Low-Cost RCTs: Applications for Home Visiting Programs

HARC
Home Visiting Applied Research Collaborative

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The Home Visiting Applied Research Collaborative (HARC) is a national research and development platform for innovation to broaden and strengthen home visiting's benefits for all families and communities. One of our hallmarks is *efficiency*, meaning we promote innovative research designs and methods that can more quickly produce results which can be used to inform practice and program improvement. This brief highlights one efficient method, low-cost randomized controlled trials (RCTs). The brief provides examples of low-cost RCTs in home visiting, describes frequently encountered challenges, and shares data sources that may be useful to those interested in conducting a low-cost RCT.

What is an RCT?

A randomized controlled trial (RCT) is a study in which a group of identified participants is randomly assigned to an intervention or control group.[1] It is generally viewed as the most rigorous, gold-standard approach for assessing the effects of an intervention. While rigorous, these studies can be costly (over $2.8 million), resource-intensive, and sometimes impractical or even infeasible.

WHAT IS A LOW-COST RCT?

A low-cost RCT is an efficient approach to test program impacts which typically either leverages *existing data* to evaluate a new program OR collects new data on an *existing program*. These approaches typically result in lower costs relative to a traditional home visiting RCTs,[3] which can cost upwards of $3 million. In contrast, low-cost RCTs can cost $300,000 or less.[4]

TRADITIONAL RCTS: BENEFITS AND CHALLENGES

Benefits

Well-designed RCTs are generally viewed as a gold standard approach to test for the effect of an intervention. This is because RCTs allows us to assume that intervention and control groups are similar on factors that may be relevant to the outcome, making the only difference between the two groups the exposure to the intervention.[5] We can thus conclude more strongly that the intervention was the cause of the change in the outcome.[6]

Challenges

While RCTs are viewed as a strong program evaluation method, they come with some key challenges. The most prominent of these is that traditional RCTs can be resource intensive, both in terms of human and financial resources, and may therefore be able to accommodate fewer study participants, cover a smaller geographic region, or collect data for shorter durations compared to other studies as a result.[5] In the context of home visiting, RCTs may also be deemed unethical, since be design an RCT requires that some individuals do not have access to a potentially beneficial program or intervention.[5] Additionally, because RCTS often have narrow or strict eligibility criteria (for example, in home visiting, relating to progress in the pregnancy upon enrollment, various

maternal characteristics such as income or maternal age, number of children, place of residence, etc.), results may not be generalizable to larger populations.[5]

STRATEGIES FOR CONDUCTING LOW-COST RCTS

There are two general strategies that can be used to conduct low-cost RCTs: using existing data and evaluating existing programs. Each of these strategies can be used alone or in combination to decrease costs while leveraging benefits of the RCT evaluation design.

Strategy 1: Use Existing Data[3]

Evaluators can use existing data to explore effects of a new program. Existing data can provide information on participant and community characteristics, program implementation, and/or program outcomes. When linked to participants (randomized to control and intervention conditions either before or after study conceptualization), existing data can be used to track and compare participant outcomes over time, minimizing the need for resource-intensive, concurrent data collection processes associated with traditional RCTs. Sources of existing data may include administrative data or data from government-administered surveys or monitoring systems.

Strategy 2: Evaluate Existing Programs[3]

Another approach to conducting a low-cost RCT is to evaluate a program that already operates; in other words, the program is funded prior to conceptualization of the RCT. Thus, program costs are covered by the implementing organization, and evaluators only need to obtain funding to fulfill the required randomization procedures, data collection, and evaluation aims. This strategy may rely on either existing or newly collected data, or a combination of the two.

EXAMPLES OF LOW-COST RCTS

Below are some examples of low-cost RCTS in the literature.

- The **South Carolina Positive Parenting Program (Triple P)** used existing administrative data to evaluate the impact of the program on child maltreatment. The study randomized 18 South Carolina counties to receive either the Triple P intervention or control condition. The intervention reduced child maltreatment, child hospital visits related to maltreatment, and foster care placements.[3,4,7]
- **Durham Connects**, a postnatal nurse home visiting program, used a low-cost, large-scale RCT to assess program impact on infant emergency medical care. Evaluators used hospital administrative records to measure child health expenditures and emergency department use through the child's second year. Findings revealed that intervention families used less emergency medical resources than families in the control group.[6,8]

HARC recently shared a scoping review of home visiting research which linked home visiting program records and administrative data.[2] This review includes RCTs, in addition to other types of study designs. While RCTs described in this brief might give insights into the process of conducting a low-cost RCT directly, this scoping review provides information on possible data sources to draw on to capture outcomes while potentially reducing data collection costs.

- In 2016, data from three **Nurse-Family Partnership** RCTs completed between 1978–2015 were linked with vital statistics data from the National Death Index to assess maternal and child mortality. Analyses suggested decreased external-cause mortality (defined in the study as unintentional injuries, suicides, drug overdose, homicide) for mothers across all three trials, a finding which approached statistical significance (p=0.054). This study design allowed investigators to answer a novel research question while leveraging existing data.[9]
- Data from an RCT of the **Healthy Families Oregon** home visiting model were linked via probabilistic matching to state administrative databases to assess potential effects of home visiting program enrollment on child maltreatment reports and enrollment in public assistance and substance use treatment programs. The study found that there were no observed differences between the home visiting and control groups in substantiated child abuse reports, but home visited families were more likely to be enrolled in public assistance and substance use treatment programs.[10]

CHALLENGES WITH LOW-COST RCTS

- Low-cost RCTs may be limited by the quality of existing data.[3] Administrative data may not include measures of interest and may not include all members of the population it targets, [11] making data linkage difficult.
- As with any study, when conducting a low-cost RCT, you will need to ensure that participants have provided approval for data to be used for the evaluation.
- It may be necessary to navigate potentially lengthy or complicated administrative procedures to access data. Acquiring data may require time-consuming data sharing agreements, especially when requesting data from organizations with more limited data infrastructure or sharing/access processes.
- Using existing data may require substantial data cleaning and exploration to prepare data to fit evaluation objectives. Most notably, a researcher will be limited to the outcomes available in the existing data source, so it might not be possible to use the most ideal measure of the desired outcome.

For more information on and guidance regarding the process, necessary resources, and time needed for data sharing in home visiting research, please see this HARC brief.[12]

OUTCOME VARIABLES AND DATA AVAILABLE FOR LOW-COST RCTS

Many low cost RCTs use existing data to measure outcomes. Below are the eight outcome domains acknowledged by the U.S. Department of Health and Human Services Home Visiting Evidence of Effectiveness (HomVEE)[i] initiative and potentially relevant data sources.[13] Of note, each state has

[i] HomeVEE is a project led by the Administration for Children and Families which reviews, assesses, and synthesizes available research to evaluate the effectiveness of home visiting programs and determine which home visiting models are considered evidence-based per U.S. Department of Health of Health and Human Services (HHS) criteria.

administrative data that may be useful in low-cost RCTs. This resource contains potentially useful administrative data sources at both U.S. and state levels.[14]

Table 1. Example Secondary Data Sources for Linkage with RCT Data

HomVEE Outcome Domains	Potential Variables and Data Sources
Child Development and School Readiness	• Graduation rate: school data • Standardized test scores: school data
Family economic self-sufficiency	• Employment: Unemployment insurance records, National Directory of New Hires, Census (neighborhood-level) • Public assistance program participation: State administrative records, Census (neighborhood-level)
Maternal Health	• Risk: Maternal Vulnerability Index • Mortality: National Death Index
Reductions in Child Maltreatment	• Child maltreatment: Child Protective Services administrative data • Child injury: Child hospital visit related to maltreatment/ hospital records
Child Health	• Emergency medical care: administrative records from hospitals, Medicaid claims data • Gestational age, birth weight: birth certificate data • Child mortality: National Death Index
Linkages and Referrals	• Home visiting administrative data
Positive Parenting Practices	• Home visiting administrative data
Reductions in Juvenile Delinquency, Family Violence, and Crime	• Crime: FBI Crime Data Explorer (community level), arraignment records

CONCLUSION

Low-cost RCTs are a potentially financially viable and efficient alternative to traditional RCTs. While there may be some limitations associated with low-cost RCTs compared to their traditional counterparts, they can serve as a feasible option for increasing the evidence base for a particular home visiting model and leveraging reliable and readily available data sources.

SUGGESTED CITATION

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