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Study evaluating how an anti-inflammatory diet (Neurogutplus) can help children with autism spectrum disorder to improve inflammatory profile , neuropsychological profile and praxic development

Submission date
22/09/2025

Recruitment status
No longer recruiting

Registration date
24/09/2025

Overall study status
Completed

Last Edited
24/09/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a developmental condition that begins in childhood. Children with ASD often experience challenges with communication, social interaction, and learning. Many of them also have problems with movement, coordination and learning. These problems can make it harder for them to play, participate in school, or carry out daily activities. Scientists are exploring how nutrition and gut health affect brain function. Some special diets may reduce inflammation, improve the gut, and support child development. Some research suggests that a special diet can improve health by reducing inflammation and supporting a healthy gut. This study tested whether a nutritional protocol could improve movement and motor development in children with autism. This diet may also help improve development, which includes skills such as balance, coordination, fine hand movements and cognitive areas. The aim of this study was to find out whether following an anti-inflammatory diet for 12 weeks could improve psychomotor, cognitive development and inflammatory profile in children with ASD. The researchers compared these children with neurotypical children (children without autism).

Who can participate?
The study involved 30 children aged 6 to 17 years. 18 children had autism (level I, according to DSM-5). They were recruited from therapy centers and support organizations in Manizales, Colombia.
12 children were neurotypical, meaning they did not have autism. They were recruited from schools in the same city.
All participants had to meet certain conditions to join:
• They could not be taking medications such as steroids, antibiotics, or immunosuppressants in the last three months.
• They could not have food allergies like milk protein allergy.
• They had to be free of serious neurological, metabolic, or immune diseases.

Children and families volunteered to join, and parents gave written consent while children gave their assent.

What does the study involve?
The study lasted 12 weeks and included four groups of children:
1. Children with autism on the anti-inflammatory diet.
2. Children with autism on their usual diet.
3. Neurotypical children on the anti-inflammatory diet.
4. Neurotypical children on their usual diet.
The anti-inflammatory diet was carefully designed by nutrition experts to reduce foods that may trigger inflammation (such as gluten, casein, refined sugars, and highly processed foods) and to increase foods rich in vitamins, minerals, fiber, and omega-3 fatty acids.
Families received:
• Personalized meal plans adapted to Colombian food culture.
• Nutritional education on how to prepare and use the diet at home.
• Regular food packages delivered every two weeks to support adherence.
• Support sessions to answer questions and encourage long-term changes.
The control groups continued their normal diets but also received general nutritional education.
Assessments were conducted before and after the 12-weeks intervention:
• A full psychomotor evaluation using the Batería Da Fonseca which measures seven areas: muscle tone, balance, body awareness, spatial and temporal structuring, laterality, motor gross and fine coordination.
• Additional measures included body weight and height, gastrointestinal symptoms, and sociodemographic information.
• Blood samples taken at the start and after 12 weeks to analyze immune markers and inflammation using advanced laboratory methods.
• Neuropsychological assessment using the Wechsler Intelligence Scale for Children WISC IV and the Child Neuropsychological Assessment (ENI 2).

What are the possible benefits and risks of taking participating?
Benefits
• Children with autism might experience improvements in fine and gross motor skills, such as better balance, coordination, or ability to use their hands for precise tasks.
• Families learned about healthy eating and received guidance that could be useful beyond the study.
• Participants benefited from regular checkups and evaluations of their development.
Risks
• Adjusting to a new diet can be challenging, especially for children with autism who may have food selectivity and strong preferences.
• Some children might experience mild digestive discomfort when new foods are introduced.
• Blood draws may cause brief discomfort.
The study team monitored families closely and provided support to minimize any risks. No serious side effects were reported.

Where is the study run from?
The research was carried out in Manizales, Colombia, through a collaboration between: Universidad Autónoma de Manizales, Universidad de Manizales, Universidad de Caldas, Centro de Bioinformática y Biología Computacional de Colombia (BIOS)

When is the study starting and how long is it expected to run for?
January 2022 to December 2024

Who is funding the study?
The project was funded by the Colombian Ministry of Science, Technology, and Innovation (MINCIENCIAS) under Contract 765-2021

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Research Code 797-124. Universidad Autónoma de Manizales.

Study information

Scientific Title
Quasi-experimental study evaluating the effect of an anti-inflammatory diet (Neurogutplus) compared to usual diet on inflammatory profile, neuropsychological profile and praxic development in children with autism spectrum disorder in Manizales, Colombia

Study objectives
This study aimed to determine the effect of an anti-inflammatory diet on the inflammatory profile, neuropsychological profile and praxic development of children with Autism Spectrum Disorder in Manizales, Colombia.
This study defines a null hypothesis and an alternative hypothesis. Null hypothesis (Ho): Consumption of an anti-inflammatory diet in children with ASD and NT children does not produce significant changes in inflammatory profile, neuropsychological profile and praxic development compared to children who do not consume the diet. Alternative hypothesis (H1): Consumption of the diet produces significant changes in inflammatory profile, neuropsychological profile and praxic development compared to children who do not consume the diet.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/05/2023, Bioethics Committee of the Universidad Autónoma de Manizales (Antigua estación del ferrocarril, MANIZALES, 70002, Colombia; +57 (606) 872 7272 Ext. 115; ceibic@autonoma.edu.co), ref: Act 150, 10 may, 2023

Study design
Quasi-experimental single-center non-randomized interventional study

Primary study design
Interventional

Study type(s)
Other, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Intervention with anti-inflammatory diet in children with autism spectrum disorder to improve inflammatory profile, neuropsychological profile and praxic development.

Interventions
A quasi-experimental study was conducted with a total sample of 30 children. Participants were recruited and assessed for eligibility and all were distributed into two groups: ASD (n =18) and NT (n =12). Participants with ASD were recruited from therapeutic support organizations, centers, and institutes, and NT participants were recruited from public and private educational institutions. Quasi-experimental non-randomized design with four groups: Autism Spectrum Disorder Experimental Group (n=9), Neurotypical Experimental Group (n=6), Autism Spectrum Disorder Control Group (n=9), Neurotypical Control Group (n=6), measurements at baseline and 12-week postintervention.

The children in the ASD and NT groups were evaluated using a sociodemographic questionnaire and clinical characteristics, nutritional status, sample collection and immune profiling peripheral blood samples, neuropsychological tests and praxic development (psychomotor profile) at the start of the study. To control for circadian and nutritional variability, all samples were collected in the morning (7:30–9:30 a.m.) following an overnight fast. Standardized venipuncture procedures were used across all participants. Samples were processed within 2 h and stored at –80 °C until cytokine analysis was conducted via a multiplex Luminex assay. The ProcartaPlexTM Human Th1/Th2 Cytokine & Chemokine Panel 1 20plex enables the exploration of immune function by analyzing 20 protein targets in a single well using the MAGPIX detection system (Luminex Corp., Austin, TX, USA) (Cat. No. EPX450-12171-901). Duplicate plasma samples were analyzed before and after the intervention with the anti-inflammatory diet.

The intervention was different for both groups:

Experimental groups: The experimental groups of children with ASD and NT received individualized and monitored nutritional interventions, which considered both benefits and possible adverse effects.
Five phases were developed to implement an anti-inflammatory diet (Neurogutplus): identification, analysis, implementation, monitoring and adherence. The identification phase involved the initial collection of dietary information and eating habits through structured interviews that allowed for the breakdown of usual intake by meal times (breakfast, lunch, snacks, etc.) and food frequency questionnaires, with the aim of identifying consumption patterns, food preferences, and possible nutritional deficiencies or excesses.
The analysis phase allowed for quantitative and qualitative assessment of the child's current diet by comparing the proportion of intake with ideal nutritional standards. Based on Resolution 3803 of 2016 of the Colombian Ministry of Health, which "establishes the Energy and Nutrient Intake Recommendations (RIEN) for the Colombian population and dictates other provisions" (Ministerio de Salud y Protección Social, 2016) and on the food composition table of the

Colombian Institute of Family Welfare (ICBF) of 2018 (Instituto Colombiano de Bienestar Familiar, 2018) , a nutritional analysis of each participating child's diet was performed to establish their nutritional imbalances.
in the implementation phase, the diet was designed according to nutritional balance criteria and scientific evidence with an anti-inflammatory approach, in order to prioritize the inclusion of foods with antioxidant and prebiotic properties, reduce the consumption of pro-inflammatory compounds such as gluten, added sugars, FODMAPs (oligosaccharides, disaccharides, monosaccharides, and fermentable polyols), and ultra-processed foods, and provide those that provide insoluble fiber in adequate amounts as required, as well as micronutrients such as vitamins and minerals, that is, zinc, and B riboflavin, A, and C vitamins. The intervention was personalized according to the needs of each child and adjusted to the cultural and family context.

During the meeting with each family in the first week, the meal plan was explained and any questions were answered. To facilitate adherence to the diet, nutritional education was provided to families on anti-inflammatory diets so that they could understand its fundamentals and how to implement it at home. To this end, a manual for parents and an individual nutritional plan format according to age group were provided. Balanced information was provided on type of diet. The foods included in the designed diet were delivered to each family every 15 days during the 12-week intervention period by personnel independent and packaged in accordance with all biosafety standards.

During the follow-up phase, periodic food consumption surveys and 24-hour recall questionnaires were conducted to validate adherence and detect deviations in dietary compliance; therefore, adherence was not a variable, but an inclusion criterion. This data allowed informed decisions to be made to maintain or adjust the intervention. These methodological control measures helped reduce the measurement and expectation biases inherent in the non-blind nature of dietary interventions.

Finally, the adherence phase aimed to promote the sustainability of dietary change through nutritional education processes, targeted at both parents and children, adapted to their level of understanding, positive reinforcement, and individualized adjustments to improve acceptance and continuity. The process is dynamic and cyclical, allowing for constant feedback on monitoring, adherence, and implementation.

Control groups: Children in the ASD and NT control groups continued their usual diets and benefited from receiving nutritional education.
At the end of the 12-week intervention, the final psychomotor and neuropsychological assessment, and sample collection and immune profiling peripheral blood samples (postest) was conducted by experts who were unaware of the pretest results and the distribution of children in the experimental and control groups.

Intervention Type
Other

Primary outcome(s)
1. Plasma concentrations of TGF-β1, IFN-γ, IL-8, and MIP-1β measured using ProcartaPlex™ Human Th1/Th2 & Chemokine Panel 20-plex (Luminex xMAP® technology) at baseline (week 0) and after 12 weeks of dietary intervention.
2. Neuropsychological profile measured using Wechsler Intelligence Scale for Children-IV (Fourth edition) and child neuropsychological assessment (ENI 2) at baseline and after 12 weeks.

3. Praxic development and psychomotor profile measured using Batería Psicomotora Da Fonseca (BPM) at baseline and after 12 weeks

Key secondary outcome(s))
1. MCP-1, Eotaxin, IP-10, GRO-α, RANTES, SDF-1α, IL-18, and MIP-1α measured using ProcartaPlex™ 20-plex panel at baseline (week 0) and after 12 weeks.
2. PBMC gene expression profile measured using single-cell RNA sequencing (scRNA-seq) at baseline and after 12 weeks.
3. Nutritional status and body composition (BMI-for-age, height-for-age, weight-for-age z-scores) measured measured using anthropometric techniques (skinfolds, circumferences) at baseline and after 12 weeks.
4. Dietary adherence measured using weekly caregiver food logs, interviews, verification of unused food packages at throughout the 12-week intervention.
5. Psychomotor factors of tonicity, balance, body awareness, spatial-temporal structuring, laterality, global praxia, and fine praxia measured using Batería Psicomotora Da Fonseca (BPM) at baseline and after 12 weeks.
6. Immune-behavioral network reorganization measured using PCA and network analysis at baseline and after 12 weeks.

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Inclusion (Autism spectrum disorder groups):
1. Children aged 6-17 years with confirmed diagnosis of level I ASD (APA, 2013).
2. Any gender.
3. Caregiver agreement to participate and follow dietary guidelines.
4. Active affiliation with the Colombian General Social Security System.

Inclusion (Neurotypical groups):
1. Children aged 6-17 years and could not have a diagnosis of autism or any other developmental disorder.
2. Any gender.
3. Caregiver agreement to participate and follow dietary guidelines.
4. Active affiliation with the Colombian General Social Security System

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit

17 years

Sex
All

Total final enrolment
30

Key exclusion criteria
Exclusion (Autism spectrum disorder groups):
1. Children with food intolerance or history of milk protein allergy
2. Children with neuromuscular, systemic inflammatory, metabolic, musculoskeletal, or immune disorders
3. Children with a nutritional diet at the time of the study.

Exclusion (Neurotypical groups):
1. Children with food intolerance or history of milk protein allergy
2. Children with autism spectrum disorder, neuromuscular, systemic inflammatory, metabolic, musculoskeletal, or immune disorders
3. Children with a nutritional diet at the time of the study.

Date of first enrolment
01/06/2023

Date of final enrolment
12/12/2023

Locations

Countries of recruitment
Colombia

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Sponsor information

Organisation
Ministerio de Ciencia, Tecnología e Innovación

ROR
https://ror.org/02h503d38

Funder(s)

Funder type
Government

Funder Name
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Funder Name
Autonomous University of Manizales

Funder Name
University of Caldas

Funder Name
University of Manizales

Funder Name
Center for bioinformatics and computational biology of Colombia-BIOS

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

· Data will be available starting September 23, 2025.
· Consent was requested and obtained from all participants.
· The data were anonymized at all times.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes