Telehealth Self-Management Program in Older Adults Living with Heart Failure in Communities with Health Disparities

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A Randomized, Controlled Trial Comparing Telehealth Self-Management to Heart Failure Clinic Outpatient Management in Black and Hispanic Disparity Patients Living with Heart Failure

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The health system's Biostatistics Unit created a randomization schedule for patient assignment, to randomize patients to either TSM or COM using permuted block randomization, with stratification by heart class, to ensure equal representation of heart class across the two groups. The primary analysis of this randomized clinical trial was based on intention to treat (ITT) principle, which included all subjects randomized. Descriptive statistics are presented as means, standard deviations, medians, ranges and frequency/percentages.

Inpatient utilization was defined in three ways, including: 1) whether an individual patient had at least one inpatient hospitalization over the 90 day period; 2) the number of hospitalizations experienced by an individual patient over the 90 day period; and 3) the cumulative length of stay (LOS) (inpatient days) experienced by an individual patient

over the 90 day period (i.e., for multiple hospitalizations, the sum of all LOS's was computed as the cumulative LOS).

ED utilization was defined as whether or not an individual patient had at least one ED visit over the 90-day period. Binary outcomes for ED visits and hospitalizations were analyzed using the standard Chi-square or Fisher's exact test. Associated 95% confidence intervals for these proportions and their differences were computed using exact methods. The number of ED visits as well as hospitalizations within each group were separately compared using Poisson regression (SAS PROC GENMOD). Due to excess zeros (i.e., zero inflation), methods for over dispersed Poisson were required for both ED visits and hospitalizations. Cumulative LOS (inpatient days) was analyzed using a negative binomial regression. HF-related hospitalizations, ED visits, and LOS were analyzed in the same fashion described above, as were cardiovascular related outcomes. Reasons for ED visits as well as hospitalizations were classified as: HF alone (yes/no), cardiovascular related alone (yes/no), or both by the clinical team.

Repeated measures analysis of variance (RMANOVA) with a mixed models approach was used to compare changes at enrollment and at 90 days between groups. New York Heart Association (NYHA) class, PHQ-4[28], MLHFQ[27] Physical and Emotional subscales were also analyzed using RMANOVA. The subscales of Anxiety and Depression, as measured by the PHQ-4, were dichotomized to presence or absence and Generalized Estimating Equations (GEE) were used to analyze these binary data. Days at home was

calculated as a proportion of days spent out of hospital during the 90 day period. The two groups were compared using the Mann-Whitney test.

Subgroup analyses included: patients hospitalized, heart class (2 vs. 3), and patients *not* receiving home care (prevalent in disparity populations). For the TSM group only, adherence was calculated, with low adherence defined as less than 10 vital signs uploads over the 90 day period.

Sample size and power calculations were based on previous literature and preliminary data from a non-disparity randomized RCT TSM study.[22] We hypothesized that 75% of patients in the COM group would be hospitalized at least once during the study period and that TSM would reduce that rate to 50% (a relative reduction of 50%). The calculation was based on a chi-square test (alpha=0.05, two-tailed) with an n=52 patients per group. All analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC).

The Northwell Health Institutional Review Board (IRB#13-518A) approved the study protocol.