

The PrEscription of intraDialytic exercise to improve quALity of Life (PEDAL) in patients with chronic kidney disease trial: A multi-centre randomised controlled trial.

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Background: Exercise interventions in haemodialysis (HD) patients have potential to improve exercise capacity, but their impact upon quality of life (QOL) remains unknown. The PEDAL study evaluated the clinical and cost effectiveness of a 6-month intradialytic exercise programme on QOL, compared to usual care for HD patients in the UK.

Methods: We conducted a prospective, multicentre randomised controlled trial (RCT) recruiting 335 HD patients and randomly (1:1) assigning them to either thrice weekly intradialytic exercise training plus usual care maintenance HD or usual care maintenance HD. The primary outcome of the study was the change in Kidney Disease Quality of Life Short Form Physical Composite Score (KDQOL-SF 1.3 PCS) between baseline and 6 months. Additional secondary outcomes included changes in peak oxygen uptake (VO₂peak), habitual physical activity levels (International Physical Activity Questionnaire and Duke's Activity Status Index), fear of falling (Tinetti Falls Efficacy Scale), symptom burden assessments (EQ5D), arterial stiffness (pulse wave velocity), anthropometric measures, resting blood pressure, clinical biochemistry, safety and harms associated with the intervention, hospitalisations, and cost-effectiveness. Here we just report the primary outcome but anticipate that additional data will be available at the time of the presentation.

Results: A total of 335 patients from haemodialysis centres in 5 regions of the UK were randomised and attended a baseline assessment. At 6 months, 114 (65%) and 122 (76%) patients remained in the exercise training group and usual care group, respectively. A median of 56% of exercise training sessions were completed by patients in the exercise training group at 3 months, with 42 % sessions completed at 6 months. The KDQOL-SF1.3 PCS score increased from 33.9 (10.6) to 34.8 (11.6) in the exercise training group and reduced from 32.9 (11.3) to 31.8 (11.3) in the usual care group. Linear regression analysing the change from baseline in KDQOL-SF1.3 PCS from treatment, whilst adjusting for baseline KDQOL-SF1.3 PCS, age, sex and diabetic status, revealed a mean difference (95% CI) of 2.4 (-0.06, 4.80), p=0.056. A 1.0 increase in PCS is associated with a 3.5% improvement in the odds of death. Multiple regression analysis indicated that improvement in KDQOL-SF1.3 PCS depended on the completion of intradialytic exercise training sessions (treatment effect=0.54 (0.14, 0.94) per 10% of sessions completed, p=0.009).

Conclusions: The PEDAL intradialytic exercise programme did not statistically improve the Kidney Disease Quality of Life physical composite score sufficient to meet the primary endpoint of this study. Such improvement as occurred in this score were directly linked to the completion of the exercise training sessions. Methods to improve engagement are needed to enhance future studies and facilitate clinical implementation.