

Autism patients report improvement in symptoms and quality of life with Zelira Therapeutics' HOPE™

Self-reported outcomes survey of 50 participants using
Zelira Therapeutics' HOPE™ formulations for symptoms
associated with Autism Spectrum Disorder (ASD)

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ABSTRACT

Autism spectrum disorder (ASD) is defined by physical and neurological disorders with associated cluster symptoms including aggression, anxiety, repetitive movement, social and communicative deficits, self-injurious behavior and seizures. These conditions affect development, motor skills, social interaction, communication and behavior.

Here we present a report of 50 patients who participated in a self-reported outcomes survey conducted within the *Hope Grows for Autism* network – a Pennsylvania based research, education and advocacy group dedicated to supporting families with Autism. The results showed improved quality of life for the patient with autism and improved quality of life for the entire family since the patient began using HOPE™ range of products (formulated THC:CBD ratios with selected terpenes) to address cluster systems associated with Autism Spectrum Disorder (ASD).

Respondents who used HOPE™ 1 tincture with a THC:CBD ratio of 1:1 with Eucalyptol, Valencene and Alpha-Pinene terpenes, HOPE™ 2 tincture with a THC:CBD ratio of 5:1 with beta-Caryophyllene, Myrcene and Alpha-Bisabolol terpenes or both products for a range of 5-133 days (average of 68 days of use) reported the following:

Significant improvements in **patient irritability (68%)**, **meltdowns (60%)**, **aggression (55%)**, **anxiety (49%)** as well as **capacity to focus (38%)**; while **69% of participants reported an improved quality of life for the patient**. In addition, **58% reported improved quality of life for the entire family**.

This finding adds to the body of evidence linking formulated cannabinoid medicines to significantly reduced symptoms including aggression, irritability, meltdowns and to an increase in focus.



INTRODUCTION

Although there has been a significant increase in Autism Spectrum Disorder (ASD) diagnoses worldwide, and it is among the most severe chronic childhood disorders in terms of prevalence and impact to the society, no specific effective treatments for ASD are currently available^{1,2}. Autism Spectrum Disorder comprises a broad group of diseases and syndromes, that impact behavior, motor skills, cognitive development, social interaction, communication, and behavior³. A 2018 report suggests that distress and lack of independence are a direct result of these functional shortfalls⁴.

Although there are a few approved prescription drugs for the mitigation of ASD symptoms with a narrow range of effectiveness, to date, families and patients with ASD have limited effective therapeutic options with measurable results on improved quality of life and social interaction^{5,6,7}. Moreover, the available options present with notable and serious side effects such as weight gain/obesity due to increased appetite, drowsiness, nausea, constipation, and vomiting⁸. There is some published evidence for use of antipsychotic, antidepressant, or anxiolytic drugs for self-aggressive behavior associated with ASD^{9,10}. In addition, a recent study suggests that antiepileptic drugs used for seizure control in ASD management may also improve sleep quality and modulate behavior¹¹. Nevertheless, none of these drugs have been reported to have a significant positive impact on the quality of life of the patients and their families.

There has been a recent surge in studies exploring the viability of CBD, CBD rich or THC/CBD extracts as a therapeutic option for individuals diagnosed with ASD. Specifically, studies suggest that patients diagnosed with refractory epilepsy and regressive autism have shown the potential of cannabinoids as safe and efficacious for symptoms associated with ASD^{12,13}. These studies, which include varying ratios of CBD/THC, showed significantly less side effects than the traditional drugs used for treatment of symptoms associated with ASD¹⁴.

Researchers are making notable progress identifying the connections between the endocannabinoid system (ECS) and autism. One 2018 study published in BMC journal *Molecular Autism* showed that patients have lower levels of anandamide, an endocannabinoid found within the body, than healthy individuals in a control group. Endocannabinoid system deficiencies or imbalances are also found in disorders linked to autism, such as seizures, anxiety, cognitive difficulties, or sleep disturbances^{15,16}.

There is reason to believe that CBD may help to alleviate some of the symptoms associated with these comorbidities. For example, CBD has been reported to reduce the frequency of convulsive seizures in sufferers of Dravet's and Lennox-Gastaut syndromes and improve their quality of life. In an animal model, low doses of CBD also helped to improve social interaction deficits^{17,18}.

METHODOLOGY

A survey was conducted through the *Hope Grows for Autism* online community of over 1,500 families and ASD patient advocacy groups to understand the patient experience with cannabis-based solutions in Pennsylvania.

Patients eligible to participate in the survey met the following criteria:

- Diagnosed with ASD;
- Received a Commonwealth of Pennsylvania approved recommendations for medical cannabis;
- Purchased one or both of the HOPE™ tincture products from an approved PA dispensary.

The purpose of the survey was to obtain early information on the self-reported efficacy of the HOPE™ products since it was approved for used by the Pennsylvania Department of Health under the Medical Marijuana Program. Responses for the first 50 participants in the survey were analyzed and presented in this report. Participants began using one or both of the formulated HOPE™ tinctures between April 2019 and June 30, 2019. During this period, 26% used only HOPE™ 1, 54% used only HOPE™ 2 and 20% of the respondents used both HOPE™ 1 and HOPE™ 2.

Survey Demographics

Used only HOPE™ 1	26%
Used only HOPE™ 2	54%
Used both HOPE™ 1 and HOPE™ 2	20%

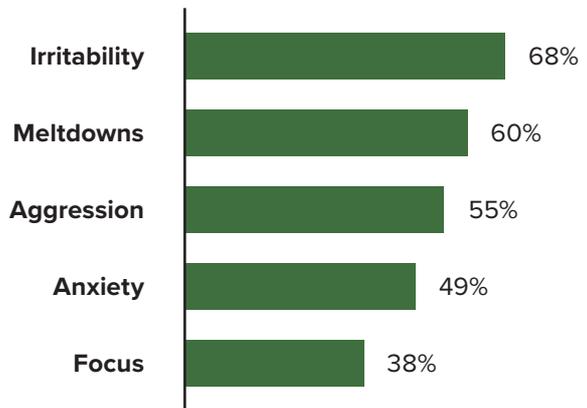


RESULTS

Respondents used HOPE™ 1, HOPE™ 2 or both products for a range of 5-133 days (average of 68 days of use) reported the following:



Improvements in Symptoms Graph A



Improvement in Quality of Life Graph B



Characteristics of Survey Participants

Self-reported Symptom	Irritability	Meltdowns	Aggression	Anxiety	Focus
Percentage of Participants	71.88%	50.00%	N/A*	62.50%	53.13%

HOPE™ Product Results

Significantly Improved	68.18%	60.47%	54.55%	48.89%	37.50%
Improved	15.91%	9.30%	13.64%	13.33%	12.50%
No Change	15.91%	23.26%	25.00%	29.79%	42.50%
Worsened	0%	0%	0%	0%	0%

*Not listed as an option in survey but was reported in results.

CONCLUSION

Overall, this survey adds to real life empirical experience data that cannabinoid-based formulations are well tolerated for the relief of symptoms associated with autism spectrum disorders. This survey appears to be the first report for a specific formulation of cannabinoid-based product or products associated with ASD.

Results from a 2019 case study, in which patients used CBD rich medicines¹⁹, showed an improved behavior in 61% of the patients with ASD and severe behavioral problems based on caregivers' rankings. However, some of the patients also reported notable side effects such as loss of appetite, sleep disorders and increased irritability in some cases. A similar observational study investigated the effect of CBD-rich cannabis oil with a small amount of THC on children with ASD who were followed for six months. Over 80% of the observed patients reported improvement in restlessness, rage attacks, and agitation. Good quality of life was reported by 67% at the six-month assessment²⁰. Together, these studies present some of the most recent findings on the effect of cannabinoid medicines with CBD and THC on the symptoms associated with ASD. Further evidence is provided by the following patient and physician testimonials:

“ *Our 5-year-old has been on HOPE™ for just over a year now, it has positively saved our lives! To think what our day-to-day was and what it is now is just remarkable... Within two weeks of Ilera HOPE™ the difference was night and day! Sleeping consistently, better appetite, better focus at school, much better overall behavior and mood...*

Survey Participant, Patient Caregiver

“ *All physicians who treat patients with Autism Spectrum Disorder should be aware that HOPE™ represents a significant addition to the potential tools we have to improve the lives of ASD patients and their families.*

Dr. Richard Magill is the Medical Director at PA Green Med and is approved by the Pennsylvania Department of Health to recommend medical cannabis to patients with approved conditions

“ *For decades the core symptoms of Autism Spectrum Disorder have been largely resistant to traditional drug therapy. Now so many of our Autistic patients are experiencing transformative results using a combination of THC, CBD and terpenes in proper combinations such as those found in the HOPE™ family of products. Kudos to the pioneering work of Erica Daniels and Ilera Healthcare for bringing us such amazing therapeutics as well as survey results with actionable information. I give all of my Autistic Families the link to HOPE GROWS FOR AUTISM as a necessary resource.*

Dr. Charles Harris, a Board-Certified Emergency Medicine Physician and Pennsylvania Department of Health approved recommender

This survey report has several limitations. The survey did not collect information on the history of ASD or associated symptoms. And this survey did not employ an objective assessment tool for changes in associated symptoms relative to baseline. All the survey responses were dependent on caregiver aided responses with no control group. However, there is a strong and widely accepted belief that the main caregivers are the most reliable source of information to evaluate the status of a patient with ASD.

People living with ASD commonly present comorbid symptoms such as irritability, meltdowns, anxiety,

aggression and hyperactivity. The impact of managing the associated symptoms on quality of life for the patient and the family is significant. There is an increase in the use of cannabinoid-based medicine in children with ASD. With regards to the results presented in this report, this is one of the first publications on the use of specific THC: CBD formulations to target symptoms of patients with ASD where patients have reported improvement in associated symptoms and quality of life for the patient and the family. There are studies being conducted in other countries, however, results from those ongoing studies are yet to be published.

Overall, this survey adds to real life empirical experience data that cannabinoid-based formulations are well tolerated for the relief of symptoms associated with autism spectrum disorders. This survey appears to be the first report for a specific formulation of cannabinoid-based product or products associated with Autism Spectrum Disorder.



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HOPE™ was created by Zelira Therapeutics and formulated by Ilera Healthcare in collaboration with HOPE GROWS FOR AUTISM.
For more information on HOPE™ formulations, please visit [IleraHealthcare.com/Hope](https://www.ilerahhealthcare.com/Hope) or contact Oludare Odumosu at oodumosu@ilerahhealthcare.com.