ORIGINAL ARTICLE

Personalized physical rehabilitation program and employment in kidney transplant recipients: a randomized trial

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SUMMARY

Kidney transplantation is the preferred treatment for kidney failure; however after transplant, reduced physical function, poor self-perceptions, and unemployment are common concerns that remain. This randomized controlled trial compared the effects of a 12-month exercise rehabilitation program (intervention) to standard care alone (control) in kidney transplant recipients. The exercise intervention consisted of a 2 day/week, 60-minute personalized, one-on-one, resistance-based exercise trainings. Eighty participants completed the study (52 intervention vs. 28 control). For individuals unemployed at baseline, there was a 52.3% increase in employment compared to 13.3 % increase in the control group after 12 months (P = <0.0001). For those already employed at baseline, 100% of individuals maintained employment in both groups after 12 months ($P = 0.4742$). For all comers, there was a positive trend for Global Physical Health ($P = 0.0034$), Global Mental Health ($P = 0.0064$), and Physical Function ($P = 0.0075$), with the intervention group showing greater improvements. These findings suggest the implementation of an exercise rehabilitation program postkidney transplant can be beneficial to increase employment for individuals previously unemployed, improve self-perceived health, physical function, and mental health, overall contributing to better health outcomes in kidney transplant recipients. (Clinicaltrials.gov number: NCT02409901).

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Introduction

Kidney transplantation is the preferred treatment kidney failure; however, it does not address all facets of the disease. These include graft failure and return to dialysis, high rates of cardiovascular disease, weight gain and obesity, infections, and the need to adhere to complex self-management instructions [1–7]. Patients have identified significant limitations and concerns that limit their quality of life including reduced physical function, poor self-perceptions, and difficulty in pursuing or maintaining employment [2–4,8–18].

A search of the United Network for Organ Sharing database from 2004–2011 revealed that of 29 809 kidney transplant recipients with stable renal function who were employed at time of transplant, 47% were

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employed at 1-year post-transplant, 44% at 3 years, and 43% at 5 years. Of 46 363 transplant recipients with stable renal function that were unemployed at time of transplant, only 5.3% were employed at 1 year, 5.6% at 3 years, and 6.2% at 5 years [19]. This drop-in employment, or lack of finding employment following transplant, is well documented [20–25].

Decreased quality of life has been found to be a common factor associated with decreased employment rate [11,21,23,26,27]. Other variables such as perceived physical and mental function (positive attitude) can predict return to work in young stroke patients [28].

While considerable research has been done to evaluate the rate of unemployment and predictive causes in kidney transplant recipients, little has been done to pinpoint strategies to improve employment rates. Physical activity has been well established to be beneficial for both healthy and chronically ill individuals [29–31]. In a recent meta-analysis, physical activity was shown to improve physical function and quality of life in kidney transplant recipients [32]. While physical activity is recognized to be beneficial, physical rehabilitation programs are not routinely offered to transplant recipients as part of standard clinical care [33]. The association between physical activity and employment in this population has not been well studied. In a small randomized pilot study, quality of life and employment rates were shown to be higher in kidney transplant recipients who performed a 12-month personalized physical rehabilitation program, in addition to standard care, in comparison to standard care alone [33]. Because of the small sample size of the study (n = 17), these findings need to be interpreted with caution and a larger-scale study is indicated. The purpose of the current trial was to assess the effects of a personalized physical rehabilitation program on employment status in kidney transplant recipients.

Material and methods

This study was a randomized controlled trial comparing the effects of a 12-month, personalized exercise rehabilitation program (in addition to standard care) to standard care alone in kidney transplant patients from 2014–2019. Participants were recruited primarily from the University of Illinois at Chicago and Northwestern University during scheduled clinical visits. Prior to data collection, all participants provided written informed consent. Enrollment ended when the desired number of participants was met. All data collection occurred at the University of Illinois at Chicago. The study was approved by the University of Illinois at Chicago Institution Review Board (Approval/Protocol #2011-0808). This protocol is registered on clinicaltrials.gov (NCT02409901).

Study participants

One hundred and thirty-five kidney transplant recipients were enrolled in this study. Participants were excluded if they were not between the ages of 18–65, did not speak English, were less than two-month post-transplant, had any other organ transplant besides kidney, were nonambulatory, had any cardiac/pulmonary disease that contraindicated physical activity, or had any contraindication to exercise testing per the American Heart Association [34]. Randomization was set to 2:1 (exercise: control) utilizing a computerized randomization program to prevent potential selection bias (randomization.com). This ratio was a priori decision, as we anticipated more participants in the exercise group to withdraw from the study compared to the control group as a result of the increased number of study visit required for this group. Ninety-three patients were randomized to the intervention group, and 42 were randomized to the control group. Eighty participants completed the full 12 months (40 male, 40 female) (flow chart of patient enrollment shown in Fig. 1).

Sample size

We conducted a power analysis based on a 2:1 (intervention vs. control) randomization design using a two-sided alpha of 0.05, an intraclass correlation (ICC) of 0.5 (common estimate for longitudinal data), and three repeated measures for the primary endpoint of employment rate. We anticipated that randomization would be able to balance most of the confounding factors between the two treatment arms; thus, the actual power should be larger. For the sample size calculation, we estimated the effect size based on our pilot data [33] and the data from Juskowa et al.[35]. The minimal estimated effect size was 0.5 which yielded an estimated total sample size of $N = 78$ (52 intervention and 26 control) with a power of 0.8 or $N = 108$ (72 intervention and 36 control) with a power of 0.9.

Intervention

Exercise rehabilitation

Participants randomized to the intervention group participated in a 1 h, one-on-one training session, two days

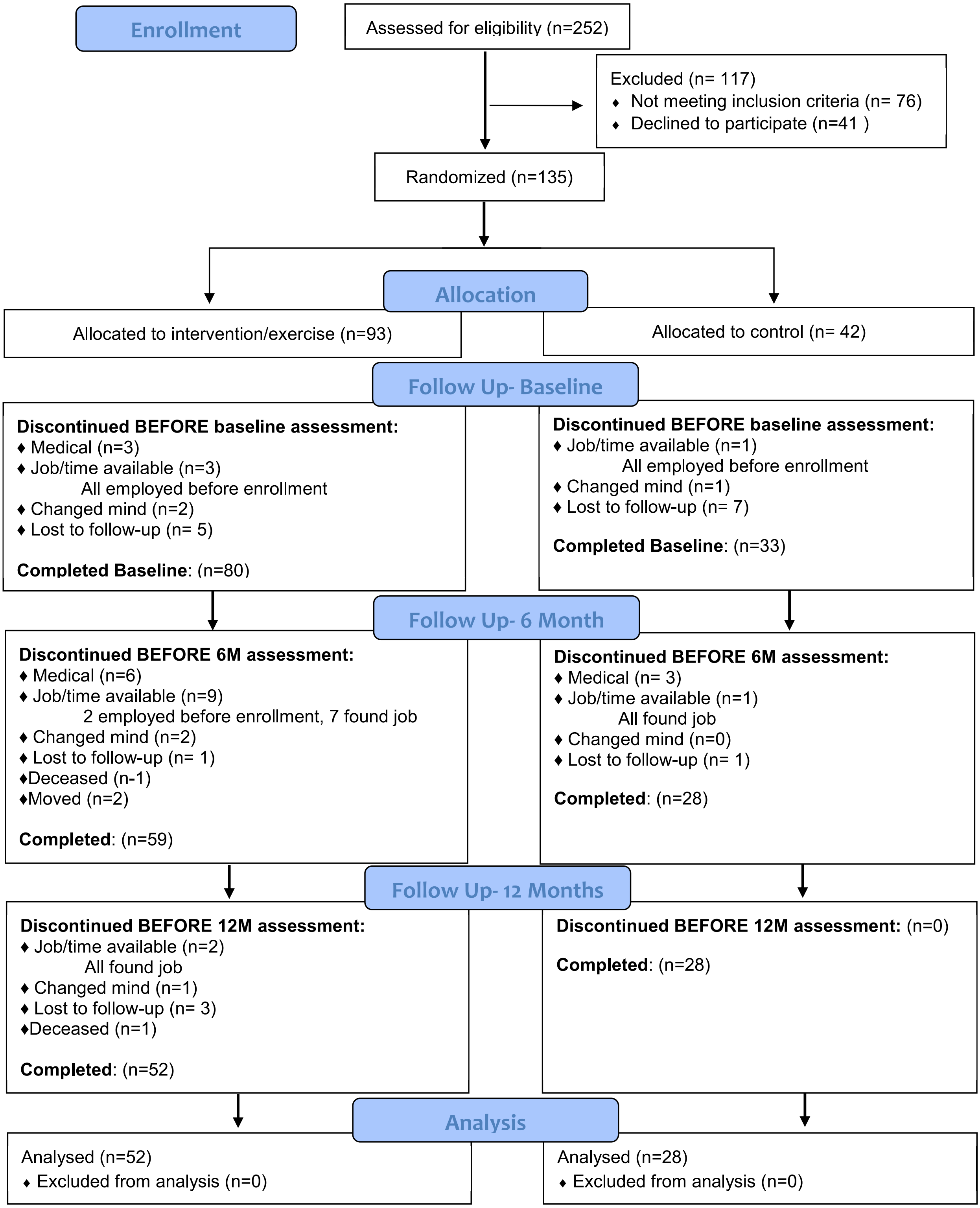

Figure 1 A flowchart depicting the enrollment of participants in the trial.

a week for 12 months. Exercise instruction was the only education provided during the intervention by the training group, and vocational guidance was not provided. The intervention incorporated a specially designed, low intensity, resistance-based exercise regime (GH Method). The focus of the program was aimed at improving individual muscle strength and function. The following exercises were prescribed: upper body: (1) biceps curl, chest press, shoulder press, triceps extension/pushdown, lat pull-downs, front row, sit-ups; lower body: leg extension, leg curl, leg press, leg abduction, leg adduction. Each exercise session was designed with a focus on minimizing patient fatigue. The program encompassed three phases:

Phase 1: Intensity was low to avoid fatigue and pain. Set 1: 30 s of exercise using 2-second concentric and 3-second eccentric contraction for each exercise. Set 2: 90 s using the same contraction speed. Exercise intensity was prescribed at 3 or below (indicating mild fatigue) using the 10-point Fatigue Scale. A minimum of 2-min rest between sets and between exercises was applied, and patients must not have reported a fatigue score of above 1 before commencing the next set. This phase lasted 2–4 weeks depending on the patient response.

Phase 2: The emphasis during this phase was on progressively developing muscle strength and function of the major muscle groups. Set 1: 15–20 repetitions at a perceived exertion of 3 or less using the 10-point Borg Scale of Perceived Exertion. The Borg scale has been validated for use during resistance exercise training [36,37]. Set 2: 10–12 repetitions on day one at perceived exertion of 3–4 on the Borg Scale and 6–8 repetitions on day 2 of each week, a perceived exertion of 4–5. Rest between sets was the same as described above. Patient fatigue and pain levels were monitored throughout the exercise session using the 10-point fatigue scale, without reaching above a 4 rating. This phase lasted 8–10 weeks depending on the patient progression and capability.

Phase 3: The emphasis during this phase was on further development of muscle strength, function, and endurance utilizing both major and smaller muscle groups. Intensity was progressively increased based on the individual response of each patient. Set 1: 25–30 repetitions at a perceived exertion of 4–5 on the Borg 10-point scale. Set 2: 12–15 repetitions at a perceived exertion of 4–6 on the Borg 10-point scale. All exercises were done without going above 4 on the Fatigue Scale. Rest periods between sets were 3 minutes, and a return to a score of 1 on the Fatigue scale before the next set is started was required. Phase 3 continued for the remainder of the study.

Prior to each session, a 5- to 10-minute light warm-up plus stretching was incorporated. These sessions were supervised by trained personnel.

Standard care

Both groups received standard care for transplant management as directed by their healthcare team. The University of Illinois at Chicago and Northwestern University have similar procedures for post-transplant follow-up which included: weekly follow-ups for the first 12 weeks, then every 2 months until 12 months, followed by yearly visits with required laboratory visits prescribed. Vocational guidance was not provided.

Variables measured

Participants in both arms of the study reported to the Integrative Physiology Laboratory at the University of Illinois at Chicago for a total of 3 testing visits: baseline, 6 months, and 12 months. Participants performed the following assessment at each visit:

Primary employment status

Employment status was attained by asking participants at each test visit whether or not they were currently employed and the type of employment obtained.

Secondary-kidney rejection

Kidney rejection was tracked for each patient by monitoring their renal function and clinical notes using the electronic medical records system.

Secondary-physical function

Participants in the intervention group only were assessed on total weight lifted during a training session. This total encompassed all repetitions done of each exercise/weight, for an overall total weight.

Secondary-general health perception and quality of life

The PROMIS Global Health short form and PROMIS 29 was administered to assess perception of general health and quality of life. The PROMIS Global Health short form is a 10-item instrument representing physical function, fatigue, pain, emotional distress, and social health as well as perceptions of general health that cut across domains. Global items allow respondents to weigh together different aspects of health to arrive at a “bottom-line” indicator of their health. Similar global health items have been found

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to be predictive of future healthcare utilization and mortality [38]. The PROMIS 29 is a short form containing four items from seven PROMIS domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and ability to participate in social roles and activities) along with a single item on pain intensity. The PROMIS questionnaires have been validated for use in kidney transplant recipients [38].

Statistical analysis

Patients who drop out before completing the baseline assessment because of medical concerns, change of mind, or death were not included in the study. Data were summarized using descriptive statistics (means, standard deviation, frequency). All available time point data from any dropouts were included in the analyses, using mixed models to accommodate the missing data. Residuals were examined to ensure model assumptions were met. All outcomes were analyzed with linear mixed models using PROC MIXED procedure in SAS 9.4 (SAS Inc., Cary, NC, USA).

To assess the differences in trajectory change of employment, physical and psychological function between the intervention and control groups over time, linear mixed models were employed using each of the endpoints as the dependent variable: group (intervention vs control), time (baseline, 6 months, and 12 months), and group*time as main fixed effects and baseline intercept as random effect. All tests were two-sided and significance was set at $P < 0.05$.

Results

Participants

Of the 113 participants that completed baseline testing, 80 (71%) completed all intervention/control prescriptions and all follow-up assessments (shown in Fig. 1). The adherence percentage for those that completed the baseline assessments in the interventions group was 65% compared to 85% in the control group. After accounting for those who dropped out of the study because of finding employment, the adherence was 73% in the exercise group (75% when including the 2 participants that had a job prior to enrollment) and 88% in the control group. Two participants died during the course of the study because of disease-related medical issues that were not attributed to the exercise intervention. Table 1 shows baseline demographics, clinical characteristics, and beginning employment status for participants based on group. There was no baseline difference in age, sex, race, donor status, weight, brachial blood pressure, serum creatinine, eGFR, or anemia status between groups. The control was shorter than the exercise group, probably a function of a slightly higher, but nonsignificant, proportion of males in the exercise group. Additionally, there was a significantly higher number of individuals employed at baseline in the control group vs the exercise group, which was an unanticipated effect of the randomization process.

Outcome measures

Employment status

For individuals that were unemployed at baseline, the exercise group experienced a 52.3% employment in 12 months (21/44 employed), whereas the control group only showed a 13.3% employment in 12 months (2/15 employed) ($P < 0.0001$) (shown in Fig. 2). In the exercise group, seven patients found jobs in the service industry, five in industry, five in office settings, three in transportation, and one in teaching. In the control group, one found a job as a security guard and one as a secretary. For those employed at baseline, employment remained consistent, with both groups showing 100% employment at both baseline and 12 months).

Kidney rejection

No patients in either group experienced kidney rejection over the 12-month study period ($P < 0.00$).

Perceived physical and mental health

The descriptive statistics for the PROMIS 10 Global Health short form and PROMIS 29 questionnaires for the 80 individuals that completed all three follow-up visits is shown in Table 2. These data are from on-treatment analysis.

There was a significant time by group interaction for Global Physical Health ($P = 0.0034$), Global Mental Health ($P = 0.0064$), and Physical Function ($P = 0.0075$), with the intervention group showing greater improvements compared to the controls in all (shown in Table 2). There was no significant difference at baseline for these variables (Global Physical Health T-score $P = 0.892$; Global Mental Health *T*-score

Table 1. Baseline demographics and clinical characteristics of 113 kidney transplant participants.

Variable	Intervention (*N* = 80)	Control (*N* = 33)	*P*-value
Age (mean years ± SD)	47.29 ± 11.56	43.18 ± 11.98	0.092
Sex			
Male	48 (60.0%)	15 (45.5%)	0.157
Female	32 (40.0%)	18 (54.5%)	
Race			
African American	54 (67.5%)	21 (63.6%)	0.249
Caucasian	10 (12.5%)	2 (6.1%)	
Hispanic	13 (16.2%)	10 (30.3%)	
Other	3 (3.8%)	0 (0.0%)	
Donor Status			
Living	40 (50.0%)	22 (66.7%)	0.106
Deceased	40 (50.0%)	11 (33.3%)	
Height (mean in ± SD)	67.92 ± 4.10	65.56 ± 4.23	0.007*
Weight (mean lbs ± SD)	223.11 ± 62.70	210.46 ± 76.58	0.363
Brachial Blood Pressure			
Systolic (mean mmHg ± SD)	135.46 ± 16.91	134.15 ± 16.84	0.708
Diastolic (mean mmHg ± SD)	82.36 ± 11.03	83.79 ± 9.03	0.513
Employment			
Employed	21 (26.2%)	17 (51.5%)	0.010*
Unemployed	59 (73.8%)	16 (48.5%)	
Anemic Patients (*N* = 56)	33 (55.9%)	23 (74.2%)	0.0895
Serum Creatinine (mean ± SD)			
Total	1.55 ± 0.50	1.43 ± 0.44	0.2441
Unemployed Only	1.36 ± 0.34	1.58 ± 0.51	0.122
eGFR (mean ± SD)			
Total	53.99 ± 14.94	55.94 ± 14.80	0.5279
Unemployed only	55.7 ± 15.7	53.9 ± 16.0	0.7111

*Significant difference between groups $P < 0.05$.

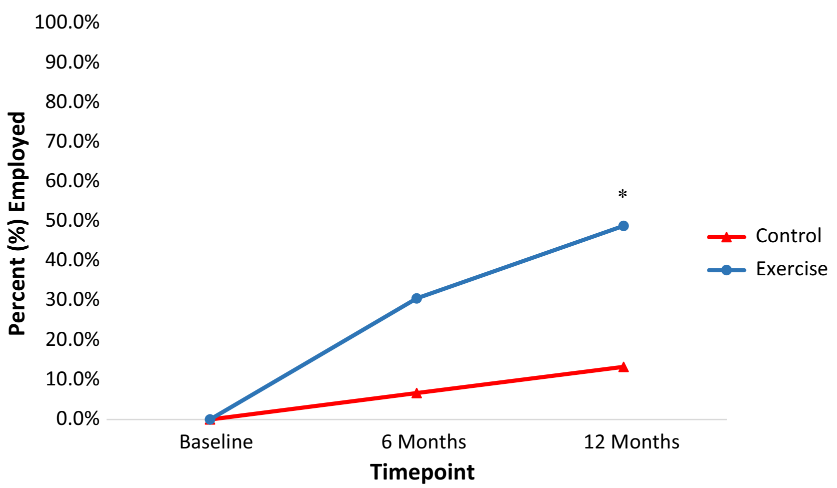

Figure 2 Comparison of employment over 12 months for patients unemployed at baseline. *Significant time by group interaction $P < 0.05$.

$P = 0.549$; Physical Function $P = 0.096$). There were no statistical differences within or between groups for the other domains assessed in the PROMIS questionnaires.

Functional capacity

A significant improvement across time was shown in total weight lifted for the exercise group ($N = 52$; $P < 0.001$).

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Table 2. PROMIS questionnaires

Questionnaire	Variable	Intervention (N = 52)			Control (N = 28)		
		Baseline	6 Months	12 Months	Baseline	6 Months	12 Months
PROMIS 10	Global Physical Health *T*-Score (mean ± SD)	44.54 ± 8.15	49.30 ± 7.78	51.58 ± 8.30*	44.77 ± 8.11	45.62 ± 7.16	46.60 ± 8.24*
	Global Mental Health *T*-Score (mean ± SD)	49.70 ± 8.99	50.86 ± 7.63	53.11 ± 7.95*	50.77 ± 6.62	49.34 ± 5.84	49.53 ± 6.69*
PROMIS 29	Physical Function *T*-score (mean ± SD)	43.68 ± 7.82	47.78 ± 9.11	48.89 ± 8.64*	46.52 ± 8.75	48.66 ± 8.55	46.45 ± 10.12*
	Anxiety *T*-score (mean ± SD)	49.73 ± 8.54	50.01 ± 8.45	49.23 ± 9.17	49.80 ± 8.63	49.70 ± 7.74	49.45 ± 9.77
	Depression *T*-score (mean ± SD)	47.84 ± 8.08	47.12 ± 7.47	47.69 ± 7.22	46.27 ± 7.77	47.45 ± 8.03	46.91 ± 8.12
	Fatigue *T*-score (mean ± SD)	48.53 ± 9.37	48.02 ± 8.40	45.03 ± 9.44	47.46 ± 8.97	48.76 ± 7.90	47.30 ± 10.08
	Sleep Disturbance *T*-score (mean ± SD)	48.78 ± 9.21	48.73 ± 9.02	48.52 ± 8.82	49.83 ± 10.79	48.96 ± 9.49	49.85 ± 10.72
	Satisfaction with Social Roles *T*-score (mean ± SD)	47.53 ± 10.75	53.58 ± 8.45	54.03 ± 9.44	48.82 ± 10.79	50.78 ± 8.85	52.82 ± 8.81
	Pain Interference *T*-score (mean ± SD)	50.15 ± 8.78	49.94 ± 8.02	48.26 ± 8.12	49.69 ± 8.37	50.08 ± 8.73	50.12 ± 9.42
	Pain Intensity Raw Score (mean ± SD)	2.48 ± 2.67	2.50 ± 2.62	1.98 ± 2.59	3.09 ± 3.33	2.96 ± 2.60	3.21 ± 3.02

*Significant time by group interaction. $P < 0.05$.

Total weight lifted at baseline was 1945.16 ± 881.01lbs, at 6 months was 5748.42 ± 2474.96 lbs., and at 12 months was 8331.20 ± 4062.51 lbs.

Discussion

This study evaluated the effects of an exercise rehabilitation intervention compared to standard of care alone in 80 kidney transplant patients over 12 months. Employment percentage for those unemployed at baseline significantly improved in the exercise rehabilitation group compared to the control group, whereas employment stayed consistent and was not significantly different between groups for those that were employed at baseline. When looking at baseline renal function (serum creatinine and eGFR), and rejection episodes over 12 months in those unemployed at baseline, there was no significant difference seen in any of these markers between groups (shown in Table 1). Considering the low national employment rates of transplant patients who were unemployed before transplant (5%)[19], and the fact that approximately 48% of these patients were employed at 12 months in our study, our findings suggest that a carefully planned and executed physical rehabilitation program can have an important and large significant effect on employment in this population. This is not only important for individual patients, but also has implications for medical care, contribution to society, and ability to function in everyday life [19,39–43].

It is well known that many factors affect employment including race and socioeconomic status can play a part in employment and should be considered when interpreting our findings. The majority of patients in our transplant program at the University of Illinois at Chicago rely on public insurance for their medical care (in 2019, 85% of our kidney transplant patients had Medicaid or Medicare). Additionally, the majority of our patients enrolled in the study were African American (as shown in Table 1). Tzvetanov et al reviewed racial and socioeconomic differences in transplant patients in relation to employment and found that 7.8% of African American's who were unemployed at time of transplant and who relied on public insurance (Medicaid or Medicare) found jobs within one year of transplant [19]. This is 40.2% lower than what our study results presented for individuals with similar medical, racial, and socioeconomic status.

Maintaining employment post-transplant for patients that were employed prior to transplant is consistent with other research findings [44]; however for those unemployed prior to transplant, little research has been done to determine ways to increase employment. While our results did not show a significant association between perceived health (mental and physical) and employment (data not shown), low levels of perceived health and function, decreased mental health, and reduced quality of life have been shown to be contributing factors to unemployment among transplant patients [11,21,23,44].

Significant improvements were noted in Global Physical Health, Global Mental Health, and self-reported physical function in the intervention group compared to the control group over time. There was a significant increase in the weight lifting capacity of the exercise group over time, providing support for an improvement in physical function. The intervention group did not have a significant effect on measures of anxiety, depression, fatigue, sleep disturbance, satisfaction with social roles, pain interference, or pain intensity compared to the controls; however, ratings of pain interference and intensity improved slightly in the exercise group over time, whereas they worsened slightly in the control group. To note, on-treatment analysis used for these data did not cause survivor bias as many dropouts in the intervention arm dropped out because of employment or new employment.

Improvements in self-reported physical function with exercise are consistent with other findings following a 12-month exercise program in kidney transplant patients [45,46]. Roi et al evaluated a supervised exercise intervention, finding improvements in self-reported physical function in the exercise compared to the control group [45]. Painter et al implemented an unsupervised/at-home exercise intervention, revealing an improvement in self-reported physical function; however, it did not reach significance when compared to the control group [46]. These findings, coupled with our results, suggest a supervised exercise program may be more beneficial for this population for improving physical function. It is possible that home exercise may not produce the same level of adherence to the intervention as supervised exercise. It is also easier to objectively document adherence during supervised exercise in comparison to self-report. While the association between self-reported physical functioning and clinical outcomes has not been established in kidney transplant patients, physical functioning has been shown to be predictive of survival in chronic kidney disease patients who are on dialysis [47,48].

Strengths of this study include the randomized controlled trial design, a supervised intervention, moderate sample size, and the long study duration (12 months). Limitations include the relatively small number of patients in the control group that were unemployed at the time of initiation of the study and the unintended higher percentage of employed patients in the control group at baseline. The probable explanation is that the restriction to only 9 am–5 pm training times being available for participants made it more difficult for individuals working traditional hours to be able to participate. Additionally, the potential effect of social support from 2 h a week of in-person trainings was not taken into account. Furthermore, we did not assess all possible factors that could contribute to employment and focused predominantly on physical exercise; however, given the fairly homogenous socioeconomic status of the patient population in our study and the fact that there were no baseline differences in age, sex, race, or ethnicity, it is unlikely these factors contributed significantly to our findings. Additionally, we had a considerable number of patients drop from the study, with more occurring in the intervention group, skewing our desired randomization stratification slightly from the desired 2:1 ratio. However, the drop percentage after accounting for patients who started new employment was only 27% in the intervention group, which could support the idea that the intervention might have worked for these individuals. In the control group, of the 33 patients who completed baseline evaluations, one dropped out because finding new employment before the 6-month follow-up. Thus, only 12.5% of the control group patients who completed baseline testing dropped out because of reasons other than finding new employment. These dropout rates are considerably lower than what is usually reported in the literature for this population. Finally, as discussed previously our population is predominantly African American, which is common in the United States, but may lead to a potential lack of translatability of our employment findings to transplant recipients in other countries, as employment opportunities and needs may be different in patients in other cohorts and in other countries. Future studies would benefit from matching for employment at baseline or only enrolling unemployed individuals, establishing a consistent social support in both groups. Furthermore, repeating this study in a different cohort would give better insight into the translatability of the study findings to the kidney transplant population worldwide.

While there were more participants that dropped out of the study after completing their baseline visit in the exercise intervention group in comparison to the control group (35% vs. 17%), 11% of these participants dropped as a result of finding a job and not being able to meet the time demands required. While the dropout total is high, withdrawing from the study because of finding employment is still considered a positive outcome.

The majority of participants that found a job did so within the first 6 months of the intervention (15/49-30.6% within 6 months; 6/44-13.6% additional between 6–12 months; total of 21/44-47.7% employed at 12 months), suggesting that the benefits associated with the rehabilitation program related to employment occurred within early on and that a shorter intervention may be adequate to observe improvements in employment for future studies or clinical application.

Conclusion

This study provides novel evidence suggesting the implementation of an exercise rehabilitation program in kidney transplant recipients can reduce unemployment, improve self-perceived health, physical function, and mental health. These findings are important for clinical practice implications and provide justification for future implementation of an exercise rehabilitation program into part of standard clinical care as a way to improve patient outcomes.

Authorship

BF, IT, EB: Designed research/study; MS, AS, LG, GH: Performed research/study**;** AK: Collected data; AK, EW: Analyzed data**;** AK: Wrote the paper; BK, BF, EB: Reviewed/Edited the paper.

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Conflicts of interest

The authors have no conflicts of interest to declare.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial*

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