Official title: Activate For Life: mHealth Intervention To Address Pain And Fatigue In Lowincome Older Adults Aging In Place

NCT03853148

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Analysis plan

Data were analyzed using IBM SPSS Version 26.0. Mean substitution was conducted to account for missing data (these did not represent more than 40% of overall dead data). Repeated measures analysis of variance (ANOVA) was used to determine significant differences for outcome variables between the 3 intervention Arms. Differences were considered statistically significant for *p*-values <0.05. Analyses were similar for outcomes in the caregiver group.

Measures of feasibility including recruitment and reach, fidelity and adherence, formal satisfaction, and drop-out proportions were evaluated. Then 95% confidence intervals for proportions were used to estimate dichotomous outcomes (e.g., the proportion of subjects who: agree to participate out of the number that are approached, the proportion who complete the intervention, the proportion who report satisfaction with the intervention, and the proportion who exit the study prematurely [drop out]). Further, the participants' reasons for drop out, and problems/issues encountered with the intervention were described via frequency distributions. For continuous measures (e.g. satisfaction scores), frequency distributions and the median and mean responses (with 95% confidence intervals) were obtained. Univariate descriptive statistics and frequency distributions were calculated as appropriate for all variables. Demographic variables obtained at baseline were described via measures of central tendency (mean, median), variability and frequency distributions as appropriate. Additionally, characteristics for those who were eligible for study versus those who were not eligible and for those who adhered to the study protocol (study completers) versus those who did not adhere (non-adherers and drop-outs) were compared to better describe the population for this study.