Effects Of Supervised Versus Home Based Exercise Training In Hemodialysis Subjects - A Randomized Clinical Trial

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Abstract: Introduction: Patients at all stages of CKD have an increased risk of cardiovascular disease, which is the most common cause of death. In stages 3 and 4 CKD, the risk of death from a cardiovascular event increases with worsening renal function and is several fold more than the risk of progression to end-stage renal disease. An exercise based lifestyle is quintessential to their survival and quality of life. However, supervised program is costly and difficult therefore feasibility of a home based exercise program against supervised program is objective of this study. Methods: This study was a randomized clinical trial design administered over 30 subjects in two groups. Group I was supervised program consisting of structured exercise based on American college of sports medicine recommendations for dialysis subjects. While group B performed a home based program mainly with warm ups, walking and a cool down. Results: this study showed that there was significant improvement in the Supervised group related to Physical functioning and HRQOL compared to Home-based group which showed comparatively lesser improvement as compared to supervised group. Conclusion: The main finding of this present study is that supervised exercise training exhibited significantly greater improvement in cardiopulmonary endurance and status as well as HRQOL in CKD hemodialytic subjects compared to the Home based group who showed comparatively lesser changes in all parameters and this result is consistent with previous literatures. However role of home based programs cannot be undermined in view of findings of this study [Lepcha T Natl J Integr Res Med, 2019; 10(5):40-48]

Key Words: Exercise, Dialysis, Kidney disease, home based

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Introduction: Chronic kidney disease (CKD) is a long-term condition, which is associated, in many patients, with physical symptoms such as fatigue, muscle weakness and reduced ability to perform activities of daily living.[1] CKD has become a serious health problem due to its prevalence, high cost, and the subsequent reductions in life expectancy and quality of life.[2] It is a worldwide public health problem which increases in prevalence with age; a global systematic review reported a median prevalence of CKD stage 3 and greater of 7.2% in individuals aged over 30 years of age, and between 23.4% and 35.8% in those aged 64 years or older. The risk of mortality is substantially elevated in this population; the average 5-year survival of western dialysis patients aged 60 years is approximately 45% (data from UK, Swedish, and USA registries).[3]

In more advanced CKD, additional risk factors include chronic systemic inflammation, oxidative stress, vascular calcification, a prothrombotic environment and anaemia.[4] The number of patients with kidney failure treated by dialysis and transplantation has increased by 57% in the last decade, While long-term dialysis may extend survival, patients' quality of life and physical function remains poor.[5] The central demographic problem of modern nephrology is the rapid increase in the number of patients with advanced renal disease ultimately requiring renal replacement therapy (RRT).[6]

Despite regular HD treatments to replace some of the lost kidney function, patients suffer from a constellation of symptoms characterized by the "uremic" syndrome. These are typically manifested as (1) autonomic and/or motor neuropathies, (2) cardiac and/or skeletal muscle myopathies, (3) peripheral vascular changes (increased total peripheral resistance, impaired oxygen delivery), (4) anemia (loss of erythropoietin production), (5) dysfunction of bone metabolism, (6) immunologic compromise, and (7) assorted physiologic complaints (nausea, vomiting, insomnia, fatigue, depression, anxiety). Common ramifications of the uremic syndrome include (1) reduced physical work capacity to approximately 50% of that in healthy age- and sex-matched persons, (2) decreased health related quality of life (HRQOL), and (3) cardiovascular disease including left ventricular hypertrophy, congestive heart failure, coronary artery disease, and hypertension.[7,8,9,10]

Reduced muscle strength and endurance in dialysis patients is multifactorial and incompletely elucidated. Reduction in physical conditioning which is one of the main stressors is associated with both reduced quality of life and increased mortality in patients receiving dialysis.[11] Muscle loss is associated with functional and metabolic deficits and reduced quality of life in CKD patients. Metabolic abnormalities due to skeletal muscle wasting can also increase visceral obesity, which increases the risk of cardiovascular disease, the leading cause of death in CKD patients.[12]

Approximately 20 to 50% of maintenance haemodialysis (HD) patients suffer from protein-energy wasting (PEW), a condition of decreased body protein and fat mass that potently predicts morbidity and mortality in this population. Muscle wasting is a key component of PEW, and it adversely affects multiple patient-centred outcomes including muscle function, exercise performance, physical function, and quality of life (QOL). [13] Cupisiti et al reported that inactivity and reduced physical functioning and performance among patients with renal failure are caused by fatigue, which in turn leads to a sedentary lifestyle. Chang et al reported that improvements in physical fitness and psychological function, which translated to improved quality of life, were noted in patients with chronic kidney disease who exercised.[14]

Cardiorespiratory capacity is reported to be dramatically low. The maximum oxygen consumption (VO2 max) in end-stage renal disease patients on HD is reported to be from 15.0 to 21.0 ml/kg/min, values that are half of those reported for healthy sedentary subjects, which range from 35.0 to 40.0 ml/kg/min.[15] Cardiovascular pathologies observed in CKD patients include left ventricular hypertrophy and arterial disease. In addition to the characteristic lesions of atherosclerosis, dialysis patients also experience thickening and fibrosis of the arterial wall in response to pressure and volume overload, loss of elastic fibres and medial fibrosis.[16,17] In relation to the cardiac problems, CKD patients undergoing dialysis treatment also suffers from impaired pulmonary function. Peritoneal dialysis causes increased intra-abdominal pressure, which results in changes in respiratory mechanics.[18] O'Hare et al reported that sedentary dialysis patients had a higher risk of death within 1 year than those who reported at least some participation in physical activity.[19] The reasons for the lack of exercise, according to the hemodialysis patients, include tiredness following dialysis treatments, unexplainable fear of exercise, Time and locational constraint, and lack of motivation.[20]

The National Kidney Foundation Disease Outcomes Quality Initiative (NKF K/DOQI) guidelines stress that physical exercise should be seen as one of the cornerstones of renal therapy. It is, therefore, important that intervention whose benefits have been demonstrated are implemented within renal clinical practice.[21] Several pioneer studies of exercise training in heamodialysis have suggested that increasing patient physical activity may improve physiological performance and possibly clinical outcomes.[22]

The most common and convenient form of exercise training of Maintainence HD patients appears to be endurance training. It has been examined most frequently as a therapeutic measure to improve physical capacity. Typically, endurance training improves VO2peak by 16%.[23] In a systematic review of 29 clinical trials conducted by Cheema BSB et al, it was shown that physical condition was significantly improved following the use of aerobic training.[24] Walking is usually the best-accepted form of exercise and is widely recommended for general health.[25,26]

The objective of study is to compare the effect of supervised versus home based exercise training in hemodialysis subjects of a tertiary care hospital in Sikkim.

Material and Methods: This study was a randomized clinical trial design. This study was performed at Dialysis unit and Department of Physiotherapy, Central Referral Hospital, Tadong, Gangtok.

Inclusion criteria were Age >18 and < 65 years undergoing hemodialysis of Both Gender, Patient undergoing dialysis for at least 3 months , Patient willing to participate in 3 weeks of our intervention with Diagnosis of CKD done by physician and Physician approval for conducting set exercise protocol and Patients should be able to walk independently.

Exclusion criteria were unstable angina and other cardiac complications (Uncontrolled arrhythmia), Lower limb amputation/ Joint replacement or lower extremity fracture within the last 6 months, Peripheral vascular disease,

Uncontrolled hypertension/ hypotension, Retina laser therapy and Severe cognitive impairment.
All the subjects who were fulfilling the eligibility criteria were recruited. Simple random sampling was used to allocate subjects in two groups. Sample size was calculated with power of 80% and a mean difference between groups for primary outcome measure as 5 required 60

Hemodialysis subjects divided in two groups. Randomization was done by block randomization method. Allocation concealment was done where 40 cards were made, out of which in 20 cards it was written as Group A and in the other 20 cards as Group B. These cards were then put into the opaque box and shuffled well. One by one, card was drawn with closed eyes. The group A was put on supervised and group B in home-based. The drawn cards were then discarded immediately.

Outcome measures were Six Minute Walk Distance (6MWD) and RAND SF-36 item health survey (version 1.0) which taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indications of perceived change in health. Ethical clearance was taken from the institutional ethics committee.

Hemodialysis subjects who were diagnosed and referred by physicians of CRH hospitals were recruited. Then the subjects who fulfilled the inclusion criteria were selected for the study. Informed consent was obtained from each subject in their own language of understanding. The baseline measures were collected after informed consent regarding name, age, sex, hospital number, month/weeks on dialysis and the comorbidities.

Subjects were then individually randomized into two groups supervised and home-based groups by using lottery method. There were 30 hemodialysis subjects in each group. Group A received aerobic and resistance training & Group B walking for 30-60 min. Pre intervention outcome measures were taken and recorded. Treatment was given for 4-5 days per week, 20-60 minutes per session for 3 weeks. After 3 weeks post intervention outcome measures were taken by the tester. Data were analysed and results were obtained.

Group b was unsupervised group; which underwent unsupervised training included Home based exercise which mainly consisted of walking and warm-up and cool down sessions. Patients were demonstrated and educated about how to conduct exercise session at home. Exercise session included Warm up period-self (stretching exercises) and cool down period. Education about RPE scale and limit of exercise was demonstrated and given in written. Home based exercise program was based on previously published literatures which mainly consisted of 30-60 minutes of walking in range of 11-13 RPE for 4-5 days a week was recommended. [27-30]

Intervention protocol was as follows: Supervised exercise training group received aerobic exercise and resistance exercises. Before exercise intervention there was a Warm up period of 10 min which mainly included stretching exercises.

After exercise session, there was a Cool down period of 10 min which included slow rhythmic movements and breathing exercises mainly.[31] The actual intervention protocol of aerobic and strength training is given as in table 1.

Table 1: shows exercise prescription for intervention group including aerobic and resistance training.

Parameter	Aerobic exercise	Resistance
Frequency	4-5 days /week	2-3 days /week
Intensity	Moderate , RPE 11-13 on a Borg scale 6-20	60-75% of 1RM
Time	20-60 min /day of continuous aerobic activity. If duration cannot be tolerated 10 min bouts of intermittent exercise to accumulate 20-60 min /day.	1 set of 10-15 repetitions
Type	Treadmill walking /cycle ergometer	Free weights

Results: Data analysis was performed using SPSS Windows, version 22. One way ANOVA was used for between the group and within group analysis. Result are shown in table 2 to 5

Table 2: Demographic characteristics of the supervised and home-based groups

Variables		Supervised group	Home-based group
Age (year)	Mean ± SD	46.8±11.9	47.1±13.4
	Range	24-64	18-65
Gender	Male	25	22
	Female	5	8
Weight		61.0±10.5	58.5±14.6
Hb (mmol/l)		7.5±2.5	7.6±1.6
Comorbidities (n):	Hypertension	13	14
	Diabetes mellitus	12	10
	Coronary heart disease	2	4
	Myocardial infraction	0	0

Table 3: shows changes within group I in outcome measures from baseline and after 3 weeks of intervention. 6MWD- Six minute walk distance; Health related Quality of life (HRQOL) has got 8 domain which is indicated by QOL1, QOL2, QOL3, QOL4, QOL5, QOL6, QOL7 and QOL8

Variables	Baseline	3 weeks	F	P
6MWD (meters)	479.15±16.0	482.65±18.9	1.409	0.247
QOL1	40.7±19.1	53.5±19.3	2.904	0.040
QOL2	31.2±15.9	53.7±20.3	9.678	0.000
QOL3	41.6±21.2	66.6±18.7	6.273	0.001
QOL4	48.4±10.0	60.5±11.5	10.242	0.000
QOL5	55.9±16.3	69.1±15.6	6.661	0.000
QOL6	46.2±15.2	63.1±15.3	7.783	0.000
QOL7	51.2±17.0	66.6±16.5	9.801	0.000
QOL8	38.7±10.6	52.2±12.0	11.833	0.000

Table 4: shows changes within group II in outcome measures from baseline and after 3 weeks of intervention. 6MWD- Six minute walk distance; Health related Quality of life (HRQOL) has got 8 domain which is indicated by QOL1, QOL2, QOL3, QOL4, QOL5, QOL6, QOL7 and QOL8

Variables	baseline	3 weeks	F	P
6MWD	482.65±19.1	472.80±15.6	1.185	0.280
QOL1	40.5±13.2	48.5±13.6	0.381	0.539
QOL2	27.5±17.9	45.0±15.3	0.734	0.394
QOL3	43.3±24.4	58.3±21.2	1.534	0.219
QOL4	43.0±10.0	49.5±9.1	1.960	0.166
QOL5	46.9±16.2	54.0±16.0	3.020	0.086
QOL6	44.3±11.8	52.4±11.1	0.000	0.997
QOL7	45.1±8.2	46.1±13.2	6.776	0.011
QOL8	34.5±8.7	40.2±7.5	1.798	0.184

Table 5. Comparison between the group I and group II in outcome measures from baseline and after 3 weeks of intervention. 6MWD- Six minute walk distance; Health related Quality of life (HRQOL) has got 8 domain which is indicated by QOL1, QOL2, QOL3, QOL4, QOL5, QOL6, QOL7 and QOL8.

Variables	Group I (Mean difference)	Group II (Mean difference)	P
6MWD	3.5±5.5	9.8±5.3	<0.05
QOL1	12.7±5.2	8.0±5.2	<0.05
QOL2	22.5±5.5	17.5±5.5	<0.05
QOL3	25.0±6.8	15.0±6.0	<0.05
QOL4	12.0±3.2	6.5±3.2	<0.05
QOL5	13.2±5.0	7.1±50	<0.05
QOL6	16.8±4.2	8.1±4.2	<0.05
QOL7	15.3±4.4	0.97±4.4	0.001
QOL8	13.5±3.1	5.7±3.1	<0.05

Discussion : The aim of the study was to compare the effect of supervised versus home based exercise training in hemodialysis subjects. Total 60 subjects participated, out of which 30 subjects were allocated in supervised group and another 30 subjects in home-based group. Subjects at the baseline did not show any statistical difference between both the groups.

Patients with CKD have reduced levels of physical functioning, which, along with low physical activity, predict poor outcomes in patients treated with dialysis. The hallmark of clinical care and rehabilitation is the orientation to and assessment of physical function and functional limitations in order to better assess well-being and quality of life and to plan for care needs, including individually appropriate interventions to prevent deterioration in functioning. The 2005 publication “K/DOQI Clinical Practice Guidelines: Cardiovascular Disease in Dialysis Patients” includes exercise recommendation for physical activity.[32]

Several previous literatures has suggested and proved exercise to be the most effective method for preventing loss of muscle mass and strength; it also prevents physical dysfunction, controls blood pressure and and enhances cardiovascular function and the immune system. Increased physical activity can also improve self-confidence and the patients' quality of life. [12]

There were primary and secondary outcome measures that were taken pre and post intervention. 6 minute walk test for cardiopulmonary endurance and status and SF-36 for HRQOL was used. During the 3weeks of exercise program, an improvement in 6MWT increased significantly as well as HRQOL improved at the end of the study.

Although it is widely accepted that exercise is beneficial in patients with CKD, improving physical functioning in general, including maximal oxygen uptake, muscle strength, nutritional and hematologic status, inflammatory cytokines, and QOL. Despite these proven effectiveness in treating patients on HD, health professionals have shown reluctance towards exercise treatments out of concern for possible complications, such as musculoskeletal injuries, arrhythmia, or heart attack. However, there has been no evidence of such complications for any of the patients on HD that participated in PRT programs over the last 30 years.[33]

This present study followed a set protocol recommended by ACSM guidelines[31] and was performed on those days when the subjects were off the dialysis. It included aerobic exercises for 4-5 days /week with RPE 11-13 on a Borg scale 6-20. Subjects performed exercises for 20-60 min /day of continuous aerobic activity and if duration was not tolerated then 10 min bouts of intermittent exercise were given to accumulate 20-60 min /day. Strengthening exercises with free weights i.e. 60-75% of 1RM, 1 set of 10-15 repetitions were performed 2-3 days. The interventions also included 10 minutes of warmup and cool down period. The same for the home based program was followed except for the protocol which was replaced with walking in normal terrain but home program was unsupervised. Unsupervised programs become unstructured and there is lack of motivation. Home based programs also rely on subjects own reporting and feedback which can influence the results. It was suggested that high-impact activities, such as aerobic exercises, should be carried out the day after HD when the physical condition of them is at its best. [24] However it would have been more difficult for the participants in home based program to commit to an exercise routine and to manage exercise intensity and other logistics without the guidance of an exercise trainer.

This study reveals that 6 MWT was improved in both the group, although experimental group showed more improvement compared to control group. The magnitude of improvement in 6MWT after the exercise program was not large, but it should be stressed that even a small improvement by old patients (average age 64 years) with a significant number of comorbidities could significantly improve self-care and functional independence, as also was underlined by Cowen et al[34] and another study by Headley et al[35] where they reported 12.7% increase in maximal peak torque in the knee joint at an angular velocity of 90°/s after 12-week intensive and longer resistance training performed by HD patients indicated the importance in the role played by rehabilitation in maintaining good physical condition.

Some authors have reported lower distances in 6MWT in CKD patients when compared with healthy individuals. In one such study, Cury et al associated the reduction in functional capacity with inefficiencies in the oxygen uptake, transport, and use caused by dysfunction of cardiovascular, respiratory and muscular systems.[36-38] Ruiter et al showed that Pre-dialytic CKD patients has reduction in maximal and submaximal exercise tolerances and 6MWT can be used for exercise prescription before an inclusion in exercise programmes which should be started early in the course of the disease.[18]

The 6MWT has been used as an outcome measure of physical function in a number of exercise training programs in the ESRD population. Our findings are in agreement with those of Ridley et al[39] in which a 14% increase in the distance walked on the 6MWT was found in 18 HD patients who underwent a 12-week exercise program in which cycle exercise was performed during HD for about 60 minutes a session at an intensity that patients reported feeling as "slightly winded." However, other studies, which have used extradialytic programs, demonstrated lesser or no change in 6MWT performance in HD subjects. Painter et al[40] also found an 8% increase in the distance walked on the 6MWT in 44 patients who participated in an 8-week home program and an 8-week intradialytic exercise program. Further, no significant changes in 6MWT distance were found in 20 HD patients who cycled for a shorter duration (20min) during dialysis (somewhat strong intensity on the Borg rating of perceived exertion scale) in combination with strength training before or after dialysis (50% of 5 repetition maximum) for 12 weeks reported by DePaul V et al.[41] Finally, Headley et al[35] reported a 5% increase in distance walked on the 6MWT after 12 weeks of off-dialysis resistance training.

This present study also measured HRQOL measured by SF-36 covering the domains such as physical health and function, role limitation due to physical health and emotional problem, energy/fatigue, emotional well-being, social function and pain. Supervised group showed highly significant in all domains except in domain 1 (physical health) comparatively. The home based group showed lesser change in all domains. This results closely relates to the study done by Trisha et al[7] where 20-week consisting of 60 minutes of cumulative duration, low-intensity intradialytic exercise program on 13 patients during the first 2 hours of dialysis showed great improvements in 6MWT and HRQOL with changes in the energy level, emotional and improved ability to perform daily activities.

Ronaldo Ribeiro et al[26] found low intensity intradialytic RE program 3 times a week, with 40% of the maximum force for 8 weeks improves strength, glucose and QOL parameters (p < 0.001), such as Functional Capacity, Physical Aspect, Reduction of Pain (in general), General Health, Vitality, Social Function, Emotional State and Mental Health. It also suggested low intensity RE program as adjuvant therapy to complement medical and dietary treatment in 60 terminal CKD patients. In another study assessing intradialytic training, using a training cycle with ergometers in the first 2h of each dialysis session, 3 times a week for 6 months, the subjects showed improvement in physical function and blood pressure and a reduction in blood glucose, which demonstrate the effectiveness of a continuous intradialytic exercise program for 6 months with regard to the improvement of a dialysis patient (Mustata S et al).[42] Koh K P et al[16] observed statistically significant improvements in muscle strength of the quadriceps and biceps were observed, improving physical function and vitality and the QOL domains in patients undergoing 12 weeks of intradialytic training.

Song woo-Jung et al[12] found that the patients who received PRT(using elastic bands and sandbags) for 30 minutes per session, 3 sessions a week, for 12 weeks improved in body composition, physical fitness, quality of life(SF-36), and lipid profile of 40 HD patients. Tomasz Golebiowski et al[29] found that cycle training for 3 times weekly for 3 months during dialysis sessions increased the duration in 6MWT and strength and QOL (SF-36) but did not influence nutrition or inflammation parameters. It also suggested cycle training as a safe method to increase the strength of lower extremities and walking ability of older CKD patients with many comorbidities.

Overall, this study showed that there was significant improvement in the Supervised group related to Physical functioning and HRQOL compared to Home-based group which showed comparatively lesser improvement as compared to supervised group. This could be due to the fact that subjects self reported about their exercise compliance which could be doubted. Previous studies have shown non-compliance in non-supervised groups due to poor motivation or health related fatigue.

Study had several limitations. Home based programs were not under our control and subjects own reporting was considered for quality of life. There are several factors which influence home programs like support and encouragement of family members and care givers. This study was held in a hilly terrain of Sikkim where walking has lot of limitations in terms of terrain and location of home. Such study should always have a future scope. Home based programs have best capacity in terms of feasibility and no cost involvement. Therefore, other ways of monitoring and community support should be increased and studied for their effect on such studies.

Conclusion: The main finding of this present study is that supervised exercise training exhibited significantly greater improvement in cardiopulmonary endurance and status as well as HRQOL in CKD hemodialytic subjects compared to the Home based group who showed comparatively lesser changes in all parameters and this result is consistent with previous literatures. However role of home based programs cannot be undermined in view of findings of this study. Our findings suggest that this exercise guideline is a promising treatment regimen in routine care of patients treated by haemodialysis. 6MWT can also be recommended as a viable, low-cost, easy-to-apply and highly accurate alternative for the determination of the functional capacity.

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