Challenging the Concept that Scientific Based Research and Randomized Controlled Trials are the 'Gold Standard' Alternative Paradigms and Mixed Methodologies

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Introduction: This paper address three controversial issues related to mixed methods research and policy. First, 'Scientific Based Research' promoted by "NCLB" reinforces diametrically opposed paradigmatic views and research methodologies. As policy, NCLB prioritizes specific methodologies prescribing what counts as scientific evidence. Second, from a critical stance, federal policies shape and control decisions that funding agencies make regarding methodologies (RCT-gold Standard). Third, top down policies are currently framed in postpositivist ontological and epistemological conceptions and should include constructivist, critical, transformative and emancipatory paradigms supporting alternative methodologies (Christ, 2014). This paper challenges current practices of prioritizing specific research methodologies used to evaluate interventions. As an alternative, logical purpose statements and research questions should be the standard used to guide decisions about appropriate methodologies and procedures.

Shortcomings of SBR and RCT: Philosophical, methodological, and ethical considerations have impact upon all stages of 'Scientifically Based Research'. More specifically, paradigmatic, methodological, and ethical considerations influence the conduct of RCT's at every stage from planning, implementing, evaluating, and disseminating results designed to indicate the strength of causal relationships. The challenge faced by those interested in promoting SBR and RCT is that unless tightly controlled experimental conditions are put into place, human based research rarely follows preordained paths. Further, when placed into experimental conditions, humans rarely act as they normally would. In terms of deductive research and RCT designs, anomalies in intervention administration or working with humans in natural conditions, often introduces 'confounding variables' and 'error'. Creating a-priori research questions and following stringent implementation and analysis procedures might reduce error, but severely limits knowledge gained to specific 'operationally defined' measurable variables. Unless the research project is a large scale replication study, the methods associated with RCT are limiting at best and inappropriate at worst.

Constructivist Research and the RCT: When qualitative data is collected and compared to quantitative data, the term 'triangulation' is often cited (Denzin, 2012). Flick (2002, p.229) first voiced concern that "triangulation is not a tool or strategy of validation but an alternative to validation" which is best "understood as a strategy which adds rigor, breadth, complexity, richness". Themes that emerge from qualitative data do not always match, and may contradict statistical results which bring into question the epistemological soundness of RCT as the Gold Standard. Dahlberg, Wittink, and Gallo (2010) also recently questioned the absolute stance of a-priori postpositivist oriented research questions citing that they make experimental designs inflexible. Knowing if an intervention is statistically different from a control group is no more important than understanding the qualities, usefulness, and challenges inherent in the intervention to the participants in the study. Christ (2010), Teddlie and Tashakkori (2009), Greene (2007), and Creswell (2009) have all questioned the concept of determining absolutes or the ability to separate facts from values. Biesta (2010) and Maxwell and Mittapalli (2010) also address epistemological issues in their perspectives related to the nature of how knowledge is produced which challenges the wisdom of relying upon numerical data statistically analyzed as the primary source of answering research hypothesis so prominent in funded research. RCT that are funded often rely heavily upon observations and survey data which may not capture intended constructs or adequately measure intervention outcomes. Validated instruments, common to RCT interventions, often are administered to a population dissimilar for which the measure was norm referenced. With these and other challenges facing those who conduct RCT, why does it continue to hold a 'Gold Standard' in terms of funded research?

Conclusions:

Philosophical, methodological, and ethical considerations have impact upon all stages of Randomized Controlled Trials including planning, implementing, evaluating and disseminating results that indicate a causal relationship. Unless tightly controlled experimental conditions are put into place, human research rarely follows preordained paths as planned. Further, when placed into experimental conditions, humans rarely act as they normally would. In terms of deductive research and RCT designs, anomalies in intervention administration or working with humans in natural conditions, often introduces 'confounding variables' and 'error'. Creating a-priori research questions and following stringent implementation and analysis procedures may reduce error, but environmental constraints often change the behaviors humans would normally exhibit. Fortunately, blending deductive and inductive research in a single study, a complimentary strength mixed methods stance (Teddlie & Tashakkori, 2009) can offset the error inherent in RCT findings and expand the ability to impart knowledge by collecting and analyzing multiple forms of data to answer emergent research questions (Christ, 2013;2010;2007). The very nature of funding agencies promoting RCT's which prioritizes an etic research perspective, and quantitative rather than qualitative methods as promoted by Weisner (2005), is counterintuitive to the nature of the study of human behavior. RCT's as promoted by organizations such as the Institute for Educational Science are seen as most successful when based upon well developed theories that dictate operationally defined constructs and carefully articulated intervention components that use valid and reliable measures that adequately capture the constructs that they purport to measure. The intervention components and accompanying measures, according to IES criteria, should be administered in a controlled environment to reduce the possible introduction of unwarranted confounding variables that contaminate findings. Sample and effect size must also be calculated, taking into consideration participant attrition. Unexpected changes in the intervention components or participant attrition reduces the likelihood that if change was detected, it was not the result of a type 1 or type 2 error or confounding variables.

Even when a statistically significant difference is noted through appropriate statistical analysis, the majority of published Randomized Controlled Trials primarily answer if there was a significant group difference or the strength of the relationship, but do not show how or why the intervention affected change in the participants, nor if the intervention was applicable, or desirable to the stakeholders. Combined, the deductive and inductive research approaches provide a more complete and holistic understanding of the strengths and challenges associated with human intervention research. The only way that policy makers and funding agencies will change their rigid interpretations of what constitutes evidence, will be when numerous sound intervention studies that incorporate alternative methodologies and paradigms are successfully published in reputable journals. This will result in changes to the way standards and policies are created, and methodologies are used in the social sciences.