

Statistical Analysis Plan for University of Washington School of Medicine,

Department of Rehabilitation Medicine study:

Efficacy and mechanism of a community wellness promotion program for middle-aged adults living
with long-term physical disability

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Statistical Analysis Plan

Design overview:

- 3-arm, randomized controlled trial
 - Arm 1: Enhance Wellness for Disability (8 sessions)
 - Arm 2: Health education (8 sessions of the CDC's "Keys to Healthy Aging")
 - Arm 3: Treatment as usual (TAU)
 - 6-month intervention period across 3 groups
 - 12-month follow-up across 3 groups

Assessment timeline:

- Patient reported outcomes collected at baseline (pre-randomization), and at 3, 6 and 12 months post-randomization
- GPS outcomes collected at baseline (pre-randomization) and at 12-month follow-up

Primary outcome variable:

1. Change in ability to participate in social roles and activities
 - Measured via the PROMIS Ability to Participate in Social Roles and Activities 8-item short form
 - Patient reported outcome
 - Results recorded as a t score

Secondary outcome variables (patient reported):

1. Change in satisfaction with social role participation
 - Measured via the PROMIS Satisfaction with Social Roles and Activities 8-item short form
 - Results recorded as a t score

2. Change in disease management self-efficacy
 - Measured via the University of Washington Self-Efficacy Scale, 6 item short form
 - Results recorded as a t score
3. Change in interference due to pain
 - Measured via the PROMIS-29 Profile, v. 2.1 pain interference subscale (4 items)
 - Results recorded as a t score
4. Change in interference due to fatigue
 - Measured via the PROMIS-29 Profile, v. 2.1 fatigue subscale (4 items)
 - Results recorded as a t score
5. Change in psychological resilience
 - Measured via the Connor-Davidson Resilience Scale, 10-item short form
 - Scores range from 0-40

Secondary outcome variables (GPS and travel log based):

1. Change in number of trips outside the home
 - Mean average per day
2. Change in radius of gyration
 - Results recorded in meters
3. Change in number of trips outside the home containing “social” elements
 - Based on integration of GPS and travel log report
4. Change in time of trips spent in activities outside of the home containing “social” elements
 - Results recorded in minutes
 - Based on integration of GPS and travel log report

Statistical Approach:

All analyses will follow an intent-to-treat approach.

Summary statistics (means, standard deviations, counts, and percentages), stratified by treatment assignment, were used to describe the study sample. ANOVAs were used as an omnibus test to determine if there were any differences in the change scores between treatment groups for each of the primary and secondary outcomes. If the omnibus test was significant, a post-hoc Tukey's honest significant difference tests were used to assess pairwise differences between treatment groups. A two-sided significant level of 0.05 was used to determine if differences were statistically significant. As there was only one primary outcome, no adjustment for multiple comparisons was used. Furthermore, Tukey's HSD test inherently controls the type I error rate for the pairwise comparisons.