

Video-Assisted Palliative Care Intervention for Patients With Advanced Dementia at Home

Dr. Nathan Goldstein

NCT03798327

Document Date: March 6, 2020

Statistical Analysis Plan

ID: GCO 17-02787

Palliative Care at Home for Dementia

NCT03798327

Nathan Goldstein – PI

March 2020

1. Overview. For continuous outcomes, we will compare the changes from baseline across multiple repeated measurement points between different treatment groups using mixed linear model to control for within-subject effect.

2. Descriptive Study. We will characterize subjects with regard to baseline and follow-up measures and change between assessments. Descriptive statistics of demographics, disease-related and treatment related variables will be calculated and compared at baseline between the treatment group and control group. T-test, Chi-square, Fishers exact test will be used as appropriate.

3. For the primary outcomes measures, we will examine changes in outcomes over time. As possible, we will test the differences in mean total scores between the main predictors of treatment groups (intervention vs. control) and time (baseline, 3 months, and 6 months), and the interaction term between these two predictors, which indicates the variation of difference of outcome trajectories between interventions and controls by baseline scores.

4. Utilization. We will measure counts of utilization including, as applicable, those related to the number of hospital admissions, number of hospital days, number of days out of hospital, and ED usage. We will perform simple counts followed by descriptive statistics between the two groups.