Statistical Analysis Plan

COVID-19 Observational Research Collaboratory

NCT05394025

Updated: June 25, 2025

Background

In a previous study, we found Veterans with a first case of COVID-19 (between 2020 and 2021) did not report more limitations in instrumental activities of daily living (IADL) at 18-months after infection relative to comparators who were contemporaneously uninfected.

Aim

In this updated longitudinal analysis, we examine whether self-reported counts of IADL changed between infected and uninfected comparators over 18 additional months of follow-up (36 months after infection).

Study Design

Prospective cohort study design with repeated surveys at 18-, 24-, 30-, and 36- months.

Population

The cohort was sampled from a parent cohort of Veterans, assembled by the COVID-19 Observational Research Collaboratory, with a first documented case of COVID-19 between March 2020 and April 2021 and uninfected matched comparators. Veterans were required to have been enrolled in VHA care, been assigned a VA primary care team, and had one or more VA primary care visits in the two years prior to cohort construction. COVID-19 infections were ascertained through the VA COVID-19 Shared Data Resource (CSDR) and Medicare claims data. Otherwise, eligible Veterans without evidence of a documented infection were considered as uninfected comparators. From this parent cohort, we conducted a stratified random sample of 100 Veterans who tested positive for COVID-19 in October, November, December, February, March, and April 2021. Sampling was further stratified by US Census region and hospitalization status. Of the 600 patients with COVID-19 a total of 235 (39.2%) Veterans consented and completed surveys; 244 uninfected matched comparators completed surveys.

Exposure

First documented COVID-19 infection (positive PCR test or clinical note) was the primary exposure of interest. Veterans without a documented history of COVID-19 infection were eligible comparators. Extensive matching, done monthly, was used to ensure comparability between groups.

Outcome

Self-reported IADL limitations were the primary outcomes of interest. The IADL instrument was initially administered at 18-months after infection (or matched index date) and was subsequently readministered three additional times 6 months apart. The IADL asks respondents whether they experienced difficulties or limitations with daily activities and functions such as with “walking across a room” or “shopping for groceries.” We report individual IADL responses but use a cumulative count of self-reported limitations (0-14) as our primary IADL score as an outcome.

Analysis

We used descriptive statistics to compare the Veterans with COVID-19 and comparators. A table of frequencies was generated to compare IADL item responses between groups at each time point. We used a linear mixed model with random intercept (respondent) and slope (survey cycle time) to assess differences in the change in IADL scores. The model included terms for age, sex, and Care Assessment Needs (CAN) score to adjust for potential important confounders. An interaction term between COVID-19 status and time was included to assess whether changes in IADL scores over time differed between the COVID-19 and comparator groups. We used a likelihood ratio test to test for statistical significance and report 95% confidence intervals for all reported model coefficients.