Exercise programme to improve quality of life for patients with end-stage kidney disease receiving haemodialysis: the PEDAL RCT

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Scientific summary

The PEDAL RCT

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Scientific summary

Background

Whether or not clinically implementable exercise interventions in haemodialysis patients improve quality of life remains unknown. The PEDAL (PrEscription of intraDialytic exercise to improve quAlity of Life in patients with chronic kidney disease) trial evaluated the clinical effectiveness and cost-effectiveness of a 6-month intradialytic exercise programme on quality of life compared with usual care for haemodialysis patients.

Design

We conducted a prospective, multicentre randomised controlled trial of haemodialysis patients from five haemodialysis centres in the UK and randomly assigned them (1 : 1) using a web-based system to (1) intradialytic exercise training plus usual-care maintenance haemodialysis or (2) usual-care maintenance haemodialysis.

Setting

The setting was five dialysis units across the UK from 2015 to 2019.

Participants

The participants were adult patients with end-stage kidney disease who had been receiving haemodialysis therapy for > 1 year.

Interventions

Participants were randomised to receive usual-care maintenance haemodialysis or usual-care maintenance haemodialysis plus intradialytic exercise training.

Main outcome measures

The primary outcome of the study was change in Kidney Disease Quality of Life Short Form, version 1.3, physical component summary score (from baseline to 6 months). Cost-effectiveness was determined using health economic analysis and the EuroQol-5 Dimensions, five-level version. Additional secondary outcomes included quality of life (Kidney Disease Quality of Life Short Form, version 1.3, generic multi-item and burden of kidney disease scales), functional capacity (sit-to-stand 60 and 10-metre Timed Up and Go tests), physiological measures (peak oxygen uptake and arterial stiffness), habitual physical activity levels (measured by the International Physical Activity Questionnaire and Duke Activity Status Index), fear of falling (measured by the Tinetti Falls Efficacy Scale), anthropometric measures (body mass index and waist circumference), clinical measures (including medication use, resting blood pressure, routine biochemistry, hospitalisations) and harms associated with intervention. A nested qualitative study was conducted.

Results

We randomised 335 patients: 175 to the exercise training group and 160 to the usual-care group; 243 patients (intervention, $n = 127$; control, $n = 116$) repeated the 6-month evaluations. A median of 47% (interquartile range 28–77%) of exercise training sessions were completed by patients in the exercise training group at 6 months. The physical component summary score increased from 33.9 arbitrary units (10.6 arbitrary units) to 34.8 arbitrary units (standard deviation 11.6 arbitrary units) in the intervention group and reduced from 32.9 arbitrary units (standard deviation 11.3 arbitrary units) to 31.8 arbitrary units (standard deviation 11.3 arbitrary units) in the control group. The mean difference in the change in physical component summary score from baseline to 6 months between the intervention and control groups was 2.4 arbitrary units (95% confidence interval −0.1 to 4.8 arbitrary units; $p = 0.055$). There were no statistically significant changes in any objectively measured or physiological outcomes. A moderate relationship existed between compliance (percentage of expected sessions completed) and both physical component summary score change (Pearson's $r = 0.5$; $p = 0.02$) and peak oxygen uptake change (Pearson's $r = 0.2$; $p = 0.03$). The cost of delivering the intervention ranged from £463 to £848 per patient per year. The number of patients with harms (serious adverse events) was similar in the intervention group ($n = 69$) and control group ($n = 56$).

Discussion

The PEDAL intradialytic exercise programme did not statistically improve Kidney Disease Quality of Life Short Form, version 1.3, physical component summary scores sufficiently to meet the primary end point of this study. Patient interviews revealed that patient engagement was related to the presence of an exercise culture, and leadership to provide this, in the renal unit. Future work should evaluate methods to improve patient engagement to enhance future studies and facilitate clinical implementation.

Trial registration

This trial is registered as ISRCTN83508514.

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