MEDTECH REPORT ON BRAINTAP®: OBSERVATIONAL IMPRESSIONS AND PROCESS ANALYSIS

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As the first participant in the med tech program case study for BRAINTAP® (a meditative device), I was excited to undergo this product evaluation both as a mental health professional and a solution-seeker about new research protocols on calming the mind. Prior to the exam, I was tasked to explore multiple study points to cover a phase-one study on its effects on the body (and of course, the mind). The IPHA clinical team and I collaborated for some time on how to proceed with this review, and what we hope to achieve by integrating multiple modalities with observational reviews on the effects of the BRAINTAP® device.

Thanks in great capacity to Dr. Robert Bard (seasoned radiologist), this tech review received a major boost through the access of advanced medical-grade ultrasound. This offered a much higher level of diagnostic power in studying the effects of this device. Also, other researchers like Dr. Roberta

Kline and Dr. Noelle Cutter dug in to offer their studies on neurotransmitters and their effects on serotonin, endorphins and dopamine. Furthermore, we drew in a short list of highly knowledgeable neurologists and psychiatrists who offered additional insight and perspective on other considerations.

MULTI-POINT EXAM

We started setting up to do baseline of my vitals as part of my biometrics. This included my blood pressure, my body temperature and my oxidation level. As part of this baseline (or the "BEFORE" portion of the exam) Dr. Bard then proceeded to do scans of eye, the side of my brain and the back of my head using various medical grade ultrasound devices where he could see my arteries and measurable blood flow. He collected all this data from by current physiology to create a means of comparing how my body would react to the BRAINTAP®. Once the baseline exam was done, Dr. Bard set the BRAINTAP® to run a 20 minute relaxation and meditation program from an App in his phone. The device covered both my eyes and ears where red and blue light would flash from these two areas. The headphones played sounds and music (what I learned was binaural beats and isochronic tones) alongside a guided narrator.

Testing a product like this, gathering first impressions (from first use) are critical because here is where I expect to identify the top-most benefits. I have prior understanding of its subtleties and nuances as it was designed for repeated use. But having test-driven other relaxation products and having a good understanding of meditation, I was attuned to searching for specific cues of what this device was doing to me.

I also noticed that there was kind of numbing effect which I recognize from other sorts of self-care protocols like acupuncture. Dr. Bard confirmed that this numbing sensation may actually be from my circulation increasing. Midway the session, I could actually feel myself sinking into the chair. My legs were no longer crossed and my hands were rested on my lap in a more settled state than I was when I came in. These were all signs that my body's tension was conforming to a calmer state.

ON PORTABLE MEDITATION

Overall, the (audio) guided meditation was very well developed-- working with you on how to relax. It works with your visualization that helps to bring you into that relaxing place. All the while, the guide drives you to stay aware of your senses and parts of your body while I sat back in my seat. On a quality scale, the experience overall was engaging. The meditative program that was running through my ears was soothing. Learning about the many other programs in the App, I can extrapolate its true advantages to mental health and calm-building. As a therapist, this can be a major breakthrough.

My understanding of meditation (from clinical studies) is its calming effect on the amygdala. The amygdala is our fear response and our fight flight or freeze response. This is usually the area of our brain that is disordered when we have anxiety or panic. The fear response to certain things is just incongruent to what is actually going on in real life. In its very primitive level, the body often goes into defense mode under fear of a potential threat. For example, if a bear was coming after you (or something that may actually cause you physical harm), this part of the brain adjusts our physiology to prepare and react accordingly- fight, flight or freeze. I think human evolution converted this into ANXIETY throughout our everyday living. Whether it be worrying about our health, financial health (like our employment status), our relationships- you name it, we probably worry about it. I describe the feeling of anxiety at is basic level as having something concrete to worry about, but the solution isn't immediately tangible. We are left grasping for something in the air and

missing every time, giving us that anxious, unsettled feeling where we are acutely aware that a solution is uncertain.

The concept behind a personal meditation device (like this) as well as the actual act of meditating can be quite helpful as a complement to psychotherapy. If used correctly, meditation can slows us down to be able to understand our anxiety-related thoughts and what solutions are actually in our immediate control. Because our brains are usually running very quickly, it takes some form of intervention to help us identify the need to slow our minds down enough to recognize what areas we could use help with. Understanding what's wrong starts with recognizing physical symptoms, which are sensations located from our head to our abdomen.



Somewhere in there, it'll sit and that that's where your physical emotions are. Most often, people have this butterfly feeling in the stomach, a tingling feeling in the stomach, pain in the neck, tightening in the shoulders, loss of breath or a tightening in the lungs.

Meditation can slow down that fear response to a point where we can better understand what is it that we are scared of. We often ruminate and our thoughts race for possible scenarios, narratives or solutions that will provide us with some sort of certainty around whatever we are worried about. But because the outcome is all in anticipation of future events, there is no way to gain a true outcome. To regain control of this 'runaway train', we need to slow down the mind to figure out what is within our control. This is where I believe meditation can be most useful.

The program I underwent was for sleep and relaxation. I can see this being useful before bed. You can also do this before hopping onto your computer, whether you're working from home or a start to your day. Bringing yourself to a calm state helps with focus. It can also help to be more mindful and can replace some of those unhealthy habits, like having a drink after work, or doing mindless eating. These are treats that we sometimes mistake for self-care, but they're actually unhealthy for us. A meditation device (like BRAINTAP®) could mark the end of your day by calming oneself down to get your blood flowing better.

ON ULTRASOUND USE

Once the BRAINTAP® session was complete, Dr. Bard came back in to re-measure all of the same vitals again. We also repeated the same scans on my eye, my temple and the back of my skull. Dr. Bard was very generous in sharing his ultrasound readings with me on the spot. (see Dr. Bard's full scan report). The results concluded that my circulation levels definitely showed a recognizable increase. As an observer, I also found extreme benefit to the use of ultrasound in a validation exercise like evaluating a medical device. Dr. Bard's tour of my scans showed real science (he calls it quantifiable) where this form of imaging can capture so much information in so little time. As opposed to an MRI or x-ray, getting scanned with an ultrasound can happen in an open space, not trapped inside a giant machine. Where an MRI is horribly loud and claustrophobic and an x-ray gives you radiation exposure, the ultrasound is completely pleasant, comfortable and instantaneous. The safety aspect makes ultrasound the tool of choice for multiple/repeated scanning in med-tech exams.