# HealthyMe Online Weight Management Education/HealthyMe at Home (HOME)

Statistical Analysis Plan

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Analysis Plans. **Baseline Comparisons.** Comparisons between arms will be performed with participants grouped according to randomization assignment. Summaries of baseline characteristics will be computed by treatment arm, as will baseline values for primary and secondary outcomes. For continuous variables, mean and standard deviation will be reported. Frequency tables will be reported for categorical variables.

**Primary Outcome.** The primary outcome is the proportion achieving 2kg weight loss at 6 months and maintaining to 12 months. We will use intention-to-treat analyses. Baseline observations will be carried forward (BOCF) for any subject not completing a 6-month or 12-month assessment. This is equivalent to assuming that those subjects not completing the 6- or 12-month assessment had no weight change. Sensitivity analyses will be conducted using pattern mixture analysis that includes missing data pattern information in the model and does not assume a missing at random mechanism. The study is powered to make two comparisons of intervention arms versus the control arm (i.e., at 6 and 12 months). Each comparison of a treatment group versus the control group will be performed using the Fisher's exact test at a significance level of 0.025 (two-sided). As a secondary analysis of the primary outcome, the actual weight loss will also be compared by the Wilcoxon rank-sum test at a significance level of 0.025 (two-sided). We will then perform a series of secondary analyses to assess whether there may be systematic bias in the patient attrition between the arms. If there is, the above BOCF analysis may be biased and an adjusted analysis needs to be performed. Although baseline variables for *all* randomized patients are balanced through randomization, patients dropping out post-treatment is a self-selection process and as a result the subset of study completers is *not* randomized. Hence the subset of study completers should be treated as an observational study rather than a randomized study. In the secondary analysis, we will examine if there are differential attrition rates between the arms by Fisher's exact test at a two-sided significance level of 0.05. Furthermore, we will compute the standardized differences of baseline patient characteristics, the baseline primary outcome measures and the baseline secondary outcome measures among the subset of patients who have the 12 month primary outcome. The standardized difference of a variable *l* is defined as,

$$d = \frac{|\bar{l}_{treatment} - \bar{l}_{control}|}{\sqrt{\frac{s^2_{treatment} + s^2_{control}}{2}}}$$

where the two statistics in the numerator are the group means and $s_{treatment}$ and $s_{control}$ are the sample standard deviations of variable *l* in the treatment and control subjects respectively. Cochran[115] offered a rule of thumb that if one or more of the group means differ by 0.25 of a standard deviation, this is an indication of lack of balance between the arms. In such a case, some form of adjusted analysis is warranted, for example, the "unbalanced" variables should be included in the multiple regressions when computing the average treatment effect. Propensity score based methods can also be used to remove bias from the uneven drop-out. If used, the probability of dropping out can be estimated through logistic regression given the baseline patient characteristics and the baseline outcome measures (assuming missing at random). The average treatment effect can then be computed using the inverse probability weighting.

**Secondary Outcomes.** Secondary continuous outcomes will also be compared using the Wilcoxon rank sum test, while categorical outcomes will be compared using the Chi-square test. In the secondary comparisons, nominal p-values will be reported without adjustment for multiple testing. If systematic bias in patient attrition between the two arms is suspected by the analysis

stated in the analysis of the primary outcome, a similar secondary analysis strategy will also be used to analyze secondary outcome measures.

**Process Evaluation**. Analyses of process in the two intervention arms will follow the proposed model in Figure 1 although not all relationships will be estimated in a single model. We will use a series of ordinary least squares regression models to separate direct and indirect effects. Priority models will be: 1) whether group differences in session attendance are apparent and whether attendance costs account for group differences in attendance, 2) whether session attendance is associated with energy intake, energy expenditure, or weight, 3) whether social support, enjoyment, nutrition literacy, and self-efficacy are associated with session attendance, and 4) whether social support, enjoyment, nutrition literacy, or self-efficacy account for any association between session attendance and energy intake, energy expenditure, or weight. Using the latter as an example, weight change would be the dependent variable and a first model would include session attendance as an independent variable. A second model would add social support, enjoyment, nutrition literacy, and self-efficacy as independent variables through which attendance may indirectly affect weight. We would replicate this model using change in energy intake or energy expenditure as the dependent variable.