Me & My Wishes: An efficacy trial of long-term care residents with Alzheimer's using videos to communicate care preferences with caregivers

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Statistical Analysis Plan

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Randomization

We will employ a randomized wait-list control design with nursing homes and assisted living facilities. We block randomized five nursing homes and three assisted living communities in the Pacific Northwest into two groups based on size, proportion of residents with Medicaid, and proportion of residents with mild to moderate cognitive impairment. In Group 1 (early intervention group) NHs, videorecording, editing, and viewing will occur within three months of baseline. In Group 2 (delayed sharing) NHs,residents will be on a wait-list; after the delayed start, their video will be produced and viewed within three months.

Primary & Secondary Outcomes

We will calculate summary statistics for baseline demographics by intervention group, to assess comparability of groups and validate randomization scheme. We will use mixed modeling to compare the outcome measures goals of care discussions and self-efficacy of communicating preferences between Group 1 (early intervention) and Group 2 (wait-list) at 3 time points. Our specific model will be: $Y = B0 + B1X + B2T + B3(X*T) + e$ where, Y= goals of care discussions or self-efficacy of communicating preferences, X = Treatment condition (Group 1vs. Group 2), T = Time point (baseline, 3 months, 6 months). Evaluation of the fixed effect of Treatment condition will tell us whether the two groups differ on average across all time points. The fixed effect of Time will tell us whether goals of care discussions change over time. Evaluation of the interaction of Treatment by Time will tell us if the groups change differentially, and will be the effect of primary interest.

Rigor and Transparency

To address rigor, we will explore missing data patterns in SPSS using the Missing Value Analysis tool. We will specify the pattern fixed effects and interactions utilizing Little's test for Missing Completely at Random. Systematic missingness (as determined by missing data patterns) may be included in our mixed effects model. To increase rigor, we will employ a propensity matching score on participant characteristics (e.g. dementia type) to help reduce any treatment vs. control confounding bias.

Power and Sample Size

Sensitivity analysis was conducted with G-Power 3.1. With a proposed sample size = 48, 2 Groups, 3 timepoints, correlation between time points = .5, power = .90, and alpha = .05, we will be able to detect a medium effectsize f = .213 using a general linear modeling of repeated measures looking for within-between subjects' interaction. T= Time point (baseline, 3 months, 6 months).

Goals of Care

We analyzed results with an intent to treat approach using SPSS Version 24.0 (SPSS, Armonk, NY). Multilevel logistic regression (generalized estimating equations [GEE] with an autoregressive (1) working correlation matrix, logit link function) were fitted to assess the primary hypotheses. The models account for the repeated measures (3 or 4 time points), correlated, data structure per person. An additive model was conducted with contrast coding for each time point, treatment, and follow-up effects.

Concordance Analysis

Analyses were conducted using SPSS Version 24.0 (SPSS, Armonk, NY) using an intent to treat approach. Multilevel linear regressions (generalized estimating equations [GEE] with an autoregressive (1) working correlation matrix) were fitted to assess concordance of preferences between the resident videos and staff and family surveys at three (intervention group) or four (wait-list control group) time points. The models account for the repeated measures (three or four time points), correlated, data structure per person. Because this study used a waitlist control design, data includes the initial baseline data for both groups and second baseline data for the waitlist group. An additive model was conducted with contrast coding for each time point, treatment, and follow-up effects. This allowed us to compare the groups by the different times they received the video, with Time 1 (Baseline) as the reference category. For example, a participant in the Immediate group at time of video sharing would receive contrast coding: Time 2 (1); Time 3 (0), Time 4 (0), Treatment (1), Follow-up (0). While a participant in the Wait-list (Control) group at time of video sharing would receive contrast coding: Time 2 (0), Time 3 (1), Time 4 (0), Treatment (1), Follow-up (0). We stratified our analysis by the three different types of participants - residents, family members, and staff members.