Study Title: A Pilot Sensor-controlled Digital Gaming Intervention With Real-time Behavior Tracking to Motivate Self-management Behaviors in Older Adults With Heart Failure

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Statistical Analysis
Power

Based on 1:1 randomization with 80% power (5% alpha), to detect a difference of 80% versus 50% in both groups of daily monitoring of weight monitoring and physical activity would require a sample size of 38 patients per group. We chose 80% as the cut-off for adequate weight-monitoring at 12 weeks, because HF patients who completed *at least* 80% of weight diaries *(5.6/7 of days per week)* were found to have significantly reduced odds for HF-related hospitalizations in comparison with patients who completed <80% of weight diaries [1]. Also, only 50% of HF participants in a remote monitoring sensor group recorded their weights >50% of the time [2]. Allowing for 10% attrition, 49 patients per group (N=98) must be recruited for a fully powered clinical trial of the SCDG intervention for HF behavior of weight-monitoring. The power analysis was performed using G*Power [3]. With a sample of 38, our study was underpowered. However, this sample size was sufficient to assess feasibility study [4] which can inform implementation of a fully powered study with fewer problems to test the SCDG's effectiveness.

Data Analysis

Descriptive statistics for feasibility included (1) the percentage of participants recruited from the total who were approached; (2) the percentage of participants (among those recruited) who were retained in the study at the end of 24 weeks in each arm and overall; (3) the number of days IG participants played the SCDG; and (4) average satisfaction with the SCDG. All open-ended questions were coded by 2 team members (CA and AS) and then analyzed using a general inductive thematic approach [5].

The observed effect sizes (Cohen's *d*) for the primary outcome of weight-monitoring days at the end of 12 weeks was calculated using the following formula: mean of days in IG minus mean of days in CG divided by average standard deviation of days in IG and days in CG. The potential clinical meaningfulness of the results (in addition to statistical significance) was based on the magnitude of the effects: small (*d*=0.20), medium (*d*=0.50), and large (*d*=0.80) [6].

All statistical analyses were conducted using SPSS Statistics for Windows, version 26 (SPSS Inc). Baseline characteristics of participants in IG and CG were compared using independent two-tailed *t* tests for continuous variables and chi-squared tests for categorical variables. Although this study was a feasibility trial, we assessed within-group trends in IG and CG using paired-sample *t*-tests (two-tailed) at baseline, 6 weeks, 12 weeks and 24 weeks. Within-group changes were presented as absolute changes from baseline. All data were presented as means with standard deviations (SD). Missing values were addressed using intent-to-treat principles with maximum likelihood estimations.

References:

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