Long COVID clinical trials a step in the right direction, but scale doesn't match the need, researchers say

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The National Institutes of Health has announced it was enrolling hundreds of people in phase 2 clinical trials that will evaluate at least

four potential treatments for long COVID.

The news underscores that the government recognizes the importance of developing treatment therapies to improve the lives of thousands of people who never completely recovered from the novel coronavirus, Northeastern researchers Kristin Kostka and Mauricio Santillana say.

"There is now a shift of acknowledging it's not in people's heads. And that's progress," says Kostka, director of the Observational Health Data Sciences and Informatics (OHDSI) at Northeastern's Roux Institute.

Santillana, who directs Northeastern's Machine Intelligence Group for the betterment of Health and the Environment (MIGHTE) in the Network Science Institute, says it's a step in the right direction, especially for those who have "debilitating cognitive symptoms" in the wake of COVID-19 infections.

The NIH announcement acknowledges "that we, as a society, should continue looking for clinical ways to support them," says Santillana, the co-author of a paper showing people experiencing cognitive problems with long COVID are less likely to be employed full time.

But Kostka says she also understands why long COVID patients question why it has taken so long to get this far with clinical trials.

Mass disabling event

"The scale doesn't match the need. This is still a drop in the ocean compared to what's necessary to systematically approach long COVID as a long-term, public health issue," Kostka says. "Long COVID is a mass disabling event. No doubt about it. Millions of previously healthy people are physiologically different post-COVID and suffering."

The NIH says the trials are part of its Researching COVID to Enhance Recovery (RECOVER) Initiative and "focus on several of the symptoms described as most burdensome by people experiencing long COVID."

The clinical trials will look at therapeutics for other conditions to see if they are effective in treating four post-COVID issues associated with sleep, the autonomic nervous system—including heart rate—memory issues or "brain fog" and viral persistence in the body.

"There's a lot of evidence to suggest that there's a few key subgroups emerging," Kostka says.

Kostka, co-author of an eBioMedicine article associating clusters of post-COVID patients with distinct pulmonary, neuropsychiatric, and cardiovascular abnormalities, says she is "hopeful that by addressing long COVID as a mosaic of post-COVID conditions, we're going to get closer to finding therapies that help improve patient lives."

Faster approval?

According to the FDA, clinical trials for new drug treatments typically go through three phases that take months or years to complete before the treatments are submitted to the federal agency for approval.

Typically, phase 1 trials involve healthy volunteers. Phase 2 trials are the first time actual patients are enrolled. Mansoor Amiji, distinguished professor in Northeastern's School of Pharmacy and Pharmaceutical Sciences, says that in the case of long COVID, existing treatments such as Paxlovid are being tested "so you don't need a phase 1 trial."

"They can start to test directly in patients with long COVID symptoms," which can translate into a streamlined approval process, Amiji says.

"If the data is positive that these drugs work to limit or minimize long COVID symptoms such as fatigue, brain fog, etc, then, yes, they will be approved more rapidly than the typical approval times we see for new drugs."

If the studies are completed in the next few months, approval may follow quickly, Amiji says. Long COVID patients have criticized the pace of developments for treatment.

"The patient advocates are frustrated with the NIH dumping billions into long COVID research with little to show for it," says Kostka, pointing to a Stat news article.

"It would behoove us as a society to be more critical about (funding research) that actually helps the patient, because this is our tax dollars," she says.

Listening to patients

Patients are advocating for themselves, but it would help if they had more of a voice, Kostka says.

"Leveraging the patient perspective is something we are getting better about in the U.S., but our colleagues in Europe have much more incentive about bringing the patient to the table sooner," she says.

"You can't get funded in the U.K. without having a patient representative on your study team guiding your design."

Paxlovid and BrainHQ

In addition to a longer regimen dose of the antiviral drug Paxlovid, the

clinical trials announced July 31 include brain training programs such as BrainHQ for neurological recovery; wakefulness-promoting drugs; a treatment for chronic heart failure and other therapeutics.

Clinical trials for seven more treatments are expected in the next few months as well, the NIH says.

It says people 18 and older interested in learning more about the trials can visit the clinical trials site and search "recover" for details including enrollment sites.

Some—but not all—people with long COVID find their symptoms resolve over time.

The KFF health policy research group says that of those who have had COVID, 11% are still experiencing symptoms but 17% who had long COVID in the past no longer have symptoms. Kostka called some long COVID case studies "quite terrifying," including those that have found dementia-type symptoms in young people.

For these individuals, she says, COVID has proved "an unlucky lottery." Effective treatments, Santillana says, "could help some sectors of our population become more functional and better connected to their lives."

Provided by Northeastern University

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