Research finds no benefit to taking fluvoxamine for COVID-19 symptoms

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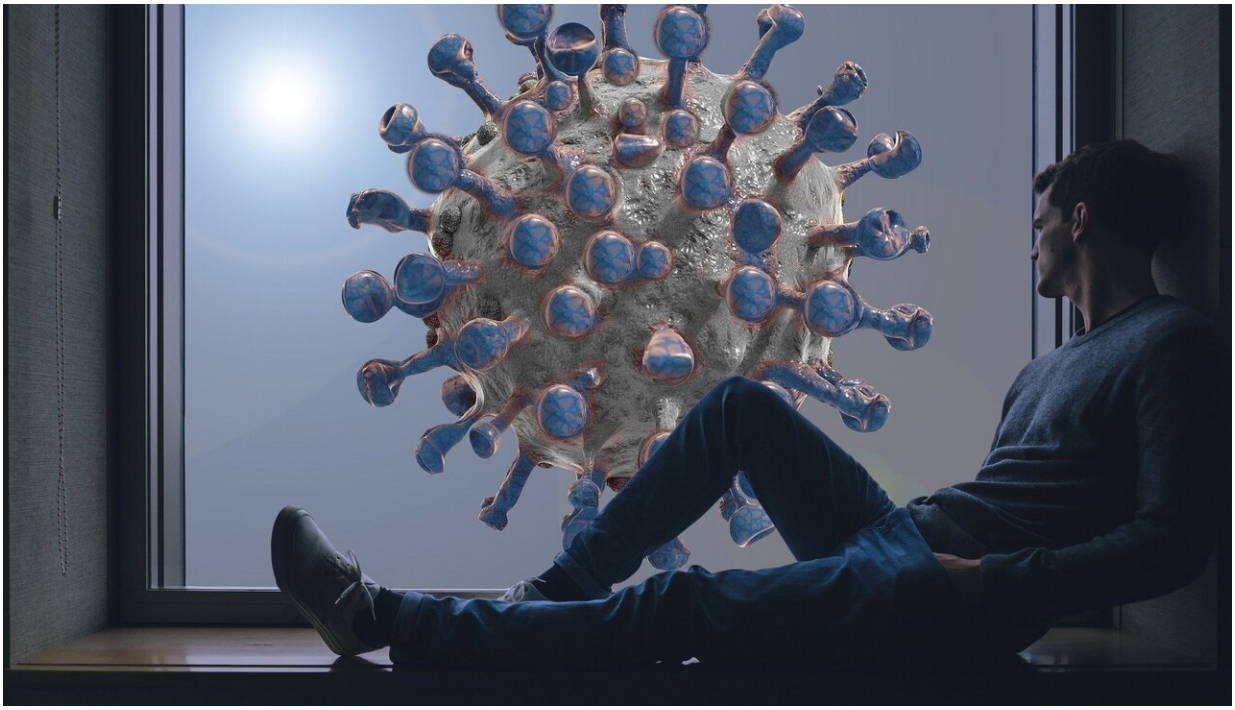

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A study led by the Duke Clinical Research Institute (DCRI) in partnership with Vanderbilt University found no symptomatic or clinical benefit to taking the antidepressant fluvoxamine at a dosage of 100 mg twice daily for 13 days for the treatment of mild-to-moderate COVID-19 symptoms.

"There was no evidence of improvement in the rate of sustained recovery in participants who took this dose of fluvoxamine versus those who took a placebo," said Adrian Hernandez, M.D., M.H.S., the study's administrative principal investigator and executive director of the DCRI.

Findings appear on *medRxiv*, a pre-publication server, and have been submitted to a peer-reviewed journal.

ACTIV-6—"The Randomized Trial to Evaluate Efficacy of Repurposed Medications"—is a nationwide, remote, double-blind study that has enrolled more than 7,000 participants. The trial has enrolled participants from across the United States to evaluate the potential benefits for treating mild-to-moderate COVID-19 with repurposed medications.

In ACTIV-6, researchers looked at the rate of sustained recovery, defined as three days without symptoms. Taking 100 mg of fluvoxamine twice a day did not speed up COVID-19 symptom recovery. There was no difference in relief of symptoms for participants taking fluvoxamine compared to a placebo.

Fluvoxamine was chosen for this study because previous evidence suggested that it may be able to reduce inflammation caused by the virus. The ACTIV-6 team previously tested fluvoxamine 50 mg twice daily for 10 days and found no benefit to taking fluvoxamine for COVID-19 treatment at that dose or duration.

Although the lower dose of fluvoxamine was not effective, the medication is safe and well tolerated. Given the favorable safety profile and efficacy found in other studies, the ACTIV-6 team decided to test the medication at a higher dose of 100 mg.

"In ACTIV-6, we are testing repurposed drugs to understand if they are effective in treating COVID-19," said Susanna Naggie, M.D., M.H.S.,

the DCRI principal investigator overseeing the study's clinical coordinating center. "We plan to study at least one more medication in ACTIV-6, and look forward to sharing results with the community as soon as possible."

Repurposed medications are those already approved by the U.S. Food and Drug Administration (FDA) for other medical indications. Fluvoxamine is one of four FDA-approved repurposed medications being tested in ACTIV-6.

The ACTIV-6 study aims to include participants from diverse backgrounds so that results from the study are applicable to everyone affected by COVID-19. The study has seen an increase in participation and interest from members of the Hispanic community. In this arm of the study, 46 percent of participants identified as Hispanic/Latino, compared to 17 percent in the lower-dose fluvoxamine arm.

"As ACTIV-6 continues to evaluate repurposed drugs for the treatment of mild-to-moderate COVID-19, we strive to reach those communities that are often underrepresented, yet most impacted by the virus," said Hernandez. "Participation from these communities is essential to ensure that we find results that might help everyone feel better faster."

Fluvoxamine is a selective serotonin reuptake inhibitor (SSRI), which is used to treat obsessive-compulsive disorder and depression. It is not approved by the FDA to treat COVID-19 and should only be taken as prescribed or as part of a clinical trial.

More information: Susanna Naggie et al, Effect of Higher-Dose Fluvoxamine vs Placebo on Time to Sustained Recovery in Outpatients with Mild to Moderate COVID-19: A Randomized Clinical Trial, *medRxiv* (2023). DOI: 10.1101/2023.09.12.23295424

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