The Impact of Type 2 Diabetes and Exercise on Liver Fat Quality (DELIVER)

IRAS ID: 241046

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NCT ID: not yet assigned

Statistical analysis plan

06/08/2018

Statistical analysis plan

Descriptive statistics will be calculated to outline the characteristics of the study sample. Normality of data will be assessed using histograms and box plots, while further analysis of skewness and kurtosis will be conducted if normality is not clear from the histograms and box plots. Depending on the distribution of data, participant characteristics will be reported as mean (SD) or median (IQR) and number (percentage) for continuous variables and for categorical variables respectively.

Baseline descriptive statistics will be summarised by treatment arm (intervention vs control). Data will be checked for parametric assumptions. For the primary outcome, change in hepatic saturated lipid index (%) from baseline to six weeks due to moderate-intensity exercise training in men with NAFLD and T2DM, treatment arms will be compared using linear regression modelling. The analysis will include a binary indicator for randomisation group as the explanatory variable, terms for the stratification category (ethnicity) and adjustments for the baseline measure of the outcome (hepatic saturated lipid index).

Complete case analysis will be utilised for the primary analysis. Intention to treat will be carried out as sensitivity analysis, using multiple imputation for missing values. Secondary outcomes will be analysed using similar methods as the main analysis, with an appropriate model selected dependent on the distribution of the outcome.

The assumptions associated with each model will be assessed and where these are not met alternative models or parameterisations will be considered. A value of $P<0.05$ will be considered statistically significant for all analyses. Statistical analyses of the baseline data and all future analysis will be carried out using STATA version 15.

Missing data will be replaced using multiple imputation or another appropriate method. In Part B, participants completing less than 85% of all training sessions will not be included in the final analysis.