MIGHTIER™

A review of Mightier as a treatment for children with ADHD

ADHD is chronically under-treated among children. Barriers to care include stigma around medication and long wait times for both psychiatric and psychosocial treatments. Digital tools can improve the standard of care. This review discusses how Mightier, a digital emotional regulation platform, can help children with ADHD see reduced symptoms, while reducing barriers to care and providing consistent results across populations.

The current under-treatment of ADHD leaves kids and families without support

ADHD effects up to 7% of children, with an additional 5% showing symptoms consistent with the disorder[1]. Current treatment for children with ADHD typically involves medication and psychotherapy. Inattention and hyperactivity symptoms are typically well controlled by medication[2]. However, ADHD is also marked by emotional symptoms and behaviors. These include anger, aggression, irritability, frustration, and outbursts, which often require additional psychotherapeutic supports. However, a severe shortage of clinicians has been further exacerbated by the ongoing COVID-19 pandemic, which has seen a marked increase in demand for mental health services[3]. Digital tools can help bridge gaps in treatment, provided that sufficient evidence supports their use[4].

Mightier as a tool to target emotional symptoms and increase access to help children with ADHD

Mightier is an evidence-based digital program that aims to help children build emotional regulation skills. These skills are highly relevant to moderating the emotional symptoms that accompany ADHD. As Mightier is a digital, in-home program, it avoids many of the access barriers created by traditional therapy.

1. Kids wear a heart rate monitor connected to the game tablet to visualize their emotions while playing.
2. Kids practice staying in the **BLUE ZONE** while facing challenges in a library of games.
3. When their heart rate rises to the **RED ZONE**, the games get more challenging.
4. Kids practice calming techniques to get back to the **BLUE ZONE**.
5. Reinforce learning with monthly Live Events & Family Games.

Mightier works by asking children to play video games while wearing a heart rate monitor and learn to apply relaxation skills like deep breathing. Mightier progress can be quantified through the high number of moments of calming practice that children experience: times when they have an elevated heart rate and are able to bring their heart rate down. Mightier is further supported by a parent app, which gives caretakers access to data and relevant curriculum written by clinicians.

Data from both the clinic and in-home usage to show immediate and long-term impacts

This review summarizes data from academic medicine and consumer use. Academic medicine trial data are sham controlled, randomized controlled trials at the Boston Children's Hospital (BCH) Outpatient Psychiatry clinic and Massachusetts General Hospital (MGH) Outpatient Psychiatry clinic. Both are teaching hospitals of Harvard Medical School. Consumer data collection comes from families who optionally participate in an ongoing open-label trial supervised by an Independent Review Board (IRB).

Study	Population	Comparators	Experimental Design	Endpoints	Measures
MGH RCT	N = 40 Ages 10-18 ADHD	Relaxation training + Mightier Relaxation training + sham Mightier	Sham controlled RCT with long term follow up	Baseline 12 weeks 3 months post intervention	DERS (Emotional regulation) CGI (Clinical improvement)
BCH RCT	N=40 Ages 10-18 Symptoms of anger and aggression	ACT + Mightier ACT + sham Mightier	Sham controlled RCT with active comparator	Baseline 12 weeks	MOAS (Aggression) CGI (Clinical improvement) PSI (Family functioning)
Mightier Opt-in	N = 77 Ages 6-14 Consumer usage	Ad-lib usage	Open label real world usage	Baseline 12 weeks	ARI (Irritability) MOAS (Aggression) Vanderbilt (ADHD symptoms)

MGH trial methods: sham controlled RCT with a long-term follow up

The MGH trial compared informal relaxation training + Mightier to informal relaxation training + sham Mightier. Children were recruited from the outpatient clinic at MGH and were aged 7-17. Seventy-two percent of participants were diagnosed with ADHD. Measures were the Difficulties in Emotional Regulation Scale (DERS) and Clinical Global Impressions, Improvement (CGI-I). Data was collected at baseline, two weeks after a ten-week intervention, and at a three month follow up visit.

BCH trial methods: sham controlled RCT with an active comparator

The BCH trial compared change in symptoms of Anger Control Therapy + Mightier to Anger Control Therapy + sham Mightier. Children were recruited based on symptom. Children had elevated externalizing symptoms, specifically elevated anger disorders. The primary diagnosis of children recruited was ODD, though 20% of the population did have a diagnosis of ADHD. Children were aged 10-18. Measures were the Modified Overt Aggression Scale (MOAS), the Parent Stress Index (PSI), and the Disruptive Behavior Disorder Rating Scale (DBDRS). Data was collected at baseline and two weeks after a ten-week intervention.

"Opt-in" methods: validation from real-world usage

Families who commercially purchase Mightier can optionally contribute data to an ongoing, open-label research trial that collects formal symptomatic assessments during treatment. The protocol collects standard clinical measures for diagnosis and symptoms: the Vanderbilt for ADHD, the MOAS for aggression, and the Affective Reactivity Index (ARI) for irritability. This data gives a sense of "real world" improvement from Mightier, outside of laboratory settings where improvement may differ.

Measuring and analyzing clinical significance

Trials of Mightier report statistical and clinical significance. Both are important. Statistical significance is often considered a lower bar. This test, reported via a comparison of means (typically a t-test) reports that two populations are measurably different. Statistical significance does not measure the degree of impact that an intervention may have. Clinical significance reports the size of the difference. Clinical significance is typically reported via effect size (or Cohen's D). Clinical significance ensures that the change makes a meaningful impact in the family's lives. Evidence-based psychosocial interventions have effect sizes of approximately 0.7[5]. Medications have an effect size of approximately 0.99[6].

A meaningful impact beyond the current standard of care

In multiple settings, Mightier has shown large effects as a standalone intervention and as an augmentation to multiple care strategies. The large effect sizes seen in the MGH data below show that compared to educational relaxation strategies alone, Mightier provides both clinically and statistically significant benefit. The BCH data adds to this picture, showing that Mightier can improve common externalizing symptoms of ADHD beyond CBT alone. The effects sizes reported in the BCH trial are effects beyond an already established CBT intervention, as the trial used an active comparator. Opt-in data, also reported, confirms that these effects are maintained with ad-lib usage in the home, where parents do not have the formal structure of a clinical trial requiring engagement. The weighted effect size for all studies is 0.84.

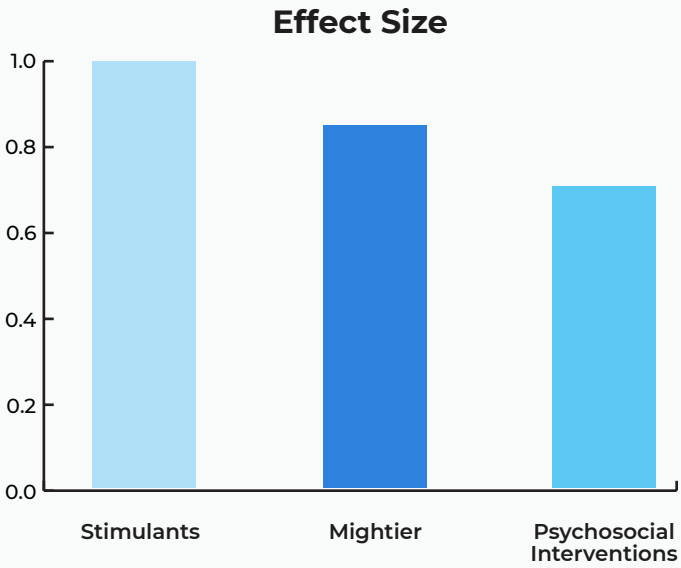
Study	Measure	Results	Effect Size (Cohen's D)
MGH	CGI-I	t=2.49, p=0.019*	0.87
	DERS	z=2.178, p=0.029*	1.12
BCH	MOAS	w = 110, p=0.015*	0.55
	DBDRS	w = 121, p = 0.032*	0.48
	PSI	t = 2.89, p < 0.01**	1.08
Opt-in	Vanderbilt, Inattentiveness score	t=6.26, p<0.001***	1.72
	Vanderbilt, Hyperactivity and impulsivity score	t=4.31, p<0.001***	1.06
	Vanderbilt, Combined score	t=18.2, p<0.001***	1.66
	MOAS	t=3.45, p=0.002**	0.7
	ARI	t=1, p<0.001***	0.62

Treatment impact maintained at least three months after stopping use of Mightier

The MCH RCT included a three month follow up on all endpoints. Children who had active Mightier treatment maintained their gains. Children in the control condition, many of whom initiated treatment, did see gains with the onset of treatment. These gains brought them to equal improvement levels with the Mightier group. A possible interpretation is that Mightier treatment provides similar gains to existing treatment modalities.

An immediate impact for children with ADHD

Many current treatments can be successful for children with ADHD. Medications remain a good option for families, however, many families are reluctant to start medication and fear side effects and stigma. Mightier provides a non-medication-based intervention for families, either as a co-therapy or as a standalone intervention. The combined effect size of Mightier indicates that it should be considered as an immediate option for children with ADHD.



The evidence understates how Mightier can avoid common limitations of psychosocial interventions. Mightier sidesteps the clinician shortage and long waitlists. Community psychosocial treatment often does not remain consistent, diminishing the efficacy observed in the lab. In fact, research has concluded "training community-based social workers in [CBT] is neither practical nor effective in improving the outcomes of their clients[7]." Mightier, as a digital intervention, provides a consistent experience for families. This could explain why Mightier effect sizes remain high even in home environments.

Limitation	Description
Long wait lines	Pre COVID-19 pandemic, average wait times for psychosocial services were a well understood barrier to care. With the pandemic, demand has increased while the supply of clinicians has not, leading to even longer wait times for individuals.
Limited engagement	Published records indicate that children receive, on average, three sessions of psychosocial care. This is far short of the 8-12 sessions required to see improvement in typical manualized therapies.
Inconsistent care delivery	In research evaluation settings, care is strictly delivered, and fidelity is measured. Outside of laboratory settings, clinicians often deviate from published norms.

These findings are limited by a moderate sample size. Between open label and RCT trials, approximately 120 children have completed academic studies. The total sample size of customer opt-in data is 77 families. The Vanderbilt effect sizes are strikingly large. Future data collection may moderate these effect sizes. However, this would make Mightier one of the most notable interventions available to families.

References

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