Exercise From Afar: Progressing At-Risk Adults to Independent Exercise for Dementia Risk Reduction

April 1, 2024

NCT #: TBD

Analysis Plans

Power/sample size. Our sample size (n=50) was selected to meet the primary objective of this study: to determine efficacy of a technology-driven exercise program for underactive adults living in Rural Kansas. We acknowledge that for clinical trials, this sample size is moderate. We hope this initial investigation will provide us with data that can be used to conduct further investigations with larger sample sizes in the future.

Analysis plans. *Primary aims.* This is a randomized, controlled trial with (1:1) allocation comparing the effects of 16 weeks of independent technology-driven exercise to a control group. Based on previous exercise clinical trial drop-out rates (~6%), we conservatively allow for 15% attrition, with a total sample size of n=50 this will leave approximately 42.5 (43) participants for analysis assuming comparable attrition in both groups. The primary analysis compares Exercise vs. Control. The primary outcome measures (exercise adherence, cardiovascular fitness, muscular strength, cholesterol and blood glucose) will be analyzed with a linear mixed model using baseline and 16-week measures. Estimated linear contrasts will assess change (baseline to 16-weeks) in the primary aims between Exercise and control. We will test with $\alpha = 0.05$.
Secondary aims. Aim 2 Statistical Plan: The analysis plan for Aim 2 will follow that described above for Aim 1 with barriers to exercise as the primary outcome. We will compare standard deviations across groups (for homogeneity of variance). Alternative strategies (e.g. transformation of variables, generalized linear mixed models, etc.) will be used if needed. Missing data for analyses of the primary aim will be imputed, thus oversampling to account for drop out is unnecessary. We will determine if the proportion of participants lost to follow-up differs by treatment and demographic characteristics (sex, age, baseline weight, $p<0.05$) between completers and those lost to follow-up. If missing data are related to treatment and/or these demographic characteristics, we will use model based multiple imputation; otherwise, we will use traditional multiple imputation. Statistical analysis will be completed with SPSS.