SER Abstract

Title: How COVID-19 Randomized Controlled Trials Reported on Demographic and Clinical Characteristics

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Mortality in COVID-19 patients varies by sex, age, race, and comorbid conditions. Because of this variation, treatments to prevent or treat COVID-19 are likely to have heterogeneous effects, making the external validity of randomized controlled trials (RCTs) especially important. To assess this validity, understanding the patterns of participation and the extent to which they report key demographic and clinical characteristics is critical.

We queried English-language articles from PubMed, Web of Science, clinicaltrials.gov, and the CDC library of gray literature databases using keywords of ‘coronavirus’, ‘covid’, ‘clinical trial’ and ‘randomized controlled trial’ from January to October 2020. We restricted to studies with “trial” in their title and reviewed abstracts to confirm they were RCTs with final results. Finally, we abstracted the demographic and clinical characteristics reported in Table 1.

From an initial 42,586 manuscripts, we identified 61 RCTs described in 57 articles (Figure 1). The trials were largely conducted in China (20), Iran (9), and the U.S. (8). Most (50) studied potential treatments, while fewer studied vaccines (8) and prophylaxis strategies (3). Study populations ranged from 10 to 5040 participants with a median of 89. All 61 reported on age, 59 on sex, 48 on the prevalence of at least one comorbidity, 22 on use of oxygen therapy, and 14 on race. Pregnant women were explicitly excluded from 46 of the trials. No trials reported on income, urban vs rural residence, or other indicators of socioeconomic status (SES).

Reporting on age, sex, and comorbidities may assist in characterizing the RCT populations; however, limited reporting on race and other markers of SES makes it difficult to draw conclusions in the most impacted populations without assuming homogeneous treatment effects. These findings highlight the need for more robust reporting of clinical and demographic factors in COVID-19-related RCTs.

Figure 1:

Diagram

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