Tech Talk

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

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Overview of Presentation

- Gaps in Advancing Health Equity
- Gaps of Randomized Controlled Trials (RCTs) and Other Designs
- Experimental Case Designs (ECDs): Overview and History
- ECDs: Benefits and Opportunities For Health Equity Research
- Prominent ECDs
- Recent Advancements in ECDs
- Examples of ECDs Used by the Presenters For Health Equity Research
- Questions

Health Equity as an Evaluation Priority

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

Increase representation of marginalized populations and hard-to-reach communities in evidence-based interventions.

Can be designed and fielded quickly.

Can yield findings in a timely manner.

Can be conducted with smaller sample sizes.

Are sensitive to cost and budget limitations.

Minimize burden on local entities and groups involved in the evaluation.

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:

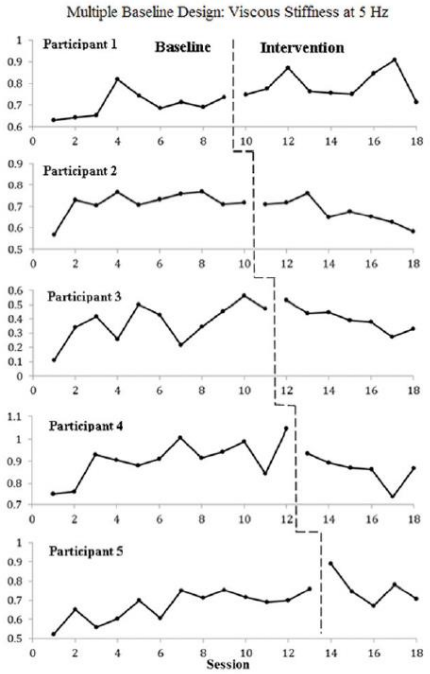
- Limited instruction in social and biological science graduate programs
- Historical reliance on visual inspection and exclusion of statistical testing
- Lack of power analysis techniques
- Lack of established design standards

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:

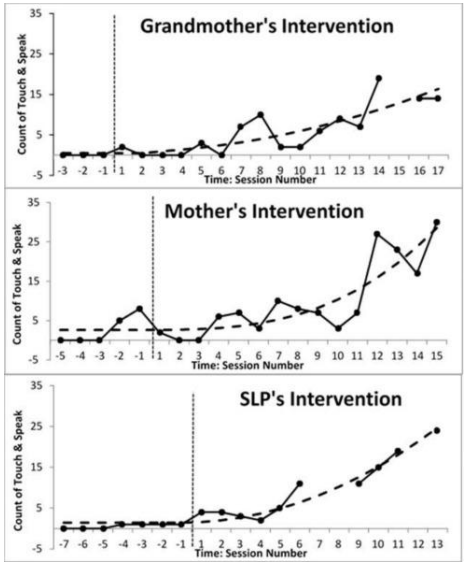
- Ability to conduct rigorous evaluations in samples and communities with small numbers of persons
- Less funding and time to complete compared with RCTs
- Ability to conduct evaluations within “real-world” settings
- Ability to more closely link treatment/intervention exposure to outcomes
- Opportunity 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

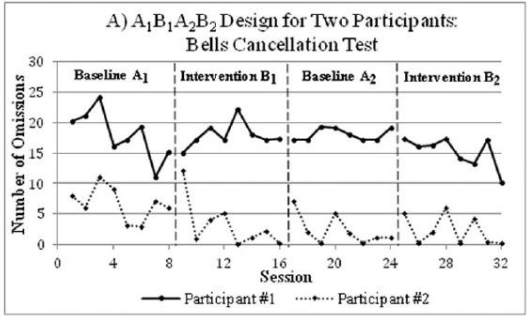
- Factors affecting strength of the design
  - Number of cases (3 or more with 2 phases each)
  - Number of data points per phase (4 or more)

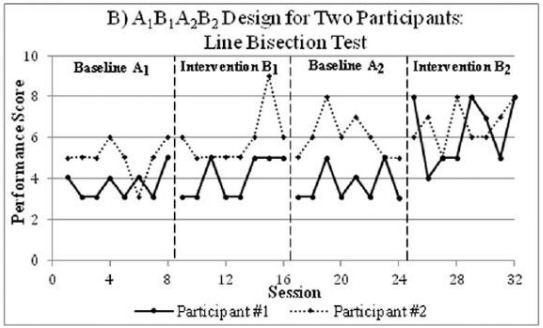


Source: Ridenour et al., 2017

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)



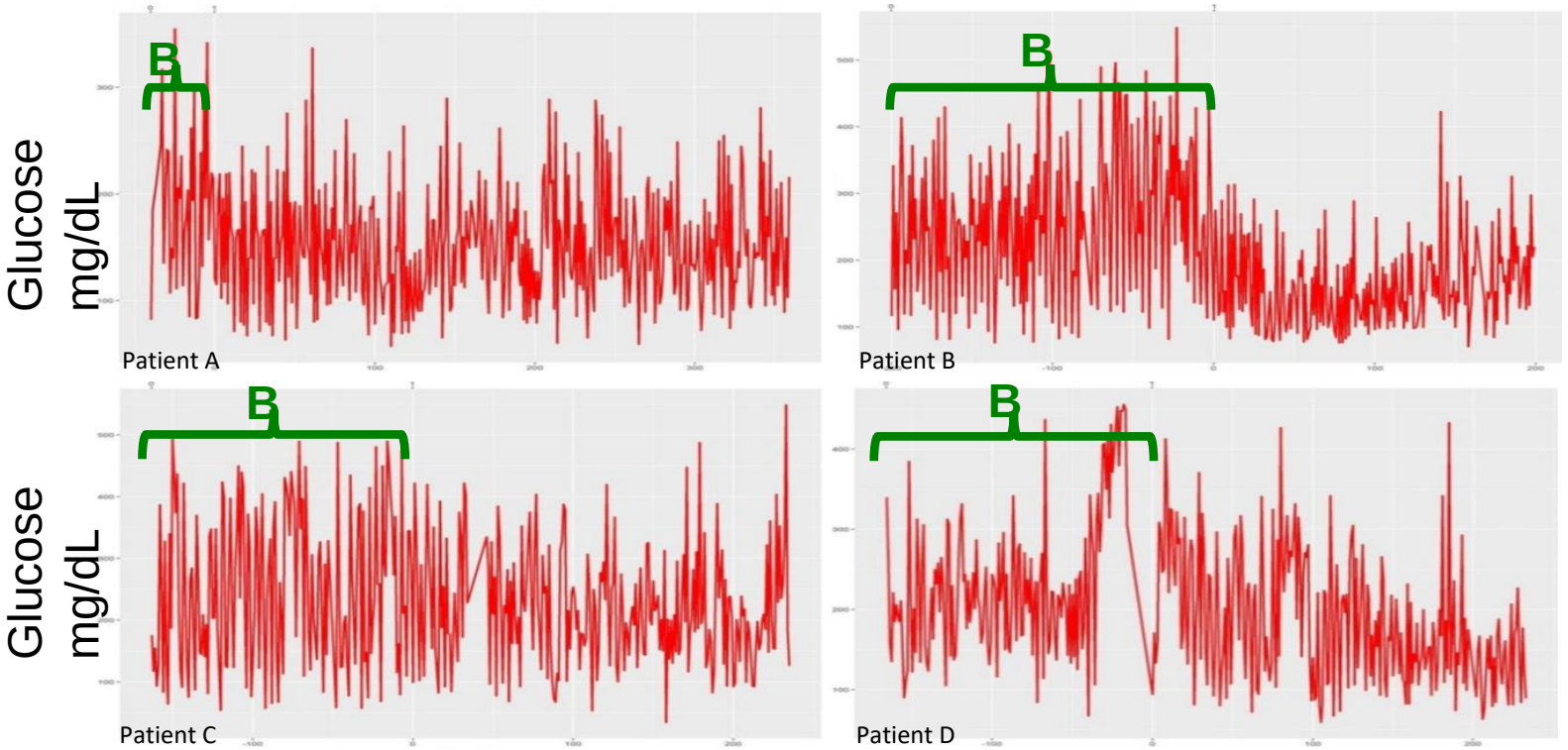


Source: Lobo et al., 2017

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

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



From: Ridenour et al., 2013

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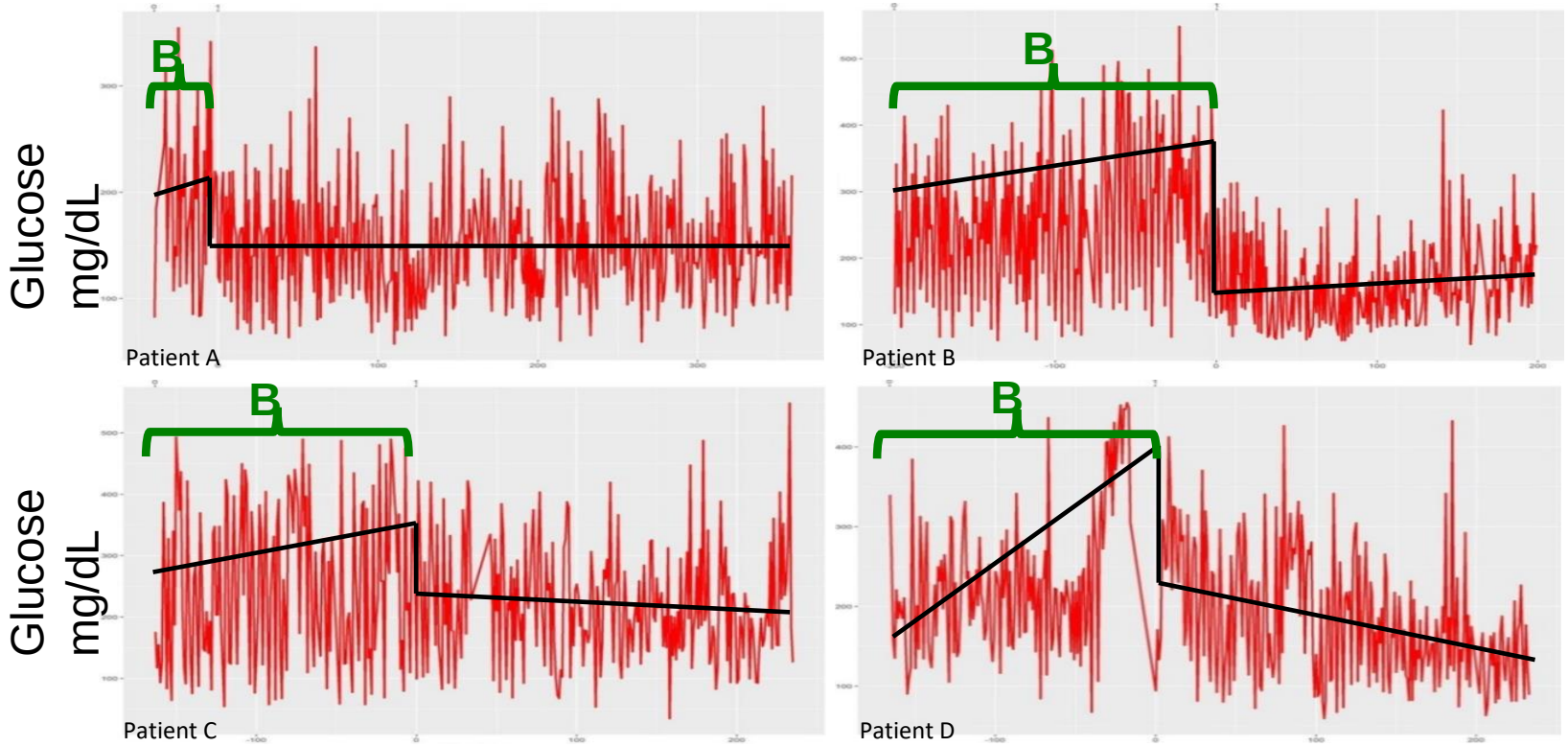

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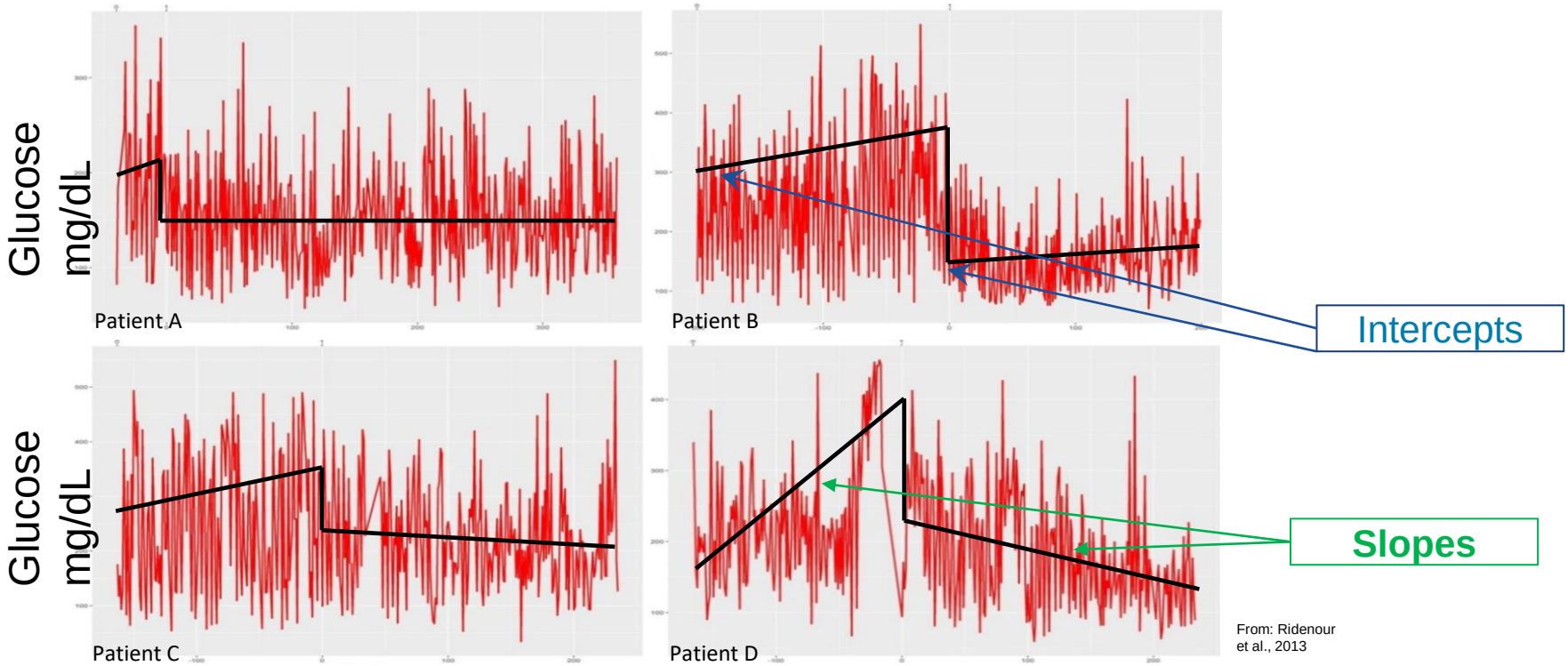

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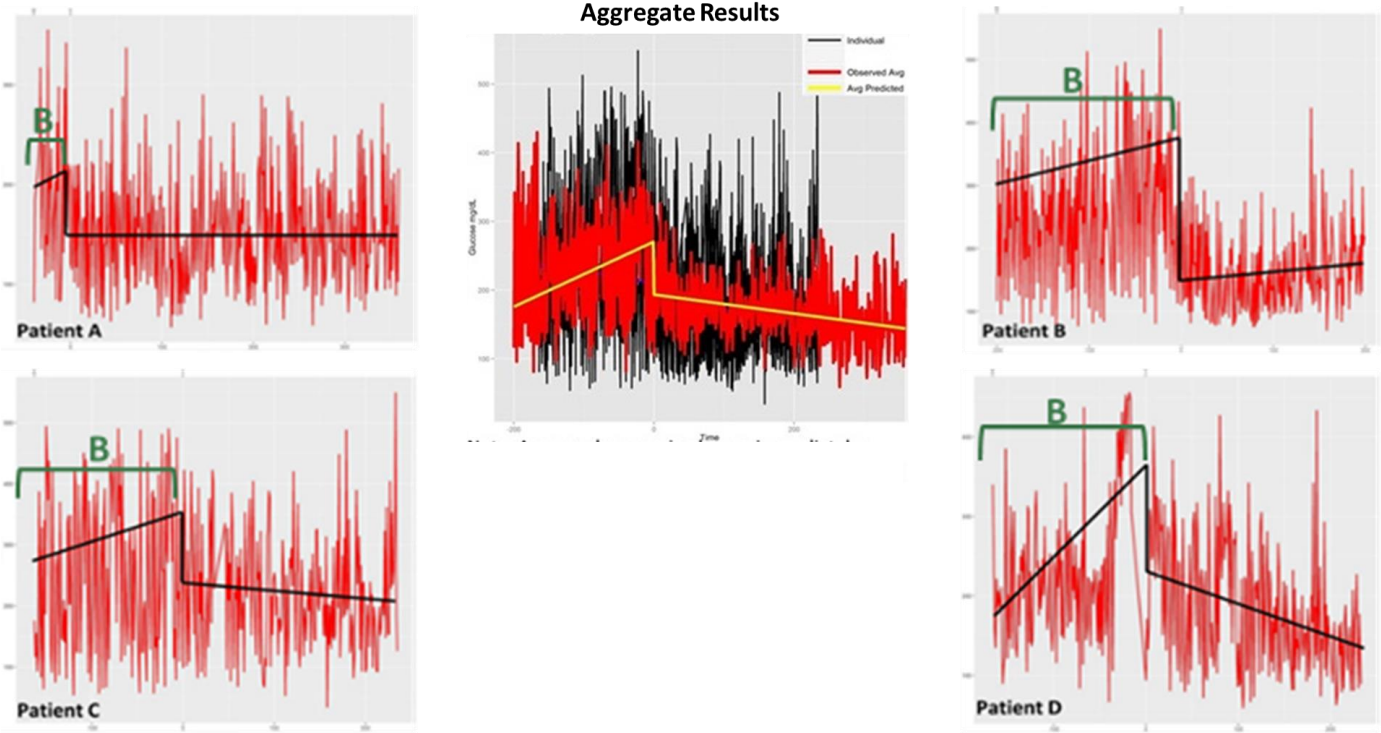
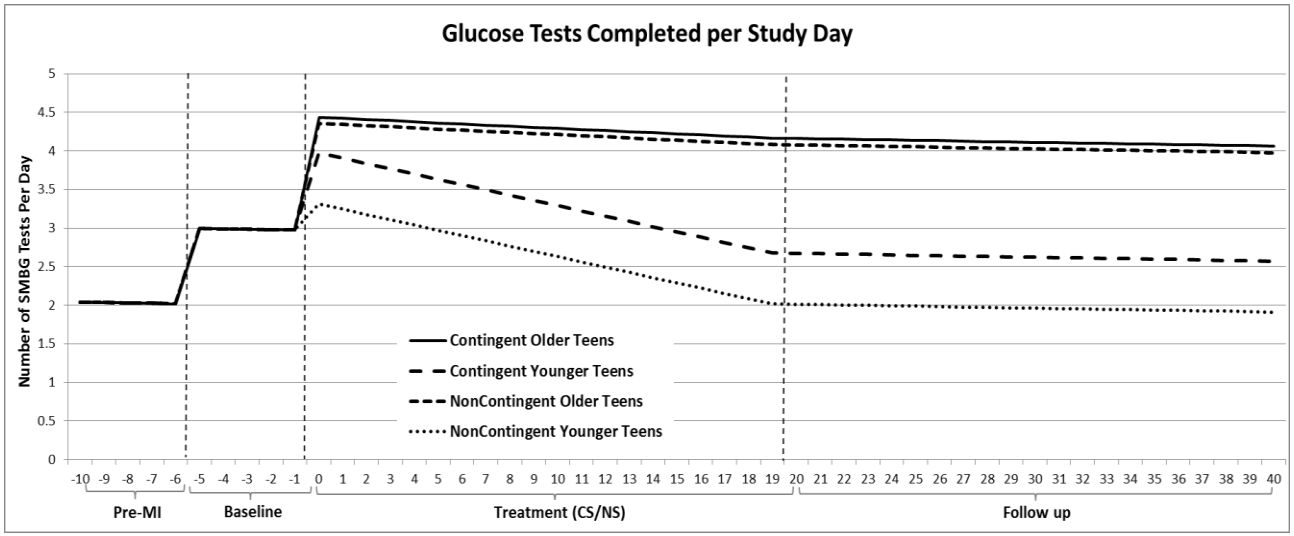


From: Ridenour et al., 2013

Hierarchical Model: Pilot Study to Increase Teen's Glucose Testing



Daily Tests = 1.9885 - 0.00501 (per day) + 0.9805 (for Motivational Interviewing) + 1.3240 (during Treatment phase) - 0.06317 (per day of Treatment phase) + 1.0430 (older teens during Treatment phase) + 0.6598 (while receiving CS) – 0.05378 (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 ($N = 70$)

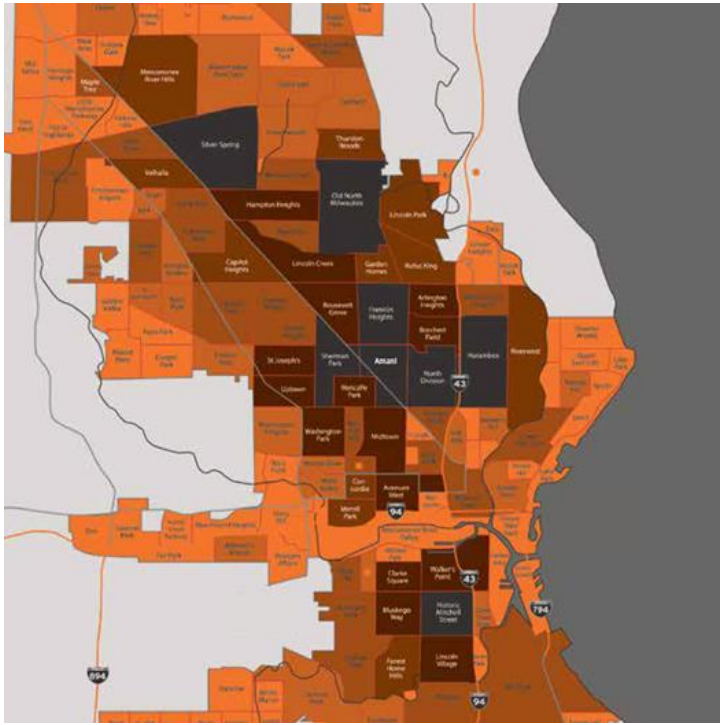
Relationship Characteristics	Victimization			Perpetration		
	Day Before	Same Day	Day After	Day Before	Same Day	Day After
Closeness	0.0689	−0.0510†	−0.0339†	0.0489	−0.0865	−0.0179†
	(0.03)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)
Commitment	0.0655	−0.0433	−0.0019	0.0317	−0.1166†	0.0123†
	(0.03)	(0.02)	(0.02)	(0.03)	(0.06)	(0.02)
Trust	0.1132	−0.1321	−0.0126	0.0394	−0.0535	0.0097†
	(0.03)	(0.08)	(0.02)	(0.03)	(0.03)	(0.01)
His Jealousy	0.1040	0.2754†	0.0117	0.0517	0.2151†	0.0094
	(0.04)	(0.08)	(0.01)	(0.04)	(0.05)	(0.01)
Her Jealousy	0.1335	0.2215†	0.0273	0.0949	0.1819	0.0276
	(0.04)	(0.08)	(0.01)	(0.03)	(0.03)	(0.01)
His Instrumental	0.0439	0.1005†	−0.0067†	0.0688	0.0648†	0.0340
Support	(0.03)	(0.08)	(0.01)	(0.03)	(0.06)	(0.01)
Her Instrumental	0.0676	0.1779†	0.0027†	0.1240	0.1199†	0.0349
Support	(0.03)	(0.08)	(0.01)	(0.03)	(0.06)	(0.01)
His TDV	–	–	–	0.0923	0.4993†	–
				(0.02)	(0.05)	
Her TDV	0.1007	0.6152†	–	–	–	–
	(0.02)	(0.08)				

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

PersonAlytics™

Analysis Info

Analysis Name:

GlucoseControl1

Analysis Description:

Test for Glucose Reduction from Humalog Bolus Doses

Input Variables

Variable that identifies participants

Patient_ID

Outcome/Dependent Variable:

A1C_Glucose

Treatment/Experimental Phases:

Phase

Baseline Phase:

0

Time Variable:

Observation_Sequence

Subgrouping Variable:

Age

How are missing data coded?

Leave this field blank if missing values are not denoted by numbers, characters, or symbols. If multi

```
##############################################################################
OUTPUT
##############################################################################
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) Obsr_S Phase1
Observation_Sequence             -0.038
Phase1                           -0.352 -0.441
Observation_Sequence X Phase1 -0.297 -0.695  0.266
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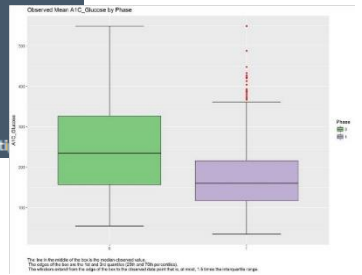
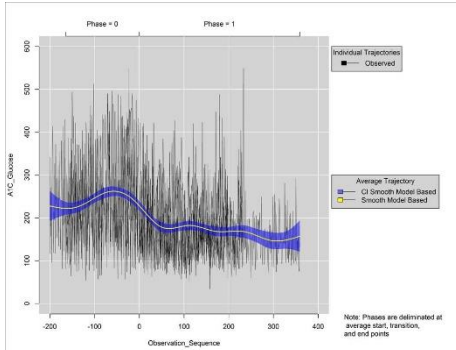
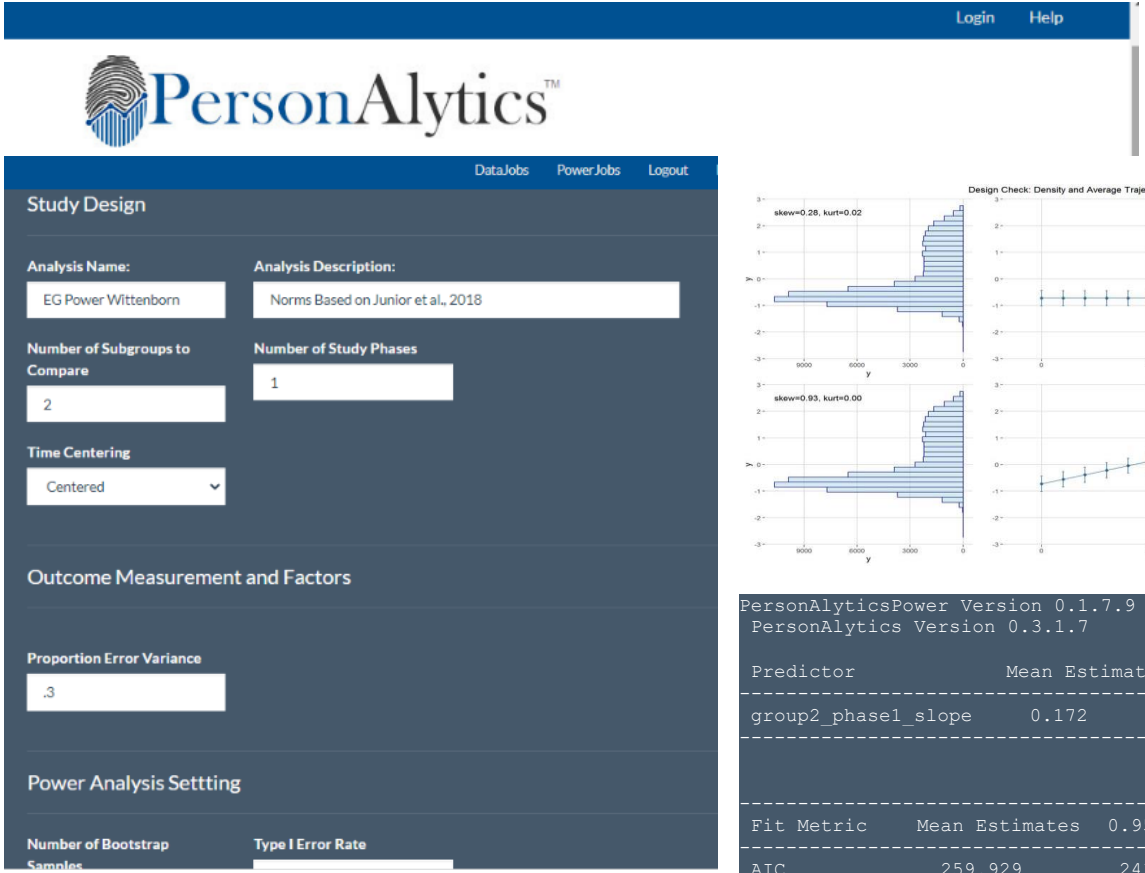




From: Tueller, Ramirez, & Ridenour, 2021



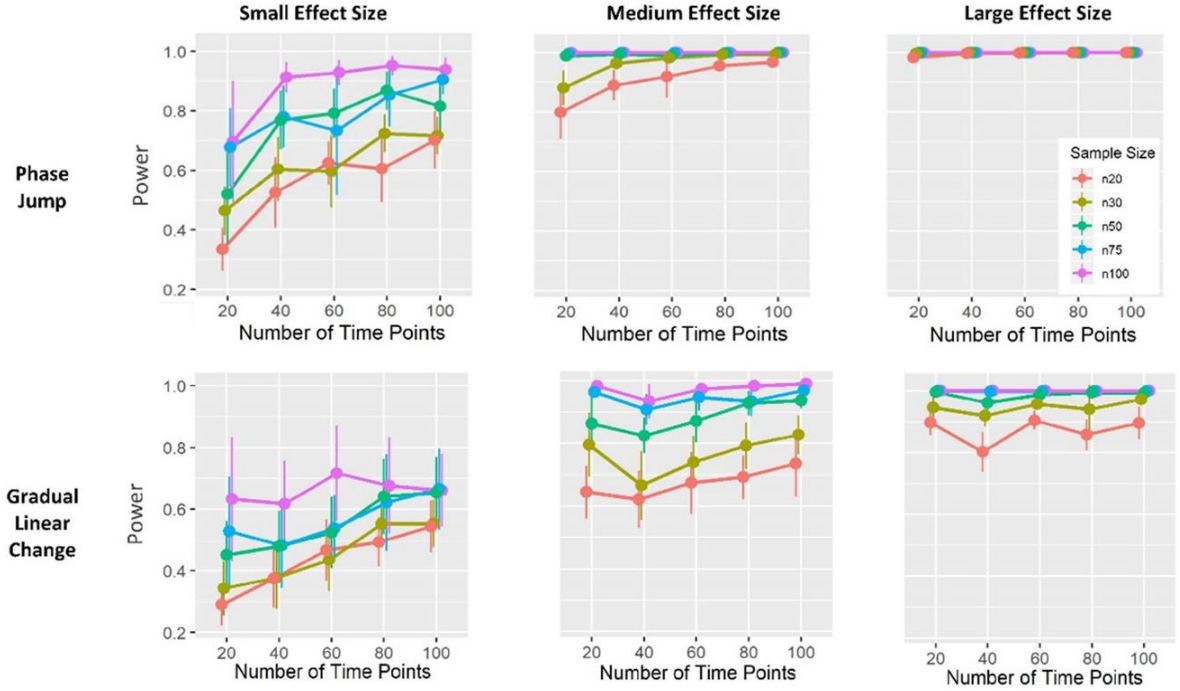

```
PersonAlyticsPower Version 0.1.7.9
 PersonAlytics Version 0.3.1.7

 Predictor             Mean Estimates  SE Estimates    Power
-------------------------------------------------------------
 group2_phase1_slope      0.172           0.001          1.000
-------------------------------------------------------------


-------------------------------------------------------------
 Fit Metric     Mean Estimates   0.95 CI Lo      0.95 CI Up
-------------------------------------------------------------
 AIC              259.929          243.848         267.922
 BIC              284.503          268.422         292.496
 LL              -124.965         -128.961        -116.924
 DF                5.000            5.000           5.000
-------------------------------------------------------------
```

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.

Questions

Would you like more information regarding ECDs? Send us your contact information so we can stay connected!