Analytic Plan

Study Title: Single arm trial of a multi-component commercial digital weight loss

NCT04302389
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We will use Research Electronic Data Capture (REDCap)[33] for data collection and monitoring completion of study assessments. We will use Grytics to downloaded engagement data and upload it to REDCap and the protected UConn server. Co-Investigator/Statistician Dr. Ran Xu will supervise data management and quality control with the assistance from PhD students and post-docs. We will use NVivo 12 (QSR International, Melbourne, Australia) to manage and analyze qualitative data and SAS 9.4 (SAS Inc, Cary, NC) to analyze quantitative data.

Aim 1: We will summarize the use of each component, engagement in the online community and virtual workshops, and answers to questions assessing program acceptability. We will calculate percent weight change from baseline to 3 months and baseline to 6 months. For participants who do not provide weight at 6 months, we will use a baseline observation carried forward method (i.e., assume no weight loss). Secondarily, we will calculate a complete case 6-month weight change. For both the intent-to-treat and complete case estimates, we will use a one-sample t-test to compare mean percent weight loss to the null hypothesis of no weight change (i.e., 0% weight loss). We will also describe the distribution of weight loss (e.g., median, IQR, range), and will calculate the proportion of participants who achieve clinically significant weight loss (i.e., ≥5%). We will assess changes in diet quality, physical activity, quality of life, external and internal eating, sleep quality, food cravings, and mood using the same approach as examining weight changes.