Online Education and Gentle Exercise Intervention (MY-Skills)

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Statistical Analysis Plan

Assess feasibility and acceptability of MY-Skills and research procedures including planned assessments. In this small RCT, we will examine feasibility and acceptability of the 8-week MY-Skills procedures and intervention compared to an exercise and health and wellness education control group. Participants will include 30 caregiving dyads randomly assigned to the two groups (15 dyads for My-Skills and 15 dyads for control group; N = 30 dyads/60 participants). Our primary hypothesis is that MY-Skills will be feasible and acceptable to caregiving dyads, as measured by benchmarks for recruitment, screening, attendance, and completion of assessments and intervention. Surveys will be administered and focus groups will be conducted to understand participant satisfaction and experiences with MY-Skills. After each intervention session, interventionists, caregivers, and care recipients will rate their satisfaction with the session content and activities. To assess change on the primary outcome (pain-related disability) and secondary outcome measures, members of the caregiving dyad will complete pre and post-assessments guided by the Biopsychosocial model (Gatchel et al., 2007).

Outcomes measures: Demographic data and outcome measures will be collected by a blinded and trained research assistant. Demographic data will include age, gender, race, ethnicity, monthly income, time with pain, any noted reasons for pain, injuries related to or caregiving, and medication use for pain. The Brief Pain Inventory (BPI) is our primary outcome measure and assesses pain-related disability (i.e. interference of pain on function and daily life) (Cleeland, 1989). The BPI interference scale is a 7-item subscale of the 11-item BPI total score. Sample size does not allow for the evaluation of mediating or moderating variables regarding the association between the treatment and decrease in pain-related disability, but will be tested in a future RCT. Patient-Reported Outcomes Measurement Information System (PROMIS) Network measures are used for constructs when available (Cella, Riley et al., 2010). The measures operationalize the key constructs of the conceptual model (see Table 5) and take into account cultural differences, stressors, and benefits for caregivers discussed in the most recent meta-analyses (Pinquart & Sorensen, 2005, 2006; Pinquart et al., 2003). Further, the measures selected for this project have been used with ethnically diverse populations. Careful consideration was given to testing burden in selecting appropriate measures. When multiple measures were established, all things being equal, shorter measures were selected. Measures were selected because they had previously been used in pain or caregiving dyad research and have excellent psychometric properties (e.g., reliability and validity). Caregivers and care recipients will each receive a $50 gift card to accommodate their time during assessments.

Data analyses. All statistical analyses will be conducted using SAS v9.3 (SAS Software, Cary, NC, USA) or SPSS v26 (IBM, 2019). To evaluate feasibility, we will use means and standard deviations or frequencies and relative frequencies as appropriate for each feasibility measure and benchmark. We will examine descriptive statistics (e.g., frequencies and relative frequencies, measures of central tendency, and measures of variation) for each outcome measure. The BPI is the primary outcome measure, where scores range from 0 to 10 with higher scores indicating more severe pain and greater interference (Cleeland, 1989). Descriptive statistics will be computed for each group (MY-Skills intervention and control), the caregivers and the care recipients and caregiving dyads overall to describe trends in the groups and participants. We will examine descriptive statistics to determine if differences exist between cohorts; we do not anticipate difference between the cohorts.

Expected Outcomes: At the completion of Aim 2, we will have data describing the feasibility and acceptability of the intervention and baseline and post-intervention data to assess change on the primary outcome (BPI), as well as several additional secondary outcome variables for both the caregiver and the care receiver.