

STAR Caregivers – Virtual Training and Follow-up

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STATISTICAL ANALYSIS PLAN

Background/overview/purpose of study:

This is a randomized trial that tests whether receipt of telehealth training for caregivers of people with dementia can reduce utilization of antipsychotic medications, as well as improve the living conditions of both the caregiver as well as the person with dementia.

Scientific questions and outcomes:

1. Is there a change in the rate of antipsychotic medication fills within eight weeks, comparing the intervention to the control arm
 - a. Main measures: Any fill within eight weeks (binary), any refill within eight weeks (binary)
2. Is there a change in standardized scales of caregiver mastery as well as dementia symptoms.
 - a. Primary scales: Revised Memory Problem and Behavior Checklist, Caregiver Mastery, Kingston Caregiver Stress
 - b. Secondary analyses: Dementia Severity Rating Scale subscales

Predictors of interest (independent variable, could be just treatment groups, indicate type as in outcome of interest section):

All analyses will adjust for gender and age, as well as the baseline score. (e.g. the caregiver mastery analysis will adjust for caregiver mastery at baseline) Our variable of interest will be the randomization group.

Unit of analysis:

The dyad of the caregiver and person with dementia.

Other data/analytic specifics (e.g. subgroups of interest, brief discussion of missing data):

Subgroups will be exploratory analyses; we are not specifically powered on any. Missing data will be accounted for via multiple imputation via chained equations, using 100 imputed datasets.

Analytic approach, special Issues and proposed sensitivity analyses:

This is a straightforward randomized trial, so analyses will be run using ordinary least squares regression with empirical standard errors for continuous outcomes, and logistic regression for binomial outcomes. Rubin's Rules will be used to combine results across the multiple imputation datasets.

Analytic software (and version if known):

Stata, version 17.0