Reviewer’s report

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

Version: 1 Date: 06 Dec 2019

Reviewer: Mike Robling

Reviewer's report:

Reviewer #1: Methods / setting

* How do the selected agencies represent other agencies in terms of other metrics (eg is there any further socio-demographic information available on clients, professional background / training of clinicians?).

The agencies participating in the training are very similar to other agencies in the system with regard to clients' socio-demographic background and providers' professional background. All agencies in Philadelphia EI serve all of Philadelphia County; therefore, there is little variability across agencies in terms of the families they serve. Services are generally provided in clients' homes therefore agencies do not serve only families near the geographic location of their offices. All providers in the county receive standard training delivered by the county. All agencies employ similar staff from a limited pool of educational backgrounds, including educators, speech pathologists, and occupational therapists. We have added more detail about this in the methods section when describing the setting and participants.

OK - thanks for that additional information.

* 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.

NB Citation 33 is not a complete reference.

* The 7-point measurement scale proposed for clinician attitudes is not a likert scale (as described) and would be better referred to a likert-like scale.

We now describe the scale as a "7-point likert-type scale" instead of likert scale.

Thanks for making the change.

* The very small numbers of clinicians being interviewed means that the authors should be cautious in interpreting the quantitative survey data.

We thank the reviewer for this recommendation. We agree, and plan to use the data as pilot data to inform the measures used in a larger community-based trial.

* Line 58, Page 14 - provide definition for EBPs
We have changed the wording in this sentence to "research-informed practices" instead of "EBPs" to improve clarity.

Thank you.

* Line 26, Page 15 - provide definition for 'Part C system'

We have defined Part C System in the manuscript.

Thank you.

* Line 29, Page 16 - does the reference to organizational and system barriers mean that these factors are not addressed at all on this feasibility study? This needs to be clarified and if so, justified, especially given the reference to ecological validity and implementation in community settings substantially referred to in Conclusions.

We refer to organizational and system barriers as potentially important factors that may influence the use of parent coaching within early intervention, however a thorough understanding of these broader factors is beyond the scope of this pilot study. We anticipate learning about organizational and system level barriers through our qualitative interviews, and plan to integrate those findings into future research evaluating organizational barriers to parent coaching more broadly. Therefore, we include a discussion of these potential barriers and the need to systematically address them. The findings from this pilot study will lead to a toolkit that is developed in partnership with community stakeholders, and tailored to the needs of this specific service system. As such, we believe, the discussion of ecological validity is relevant and appropriate for this toolkit. We have added the need for a thorough evaluation of organizational and system-level barriers as an important direction for future research within the discussion to address this comment.

OK, thanks
* 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.

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.

* Line 29, page 18. 'For all video recorded and coded data, at least 20% will be coded by a second observer balanced across experimental conditions and participants'. Can the authors clarify what they mean by experimental conditions in this feasibility study?

This sentence refers to the baseline and intervention phases of the single-subject design of the pilot study. Inter-observer agreement data will be collected in 20% of sessions, across baseline and intervention phases of the study. We have clarified this in the text.

Thank you.

* 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.

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?

* 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.
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.

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