14

Exercise for people living with frailty and receiving haemodialysis: a mixed-methods randomised controlled feasibility study.

Mrs Hannah ML Young[1], Dr Daniel S March[2], Dr Patrick Highton[2], Dr Matthew PM Graham-Brown[2], Mr Darren C Churchward[2], Miss Charlotte Grantham[2], Mrs Samantha Goodliffe[5], Dr Sharlene Greenwood[3], Dr Helen Eborall[4], Professor Simon Conroy[5], Professor Sally J Singh[6], Professor Alice C Smith[5], Professor James O Burton[2]

[1]Department of Respiratory Sciences, University of Leicester, Leicester, United Kingdom, [2]Department of Cardiovascular Sciences, University of Leicester, Leicester, United Kingdom, [3]Department of Physiotherapy and Renal Medicine, King's College Hospital and Department of Renal Medicine, King's College London, London, United Kingdom, [4]Social Science Applied to Healthcare Improvement Research (SAPPHIRE) Group, Department of Health Sciences,, Leicester, United Kingdom, [5]Department of Health Sciences, University of Leicester. , Leicester, United Kingdom, [6]Centre for Exercise & Rehabilitation Science, Leicester Biomedical Research Unit, Glenfield Hospital, Leicester, United Kingdom

Introduction.
Frailty is highly prevalent haemodialysis (HD) patients, leading to poor outcomes. Intradialytic cycling (IDC) is the predominant form of rehabilitation offered, but may not be suited to those who are frail. This study aimed to determine whether a randomised controlled trial (RCT) of IDC is feasible for frail HD patients and explore how the intervention may be tailored to their needs.

Methods.
Design: Mixed-methods feasibility RCT. Participants: Adult HD patients with a Clinical Frailty Scale Score of 4-7 (vulnerable to severely frail). Interventions: Six-months, thrice-weekly, progressive, moderately intense IDC or usual care. Outcomes: Primary feasibility outcomes were: eligibility of >50%; recruitment of >50%; loss to follow-up of <20%; outcome acceptability of >80% and exercise adherence of >70%. Acceptability of trial procedures and the intervention were explored via semi-structured interviews with n=25 frail HD patients who both participated in (n=13,52%), and declined (n=12,48%), the trial. Secondary outcomes included incidence of falls and measures of exercise capacity, physical functioning, physical activity and patient-reported outcomes (PROMS).

Results.
124 (31%) people were eligible, 64 (52%) consented and 51 (80%) completed a baseline assessment. N=39 (76.5%) male, 65 years (IQR 56-70). 23 (45%) were vulnerable, 12 (23.5%) mildly, 13 (25.5%) moderately and 3 (6%) severely frail). 24 (47%) received IDC and 27 (53%) usual care. Overall n=6 (12%) were lost to follow-up. The exercise group completed 74% of sessions. Up to 70% of secondary outcome data was missing.

Exploratory analysis found the crude falls incident rate ratio (IRR) was 1.95 (95%CI 0.63 to 7.18), suggestive of an almost two-fold increased incidence of falls within the usual care group. Exercise capacity was maintained in the exercise group, but deteriorated in the usual care group, resulting in an overall difference in ISWT distance of 36m (95%CI -12 to 84) and EWST time of 181 seconds (95%CI -92 to 453). The time taken to complete the STS5 increased in the usual care group, but was maintained in the exercise group, resulting in an overall difference of 5 seconds (95%CI -4 to 15). Other functional tests and PROMS were unchanged. Steps increased in the exercise group vs usual care group (859 steps/day, 95%CI -825 to 2543 on HD days and 888 steps/day, 95%CI -84 to 1861 on non-HD days). N=13 (25%) experienced a serious adverse event unrelated to the study.

Interview participants outlined several ways to encourage trial participation and retention. Maintaining ability to undertake activities of daily living and social participation were outcomes of primary importance. The primary barrier to exercise was the perception that it was unsuitable or unsafe. Participants desired a more varied exercise programme which included preparation, choice, and offered companionship and individualised progression.

Discussion.
With changes to trial design and processes a definitive RCT is feasible. Wide-scale adaptation to the intervention incorporating education, behaviour change, and a multi-component exercise programme (strength, balance, task-training, backward chaining and increased habitual activity) supported by a decision-tool to adapt exercise during periods of ill-health and fluctuating symptoms may be more efficacious than IDC in this population.