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# CYCLE-HD: Improving cardiovascular health in patients with end stage renal disease using a structured programme of exercise. A randomised controlled trial.

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Introduction
Haemodialysis patients are at greatly increased risk of cardiovascular morbidity and mortality. Exercise training may positively impact several of the risk factors associated with cardiovascular death amongst people receiving haemodialysis. The primary aim of this trial was to investigate the effect of a structured programme of intradialytic cycling on left ventricular (LV) mass, a strong predictor of cardiovascular outcome in this population.

Methods
In an open-label, blinded end-point, cluster randomised controlled trial, adults undergoing maintenance haemodialysis received either a six-month structured, progressive programme of intradialytic cycling (exercise group) or standard care (control group). The primary outcome was change in LV mass at six-months measured by cardiac MRI. Pre-specified secondary outcomes included measures of physical functioning, quality of life and ventricular arrhythmias. Primary and secondary outcomes were analysed on an intention-to-treat basis, using linear mixed-effects models adjusted for baseline value according to a pre-specified statistical analysis plan.

Results
A total of 130 people were recruited to the trial and completed baseline assessments (65 both groups), with 101 completing the trial protocol (control group n=50, exercise group n=51). Groups were well-matched for age, sex, ethnicity, dialysis vintage and comorbidities. Participants in the exercise group progressed training as per protocol and completed 71.7% of planned exercise sessions. At baseline, mean LV mass in the exercise group was 121.3g (±45.4) and was 116.5g (±35.9) in the control group. At six-months, mean LV mass reduced to 111.3g (±41.0) in the exercise group and increased to 118.1g (±37.5) in the control group, representing a treatment effect of 11.1g (P<0.001) between groups in favour of the intervention. There was no evidence of an increase in either ventricular ectopic beats or complex ventricular arrhythmias as a result of exercise. There was some evidence to suggest that those randomised to exercise increased their general physical activity levels, with the average daily step count being higher in the exercise group at follow-up by 732 steps (95% CI: -75, 1539; p=0.08). There was no apparent effect on physical function or quality of life. A total of 51 serious adverse events reported in 31 patients; none of the events were related to the intervention or trial procedure.

Conclusion
Among subjects undergoing haemodialysis, a six-month programme of intra-dialytic cycling led to a reduction in left ventricular mass. Funded by the National Institute for Health Research (ISCTRN11299707).