

MO589 **EXERTION2 TRIAL: THE WEIGHT GAIN PREVENTION IN RENAL TRANSPLANT ONLINE STUDY—A RANDOMIZED CONTROLLED FEASIBILITY TRIAL**

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BACKGROUND AND AIMS: Adverse weight gain within the first year of receiving a kidney transplant is associated with adverse health outcomes. Kidney transplant recipients (KTRs) have asked for support with physical activity and following healthy lifestyles. There is no recognised intervention to address weight gain prevention for new KTRs. Usability of an online intervention to prevent weight gain in new KTRs has recently been reported. The aim of this study was to examine the feasibility of undertaking a randomised controlled trial of an online intervention group (IG) compared with usual care (UC) to address weight gain prevention in new KTRs.

METHOD: Participants were recruited from two south-London transplant sites, had a kidney transplant within 3 months, and had access to an internet compatible device. Exclusion criteria included history of an unstable medical condition, non-English speaking or <18 years. At baseline assessment participants were randomized to either UC or IG. The UC group received standard dietary and physical activity education. The IG received access to a 12-week password-protected website, weekly email reminders, and could contact the research physiotherapist via a secure message function.

Primary feasibility outcomes included screening rates, consent rates, adherence to study visits, acceptability of outcomes, engagement with the intervention, retention, willingness to be randomized, adverse events, hospitalizations, experience using the online intervention and experience taking part in the trial. Secondary outcomes were recorded at baseline, 3- and 12-months. These included body weight, body mass index (BMI), bioimpedance (BIA), pulse wave velocity (PWV), augmentation index (AI) and six-minute walk distance (6MWD).

RESULTS: Seventeen new KTRs (median age 49 years, 10 males, median 62 days post-transplant) were randomized to the IG ($n = 9$) or UC ($n = 8$). Screening rate was 84.2% (95% CI: 68.8–94.0), recruitment 62.5% (95% CI: 43.7–79.0) and intervention adherence at 12 months was 76.4% (95% CI: 50.0–93.2). All pre-set progression criteria for feasibility were achieved. There were no associated adverse events. Qualitative analysis revealed four themes; optimizing participation and recruitment, impact of Coronavirus disease 2019 (COVID-19), engagement is a choice (technical and personal factors) and mechanisms of action (assessment and intervention factors). The IG appeared to stabilize median body weight across the study; 94.5 kg, (IQR: 63.0, 102.0), 95.0 kg, (IQR: 66.7, 105.3) and 94.7 kg (IQR: 77.2, 117.3). Whereas UC participants increased [81.3 kg, (IQR: 73.6,94.6), 86.2 kg (75.4, 96.5) and 93.3 kg (70.3, 101.9)]. IG increased 6MWD [450 m, (IQR: 450, 540), 525 m (IQR: 472.5, 615) and 495 m (IQR: 465, 615)] and UC decreased 6MWD [517.5 m (IQR: 436, 570), 507.5 m (IQR: 442.5, 605) and 435 m (IQR 435, 555)]. All other outcomes were comparable across the sample.

CONCLUSION: Limitations include inadequate power and small sample size, and it was a single-centre study. Integrated mixed methods analysis demonstrate congruency of both qualitative and quantitative data. Participant attitudes, experiences and engagement with the study and intervention provide insight for future trial design. A future definitive trial is warranted and welcomed by KTRs.

MO590 **A HOME-BASED EXERCISE AND PHYSICAL ACTIVITY INTERVENTION AFTER KIDNEY TRANSPLANTATION: IMPACT OF EXERCISE INTENSITY. THE PHOENIX-KIDNEY STUDY PROTOCOL**

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BACKGROUND AND AIMS: Advances in the field of kidney transplantation have led to improved postoperative survival rates, but age-standardized mortality nonetheless remains 2- to 7-fold higher in kidney transplant recipients—with cardiovascular disease representing the leading cause of death in recipients with a functioning graft. Poor physical fitness, not completely recovering after transplantation, adds to the heightened cardiovascular risk of hypertension, diabetes, dyslipidemia and obesity. So does the post-transplant continuation of gut microbial dysbiosis, which recently emerged as a modulator of muscular, metabolic and cardiovascular health. Exercise-based rehabilitation and physical activity interventions may prove pivotal in the care of kidney transplant recipients to address aforementioned outcomes.

METHOD: At 3 months post-transplant, a probability sample of 147 adult kidney transplant recipients from two independent Belgian transplant centers will be randomly allocated to either 6 months of home-based moderate-intensity training (MIT, $n = 49$), concurrent moderate- and high-intensity training (MHIT, $n = 49$) or usual care (CON, $n = 49$) (Figure 1). High-intensity training sessions in MHIT are based on the Scandinavian model (four blocks of 4 min at high intensity interspersed by 3 min of active recovery), performed twice a week, and of equivalent energy expenditure as moderate-intensity training (Figure 2). MIT and MHIT will perform similar muscle strengthening exercises, twice a week. The training intervention will be followed by an individualized activity intervention aiming for long-term physical activity maintenance in MIT and MHIT; using motivational interviewing techniques, co-creation of an action plan adapted to the patients' preferences, goal-setting, gradually decreasing follow-up prompts over time and self-monitoring of physical activity behavior. Study participants will be followed-up till 2 years after transplantation. We hypothesize that the study intervention will improve our primary outcome cardiorespiratory fitness, assessed as peak oxygen uptake, at 9 months post-transplant. Secondary outcomes include muscle fitness, motor fitness, body composition, cardiovascular health, gut microbiome characteristics, health-related quality of life, safety, cost-effectiveness and implementation outcomes (Figure 1). The role of training intensity and the role of baseline gut microbiome characteristics as predictor of individuals' training response will be explored.

RESULTS: Results from this two-phased RCT will provide novel insights in the safety, implementation potential, cost-effectiveness and effectiveness of a home-based exercise program and physical activity intervention in *de novo* kidney transplant recipients to improve physical fitness, cardiovascular health, gut microbiome characteristics and health-related quality of life.

CONCLUSION: PHOENIX-kidney represents the first adequately powered multicenter RCT evaluating basic, clinical and health-economic outcome parameters in response to an exercise training and physical activity intervention in kidney transplant recipients.