

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Does an intensive self-management structured education course improve outcomes for children and young people with type 1 diabetes? The Kids In Control OF Food (KICK-OFF) cluster randomised controlled trial protocol.
AUTHORS	Price, Katherine; Wales, Jerry; Eiser, Christine; Knowles, Julie; Heller, Simon; Freeman, Jenny; Brennan, Alan; McPherson, Amy; Wellington, Jerry

VERSION 1 - REVIEW

REVIEWER	Dr. Nivedita Aswani Consultant Paediatrician Derbyshire Children's Hospital Uttoxeter Road Derby DE22 3NE
REVIEW RETURNED	12-Dec-2012

- The reviewer completed the checklist but made no further comments.

REVIEWER	Jordan E. Pinsker, MD Chief, Pediatric Endocrinology Tripler Army Medical Center Honolulu, HI, USA Statement of Competing Interests: None
REVIEW RETURNED	14-Dec-2012

THE STUDY	<p>1) Page 6, Line 21 (Methods - Table 1) - Exclusion criteria include "Major behavior problems." In the text of the table and just below (line 49) in subject withdrawal, this is listed a reason they cannot participate in group activity. Yet the table also implies they will not be selected for the study up front if they have a behavior problem, as it is an exclusion criteria. Thus I am not clear when they are excluded.</p> <p>This type of behavior problem can be a primary problem in the patient, or a result of the chaotic social situation a child may face at home. Of course, social support is most predictive of diabetes outcomes in children, so children who "act out" due to lack of family stability universally have worse outcomes. Please clarify exactly what major behavior problems mean, and if patients are excluded up front from recruitment, or only if they disrupt the group classes, as the study is potentially excluding an important population who need the most help.</p> <p>2) Page 8, Line 40 (Biomedical Outcomes) – Please expand the</p>
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	<p>definition of hypoglycemic events. Does this only include a seizure? Or is the study measuring something similar to the American Diabetes Association 5 point scale on hypoglycemic events (American Diabetes Association Workgroup on Hypoglycemia, Diabetes Care, May 2005). This is important because if you only record hypoglycemic seizures, there may be too few events to see a meaningful difference between groups and/or A1c changes.</p>
<p>GENERAL COMMENTS</p>	<p>This is an excellent, well structured, manuscript that describes an important program that has great potential to improve pediatric type 1 diabetes care. The authors should be commended for including QOL as an important outcome measure, as this may change even in patients who already have A1c within the recommended range and is very important.</p> <p>My only concerns are minor clarifications of the methods as noted above.</p> <p>If the results of the study intervention prove to be helpful, I hope the authors will share the details of the courses they offer so others can learn from and build on their efforts.</p>

VERSION 1 – AUTHOR RESPONSE

The original paper has been revised to answer each of these. In particular, there is clarification about children with behaviour problems. Those with known severe behavioural difficulties that require psychiatric input are excluded from recruitment. However unanticipated challenging behaviour may emerge during the KICK-OFF course. Educators will make every effort to manage this behaviour and encourage ongoing participation but we felt that there needs to be the option to withdraw a child whose behaviour proves unmanageable and significantly disruptive or dangerous to others. We certainly plan to publicise the results on this study widely and would consider sharing data.