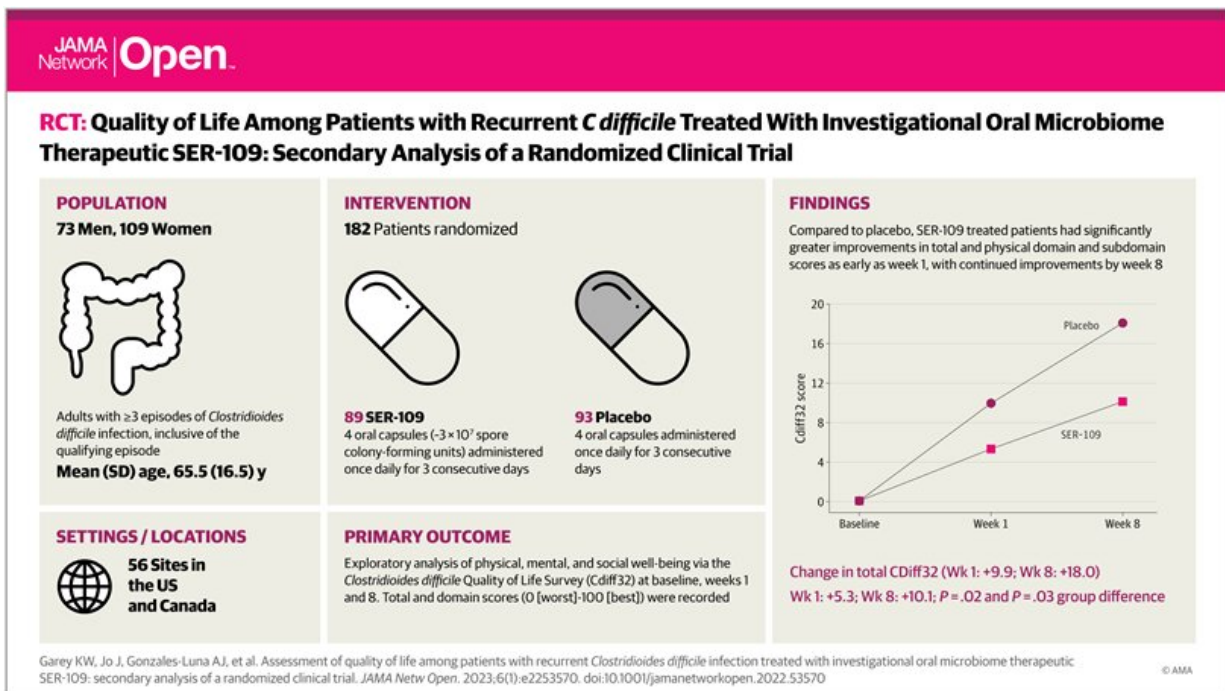


New live bacterial product for stubborn superbug improves quality of life

January 31 2023, by Laurie Fickman



Visual abstract. Credit: *JAMA Network Open* (2023). DOI: 10.1001/jamanetworkopen.2022.53570

Kevin Garey, a professor of pharmacy practice and translational research at the University of Houston College of Pharmacy, is reporting the first well-controlled study to demonstrate that a microbiome therapeutic, SER-109, is associated with significant quality of life improvement in patients with the debilitating recurrent infection and disease caused by

Clostridium difficile (or C. diff).

SER-109 is a pill with live, purified Firmicutes bacterial spores designed to compete metabolically with C. diff and restore colonization resistance to C. diff.

In the world of superbugs (bacteria that have grown resistant to antibiotics), C. diff is among the most stubborn. Symptoms of C. diff infection are not only life-threatening but can persist for long periods, especially in persons with recurrent disease.

"In this exploratory analysis, patients treated with SER-109 had significantly greater improvements in health-related quality of life (HRQOL) scores compared to placebo-treated patients as early as Week 1, with continued steady and durable improvements by Week 8," reported Garey in the *Journal of the American Medical Association (JAMA) Network Open*. He developed the disease-specific Quality of Life Survey (Cdiff32) measurement. "These findings suggest that an investigational microbiome therapeutic may improve HRQOL, an important patient-related outcome."

A new medicine to fight C. diff is highly in demand: C. diff is the most common health care-associated [infectious agent](#) in the U.S. and is estimated to cause more than 460,000 infections and 20,000 deaths annually. C. difficile infection (CDI) is a debilitating disease causing up to 10 to 20 watery bowel movements daily, leading to poor HRQOL, loss of productivity, anxiety and depression.

"Currently approved antibiotics generally lead to symptom resolution through reduction of toxin-producing bacteria. However, sustained efficacy rates remain modest since antibiotics do not kill dormant C. difficile spores nor address the disrupted microbiome, the underlying cause of recurrent disease," said Garey.

The effectiveness of SER-109 to improve quality of life was tested in 182 adults with *C. diff* infections using a quality-of-life questionnaire originally developed by Garey and his colleagues.

Another positive finding was the observed improvements in the mental domain and subdomain scores in the eighth week of the study in patients taking SER-109 regardless of clinical outcome.

"Several interesting hypotheses arise from this novel observation, which may be related to the potential role of the microbiome in disorders related to the gut-brain axis. CDI is associated with a disrupted [microbiome](#), which has been associated with [mood disorders](#), including anxiety and depression," said Garey.

More information: Kevin W. Garey et al, Assessment of Quality of Life Among Patients With Recurrent *Clostridioides difficile* Infection Treated with Investigational Oral Microbiome Therapeutic SER-109, *JAMA Network Open* (2023). [DOI: 10.1001/jamanetworkopen.2022.53570](#)

Provided by University of Houston

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