Author’s response to reviews

Title: Parent Empowerment and Coaching in Early Intervention: Study Protocol for a Feasibility Study

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Author’s response to reviews:

1. Previous Reviewer comment and Response:
   * Is the Project ImPACT Fidelity of Implementation for Coaching Form a validated measure - please clarify?

   The Project ImPACT Fidelity of Implementation for Coaching Form has been used in a number of studies evaluating the effectiveness of Project ImPACT (Ingersoll & Wainer, 2013; Stadnick et al., 2015; Stahmer et al., 2019; Wainer, Pickard, & Ingersoll, 2017); however it has not been evaluated in a systematic psychometric validation study.
Thank you for adding the description of its use in previous evaluations. For the first cited use of the rating scale (Stadnick et al 2015), there doesn't seem to be any mention of its use in the paper (which only addresses parent behaviour). However, the measure is described in the second cited paper (Wainer, Pickard and Ingersoll 2017) but doesn't state the number of items. Stahmer et al 2019 describes the use of an adapted measure of the PIT Parent Coaching Strategies - a 22-item likert-type scale (adapted from the Fidelity of Implementation for Coaching Sessions Form). Ingersoll and Wainer 2013 refers to assessment of parents (and not providers) across five dimensions of the PI fidelity form. Therefore, it's still not quite clear which version of the rating measure is being used, how many items it comprises and how well established the rating form is. This can possibly be addressed easily with a small expansion of its description and adjusting the citations used.

Thank you for your careful read of the manuscript and the citations. The Project ImPACT Fidelity of Implementation for Coaching Form is a 20-item likert-type scale. The form was used in the Stadnick et al., 2015 study. The authors state “Clinicians had received formal training in Project ImPACT by the intervention developers and had met intervention adherence according to standard fidelity measures provided by the developers.” (page 2094). I have confirmed with the authors that the “fidelity measures provided by the developers” was indeed the Project Project ImPACT Fidelity of Implementation for Coaching Form. The PIT coaching fidelity form was adapted from the Project ImPACT Fidelity of Implementation for Coaching Form used by Stahmer et al., 2019 and includes two additional items (22 total). We have removed the Ingersoll & Wainer 2013 citation, as the reviewer is correct, and this study only reports on parent fidelity. We thank the reviewer for this careful attention to detail.

2. NB Citation 33 is not a complete reference.

We have corrected this error; citation #33 is now accurate.

3. Previous Reviewer comment and Response:

* Phase 4 - it is not stated that the clinicians will be trained (or otherwise subject to the implementation intervention toolkit developed by the CAB). Does this occur when ‘Clinicians will have completed training in Project ImPACT at least one month prior to recruitment to ensure some experience with the program’? Can this be clarified?
We will introduce the implementation strategy toolkit individually with each clinician. All training will occur following completion of Project ImPACT training. Consistent with a multiple-baseline design, the toolkit will be introduced with each subsequent clinician when the preceding clinician attains 80% coaching fidelity or fidelity stabilizes across three sessions, until the toolkit has been introduced across all 3 clinicians within each agency.

Additional Reviewer Comment:

Thank you. Can you clarify though what 'fidelity stabilizes across three sessions means' in practice? On the face of it, fidelity could stabilise at any threshold (eg 50% or 80%). I realise this is a facet of the single-case design, but a description for the general reader would be useful.

This is an excellent point. In the event that a provider does not attain 80% coaching fidelity in the pilot single-case design study, a contingency plan consistent with best practices in single-case intervention research design standards (Kratochwill et al., 2013) will be adopted. Each provider’s coaching fidelity data will be graphed and visually analyzed following each session to evaluate level, trend, and variability of the data points. If these analyses indicate that a provider’s coaching fidelity is 1) stable and 2) not demonstrating an increasing trend over three consecutive sessions, the implementation toolkit will be introduced with the subsequent provider in the multiple baseline design, while continuing to intervene and monitor coaching fidelity with the previous provider. We have clarified this in the text on page 19-20.

4. Previous Reviewer comment and response:

* Line 58, page 19. A criterion for clinician competency is referred to (80%) but it has not been clarified how this is determined prior to this point. If this relates to the assessment of fidelity on line 39, page 17 this should be made clearer when introduced but it is also not clear how this will happen in practice if the rater is undertaking a blinded assessment of both pre and post intervention sessions.
The criterion for introducing subsequent phases within the multiple baseline design is 80% coaching fidelity across three consecutive sessions. Providers will be video recording their sessions, and submitting the videos for fidelity scoring following each session. A trained research assistant will code fidelity for each video. The research assistant will not be informed whether the video depicts a session from a baseline or an intervention phase. Given the multiple baseline design, there will be several providers submitting videos each week, with some providers in the baseline phase and others in the intervention phase. This will allow the coder to code blind to intervention phase across providers. The PI will review the fidelity ratings after coding to determine when each clinician will move from baseline to the next phase.

Additional Reviewer Comment:

Thank you. Please note the comment above about 'fidelity stabilizes' which is relevant here. Also, does '80% coaching fidelity across three consecutive sessions' mean an average of 80% or more across the three sessions combined (including where fidelity actually may dip in session three, for example) or a minimum of 80% at each session?

The 80% criterion refers to a minimum of 80% fidelity in each session, not an average of 80% across the three sessions. We have clarified this in the text on page 19.

5. Previous Reviewer comment and response:

* Line 19-43: the description of the planned analysis is too general. The plan also is simply before and after comparison with very small numbers involved and there is no clarification of what would be taken as evidence of change or feasibility (overall a clearer statement of feasibility objectives and / or progression criteria would be very useful). Some narrative description would be useful, and for example tying this to the intervention logic model. If this study is a precursor to a RCT as suggested is it anticipated that further work after the feasibility study will nevertheless still be required to then justify a trial?
The description of the analysis is consistent with established protocols for single-case research design. Single-case research design is ideal for studies with small samples, and allows for rigorous analysis of intervention effects (Kazdin, 2019). The multiple baseline design to be used in the pilot study is an established method to systematically evaluate intervention effects and allows for causal inferences. We will evaluate change in provider coaching fidelity within the pilot study as the primary outcome of interest following the introduction of the toolkit, using the multiple baseline design procedures. We will also collect secondary outcome data regarding changes in parent's use of the intervention techniques, and children's change in social communication. These secondary outcome data are exploratory and will allow us to gather some preliminary data regarding any pre- and post-changes to child and family outcomes observed following changes in provider coaching. We have clarified this in the text. We also have added a clearer description of our definition of feasibility for the pilot study.

Additional Reviewer Comment:

The clarification the feasibility objectives is good thank you. I am less familiar with single case designs and the implications for analysis. The cited paper by Kazdin does refer to data evaluation and broad approaches to both data visualisation and statistical analysis. If the approaches proposed are principally the former (which I think is the case), then it might be useful to summarise as that.

The reviewer is correct; the planned analyses are primarily visual analyses. We have clarified this in the text on page 19.