Protocol: A Randomized Controlled Trial of Lifestyle Modification and Lorcaserin for Weight Loss Maintenance

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Statistical Analyses

The planned randomized sample size of 136 participants allowed 20% attrition and was estimated to be adequate to evaluate the two co-primary end points with a combined power of at least 80% (two-sided tests). The co-primary outcomes were evaluated using Holm's adjustment for multiple comparisons (27), such that the smaller of the two resulting p values would be compared at alpha equal to 0.025 and, if significant, the other contrast would be evaluated at 0.05. Secondary outcomes were tested at the 0.05 alpha level.

Randomized groups were compared on baseline characteristics, and variables that differed between conditions were included as covariates in the final analyses. The percentages of participants who maintained losses ≥5% or ≥10% of initial weight at week 52 were analyzed using logistic regression. Participants who did not complete the week-52 assessment were considered not to have maintained the loss. Nested mixed models with residual maximum likelihood were used to compare the treatment groups in weight change from randomization to week 52 and in changes in cardiometabolic risk factors and psychosocial measures (14).

All randomized participants were included in the primary intention-to-treat (ITT) analyses. Sensitivity analyses included: a modified-ITT analysis that included only individuals who received medication and attended at least one post-randomization visit; an ITT analysis that included all available weight measurements (i.e., weights measured at clinic visits or outcome assessments); a completers analysis; and a last-observation-carried-forward analysis.