

Factsheet: Autism spectrum disorder (ASD)

BACKGROUND

Autism, also referred to as Autism Spectrum Disorder (ASD), is a lifelong disorder affecting around 168 million people around the world. ASD is not an intellectual disability or a mental health condition – it is a complex neurodevelopmental condition involving persistent challenges with social communication, restricted interests, and repetitive behaviour. The degree of impairment in functioning because of these challenges varies between individuals.

The ten countries with the highest autism rates in the world are the United Kingdom, Sweden, Japan, the USA, the Netherlands, Ireland, Brunei, Canada, Singapore, and Andorra. Australia has the thirty-seventh highest autism rate in the world.

SYMPTOMS

There may be different signs of ASD at different ages. In the first year, a baby with ASD might not be interested in other people. They may not make eye contact, smile or gesture like other babies. As toddlers, children with ASD might not respond to their name, focus on activities repetitively, speak differently and show no interest in playing with other children. Older children with ASD might have difficulties in social situations, following instructions or making friends. Adults with ASD may feel like they don't quite fit in, experiencing difficulties with relationships, work and social situations.



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DIAGNOSIS

A specialist such as a paediatrician, a psychiatrist or a psychologist, needs to confirm an ASD diagnosis using a set of standard tests. A diagnosis of ASD will also include a classification based on the level of support the person requires:

- Level 1: people requiring support
- Level 2: people requiring substantial support
- Level 3: people more severely affected and requiring very substantial support.



TREATMENT

While there is no "cure" for autism, there are several interventions that can improve a child's functioning including behavioural therapy, speech therapy, and occupational therapy. Autism-related irritability can be reduced by medications approved by the US Food and Drug Administration (FDA) such as aripiprazole and risperidone, however both drugs come with side effects (some serious).

NEUROTECH'S WORLD FIRST HUMAN CLINICAL STUDY TO TREAT ASD

Neurotech's world's first medicinal cannabis derived biopharmaceutical, NTI164, has been successfully studied in children with ASD. The Phase I/II study was conducted by Professor Michael Fahey, Head of Paediatric Neurology at Monash Children's Hospital, Melbourne.

The trial demonstrated that treatment with NTI164 is associated with statistically significant and clinically meaningful symptom improvement relating to severity of illness, social behaviour and communication. Data shows children taking NTI164 daily experienced marked improvement with socialisation, attendance at school, and classroom behaviour. These children also experienced improvement to their levels of anxiety, irritability and hyperactivity.¹



The side effects reported were not serious or severe and did not significantly interfere with patients' functioning. Importantly, there was no evidence that prolonged use of NTI164 in these patients can lead to any form of therapeutic tolerance as measured by a slow reversion of symptoms through extended use,¹ which highlights chronic administration of NTI164 is required to achieve significant improvements in clinical outcome measures. To put the above improvements into a real-life context, below are verbatim comments provided to trial co-ordinators by parents:

- *"We have never felt so hopeful as we do now. This therapy has changed our whole life."*
- *"[M] is thriving. I have to pinch myself at times. He was a kid that was always excluded and now he is going on playdates, socialising and enjoying his siblings."*
- *"I wake up feeling happy. Seeing [R] smile means the world. We are so grateful and lucky to be a part of this life-changing program."*
- *"We have had our occupational therapist and school teacher both ask if [D] is on a new "therapy" - he is like a different child. Focused, settled and less anxious."*



WHY NTI164?

Preclinical studies to date have shown that NTI164 is a potent anti-inflammatory, neuro-modulatory agent, making it an ideal candidate for the treatment of chronic neuro-inflammatory disorders such as ASD. NTI164's unique combination of CBDA and other minor cannabinoids work together to create an 'entourage effect' that is more potent than CBD alone, with only 0.3% THC. Preclinical and clinical studies to date have shown that NTI164 is a powerful neuro-anti-inflammatory modulator, can suppress a wide range of inflammatory cytokines, and improves neuronal cell viability and overall health.

FOR MORE INFORMATION

Visit <https://neurotechinternational.com/biopharmaceutical-trials> for up to date information about NTI164 and associated clinical trials focused on the treatment of rare paediatric neurological disorders including Autism spectrum disorder (ASD), PANS/PANDAS², Rett syndrome and cerebral palsy. NTI164 has been exclusively licenced by Neurotech International for neurological applications globally.

REFERENCES

- <https://www.psychiatry.org/patients-families/autism/what-is-autism-spectrum-disorder>
- <https://www.autismspectrum.org.au/about-autism/what-is-autism>
- <https://wisevoter.com/country-rankings/autism-rates-by-country/>
- <https://www.healthdirect.gov.au/autism#diagnosed>
- <https://neurotechinternational.com/asx-announcements/>¹

¹NTI164 Clinical Trial, results on file. <https://www.investi.com.au/api/announcements/nti/88fe63d6-dcf.pdf>

²Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)