

CAHE JC Critically Appraised Article Summary

Journal Club Details

Date of submission	March 2009
Journal Club location	Port Pirie Regional Health Service
JC Discipline/s	Occupational Therapy
JC Facilitator	Andrea Fisher

Clinical Scenario

What is the effect of gluten-free diet on social behaviour of children with autism?

Review Question/PICO/PACO

- P** Autistic children
- I** Gluten-free diet
- C** No intervention or change in diet
- O** Decrease in autistic traits, improved social behaviour

Article/Paper

Elder JH, Shankar M, Shuster J, et al (2006) The gluten-free, casein-free diet in autism: results of a preliminary double blind clinical trial. *Journal of Autism and Developmental Disorders* 36(3): 413-420.

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Article Methodology: Double blind cross over clinical trial

Returned JC on: 2 March 2009

By CAHE staff member: Lucyllynn Lizarondo

Ques No.	Yes	Can't Tell	No	Comments
1	✓			The trial asked a clearly focused question: Participants: children with autism, diagnosed according to DSM IV criteria and Autism Diagnostic Interview Revised Intervention: Gluten and casein-free food items (GFCF) Outcomes: Childhood Autism Rating Scale (CARS); urinary peptide levels (UPL); Ecological Communication Orientation (ECO) Language Sampling Summary; observations of child and parent behaviour
2	✓			Subjects were randomly assigned to either GFCF or a placebo diet, in a cross-over clinical trial. This is an appropriate study design to address the research question. By using this approach, patient variation is minimised, which makes it more efficient than a similar-sized parallel group trial in which each subject is exposed to only one treatment. Unlike most crossover trials, where the principal drawback is the “carry over” of treatment, the diets in this study did not require a wash-out period according to dietary consultants. Is it worth continuing? YES
3		✓		This is a crossover trial, which means that all patients on both groups experienced the same forms of intervention. As mentioned above, patient variation between groups was minimised. It is important to note however, that there was a large within-group variance, which is a common problem in a study of children with autism. There is wide variability among children regarding behavioural and developmental traits and levels. The heterogeneity of sample in this study made it difficult to draw definitive conclusions.
4	✓			It seems that every effort was made by the investigators to achieve blinding. Children, parents, and all of the investigative team, with the exception of the data manager and dietician, were blind to the dietary order.
5	✓			Of the 15 who participated in the trial, only 13 completed the 12-week protocol. A “missing at random” model was employed for these 3 subjects whose data were incomplete on major variables.
6	✓			All outcomes were measured and collected in the same way and in the same time period for all participants in both groups.
7			✓	No power calculation was done. The sample size was very small.
8				Results were presented using means, standard deviations and p-values which showed whether or not significant differences exist between groups. Bottom line result: There were no statistically significant differences between groups in all of the outcome measures.

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Ques No.	Yes	Can't Tell	No	Comments
9				There was a small number of participants and wide variability among the children, which made it difficult to draw definitive conclusions.
10				As this study has significant methodological flaws, the evidence contained in this trial was not sufficient to support or even refute any existing dietary practice among children with autism. This study, whilst it did not generate significant findings, has highlighted the methodological issues and suggested ways on how to improve future research.

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