

A Comparison of Methods for Testing and Mobilizing Health Interventions in Childhood: Preliminary Findings from A Realist Systematic Review



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Background

- Innovative methods to test health-care interventions have recently emerged to help provide more personalized, targeted, effective and scalable interventions (Chawla & Davis, 2013; Naudet, Falissard, Bousageon & Healy, 2015).
- Given the importance of the early years for children's health and development, the need for improved interventions for vulnerable children and families has become a public and child health imperative.
- Traditional randomized control trials (RCTs), considered the gold standard in clinical experimental design, suffer from serious limitations due to costs associated with the necessity for large sample sizes, time demands to translate research into practice, and issues with generalizability of results due to strict eligibility criteria (Campbell & Stanley, 2015; Spieth et al., 2016).
- Moreover, RCTs do not allow researchers to make mid-course adaptations based on their learning during different phases of RCTs.
- While RCTs offer many benefits, the identified limitations indicate a need to identify newer and faster methods for identifying effective interventions, especially to improve or promote children's health, in a timelier manner.
- Thus, new accelerated methods are emerging to address limitations of RCTs; it is critically important to uncover newer, innovative and faster methods to test interventions.

Objective

- The objective of this paper is to compare methods for intervention evaluation including traditional RCTs and the newer innovative designs for their efficiency and ability to rapidly build knowledge to impact children's health and development in a variety of settings.
- Thus, the research question addressed by our review is "How do the newer, innovative and accelerated methods for intervention evaluation compare to RCTs in their ability to test and mobilize interventions to support children's health and development?"

Results & Discussion

- Our methods revealed a number of sources including peer-reviewed journal articles, webpages and reports. The number of journal articles found was as follows: "rapid-cycling trial*" (n = 3), "fast-iteration research*" (n = 5), "fast-fail trial*" (n = 3), in combination with the terms "method*/methodology and design*".
- The title and abstract of each article were reviewed by the first author for inclusion and the second author.
- The final set of articles included 11 articles as shown in Table 1.
- We also identified 12 non peer-reviewed articles/opinion editorials from other sources (e.g. webpages, reports, etc.) – a work in progress.
- Four accelerated methods to test interventions were identified:
 - Frontiers of Innovation (FOI) IDEAS method** (e.g. Center on the Developing Child, 2016): FOI IDEAS method consists of 3 main components including theory of change, program and material development, and an evaluation plan. FOI IDEAS method involves well-organized but flexible approaches to facilitate intervention evaluation, and fast-cycle iteration by utilizing research methods and tools in highly specific and rigorous ways to test early interventions.
 - Pragmatic and explanatory clinical trials** (e.g. Zwarenstein et al., 2008): Pragmatic trials are designed to test interventions in the full spectrum of everyday clinical settings with flexible eligibility criteria to maximize applicability and generalizability of results. Explanatory trials are overlaid on RCT design; they are the best suited method to explore if and how an intervention works, and the whole experiment is designed with strict eligibility criteria to maximize an intervention's efficacy. Both methods suffer the issues of internal and external validity respectively.
 - Rapid-cycle Research methods** (e.g. Johnson, Gustafson, Ewigman, 2015): Rapid-cycle methods involves evaluation of an intervention early and often in a pilot program or policy implementation process. Rapid-cycle improvement methods are used to change the program or policy to address issues raised by the early findings. However, the definition of rapid and how to include cyclical processes in research design are points still being debated and tested nor this method has been employed to test early interventions.
 - Fast-fail Trials** (e.g. Insel, 2015): The fast-fail method aims to tie innovative interventions to underlying disease mechanisms from the very beginning by funding small early-stage interventions that include a clearly defined biological "readout" of whether an intervention has hit its intended target (Insel, 2015). Interventions that fail to improve the target outcomes are discarded, saving valuable resources to test other promising interventions. To date, this method has been used in only one published study to test the effectiveness of psychiatric medications.

A set of three components of FOI IDEAS method



Methods

- A realist systematic review was undertaken, as this approach is capable of synthesizing a large and diverse selection of literature to make recommendations about what works for whom and under what circumstances (Pawson 2006). and specific to this review, for child health and development research.
- The rewards of realist review methods include the potential for more pragmatic conclusions compared to alternative approaches to systematic reviewing.
- This concept is captured succinctly as a "digging for nuggets approach" (Pawson, 2006b, p. 134). Thus, eligible sources include, for example, peer and non-peer reviewed studies, as well as internal program evaluations, and unpublished, but publicly available research reports.
- Key to the realist approach is the need for expert judgment and insight into the identification, selection, summary, and analysis of the identified literature during the review.
- Electronic databases including MEDLINE, PubMed, EMBASE, PsycINFO, CINAHL were searched using the search terms intervention(s), randomized control trial(s), rapid-cycling trial(s), fast-iteration research, fast-fail trial(s), in combination with the terms method(s)/methodology and design(s).
- Ancestry searches identified additional articles from retrieved papers' reference lists. Given the rapid pace of innovation in this field, grey literature, relevant reports, web pages, and conference presentations were also included in the retrieved materials.

Table 1. Included Sources: Peer-Reviewed Papers of Primary Studies

Study Identifier	Intervention characteristics	Participants	Method of Evaluation	Outcomes
Schindler, H. S., Fisher, P. A., & Shonkoff, J. P. (2017)	Filming Interactions to Nurture Development (FIND)	15 Fathers and their children	FOI IDEAS Method	Children's mean behavior problem scores decreased from 9.25 (SD = 3.55) at baseline to 8.33 (SD = 2.42) at posttest
Center on the Developing Child at Harvard University. (2016)	Descriptive paper on the rationale and development of method FOI IDEAS Method	Descriptive paper	FOI IDEAS Method	Descriptive paper
Johnson K, Gustafson D, Ewigman B. (2015)	Descriptive paper on the rationale and development of rapid-cycle research methods	Descriptive paper	Rapid-cycle research methods	Descriptive paper
Pickering, Herasevich, Ahmed & Gajic, (2010)	AWARE (Ambient Warning and Response Evaluation), an environment enhancement program in a tertiary care institution's ICU	8 patients	Rapid-cycle research methods	AWARE significantly improved the performance and efficiency of ICU patient work up as compared to standard electronic environments
Steven et al., 2014	Evidence-based Practice for Improving Quality (EPIQ) trial for quality improvement (QI) in NICUs	5812 infants born at ≤32 weeks' gestation and admitted to 19 level 3 NICUs	Rapid-cycle research methods	EPIQ trial (EPIQ, NICUs) reduced the incidence trend of nosocomial infection and bronchopulmonary dysplasia
Smith, J. D., Stormshak, E. A., & Kavanagh, K. (2015).	Pragmatic effectiveness-implementation hybrid trial of the Family Check-Up (FCU) conducted in 3 community mental health agencies	71 families	Pragmatic trial	Families in the FCU condition experienced significantly reduced youth conduct problems in comparison to usual care and completion of the FCU resulted in larger effects
Treweek, S., & Zwarenstein, M. (2009).	Descriptive paper comparing Pragmatic and explanatory trials	Descriptive paper	Pragmatic and explanatory trials	Descriptive paper
Zwarenstein, M. (2017).	Descriptive paper on the rationale and development of pragmatic and explanatory trials	Descriptive paper	Pragmatic and explanatory trials	Descriptive paper
Zwarenstein, M., Treweek, S., Gagnier, J. J., Altman, D. G., Tunis, S., Haynes, B. & Moher, D. (2008).	Descriptive paper on the rationale and development of pragmatic and explanatory trials	Descriptive paper	Pragmatic trials	Descriptive paper
Carlezon & Krystal, 2016	Kappa-opioid receptor (KOR) antagonists for the treatment of a variety of neuropsychiatric conditions, including depressive, anxiety, and substance abuse disorders	Descriptive paper	Fast-fail trials	Descriptive paper
Szabo et al., 2015	Maximum-tolerated dose (MTD) of belinostat administered prior to and in combination with cisplatin (P), doxorubicin (A) and cyclophosphamide (C) in thymic epithelial tumor	26 patients	Fast-fail trials	This study identified the MTD of belinostat in combination with PAC and indicates that the combination is active and feasible in TETS
Insel, T. R. (2015)	Psychiatric medications	Descriptive paper	Fast-fail trials	Descriptive paper

Conclusion & Limitations

- FOI IDEAS method is a better suited method to evaluate early intervention, as compared with other available accelerated methods that most likely rush the research-to-action cycle compromising the internal validity.
- FOI IDEAS method provides an evidence-based method to identify and understand key factors operating during intervention evaluation to increase methodological rigor and internal validity. Likewise, this method enables research teams to test the effectiveness of interventions in different contexts because of the flexibility and short duration of micro-trials.
- However, FOI IDEAS method is a relatively new method and still needs to be further evaluated by conducting future studies.
- Despite this fact, the significant advantages of employing this method make it a preferred choice for evaluating innovative interventions akin to the ATTACH intervention. In turn, this approach may also contribute significantly by way of provisions of personalized healthcare in more precise and cost-effective ways.

FOI IDEAS Method's Common Theory-of-change Template

