

PROTOCOL TITLE: EM/PROTECT: Improving Depression in Elder Mistreatment Victims

PRINCIPAL INVESTIGATOR: Dr. Jo Anne Sirey, PhD, Weill Cornell Medicine

IRB Protocol #: 1703018101

ClinicalTrials.gov Identifier: NCT03241225

Current Version: November 24, 2021

Descriptive statistics for continuous (median and interquartile range; IQR) and categorical (frequency and percentage) were reported on demographics and clinical characteristics of two treatment groups at baseline. A Mann-Whitney test and Fisher's exact test were conducted to test the difference between PROTECT and Usual care for continuous and categorical variables, respectively.

Remission rate was defined as the percentage of participants with MADRS scores  $\leq 10$  at Week 9. Response was defined as a reduction of  $\geq 50\%$  in MADRS scores from baseline to Week 9. We conducted two mixed-effects linear regression models to compare the trajectories of change in MADRS scores and WHOQOL scores between PROTECT and Usual care, respectively. Each model included fixed effects of treatment (PROTECT vs. Usual care), time, and their interaction, as well as a participant-specific random intercept. Both models were adjusted for age and gender. Site and its interaction with treatment were initially included in the model but were dropped as their effects were statistically non-significant. A two-sided p-value less than 0.05 was considered statistically significant. Intent-to-treat analyses are presented with all available data in the mixed-effects models. Remission and response rates were calculated based on 30 patients with complete data. All analyses were conducted in R 3.6.1 (R Foundation for Statistical Computing; <http://www.r-project.org/>).