

## **Brain Magnetizer Approved For Treatment-Resistant Depression**

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The US Food and Drug Administration (FDA) gave the green light earlier this month for a new non-invasive treatment for depression that relies on a magnetic device to stimulate the brain by sending magnetic pulses through the skull.

Intended for patients whose depression is not responding to anti-depressants, the new therapy, called transcranial magnetic stimulation or TMS, is said to have none of the risks of other interventions such as surgically implanted electrodes and electric shock therapy. The FDA approved it on 7th October and it is available only on prescription.

The TMS device was developed by Neuronetics Inc of Malvern, Pennsylvania, and is called NeuroStar. It started out as a research project at the Medical University of South Carolina (MUSC) who describe it as the first and only such device to be cleared by the FDA for the treatment of severe depression.

NeuroStar can only be used with adult patients with a major depressive disorder, commonly termed treatment-resistant depression, whose symptoms are unchanged by drugs and other therapies.

Dr Mark George, who is based at MUSC and pioneered, with others, on the use of TMS to treat depression, said developments like TMS are "opening up a whole new area of medicine".

"There's a whole field now that's moving forward of noninvasive electrical stimulation of the brain," said George.

The FDA approved the new device because a clinical trial submitted by Neuronetics that compared TMS with a "sham" device concluded that patients treated with the real device showed some improvements.

The trial was triple blind, that is neither the patients nor the doctors, nor the people who rated the depression measures, knew who was treated with TMS and who was treated with the sham device.

According to the Associated Press however, the trial was "fraught with statistical questions" and the FDA's own scientific advisers were concerned about it. The agency cleared the device after focusing on a subset of 164 patients who were not severely treatment resistant.

MUSC is currently doing another trial under the auspices of the National Institutes of Mental Health (NIMH) involving 260 patients that is expected to announce results sometime next year.

TMS stimulates the nerve cells of the brain from outside the body: it is non invasive (no surgery involved) and non-systemic (does not get into the bloodstream).

NeuroStar TMS therapy delivers strong and focused MRI-strength magnetic pulses to the part of the brain that is linked to depression and mood regulation. Patients don't need to be sedated or anesthetized and stay awake for the whole outpatient procedure which takes 40 minutes in the psychiatrist's office.

Typically, patients receive the therapy every day for 4 to 6 weeks. The cost however could be a significant factor, since each session costs between 200 and 300 dollars a time.

George told New Scientist that he was delighted that "patients with depression have a new treatment option without the side effects of medications".

However, he said some scientists were sceptical about the trial results, saying that patients can tell if they are getting the real thing or not. He said the new trial should overcome this problem.

Source: Medical University of South Carolina, Associated Press, New Scientist.

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