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YOUR HEALTH

From Meditation to Medication: Headspace Has a Prescription Strategy

The mindfulness app plans a new company with the goal of developing FDA-approved treatments for health problems



By

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You might know Headspace as a meditation app. What if it were also a prescription medication?

The California-based company recently launched Headspace Health, a subsidiary whose executives' goal is to apply to the U.S. Food and Drug Administration as a prescription meditation app by 2020. The company will soon launch a series of clinical trials to support an application.

The prescription products would include a specific dose and meditation technique for different health conditions, says Megan Jones Bell, the company's chief science officer, who will lead the new health effort. "This will likely be a unique code that the physician gives a patient" for access to the program, she says.

They wouldn't copy the company's current programs, which are designed for wellness. They would be created and tailored specifically for each condition they treat.

The FDA has cleared prescription mobile medical apps for various conditions in the past, such as substance abuse, and treats them as medical devices. Headspace believes the new products will require a prescription because the FDA's guidelines on software as a medical device say that digital interventions that treat a disease require a prescription and doctor supervision.

The announcement comes as meditation has grown in popularity, fueled in part by a growing number of apps.

According to the most recent statistics from the National Institutes of Health, in 2012 about 8%, or 18 million U.S. adults, reported meditating. Headspace reports having 30 million users, up from 10 million a year ago.

Research into meditation's impact on health is ongoing. Researchers are unclear on whether people benefit from a meditation app the way they can from group or individual meditation.

"The evidence is the strongest for meditation related to blood pressure, irritable bowel syndrome and certainly in the area of lower-back pain," says Wendy Weber, acting deputy director of the National Center for Complementary and Integrative Health, part of the NIH. There is also a growing body of evidence showing how meditation can help patients with depression.

Dr. Weber says some may prefer more personal ways to learn meditation. "I do think that working with a teacher, they can customize and work with you if you're struggling, whereas an app format may not have that sort of structured assistance," she says.

On the other hand, doctors are always looking for non-pharmacological approaches to pain management. Connecting patients to things like meditation through data-supported apps could be one way of doing that, she says.

Aditi Nerurkar, medical director of the Cheng-Tsui Integrated Health Center at Beth Israel Deaconess Medical Center in Boston, has been suggesting meditation to her patients for years. She says more patients are asking her about meditation apps. She usually teaches her patients how to meditate in person.

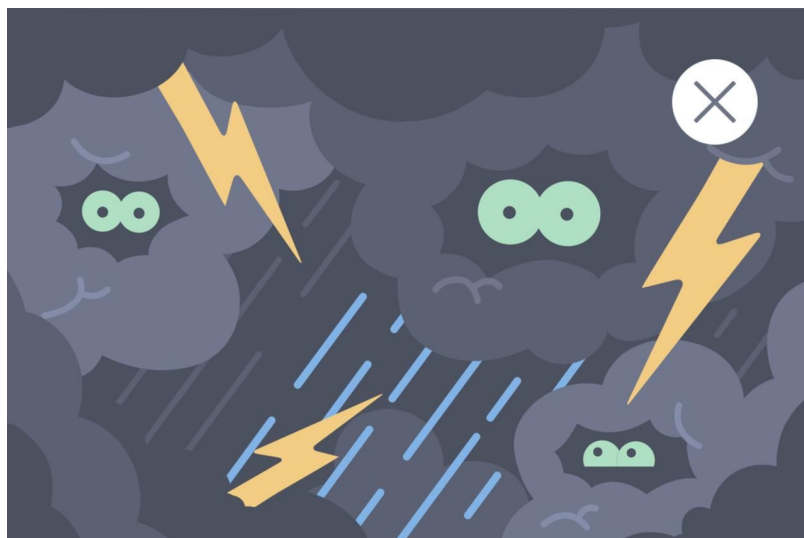
Dr. Nerurkar, who has no financial or research relationships with any apps, says she uses them herself sometimes. She usually recommends three to her patients: Headspace, Calm and Insight Timer. All have at least some free content. Headspace charges for some as well.

"Whatever allows you to practice on a consistent basis, that's what you should do," she says, "whether that's an app, by yourself or in a group."

Headspace is launching its first phase-one trials this summer, but declined for competitive reasons to disclose which health condition it will be studying.

"We've identified a dozen conditions that we plan to pursue," says Dr. Bell, a psychologist working with a team of about seven health professionals.

Separately, Headspace is working with researchers across the world studying its products' impact on employee health and well-being. About 65 studies are completed or under way looking at outcomes like work productivity, employee stress and absentee rates.



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Headspace has a number of wellness apps designed to teach people how to meditate and to alleviate stress and anxiety. Now, it hopes to create a new line of prescription apps to treat specific health conditions with the creation of a new subsidiary, Headspace Health. PHOTO: HEADSPACE INC.

Some include taking blood samples to measure different hormones, and brain scans. The studies using brain scans are being done with novice meditators. “A lot of meditation studies have been done with monks,” Dr. Bell says. “We’re interested in seeing what changes in the average person’s brain.”

Aric Prather, an assistant professor in the department of psychiatry and the Weill Institute for Neurosciences at University of California, San Francisco, is leading a study testing Headspace

with UC employees who report increased stress levels. The study, which aims to recruit several thousand patients, will compare those using Headspace for at least 10 minutes a day for eight weeks with a control group.

David Creswell, an associate professor in psychology at Carnegie Mellon University in Pittsburgh, is planning to work with Headspace on a large workplace study examining its impact on the brain and immune system. The study would replicate similar studies he's done testing the impact of meditation performed during in-person sessions, which showed a positive impact on brain functioning and the immune system.

Dr. Creswell's research has already tested a 14-day mindfulness meditation app developed at Carnegie Mellon used for 20 minutes a day. The study, published in the journal *Psychoneuroendocrinology* in January, included 135 stressed adults divided into three different groups. Two weeks of mindfulness training was enough to reduce cortisol levels and blood pressure, two biological signs of stress.

They also found that use of the app improved the participants' reporting of positive emotions and increased their social interactions.

"What this study suggested to me was that these smartphone approaches can be very powerful," Dr. Creswell says. "They're cheap, they're easy to disseminate and they're effective in terms of hard-to-reach populations that may not want to come in for weekly classes or programs."

Other meditation apps are also delving into the realm of health.

Buddhify, a U.K.-based app, created a product for cancer patients with a University of Pittsburgh Medical Center oncologist two years ago.

The free website, Kara, is designed to help cancer patients with the range of difficult emotions they often deal with, says Rohan Gunatillake, founder of Buddhify.

And a Boston-based company called 10% Happier worked with Arizona State University to test its app's use with cancer patients, comparing its impact on pain relief to in-person meditation, says Samuel Johns, head of product engagement and coaching for the company. Researchers are still analyzing the results.

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