ValidationInstitute

2023 Validation Report

Review for: Acacia Mental Health

Validation Achieved: Program Validation

Valid through: July 2024

Company Profile

Category:	**Mental Health**
Website:	https://acaciaclinics.com/
Public or Private:	Private
Year Established:	2017
Main Contact:	David Carreon, M.D.
Company contact:	Owen Muir, M.D. owen@acaciaclinics.com

Description:

Acacia Mental Health is the leader in Accelerated TMS worldwide. They are dedicated to bringing cutting-edge neuroscience with compassionate care - a hope to those who have tried everything. They offer comprehensive psychiatry, therapy, and holistic Treatments. Their dedicated care coordinators help guide people through their integrated, customized treatment process. They are committed to helping you flourish: Mind, Body, and Soul. They are passionate about helping those with treatment-resistant depression. Learn more about HOPE-TMS (SM), and the research we do with SAINT(TM) TMS at Acacia.

Acacia provides rapid treatment of treatment resistant OCD with B.R.A.I.N. Protocol.

Claim Assertion for Validation

BRAIN™ is a cost-effective way to address treatment-resistant obsessive-compulsive disorder with remission rates >30%. This treatment is safer, more effective, and faster-acting than all currently available treatments for this condition. Its ability to work rapidly and without additional pharmaceutical augmentation will reduce health care costs in affected individuals across pharmacy and direct mental health spending, all at lower risk to the patient's health.

Method / Calculation / Examples

As noted in the validation summary, a double-blinded sham treatment methodology was used. This is considered the gold standard in procedure-based research and is the reason that the Program Validation level was achieved.

Findings & Validation

Validation Institute confers its highest level of validation, Program Validation, to Acacia Mental Health for their Behavioral Response Augmented Intelligent Neuromodulation protocol (B.R.A.I.N.) treatment of treatment-resistant obsessive-compulsive disorder (OCD), using a specific protocol of Assessment, Provocation Design, and Neuromodulation, as described here.

By way of background, treatment-resistant OCD is quite common and has high morbidity and mortality[1]. Of the 2-3% of the population with OCD[2], it is believed that about half[3] are resistant to the conventional pharmacologic regimen coupled with therapy. While residential therapy (costing $60,000/month for several months) shows some improvement, it is cost-prohibitive for most patients and is usually not covered by self-insured companies. For comparison, Invasive neurosurgery for deep brain stimulation with DBS for OCD is still evaluated to be cost-effective.[4]

The protocol consists of an initial assessment, which is performed by Acacia team members, including a clinical interview, psychological assessments, and process of obtaining informed consent, a process routinely performed by telehealth. Coordination of care with referring providers also takes place. Additional diagnostic procedures as appropriate can include fMRI and structural MRI and EEG, for targeting of treatment. The patient is then given a course of brain stimulation with Transcranial Magnetic Stimulation, generally standardized to 10 treatments of 8.5 minutes each, spaced out by 50 minutes, over the course of 5 days. The patient receives subsequent clinical follow up thereafter.

Findings & Validation

As is often the case with Program Validations, our bestowing of this level of validation is based on multiple inputs.

First and foremost is a double-blinded sham treatment study in which the arm receiving the treatment achieved "full response" (defined by the Yale-Brown Obsessive Compulsive Scale showing a 30% YBOCS reduction[5]) 45.2% of patients were in remission at a one-month follow-up; by contrast, only 11% of the control group showed improvements initially, and 17.8% at a one month follow up. As a randomized controlled trial, this study used "full response" as its criteria, not remission.

When the treatment was provided in the real world to patients who might have been excluded from clinical trials, it was discovered that it performed better than in the initial controlled research studies. This is the opposite of the pattern usually found— often, interventions perform less well in the real world than they did in clinical trials. In this case, first and sustained response rates were 72.6% and 52.4%, respectively. The response rate was 57.9% in patients after 29 sessions in published phase 4 studies.[6]

More detailed follow-up revealed remission of OCD symptoms was possible in patients with treatment-resistant OCD (remission was defined as an endpoint Yale-Brown Obsessive-Compulsive Scale score < 12). 145 patients from 10 sites met the inclusion criteria, of whom 46 remitted, representing a 31.7% remission rate.[7]

Findings & Validation

Further, the effect was durable in 60 patients from 7 centers for whom there was 'durability' data. Of those, 86.7% had 'durability' of ≥1 year.[8]

A subsequent RCT revealed that this methodology treated depression and OCD when they occurred together.[9]

Second, as with Virta's Program Validation (in which the rate of Type 2 diabetics getting off insulin on their own is trivially low), with treatment-resistant OCD, the number of cases of "spontaneous remission" is virtually zero. Therefore, even absent a control arm for the study above, participation bias would not be listed as a limitation.

Third, the "lost to follow-up" and dropout rates amongst 192 qualifying patients who started the treatment plan were 6%, with full data sets received for 180. (Typically, those two rates are much higher, creating a "survivor bias."). It also indicates that the patients were overwhelmingly satisfied enough with their progress to continue.

Limitations

As is generally the case with Program-Level validations, there are no study design asterisks (as there would be in a participants-vs-non-participants design).There are always unknown factors that can influence results, and sample size is always an issue.

Mental health is very difficult to assess, but it is the case that whatever the unknowns are, this study is the most valid in the relevant part of the mental health field.

Works Cited

[1] 14% of people with OCD will attempt suicide at least once. Death-by-suicide rates in OCD are shown to range from 0.7% to 1.4% per 100,000 diagnosed. This compares to the death-by-suicide rate of depression, which is 0.2%.
Source: The Epidemiology of Suicide by Silke Bachmann, Int J Environ Res Public Health. 2018 Jul; 15(7): 1425.)

[2] https://www.psychiatrictimes.com/view/treatment-resistant-ocd-strategies-and-novel-treatment-options#
[3] https://doi.org/10.1016/j.pnpbp.2005.11.028
[4] https://journals.lww.com/md-journal/Fulltext/2017/07070/The_cost_effectiveness_of_deep_brain_stimulation.36.aspx
[5] https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2019.18101180
[6] https://www.sciencedirect.com/science/article/pii/S0022395620310657
[7] https://www.brainstimjrnl.com/article/S1935-861X(22)00139-5/pdf
[8] https://doi.org/10.1016/j.brs.2021.12.011
[9] https://www.brainstimjrnl.com/article/S1935-861X(21)00076-0/fulltext

Validation and Credibility Guarantee

Acacia Mental Health Behavioral Response Augmented Intelligent Neuromodulation protocol (B.R.A.I.N.) achieved **Program Validation**. Validation Institute is willing to provide up to a $50,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit https://validationinstitute.com/credibility-guarantee/.

Program Validation
Program has strong evidence of significant impact on both patient outcomes and on medical costs. Evidence is assessed based upon the certainty it provides that the result is due to the program and not to other factors, such as recruiting people to participate in the program who are most likely to succeed.

Savings
Can reduce health care spending per case/participant or for the plan/purchaser overall.

Outcomes
Product/solution has measurably improved an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Metrics
Credible sources and valid assumptions create a reasonable estimate of a program's impact.

Contractual Integrity
Vendor is willing to put a part of their fees "at risk" as a guarantee.

VALIDATION INSTITUTE
500 West Cummings Park
Woburn, MA 01801

Validation Expiration: July 2024

CERTIFICATE OF VALIDATION

Applicant:	**Acacia Mental Health** 877 W Fremont Ave, Ste. N3, Sunnyvale, California 94087, US
Product:	Behavioral Response Augmented Intelligent Neuromodulation protocol (B.R.A.I.N.)
Claim:	BRAIN™ is a cost-effective way to address treatment-resistant obsessive-compulsive disorder with remission rates >30%. This treatment is safer, more effective, and faster-acting than all currently available treatments for this condition.
Validation Achieved:	**Program Validation**
Validation Award Date:	July 2023

Linda K. Riddell, MS
VP, Population Health Scientist
Validation Institute

Benny DiCecca
Chief Executive Officer
Validation Institute

About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.

Validation Review Process

Validation Institute has a team of epidemiologists and statisticians who review each program. The team focuses on three components:

- Evidence from published literature that a similar intervention had similar results.
- The reliability and credibility of the data sources.
- The rigor of the approach to calculating results.

To achieve validation, the program has to satisfy each of these components. VI's team then summarizes the review into a report which is publicly available. Details of VI's review are available with the program's permission.