Use of Pedometers to Measure and Increase Walking Among Patients with ESRD

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Methods

Inclusion and exclusion criteria

We enrolled patients from three San Francisco dialysis clinics. Inclusion criteria were age ≥18 years, receiving in-center HD or any form of PD, having access to a telephone, and being ambulatory. Patients using a cane or other assistive device were eligible, but those who used wheelchairs or scooters were excluded. Patients provided informed consent to participate. The study was approved by the UCSF Committee on Human Research.

Baseline testing

Participants were asked their race and ethnicity, and medical records were reviewed for information about dialysis prescription, laboratory results, comorbid conditions, and medications.

Physical Activity Measurement

Physical activity was measured using pedometers (Accusplit AE120, Livermore, CA). Patients were asked to wear the pedometer on their belt or waistband continuously during waking hours for one week and to record their steps for each day in a step diary and then re-set the pedometer each morning. Step counts were relayed to study personnel in person at their regular dialysis session or via telephone for patients treated with PD.

Physical function and performance

Physical function was assessed immediately prior to a mid-week HD session or on the day of a regularly scheduled PD clinic visit. We administered the Short Performance Physical

Battery (SPPB), an objective assessment of lower extremity function comprising tests of gait speed over 4 m, repeated chair standing, and static and dynamic balance tests. We also administered the Physical Functioning (PF) Scale of the SF-36, (range 0-100, higher scores indicate better physical function).

Symptoms

We used the Vitality scale from the SF-36 (range 1-100, higher scores indicate less fatigue) as well as the modified Dialysis Symptoms Index (DSI). The modified DSI is a 29-item list of symptoms developed specifically for dialysis patients (range 0-29 in symptom burden and 0-145 in symptom severity). We also assessed depressive symptoms using the Center for Epidemiologic Studies – Depression instrument (CES-D).

Endothelial function

We measured the reactive hyperemia index with peripheral arterial tonometry (RHI-PAT), a non-invasive measure of endothelial function, using the EndoPAT 2000 (Itamar Medical), according to their published protocols.

Heart Rate Variability

During the five minutes of baseline recording for endothelial function testing, we also assessed time and frequency domain measures of heart rate variability. Specifically, we ascertained the SDNN (standard deviation of NN intervals, the interval between normal R-R peaks on an electrocardiography waveform) and the LF/HF (ratio of low to high frequency power). The LF band primarily represents baroreceptor activity during rest, whereas the HF band

is an indicator of parasympathetic activity and respiratory variation. Although these parameters were originally derived from 24-hour recordings, they have been validated over shorter intervals, including 5 minutes. Patients who had baseline arrhythmia were excluded from analyses of HRV (n=10).

Randomization

Patients were randomly assigned to participate in a 3-month intervention program or control group in a 1:1 ratio, stratified by dialysis modality. We targeted enrollment of 12 PD patients and 48 HD patients. This sample size was chosen to provide 80% power to detect an increase of 1,000 steps or greater in the intervention group compared to the control group despite predicted levels of dropout, which we felt would be a clinically significant change. Randomization was performed using the web site Randomization.com (http://www.randomization.com) using variable block sizes, with assignments placed into sequentially numbered opaque envelopes that were opened by study personnel and assigned after recruitment and baseline assessment.

Intervention

Our intervention consisted of providing pedometers in conjunction with weekly semi-scripted counselling sessions in which a member of the study team called the participant at a scheduled time each week. Participants in the intervention group were asked to continue wearing their pedometers and to record their step counts for 3 months. During the weekly counselling session, participants reported their step counts, and research personnel provided specific goals for daily activity in the upcoming week and advised about ways to incorporate more walking into participants' daily routine. We recommended that participants in the intervention group increase their activity by 10% compared to the prior week. However, if patients did not meet their weekly target, we did not set a higher target for the subsequent week. For patients who had periods of reduced activity (e.g., after hospitalizations

or other events), we revised their goals (i.e., increasing in 10% increments of their new "baseline" daily steps).

Patients in the control group were asked to return the pedometers after recording step counts during the initial week of data collection and were not contacted during the intervention portion of the study. We measured step counts after 3 months in both groups to evaluate the effect of the intervention (the control group was given their pedometer back to record their step counts for one week prior to the 3-month assessment for comparison with the intervention group). After the 3-month assessment, pedometers were returned to study personnel by both control and intervention groups. In order to study whether any gains in activity were maintained without active intervention, we measured step counts again in both groups after an additional 3 months. Participants in both groups received general information about the potential benefits of increasing physical activity before randomization, including the American Heart Association and American College of Sports Medicine recommendations for older individuals or individuals with chronic conditions.

Statistical Analysis

Patients' baseline characteristics were summarized as median (25th, 75th percentile) for continuous variables or frequency and percentage for categorical variables. For physical activity, we calculated average daily steps over the week prior to each assessment for each participant and reported the median of those average daily step counts. The primary outcome was between-group difference in change in step count. We used mixed effects linear (for continuous outcomes) regression analyses to assess changes at 3 and 6 months for outcomes, steps, symptoms, endothelial function and heart-rate variability. We accounted for the stratification factor (dialysis modality), and sex, by adjusting for them in each model. We also examined whether outcomes differed among HD and PD patients in a pre-specified subgroup analysis via a group by subgroup interaction test. We performed post-hoc

analyses using linear mixed modeling to examine the association between post-intervention changes in step count and outcomes as well as the association of patient characteristics with the change in step count from baseline.

Two-sided p-values <0.05 were considered statistically significant. Statistical analyses were performed using Stata, version 14 (StataCorp, College Station, TX).