



Revisiting a non-significant findings study: A parent mentor intervention trial as exemplar



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ABSTRACT

The purpose of this paper is to describe an interactive process for revising a parent social support intervention study with non-significant quantitative findings but strong clinical significance. We will present the methodological challenges that were problematic in the original intervention that potentially contributed to the non-significant findings, and a revised plan of action for conducting a future parent social support intervention. Of note, we have reconsidered the theory used to frame the original study, the randomization process, the intervention clarity and fidelity plan, what measures would better capture the effect, and the development of a more robust analysis plan that considers intra-family correlation, mediation and moderation (mixed model analysis). We will present the revision for each of these methods supported by recent empirical literature. Although this process may not be appropriate for all non-significant interventions, it should be considered with any study that has clinical significance.

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“Many of life's failures are people who did not realize how close they were to success when they gave up.” – Thomas A. Edison

Thomas Edison's inspirational quote brings to mind the ‘file drawer problem,’ a phrase given to a phenomenon where the file drawer becomes the ‘home’ for 95% of studies completed that did not have significant findings (Rosenthal, 1979). Rosenthal indicated that journals primarily accept studies with statistically significant results (~5% of all studies conducted). This publication bias influences what we know and how we conduct future studies. For instance, when considering meta-analyses, which influences future funding, clinical recommendations, and policy, only significant findings are included. Thus, some of the unpublished non-significant findings could alter the *p* values and effect sizes (the estimate of the magnitude of the intervention on outcome variables) reported (Berman & Parker, 2002).

According to the Tufts Clinical Translational Science Institute (CTS) study phase criteria (2013) when non-significant findings occur it is suggested that researchers revisit the study in an iterative process to consider possible barriers that may have contributed to these results

(2013). This iterative process includes the following five steps for behavioral studies:

- 1) consider a different theoretical framework that better addresses the intended intervention (including mediators and moderators to better explain the effect of, and strength of the intervention) (Keller, Fleury, Sidani, & Ainsworth, 2009; Resnick et al., 2005);
- 2) consider an alternative randomization process, especially for interventions that are preference-directed (Coward, 2002; Sidani, Miranda, Epstein, & Fox, 2009);
- 3) develop a precise description of the dose and timing of the intervention and comparison group as well as a more precise intervention fidelity plan over the course of the study (Conn, 2009; Conn, Rantz, Wipke-Tevis, & Maas, 2001; Gross, 2005; Reed et al., 2007);
- 4) consider different measures based on the alternative framework (Keller et al., 2009);
- 5) consider effect sizes and a more robust analysis plan (Baron & Kenny, 1986; Mays & Melnyk, 2009)

In fact, ‘missing what was really there’ (Clark, 1996) is a commonly reported problem in intervention research where non-significant findings are countered by positive qualitative analysis with the study participants (Rearick et al., 2011). Too often hearing ‘I could have found something’ defeats the purpose of the fidelity of the study. We must remain as Clark states “conscientious about making sure we do not find what is not there.” Embracing non-significant findings is

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central to science and requires us to continue to be curious about what didn't emerge in the findings. To quote Neil Gershenfeld a director at MIT stated, "Truth is just a model. The common misperception about science is that scientists seek and find truth. They don't—they make and test models (Jha, 2011)." Thus, it may be a reasonable goal to revisit key components of theory-driven interventions with non-significant findings when clinical significance speaks to the efficacy of the recipients' perspectives.

Taking all of this information into consideration, we decided to use the iterative process outlined above (Tufts, 2013) and revisit a study that some would suggest stay in the file drawer due to non-significant quantitative findings. The study in question, STEP (social support to empower parents) was a fully powered randomized controlled trial (RCT) that matched parents of children newly diagnosed with type 1 diabetes (T1D) with a peer parent mentor (an experienced parent raising a child with T1D) who would provide social support as needed (Sullivan-Bolyai et al., 2010). The quantitative findings were non-significant; however, the qualitative findings strongly supported clinical significance (Rearick, Sullivan-Bolyai, Bova, & Knafel, 2011). We have been encouraged by the parents of children with T1D and our parent mentor community to consider other possible approaches and rework the intervention. In addition, the Cardiff University, Wales, Diabetes Team have been networking for several years with our team at the University of Massachusetts Medical School to develop a similar project for the parents in their clinic. The encouragement and collegiality has sparked common interests to further explore family focused parent support interventions.

Thus, the purpose of this article is to describe an interactive process for revising a study using the STEP study as a starting point. We will focus on several methodological challenges that were problematic in the original study that may have contributed to the non-significant findings. These changes include reconsidering a theory-driven intervention vs. original theoretical model that framed our study, preference-driven randomization, intervention clarity and fidelity, different measures, and a more robust analysis plan that considers intra-family correlation, mediation and moderation (mixed model analysis). We will present the revision for each of these methods supported by recent empirical literature.

1. Description of the STEP Study

In STEP (RCT) we carefully selected, consented and trained 10 (7 mothers and 3 fathers) parent mentors who were non-threatening, excellent at active listening, and raising children with T1D (using a parent mentor curriculum adapted from Ireys' (Ireys, Chernoff, DeVet, & Kim, 2001; Sullivan-Bolyai et al., 2010). They were trained to provide 1:1 social support peer mentorship (via visits, phone call and/or e-mail communication) that included informational, affirmational and emotional support over the course of 12 months. After training the mentors, we recruited, consented, and randomized 60 parents of children newly diagnosed with T1D from two pediatric diabetes centers in the northeast United States. The parent mentors provided social support to 32 mothers in the experimental arm. Control group parents (28 mothers) were given a phone number of a parent contact (an experienced parent who did not receive the parent mentor curriculum training) who they could call for support.

There were no statistically significant differences (Sullivan-Bolyai et al., 2010) between the two groups at any of the data points (3, 6, or 12 months) for parent concern, confidence, worry, impact on the family, or perceived social support. This occurred despite the fact that we (a) conducted a pilot study that suggested that the intervention was feasible and had potential efficacy (Sullivan-Bolyai et al., 2004), (b) used a theoretical framework to guide the intervention, (c) conducted a power analysis, (d) thoroughly trained all of the parent mentors, and (e) used reliable and valid measures.

However, there were positive qualitative findings through post-intervention interviews with those parents who received the intervention. So why then, did we not see quantitative differences when commonly we heard from parents "You need to offer this support to every parent with a child newly diagnosed"? Using the Tufts CTS five-point structure to consider these seemingly contradictory findings, we will present several areas in the research process that we want to revisit and test.

Furthermore, our lack of quantitative findings appear to be common and are reflected in a recent systematic review of peer parent support studies whereby seven quantitative and one mixed methods peer parent support intervention studies did not consistently substantiate its benefits (Shilling et al., 2013). Their recommendations include addressing many of the methodological challenges we plan to address in this article.

2. Theoretical framework and theory-driven interventions: An alternative approach

Theory is critical in the development and implementation of complex behavioral interventions. It helps target the problem at hand, and identify the variables or concepts that we want to influence, or change. It helps us craft the actual intervention, focusing on the critical inputs (the concepts at the heart of the intervention such as education, or social support) and the key ingredients (the actual activities that form the intervention, such as teaching something visually or providing a parent mentor who offers parents affirmational support) (Keller et al., 2009). Theory is critical in guiding our choice of measures and for attaining the specificity necessary to show change in outcome variables, especially with complex behavioral interventions in a family system where change may result in only small effect sizes (Baranowski, Lin, Wetter, Resnicow, & Davis, 1997; Hampson et al., 2000; Keller et al., 2009). Thus, if we are hoping to demonstrate an intervention effect, using rigorous specificity in development of the intervention is critical.

Theory provides the broader context for understanding the potential generalizability of results. Theory-driven interventions can also help predict behavioral changes, linking causal factors to help explain why and how some interventions may work better for targeting certain clinical outcomes through the use of mediator and moderator variables.

Thus, using theory to help define the problem, select possible variables that may mediate between the intervention and the outcomes, and/or moderate the intervention will help us determine what interventions work with a certain population, and help explain how it works.

Intervention mapping is an efficient approach to help determine how to best select a theory with variables of interest, and the key ingredients of the intervention (specific activities in the intervention) that result in dependent variable change (Conn et al., 2001). Mapping the intervention is being incorporated into the UK Cardiff team work in a feasibility study of parents mentoring families with a child recently diagnosed with T1D (Parent Listen Understand and Support (PLUS)). Whilst broadly following the STEP intervention model, this team is using a logic model format (Kellogg, 2004) to develop a framework that links the theoretical assumptions of the program with the outcomes (both short-term and long-term) and program activities and processes.

As we ponder the non-significant findings of STEP we must reconsider the theory that framed the study, that being Ireys Social Support Theory (Ireys, Chernoff, Stein, DeVet, & Silver, 2001). It may be that this theory was at too early a stage of development with limited empirical testing to use with a different sample ie parents at a different point in relation to the diagnosis. In Ireys' work the parent mentors worked with parents at least 1 year out from their child's diagnosis whilst in STEP their children were newly diagnosed with T1D.

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