

# Combined human milk oligosaccharides (HMOs) and probiotics intervention for children with autism.

ACTRN12621001575820

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Status	RECRUITING
Sponsor	University of Queensland
Enrollment	60 participants

## Plain Language Summary

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Many children with autism spectrum disorder (ASD) experience digestive problems and behavioural difficulties, including irritability, aggression, and anxiety. Growing research suggests that the gut microbiome — the community of bacteria living in the digestive system — plays a role in brain and behaviour through what is called the gut-brain axis.

This study tests whether a combination of human milk oligosaccharides (HMOs, a type of prebiotic fibre) and probiotics can improve behaviour and reduce irritability in children with ASD. The study runs in two phases: eight weeks of a blinded randomised trial (where neither parents nor researchers know who is getting the real product), followed by eight weeks where all participants receive the active supplement.

Your child may be eligible if they are aged 5 to 12 years and have a confirmed diagnosis of ASD or a related condition. Children with gut diseases like inflammatory bowel disease, cow's milk allergy, or those who have recently taken antibiotics or probiotics are not eligible. The supplement comes in a form that can be mixed into food or drink, making it easy to administer.

## Key Eligibility Criteria

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### Inclusion (2)

- Aged 5.00 years to 12.99 years
- A confirmed diagnosis of ASD or Pervasive Developmental Disorders (PDD) including autistic disorder, Asperger's disorder (AS); PDD not otherwise specified (PDD-NOS); and atypical autism.

### Exclusion (9)

- Organic GI disorders such as inflammatory bowel disease, coeliac disease, eosinophilic disorders, or current infection of the GI tract.
- Bowel surgery or short bowel syndrome.
- Participants with a diagnosed cow milk protein allergy.
- Participants who suffer from the conditions listed below or who are taking any of the following medications or supplements:
  - a. antibiotics or antifungals in the last two months
  - ... and 4 more (see full listing online)

## Locations (1 total)

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ACT,NSW,NT,QLD,SA,WA,VIC, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621001575820>

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