Shauna Stansbury’s 14th birthday party was memorable, but not for the right reasons.

The celebration turned sour when Stansbury, now 21, was beset by a headache she compared to “someone hammering my skull from the inside, a constant pounding.” The pain reduced her to tears, she recalled.

The birthday gone bad began a long ordeal for Stansbury, who said she experienced headaches of varying intensity nearly every day for the next seven years. They frequently progressed to what she described as migraines that sent her to dark rooms where she pressed cool cloths to her forehead to stave off nausea and vomiting.

The bouts forced her to get home schooling and prevented her from working. After her family moved from Westcliffe, Colo., to Denver, she enrolled at Front Range Community College, but the headaches led her to quit after one semester.

“Having headaches all the time was a killer,” Stansbury said. “They had a crippling effect. I couldn’t think or focus.”

The headaches haven’t gone away completely, but they are now a smaller part of her life, thanks to a device called the Cefaly that she received as part of a clinical trial led by Marius Birlea, MD, a neurologist with the University of Colorado School of Medicine. Birlea directs the Headache Clinic at University of Colorado Hospital.

**Pounding on migraines**

The Cefaly was approved by the FDA as the first migraine-prevention device in 2014. It fits across the forehead like a headband. An electrode delivers electrical stimulation to the upper branches of the trigeminal nerve,
which is responsible for transmitting feeling from the face to the brain. The trigeminal nerve plays a major role in the brain-activity disturbances that trigger migraines.

The original randomized, controlled Cefaly trial targeted 67 patients with “episodic” migraines – six or seven days a month on average, Birlea said. The trial showed the device to be safe and effective in reducing the number of headaches patients experienced and the number of medications they took to control them. Birlea said the Cefaly seems to work in some patients by electrically stimulating pathways in the brain that suppress pain and restoring its capacity to defend against migraine.

**Birlea’s trial** sets its sights on determining if the Cefaly can help prevent headaches in chronic migraine sufferers like Stansbury who have 15 or more headache days per month and have not been able to control them consistently with prescribed medications.

“These are very disabled patients,” Birlea said. “Many of them can’t go to work and can’t advance socially because of their headaches.”

**The headache diaries**

His trial is still enrolling patients, but as of late June, 31 – including Stansbury – had completed the trial’s regimen. Patients record in a paper diary the number of headaches they experienced, their intensity and medications they took. After a one-month baseline period, they use the Cefaly for at least one 20-minute period each day and record the same information for three months.

Birlea presented his preliminary findings in June at the *annual American Headache Society Scientific Meeting* in San Diego. The patients who completed the trial had significant reductions from the baseline period in the number of days with headaches lasting at least four continuous hours. The headaches were less intense and the patients took fewer medications to control them.

Patients with “permanent/continuous” headaches made up half the study group, Birlea noted. Yet even when this especially debilitated group was included, the average number of days with headaches patients described as moderate to severe fell by 16 percent. In patients who had chronic, but not permanent headaches, the drop was nearly 40 percent.

The number of diagnosed migraine days fell “only” 5 percent for those with permanent headaches, but 41 percent for those who did not have permanent headaches.

**Heading off pain**

Stansbury began the trial Jan. 20, completed it and is still using the Cefaly. “It changed my life,” Stansbury said of the device. “My life is easier. I have more energy and less pain. It’s been amazing for me.”

She said she puts the device on every morning, placing the electrode above her eyebrow and running it for 15 to 20 minutes. The stimulation produces a tingling sensation that she found unpleasant at first, but she got used to it. She frequently turns it on for another 10 to 20 minutes shortly after the first treatment.

The migraines haven’t gone away completely, Stansbury stressed. She self-administers Toradol injections periodically and recently received a Botox injection at UCH, which was prohibited during the trial. But she believes the Cefaly has helped not only to prevent migraines but also decrease their severity.
“It nips them in the bud,” she said. She’s even had an occasional headache-free day—something she hasn’t experienced very often since her birthday seven years ago.

“I’m dealing with other medical issues, but I feel now that I can control my headaches enough for school and work,” Stansbury said. “I want to make my own money and learn. Every day I am fighting for that.”

The Cefaly isn’t a cure-all for migraine, Birlea said, but it offers a good option for patients like Stansbury after other therapies fail or even as a first choice.