Using Experimental Case Designs to Evaluate and Develop Culturally Sensitive and Responsive Interventions

Dallas Elgin, PhD (delgin@rti.org)
Ty Ridenour, PhD (tridenour@rti.org)
Kineka Hull, PhD (khull@rti.org)
Laurie Hinnant, PhD (hinnant@rti.org)
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COVID-19 has helped to emphasize the need to address health equity in public health programs.

Program evaluations now need to reflect this priority and be responsive to it.

Many existing methods – while rigorous – fall short in being sensitive to health equity and today’s evaluation needs.
Intersectionality that May Impact Evaluation

- Gender Identity
- Sexual Identity
- Sexual Orientation
- Race
- Nationality
- Socioeconomic status
- Education Level
- Religious affiliation
- Ability (physical, mental, emotional)
- Age
- Regional identity
- Looks/Sounds (accents)
## Public Health Evaluation Gaps

<table>
<thead>
<tr>
<th>Increase representation of marginalized populations and hard-to-reach communities in evidence-based interventions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be designed and fielded quickly.</td>
</tr>
<tr>
<td>Can yield findings in a timely manner.</td>
</tr>
<tr>
<td>Can be conducted with smaller sample sizes.</td>
</tr>
<tr>
<td>Are sensitive to cost and budget limitations.</td>
</tr>
<tr>
<td>Minimize burden on local entities and groups involved in the evaluation.</td>
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</tbody>
</table>
Addressing Gaps

- For programs to be culturally sensitive and responsive, innovations in evaluation design are required.

- Recent innovations in experimental case designs offer key benefits including:
  - the ability to employ within-subject experimental methods in communities and populations with small samples;
  - conduct experimental evaluations with reduced time and costs;
  - and provide increased representation of marginalized and hard-to-reach communities in developing evidence-based interventions.
Limitations of RCTs and Other Designs

**RCTs are the basis for many gold standard approaches to program evaluation.**

- Well-documented strengths related to limited assumptions, establishing balance on observables and unobservables, and estimating causal effects.

**At the same time, RCTs are limited to specific research scenarios.**

**RCTs typically:**

- Underrepresent racial and ethnic minorities and underserved communities
- Require large sample sizes
- Are expensive
- Rely on data that are typically collected 3-6 months after treatment
Limitations of RCTs and Other Designs

Methodological requirements and limitations can result in RCTs being prohibitive or infeasible for many interventions.

- Largely for these reasons, the vast majority of programs in local communities, states and provinces, and countries are never evaluated” (Kazdin, 2021).

Rapid Cycle Evaluations are often proposed as an alternative to RCTs.

- They provide timely information on intervention effects but at the expense of rigor.
ECDs: Overview and History

ECDs encompass a body of experimental methods that have been used for over 50 years in psychology, education, medicine, and other fields

- Also known as Single Case Designs, N-of-1/N=1, Within-Subject, and Idiographic Clinical Trials

Despite a lengthy history, more widespread use has been hindered by:

- Limited instruction in social and biological science graduate programs
- Historical reliance on visual inspection and exclusion of statistical testing
- Lack of power analysis techniques
- Lack of established design standards
ECDs: Overview and History

ECDs encompass a body of experimental designs with the goal of assessing causal relationships between interventions and outcomes.

General requirements:

- **Cases (individuals or groups) are repeatedly assessed**
- **One or more outcomes**
- **Baseline and intervention phases**
- **Stability of performance**

Source: Lobo et al., 2017
ECDs: Benefits and Opportunities for Health Equity Research

In contrast to RCTs, ECDs provide critical, innovative opportunities to:

- Conduct rigorous evaluations of culturally sensitive and responsive interventions
- Identify those interventions that promote greater equity

Critical strengths of ECDs include:

- Ability to conduct rigorous evaluations in samples and communities with small numbers of persons
- Less funding and time to complete compared with RCTs
- Ability to conduct evaluations within “real-world” settings
- Ability to more closely link treatment/intervention exposure to outcomes
- Opportunity to develop and test “precision treatments”
- Increased representation of racial and ethnic minorities and underserved communities in developing evidence-based treatments
Prominent ECDs: Multiple Baseline

- Multiple Baseline Design: Multiple cases entering baseline at the same time, with each case entering the intervention phase at staggered times
  - Most common method - 69% of ECDs (Smith, 2012)

- Cases can be:
  - Multiple units with the same behavior in similar contexts
  - Same unit with multiple behaviors
  - No limit on the number of cases

- Factors affecting strength of the design
  - Number of cases (3 or more with 2 phases each)
  - Number of data points per phase (4 or more)

Source: Ridenour et al., 2017
Prominent ECDs: Treatment Reversal/Withdrawal

- **Design:** Characterized by a given case alternating between phases without and with intervention
  - ABAB design

- Most appropriate for interventions where the impact reverses/decays at removal

- Intervention’s impact is ideally seen at each phase change

- Factors affecting strength of the design
  - Number of phases (4 or more)
  - Number of data points per phase (3 or more)

Source: Lobo et al., 2017
Recent Advancements in ECDs

- Recent methodological advances have greatly improved the rigor of ECDs and provide key opportunities for conducting rigorous evaluations of culturally sensitive and responsive evaluations
  - Development of standards for rigorous designs
  - Meta-analysis
  - Design-comparable effect sizes
  - CONSORT Diagrams and power analysis
  - Rigorous statistical analysis (e.g., hierarchical linear models)
  - Community-level applications

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Hierarchical Model: N-of-1 Pilot Study to Test “Manual Pancreas”

Glucose mg/dL

Patient A

Patient B

Patient C

Patient D

From: Ridenour et al., 2013

www.rti.org
Hierarchical Model: N-of-1 Pilot Study to Test “Manual Pancreas”

From: Ridenour et al., 2013
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www.rti.org
Hierarchical Model: N-of-1 Pilot Study to Test “Manual Pancreas”

Aggregate Results

From: Ridenour et al., 2013
Hierarchical Model: Pilot Study to Increase Teen’s Glucose Testing

\[
\text{Daily Tests} = 1.9885 - 0.00501 \text{ (per day)} + 0.9805 \text{ (for Motivational Interviewing)} + 1.3240 \text{ (during Treatment phase)} - 0.06317 \text{ (per day of Treatment phase)} + 1.0430 \text{ (older teens during Treatment phase)} + 0.6598 \text{ (while receiving CS)} - 0.05378 \text{ (per day of Treatment phase for younger teens)}
\]

From: Raiff et al., 2016
# Emotions Preceding and Following Interpersonal Violence

## Table 4: Associations between relationship context measures and either TDV victimization or perpetration (N = 70)

<table>
<thead>
<tr>
<th>Relationship Characteristics</th>
<th>Victimization</th>
<th></th>
<th>Perpetration</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day Before</td>
<td>Same Day</td>
<td>Day After</td>
<td>Day Before</td>
<td>Same Day</td>
</tr>
<tr>
<td>Closeness</td>
<td>0.0689</td>
<td>−0.0510*</td>
<td>−0.0339†</td>
<td>0.0489</td>
<td>−0.0865</td>
</tr>
<tr>
<td></td>
<td>(0.03)</td>
<td>(0.02)</td>
<td>(0.02)</td>
<td>(0.02)</td>
<td>(0.02)</td>
</tr>
<tr>
<td>Commitment</td>
<td>0.0655</td>
<td>−0.0433</td>
<td>−0.0019</td>
<td>0.0317</td>
<td>−0.1166†</td>
</tr>
<tr>
<td></td>
<td>(0.03)</td>
<td>(0.02)</td>
<td>(0.02)</td>
<td>(0.03)</td>
<td>(0.06)</td>
</tr>
<tr>
<td>Trust</td>
<td>0.1132</td>
<td>−0.1321</td>
<td>−0.0126</td>
<td>0.0394</td>
<td>−0.0535</td>
</tr>
<tr>
<td></td>
<td>(0.03)</td>
<td>(0.08)</td>
<td>(0.02)</td>
<td>(0.03)</td>
<td>(0.03)</td>
</tr>
<tr>
<td>His Jealousy</td>
<td>0.1040</td>
<td>0.2754†</td>
<td>0.0117</td>
<td>0.0517</td>
<td>0.2151†</td>
</tr>
<tr>
<td></td>
<td>(0.04)</td>
<td>(0.08)</td>
<td>(0.01)</td>
<td>(0.04)</td>
<td>(0.05)</td>
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<tr>
<td>Her Jealousy</td>
<td>0.1335</td>
<td>0.2215†</td>
<td>0.0273</td>
<td>0.0949</td>
<td>0.1819</td>
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<td></td>
<td>(0.04)</td>
<td>(0.08)</td>
<td>(0.01)</td>
<td>(0.03)</td>
<td>(0.03)</td>
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<tr>
<td>His Instrumental Support</td>
<td>0.0439</td>
<td>0.1005†</td>
<td>−0.0067†</td>
<td>0.0688</td>
<td>0.0648†</td>
</tr>
<tr>
<td></td>
<td>(0.03)</td>
<td>(0.08)</td>
<td>(0.01)</td>
<td>(0.03)</td>
<td>(0.06)</td>
</tr>
<tr>
<td>Her Instrumental Support</td>
<td>0.0676</td>
<td>0.1779†</td>
<td>0.0027†</td>
<td>0.1240</td>
<td>0.1199†</td>
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<tr>
<td></td>
<td>(0.03)</td>
<td>(0.08)</td>
<td>(0.01)</td>
<td>(0.03)</td>
<td>(0.06)</td>
</tr>
<tr>
<td>His TDV</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.0923</td>
<td>0.4993†</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>(0.02)</td>
<td>(0.05)</td>
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<tr>
<td>Her TDV</td>
<td>0.1007</td>
<td>0.6152†</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td></td>
<td>(0.02)</td>
<td>(0.08)</td>
<td></td>
<td></td>
<td></td>
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</table>

All coefficients reached p < .05 level of statistical significance. Parenthetical values are standard errors. Within the “Day Before” and “Same Day” columns, events of TDV (victimization or perpetration) are the dependent variable whereas TDV is the independent variable in “Day After” columns. † This aggregate (or “fixed”) effect varied significantly among participants (i.e., was a significant random effect).
Adverse Community Experiences and Resilience in Milwaukee

- Adverse Community Experiences and Resilience (ACE|R) prevention framework
  - Three strategies:
    - Equitable opportunities (e.g., restorative practices)
    - People and norms (e.g., social norms)
    - Places (e.g., transportation)
- Community engagement to meet local priorities
- *Idiographic Clinical Trial:*
  10 communities randomized to ACE|R or “care-as-usual”
- Outcomes (monthly):
  - Violence (e.g., police data)
  - Child maltreatment (e.g., DCF)
  - Fighting (school suspensions)
- Additional “control” communities to be identified

Funded by CDC Grant# R01 CE003191
Unconditional ICC = 1
Conditional ICC = 0.088
RMSE = 0.1645364

Linear mixed-effects model fit by maximum likelihood
AIC   BIC   logLik
18244.08 18286.86 -9114.039

Random effects:
Formula: ~Observation_Sequence | Patient_ID
Structure: General positive-definite, Log-Cholesky parametrization
StdDev    Corr
(Intercept)          28.6891090  (Intr)
Observation_Sequence  0.1261112   -0.534
Residual            84.9416238

Fixed effects: A1C_Glucose ~ Observation_Sequence * Phase
Value Std.Error   DF  t value  p-value
(Intercept)                   270.59448 16.015814 1546 16.895455       0
Observation_Sequence           0.47126  0.098499 1546  4.784419       0
Phase1                          -76.62388  8.854657 1546  -8.653511       0
Observation_Sequence X Phase1  -0.61277  0.090139 1546  -6.798085       0
Correlation:
(Intr) Observation_Sequence  -0.038
Phase1                        -0.352   -0.441
Observation_Sequence X Phase1 -0.297  -0.695   0.266
### Study Design

**Analysis Name:** EG Power Wittenborn  
**Analysis Description:** Norms Based on Junior et al., 2018

<table>
<thead>
<tr>
<th>Number of Subgroups to Compare</th>
<th>Number of Study Phases</th>
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<tbody>
<tr>
<td>2</td>
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<table>
<thead>
<tr>
<th>Time Centering</th>
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<tbody>
<tr>
<td>Centered</td>
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</table>

### Outcome Measurement and Factors

**Proportion Error Variance:** .3

### Power Analysis Setting

<table>
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<th>Number of Bootstrap</th>
<th>Type I Error Rate</th>
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</table>

<table>
<thead>
<tr>
<th>AIC</th>
<th>BIC</th>
<th>LL</th>
<th>DF</th>
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</thead>
<tbody>
<tr>
<td>259.929</td>
<td>284.503</td>
<td>-124.965</td>
<td>5.000</td>
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### Fit Metric

<table>
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<tr>
<th>Predictor</th>
<th>Mean Estimates</th>
<th>SE Estimates</th>
<th>Power</th>
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</thead>
<tbody>
<tr>
<td>group2_phase1_slope</td>
<td>0.172</td>
<td>0.001</td>
<td>1.000</td>
</tr>
</tbody>
</table>

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From: Tueller, Ramirez, & Ridenour, 2021
PersonAlytics Power Analyses: Monte Carlo Simulations

Note: Each dot represents an averaged simulations across 43 design factor combinations. Power curves are not monotonic due to estimates being aggregated across other design features: proportion of observations in the baseline phase, rare disease population size, and proportion of intraindividual variability due to residual error.
Would you like more information regarding ECDs? Send us your contact information so we can stay connected!

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