

PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Testing of a synthetic phonics-based targeted reading intervention for students with reading difficulties in Year 1: Protocol for an efficacy randomised controlled trial
AUTHORS	Quach, Jon; Clinton, Janet; Dawson, Georgia; Smith, Libby; Serry, Tanya; Goldfeld, Sharon

VERSION 1 – REVIEW

REVIEWER	Reviewer name: Professor Carole Torgerson Institution and Country: Durham University, United Kingdom Competing interests: None
REVIEW RETURNED	18-May-2018

GENERAL COMMENTS	<p>This is a protocol for an individually randomised controlled trial. It is unclear why this has only just been submitted for publication, given that the trial is well underway - with only data collection and analysis remaining.</p> <p>The basic design and design features and components all seem sound (with the exception of the per protocol analysis following ITT analysis (see below).</p> <p>The per protocol analysis is not appropriate - I suggest the statistician undertakes a CACE analysis to explore non-compliance.</p> <p>Reporting using the CONSORT checklist and flow diagram is essential.</p>
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VERSION 1 – AUTHOR RESPONSE

1. Suggestion of using a Complier Average Causal Effect (CACE) analysis to explore non-compliance, as opposed to the per protocol analysis

Response: Thank you for this suggestion. We have now included the CACE analysis as part of our analysis plan. As we used an opt out consent process, we had 2 children opt out of the study, and another 13 children who did not complete the screening (equates to 1.9% of possible sample). In addition, only 1 child did not receive the intervention. Therefore, the CACE analysis may not be appropriate given the almost complete compliance to the intervention as all children receive the intervention.

However, as part of our process evaluation, we will be able to determine whether there are factors or specific thresholds (ie. Varying degrees of dosage as measured by attendance rate, levels of fidelity measured by teacher surveys and lesson observations) which are related to or interact with improved outcomes. This will enable us to determine whether the proposed per protocol criteria set by the program developers is associated with improved outcomes in the intervention group.

Findings from these analyses will inform future studies as to the criteria associated with compliance for CACE analysis.

2. It is unclear why the protocol is just been submitted for publication

Response: We would like to highlight that the protocol submitted aligns with our RCT registration, indicating that there have been minimal changes in the study design during the conduct of the RCT. In addition, the data collection is still in progress and therefore the study has not been completed. The protocol has not previously been submitted as it was not permitted by the funding body. However, a recent change in policy has enabled us to be able to submit the protocol for publication.

3.Reporting using the CONSORT checklist and flow diagram is essential

Response: We agree and will be reporting our findings according to the CONSORT checklist and flow diagram. Our intention to do so has been added to the manuscript.