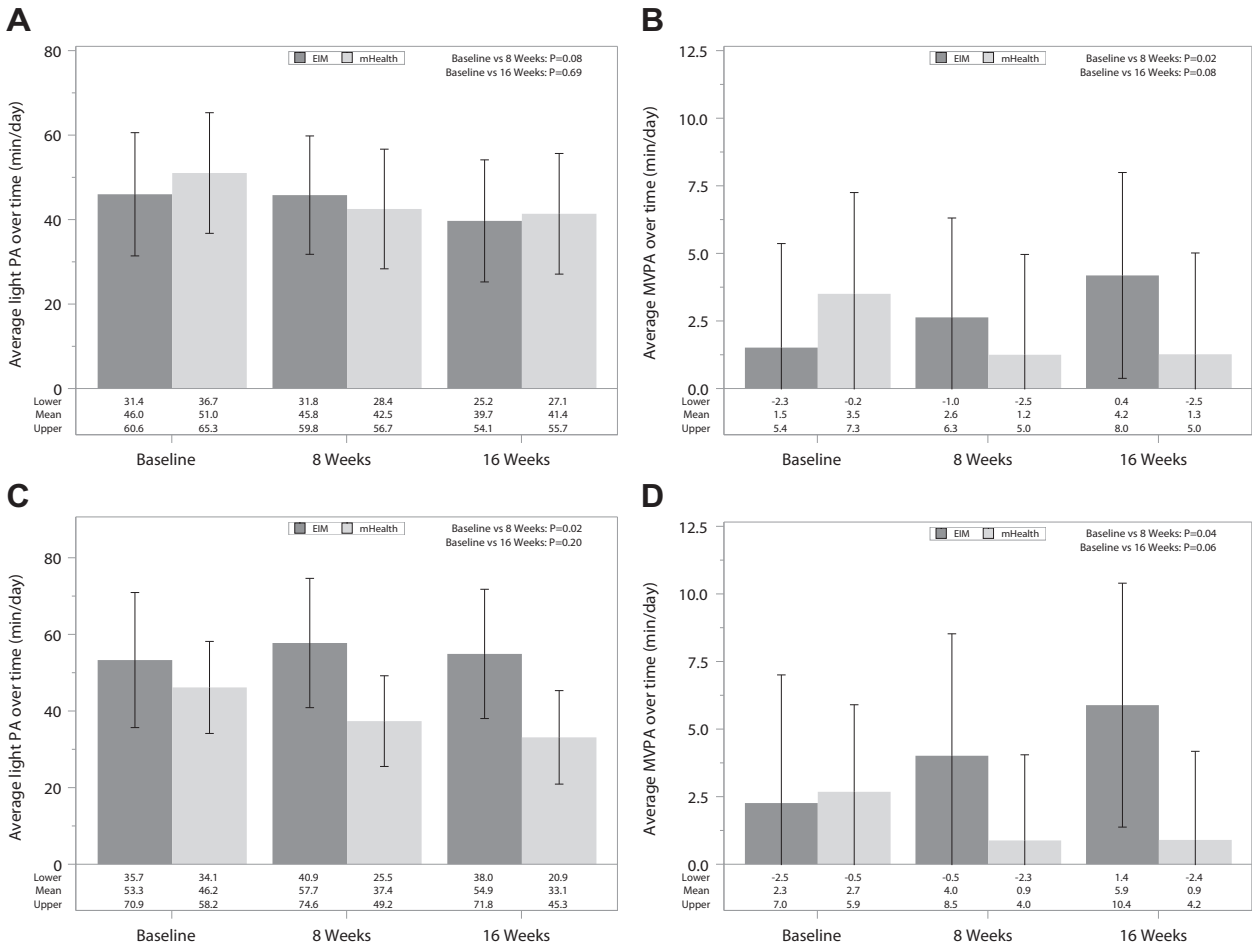

Figure 3. Intensity of physical activity assessment over time in the intervention.* (A) Minutes of light physical activity (PA) per day over time in intention-to-treat analyses (N = 28 for Exercise Is Medicine [EIM] and N = 28 for mobile health [mHealth]). Differences in EIM versus mHealth as follows: −0.2 (standard errors [SE] 5.8) versus −8.5 (SE 5.4) minutes per day comparing 8 weeks with baseline, P = 0.08, and −6.3 (SE 6.0) versus −9.7 (SE 5.5) minutes per day, P = 0.69, comparing 16 weeks with baseline. (B) Minutes of moderate to vigorous PA (MVPA) per day over time in intention-to-treat analyses. Differences in EIM versus mHealth as follows: 1.1 (SE 1.6) versus −2.3 (SE 1.5) minutes per day comparing 8 weeks with baseline, P = 0.02, and 2.7 (SE 1.7) versus -2.2 (SE 1.6) minutes per day, P = 0.08 comparing 16 weeks with baseline. (C) Minutes of light PA per day over time in as-treated analyses (N = 16 for EIM and N = 30 for mHealth). Differences in EIM versus mHealth as follows: 4.5 (SE 7.0) versus −8.8 (SE 4.7) minutes per day, P = 0.02, comparing 8 weeks with baseline, and 1.6 (SE 7.0) versus −13.0 (SE 4.9) minutes per day, P = 0.20, comparing 16 weeks with baseline. (D) Minutes of MVPA per day over time in as-treated analyses. Differences in EIM versus mHealth: 1.7 (SE 2.0) versus −1.8 (SE 1.4) minutes per day comparing 8 weeks with baseline, P = 0.04, and 3.6 (SE 2.0) versus −1.8 (SE 1.4) minutes per day, P = 0.06, comparing 16 weeks with baseline. *In the intention-to-treat analysis, sample sizes were 20, 24, and 21 in the EIM group and 23, 24, and 23 in the mHealth group at the baseline, 8-week, and 16-week assessments, respectively. In the as-treated analysis, sample sizes were 13, 16, and 16 in the EIM group and 30, 32, and 28 in the mHealth group at the baseline, 8-week, and 16-week assessments, respectively.

patients in earlier stages of CKD and with a larger sample size, Rossi et al[35] demonstrated improvements in both self-reported physical activity levels and physical function measures such as 6-minute walk test at the end of twice-weekly exercise sessions delivered for 12 weeks. Other exercise intervention studies in persons with CKD have described improvements in self-reported physical activity levels[13,52] but to our knowledge, none included objectively measured activity trackers.

In our study at baseline, participants performed poorly on assessments of physical function, walking an average of 406 (SD, 117) m on the 6-minute walk test compared with 571 (SD, 90) m observed in the general population.[53] Forty-six percent of all participants were considered to have weak handgrip strength compared with the general population[53] and walked a mean of approximately 5,000 steps per day, between about the 10th and 20th percentile of US adults.[54] Because our study design did not have a run-in period, it is likely that the "baseline" physical activity level reflects a boost after initial recruitment, assessment, 1-on-1 physical activity counseling, and provision of a wearable activity tracker. Furthermore, although the mHealth alone group had lesser

Table 3. Mental Health Measures of Study Participants During the 16-Week Study Period

	Intention to Treat						As-Treated					
	EIM		mHealth				EIM		mHealth			
	N	Adjusted Mean (SEM)	N	Adjusted Mean (SEM)	Mean Diff	95% CI	N	Adjusted Mean (SEM)	N	Adjusted Mean (SEM)	Mean Diff	95% CI
CES-D												
Baseline	28	14.1 (1.9)	28	11.8 (1.9)	2.3	−3.1 to 7.8	17	16.2 (2.4)	39	11.5 (1.6)	4.7	−1.1 to 10.4
8 wk	17	12.3 (2.2)	24	12.7 (2.0)	−0.4	−6.4 to 5.5	15	13.9 (2.6)	26	12.4 (1.7)	1.5	−4.7 to 7.7
16 wk	12	15.9 (2.8)	21	12.6 (2.1)	3.3	−3.6 to 10.3	10	16.8 (3.1)	23	12.6 (1.9)	4.2	−3.1 to 11.6
Brief Resilience Scale												
Baseline	28	3.7 (0.2)	28	3.6 (0.2)	0.1	−0.3 to 0.6	17	3.6 (0.2)	39	3.7 (0.1)	−0.1	−0.6 to 0.4
8 wk	17	3.7 (0.2)	24	3.5 (0.2)	0.2	−0.3 to 0.6	15	3.5 (0.2)	26	3.6 (0.1)	−0.1	−0.6 to 0.4
16 wk	12	3.9 (0.2)	21	3.5 (0.2)	0.4	−0.1 to 0.9	10	3.8 (0.2)	23	3.6 (0.2)	0.1	−0.5 to 0.7
Exercise Confidence Survey												
Sticking to it												
Baseline	28	4.2 (0.2)	28	4.1 (0.2)	0.1	−0.4 to 0.6	17	4.1 (0.2)	39	4.2 (0.2)	−0.1	−0.6 to 0.4
8 wk	17	3.9 (0.2)	24	3.7 (0.2)	0.2	−0.3 to 0.8	15	3.9 (0.2)	26	3.7 (0.2)	0.1	−0.4 to 0.7
16 wk	12	3.9 (0.3)	21	3.6 (0.2)	0.3	−0.4 to 0.9	10	4.1 (0.3)	23	3.6 (0.2)	0.5	−0.2 to 1.2
Making time for exercise												
Baseline	28	4.3 (0.2)	28	4.0 (0.2)	0.2	−0.3 to 0.8	17	4.3 (0.2)	39	4.1 (0.2)	0.2	−0.4 to 0.7
8 wk	17	3.9 (0.2)	24	3.9 (0.2)	0	−0.6 to 0.6	15	3.9 (0.2)	26	4.0 (0.2)	0	−0.6 to 0.6
16 wk	12	4.0 (0.3)	21	3.7 (0.2)	0.3	−0.4 to 0.9	10	4.3 (0.3)	23	3.7 (0.2)	0.6	−0.1 to 1.3
SF-12												
Physical Component Summary score												
Baseline	28	41.3 (1.1)	28	41.2 (1.2)	0.2	−3.1 to 3.4	17	41.3 (1.4)	39	41.2 (1.0)	0.1	−3.3 to 3.6
8 wk	17	42.5 (1.3)	24	39.3 (1.3)	3.2	−0.5 to 6.8	15	42.6 (1.5)	26	39.5 (1.2)	3.1	−0.7 to 6.9
16 wk	12	40.9 (1.5)	21	39.4 (1.3)	1.5	−2.5 to 5.6	10	40.8 (1.7)	23	39.6 (1.2)	1.2	−3.0 to 5.4
Mental Component Summary score												
Baseline	28	45.8 (1.6)	28	47.1 (1.7)	−1.2	−6.0 to 3.5	17	44.6 (2.0)	39	47.4 (1.4)	−2.8	−7.8 to 2.2
8 wk	17	46.1 (2.0)	24	45.8 (1.8)	0.3	−5.1 to 5.7	15	45.7 (2.1)	26	45.9 (1.7)	−0.2	−5.8 to 5.3
16 wk	12	42.2 (2.3)	21	45.6 (1.9)	−3.3	−9.4 to 2.7	10	43.2 (2.6)	23	44.6 (1.8)	−1.4	−7.7 to 4.8

Note: SF-12 mental health component scores were lower than the mean for individuals without serious mental or physical at baseline and throughout the course of the study conditions (Ware et al, mean ± SD Physical Component Summary scores: 47.42 ± 0.4; Mental Component scores: 53.82 ± 0.3).[25] CES-D scores for both study groups were on average <15, suggesting subclinical or absence of depression.[24] The overall mean Brief Resilience Scale score for study participants throughout the study is scored as "normal resilience" (3.00-4.30).[28] The Exercise Confidence Survey is scored from 0 to 5, with higher scores indicating higher confidence.[27]
Abbreviations: CES-D, Center for Epidemiological Studies-Depression; EIM, Exercise Is Medicine; mHealth, mobile health; SEM, standard error of mean; SF-12, 12-Item Short-Form Health Survey.

benefit as compared with the EIM group, the effect of no intervention at all was not studied; therefore, some potential benefit may have accrued in this group as well.[55]

However, we observed an additional benefit of the small-group sessions, with as-treated analyses demonstrating modest but consistent improvements in daily steps, distance traveled, and both light and vigorous physical activities at 8 weeks compared with the mHealth group. The "fading out" of the effect after the discontinuation of the intervention at 8 weeks is consistent with exercise intervention literature[52,55,56] and highlights the critical need for a sustainable intervention of longer duration and of interventions integrating novel behavioral modification strategies, including modelling and incentivization.[57]

Although we did not expect major changes in anthropometrics, physical function, or mental assessments due to the small size and short duration of this study, the lack of variation in these objective measurements over time has been seen in many but not all[35] other studies of both persons with CKD and end-stage kidney disease.[9] Participants can experience disappointment and frustration with exercise programs when focused mainly on weight loss and functional measures due to embarrassment and other exercise-related physical and emotional barriers that can diminish the overall perceived benefit of exercise. The importance of improving fatigue and life participation, defined as the ability to participate in meaningful life activities such as work, school, and recreational activities, is emerging as a critically important outcome among persons receiving dialysis[58-60] and kidney transplant recipients.[61] Although improvements in patient-reported outcomes have been reported in other CKD exercise intervention studies,[13,35] these have not been the primary outcome of interest. Physical function measures obtained throughout the course of this study did not reflect the modest changes in physical activity or the subjective patient-reported benefit provided to investigators in testimonials. Due to high participant and clinician interest, the exercise intervention was successfully converted to a CKD-tailored program available at one of the clinical sites (San Jose, CA), supported financially by the local chapter of the National Kidney Foundation. Thus, further research is needed to ensure that exercise programs are being designed with a focus on patient-centered outcomes, implementation, and scalability.

Limitations of our study include its small sample size, high rate of drop out, and unblinded design without a run-in period to obtain unbiased baseline measures of physical activity. Although we worked in diverse settings, due to resource-limitations, we restricted recruitment to persons with conversational English capabilities. We used wearable activity tracker data, rather than accelerometers, to measure daily physical activity, although similar device-based step count data have been correlated with outcomes in the National Health and Nutrition Examination Survey[54] and are used in various clinical settings.[33,62]

To our knowledge, this is the first study to implement a technology-enabled group-based exercise intervention in persons with advanced CKD. During this first phase, in which we had a diverse sample and well-balanced randomization, we learned that a pragmatic approach with integration into the clinical setting is feasible and safe but that increased support around hospitalizations may be required to augment retention in group exercise sessions. We observed high patient acceptability and satisfaction and modest benefits in physical activity levels that faded over time, indicating crucial need for focus on patient-reported outcomes and sustainability of programming beyond 8 weeks. Our work will inform future larger scale implementation of CKD-tailored exercise programming in underserved populations using remote access and simplified accessibility.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Item S1: Description of wearable activity tracker used in study

Item S2: Video testimonials from 2 EIM-CKD participants

Table S1: Exercise Is Medicine in CKD Study Inclusion and Exclusion Criteria

Table S2: Physical Function Measures of Study Participants During the 16-Week Study Period

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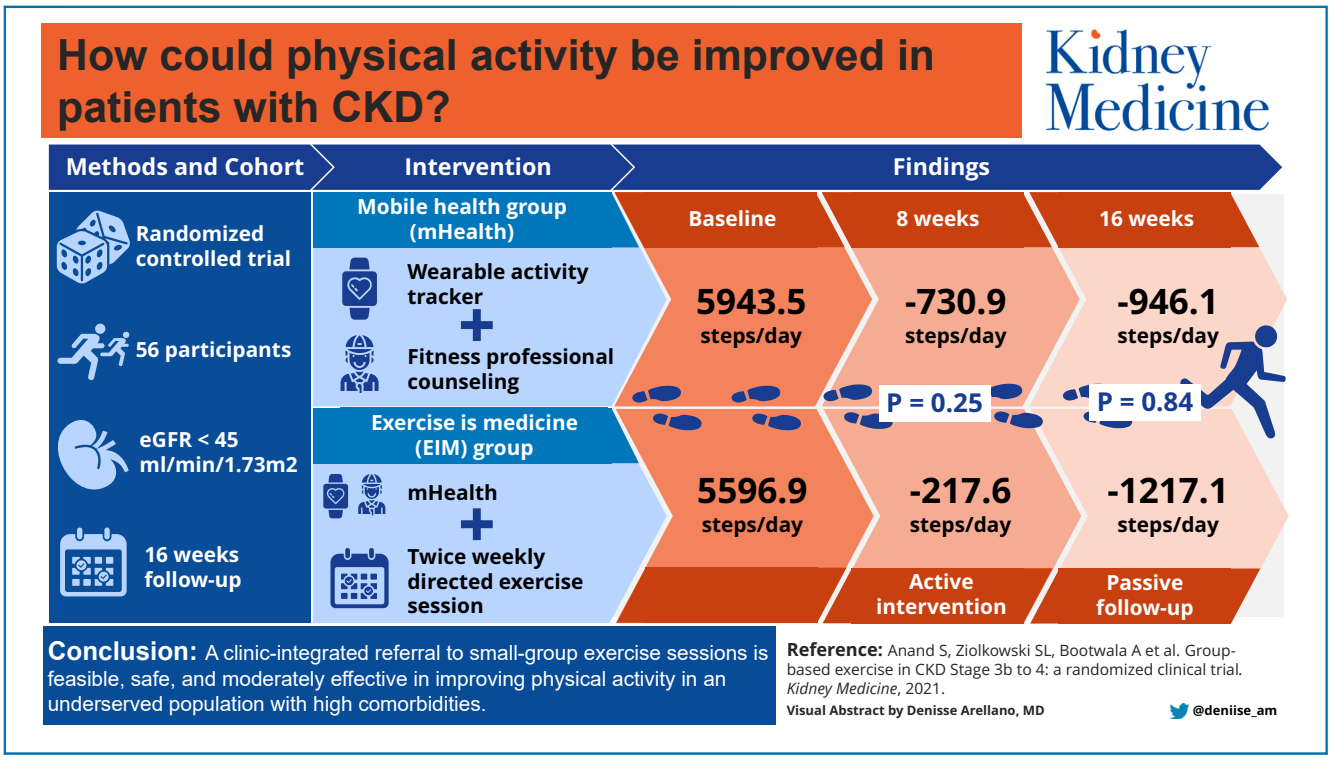
How could physical activity be improved in patients with CKD?
Kidney Medicine
Methods and Cohort
Intervention
Findings
Randomized controlled trial
56 participants
eGFR < 45 ml/min/1.73m2
16 weeks follow-up
Mobile health group (mHealth)
Wearable activity tracker
+
Fitness professional counseling
Exercise is medicine (EIM) group
mHealth
+
Twice weekly directed exercise session
Baseline
8 weeks
16 weeks
5943.5 steps/day
-730.9 steps/day
-946.1 steps/day
P = 0.25
P = 0.84
5596.9 steps/day
-217.6 steps/day
-1217.1 steps/day
Active intervention
Passive follow-up
Conclusion: A clinic-integrated referral to small-group exercise sessions is feasible, safe, and moderately effective in improving physical activity in an underserved population with high comorbidities.
Reference: Anand S, Ziolkowski SL, Bootwala A et al. Group-based exercise in CKD Stage 3b to 4: a randomized clinical trial. Kidney Medicine, 2021.
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