Advanced Topics in the Design and Analysis of SMARTs, Part II

Module 7
Outline

- Organizational-level Adaptive Interventions and Clustered SMART Studies
- Pilot Studies in Adaptive Interventions Research
- Seemingly-restricted SMART Studies
- Business-as-usual “control” conditions in SMARTs
Outline

• **Organizational-level Adaptive Interventions and Clustered SMART Studies**
• Pilot Studies in Adaptive Interventions Research
• Seemingly-restricted SMART Studies
• Business-as-usual “control” conditions in SMARTs
Organizational-level Interventions in Education

- In education, interventions often take place at the level of organizations (e.g., counties, schools or classroom)
- Often, organizational-level interventions are intended to improve outcomes at the level of the organization and at the level of units within the organization
- Examples:
  - Professional development interventions
  - *Classroom Supports* intervention for children with autism
- Organizational-level interventions can also be adaptive
Organizational-level Adaptive Interventions

Often, it is necessary to adapt and re-adapt organizational-level intervention in order to improve outcomes for the greatest number of students within the organization.
Example: School-level Adaptive Intervention
PI: Amy Kilbourne, University of Michigan

In-Person Training + REP
Introduction to CBT Principles and Materials + Replicating Effective Programs
Month 0 (January)

REP + Coaching
+ CBT Skills Coaching
Month 2

REP + Coaching
Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?
Month 4

REP + Coaching + Facilitation
+ business-oriented intervention designed to address organizational barriers not related to CBT skills
Until Month 15

Yes

No
Example Question 1

In the context of this adaptive intervention: What is the effect of offering vs not offering the Coaching intervention component?

**In-Person Training + REP**
- Introduction to CBT Principles and Materials + Replicating Effective Programs
  - Month 0 (January)

**REP + Coaching**
- Month 2
- + CBT Skills Coaching

Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?

**REP + Coaching**
- Yes

**REP + Coaching + Facilitation**
- No
- + business-oriented intervention designed to address organizational barriers not related to CBT skills
  - Until Month 15
Example Question 1 (stated differently)

In the context of this school-level AI: At month 2, following In-Person Training + REP, what is the effect of augmenting intervention with Coaching versus not?

In-Person Training + REP
- Introduction to CBT Principles and Materials + Replicating Effective Programs
  - Month 0 (January)

REP + Coaching
- + CBT Skills Coaching
  - Month 2

Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?
- Yes
  - REP + Coaching
- No
  - REP + Coaching + Facilitation
    - + business-oriented intervention designed to address organizational barriers not related to CBT skills
  - Until Month 15
Example Question 1

In the context of this school-level AI: At month 2, following In-Person Training + REP, what is the effect of augmenting intervention with **Coaching** versus not?

Effectively, this question is a comparison of an adaptive intervention with Coaching vs. one that does not include Coaching.
Example Question 2

Among schools that respond sub-optimally to REP + Coaching at Month 4, what is the effect of augmenting school-level intervention with **Facilitation** vs. not?

**In-Person Training + REP**
- Introduction to CBT Principles and Materials + Replicating Effective Programs

Month 0 (January)

**REP + Coaching**
- REP + Coaching + CBT Skills Coaching

Month 2

**Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?**

**REP + Coaching + Facilitation**
- + business-oriented intervention designed to address organizational barriers not related to CBT skills

Until Month 15
Example Question 2

Among schools that respond sub-optimally to REP + Coaching at Month 4, what is the effect of augmenting school-level intervention with Facilitation vs. not?

In-Person Training + REP
- Introduction to CBT Principles and Materials + Replicating Effective Programs
  - Month 0 (January)

REP + Coaching
- + CBT Skills Coaching
  - Month 2

Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?

Yes
- REP + Coaching

No
- REP + Coaching
  - + business-oriented intervention designed to address organizational barriers not related to CBT skills
  - Until Month 15
Example Question 3

In the context of this adaptive intervention: What is the effect of offering vs not offering the Facilitation intervention component to sub-optimally responding schools?
Example Question 3

In the context of this adaptive intervention: What is the effect of offering vs not offering the **Facilitation** intervention component to sub-optimally responding schools?

In-Person Training + REP

- Introduction to CBT Principles and Materials + Replicating Effective Programs

Month 0 (January)

REP + Coaching

- + CBT Skills Coaching

Month 2

REP + Coaching

- + CBT Skills Coaching

Month 4

Each SP at school delivered 3+ CBT sessions to >10 students & identified <2 delivery barriers?

Yes

REP + Coaching

- + business-oriented intervention designed to address organizational barriers not related to CBT skills

Until Month 15

No
Example Question 3

In the context of this adaptive intervention: What is the effect of offering vs not offering the Facilitation intervention component to sub-optimally responding schools?

Thus, in this case, this question evaluates both the Facilitation component and the monitoring component.
Example Question 4

• We could also ask questions related to how best to further tailor the Coaching or Facilitation intervention components

• Examples:
  • Does the effect of Coaching differ depending on school-aggregated SP knowledge of Cognitive Behavioral Therapy (CBT)? SP perceptions of CBT?
  • Among sub-optimally responding schools at Month 4, does the effect of Facilitation differ depending on how much school administrative support is provided for CBT implementation during the first 4 months?
Outcomes at the level of units within the school

• Number of CBT sessions delivered by the mental health school professionals (SPs) within the school (primary SP outcome)
• CBT knowledge, perception, skills, or championing skills of SPs within schools (secondary SP outcomes)
• Change in severity of anxiety among children at the school identified to be in need of CBT after 2 months of REP (secondary child outcomes)
Example Clustered SMART

PI: Amy Kilbourne, University of Michigan

<table>
<thead>
<tr>
<th>First-stage intervention</th>
<th>Intermediate outcome</th>
<th>Second-stage intervention</th>
<th>Experimental Conditions</th>
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<tr>
<td>REP</td>
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<td>Eligible</td>
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<td>B</td>
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<tr>
<td>REP + Coaching</td>
<td>Ineligible</td>
<td>Add Facilitation</td>
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<td>Eligible</td>
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<td>Add Facilitation</td>
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Three month REP run-in period

Month 0  Month 3  Month 5  Month 18

**REP** → Replicating Effective Programs; low-level implementation strategy that provides manualization of intervention (e.g., CBT), didactic training, & technical assistance

**Coaching** → In-person coaching during CBT groups at the school for a minimum 12 weeks

**Facilitation** → Phone calls with an expert in CBT & strategic thinking for a minimum of 12 weeks
Analysis and Sample Size Calculation in Clustered SMARTs

- When the outcome is at the level of units within the org, standard methods of analysis (sample size) can be used if the primary aim of a Clustered SMART is to estimate (test):
  - main effect of first-stage treatment,
  - effects of second-stage treatment among sub-optimally responding schools
- When outcome is at the level of the organization, standard methods also can be used for the above & for comparing embedded AIs.
Analysis and Sample Size Calculation in Clustered SMARTs

• When the outcome is at the level of units within the organization, newer methods are needed for
  • **Analyses** that seek to estimate the effect of embedded AIs
    • These analyses are similar to those learned in previous modules (e.g., weighted least squares)
  • **Sample size** methods if the primary aim is to test the comparison of two embedded AIs that begin with different treatments
Sample Size Calculation in Clustered SMARTs

Newer methods are needed if the primary aim is to test the comparison of two embedded AIs that begin with different treatments on an outcomes at the level of units within the organization.
Sample Size Calculation in Clustered SMARTs

Formula for the comparison of two embedded AIs that begin with different stage 1 intervention components

\[ N = \frac{4 \left( z_{1-\alpha} + z_{1-\beta} \right)^2}{m\delta^2} \times (1 + (m - 1)\rho) \times (2 - r) \]

- \( N \) is the total number of organizations (randomized at stage 1)
- \( m \) is the avg. no. of outcome units within each organization
- \( \delta \) is the standardized effect size for the comparison
- \( \rho \) is the outcome’s intra-class correlation (ICC)
- \( r \) is the probability of response to first-stage treatment
Sample Size Calculation in Clustered SMARTs

Formula for the comparison of two embedded AIs that begin with different stage 1 intervention components

\[ N = \frac{4 \left( z_{1-\alpha} + z_{1-\beta} \right)^2}{m\delta^2} \times (1 + (m - 1)\rho) \times (2 - r) \]

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- \( \delta \) is the standardized effect size for the comparison
- \( \rho \) is the outcome’s intra-class correlation (ICC)
- \( r \) is the probability of response to first-stage treatment

As before, this is the standard formula for a 2-arm cluster-randomized trial but with a SMART inflation factor, \( 2 - r \)
Sample Size Calculation in Clustered SMARTs

\[ N = \frac{4 \left( z_{1-\alpha/2} + z_{1-\beta} \right)^2}{m \delta^2} \times (1 + (m - 1) \rho) \times (2 - r) \]

- A common concern in cluster randomized trials is that the sample size requirement increases proportional to the intra-class correlation (\(\rho\)).
- One approach to improving power (reducing sample size) is to adjust for a baseline, cluster-level covariate that is correlated with the outcome (e.g., baseline measure of the outcome)
Sample Size Calculation in Clustered SMARTs

Formula for the comparison of two embedded AIs that begin with different stage 1 intervention component

\[ N = \frac{4 \left( z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2}{m\delta^2} \times (1 + (m - 1)\rho) \times (2 - r) \times (1 - \alpha^2) \]

- \( \alpha \) is the correlation between the baseline, cluster-level covariate and the outcome (similar to repeated measures adjustment)
- \( N \) is the total number of organizations (randomized at stage 1)
- \( m \) is the avg. no. of outcome units within each organization
- \( \delta \) is the standardized effect size for the comparison
- \( \rho \) is the outcome’s intra-class correlation (ICC)
- \( r \) is the probability of response to first-stage treatment
Organizational-level Adaptive Interventions

- Often, it is necessary to adapt and re-adapt organizational-level intervention in order to improve outcomes for the greatest number of students within the organization.

- Organizational-level adaptive interventions may include sequences of intervention components at multiple levels (e.g., the classroom and the child within the classroom).
  - A multi-level adaptive intervention is a special type of organizational-level adaptive intervention.
Example: Multi-level Adaptive Intervention
PI: Connie Kasari, UCLA

Re-making Recess (RR)
A school-playground intervention to facilitate social interaction; delivered by a school paraprofessional
Start of the school year

RR + Classroom Supports (CS)
+ provides teachers with skills (e.g., visual supports, transitions) to improve behavioral regulation and classroom management
Week 4

RR + Classroom Supports (CS) + Peer
+ Peer-mediated social skills intervention
Week 8

Is the child a slower responder (CGI ≥ 3)?

RR + CS + Peer
Week 20

RR + CS + Peer + Parent
Until end of school year

+ Individual-level

Social engagement is measured on the playground at weeks 8 and 20 by the paraprofessional using the CGI (Clinical Global Impressions); the CGI is a 7-point scale (1=very much improved to 7=very much worse)
Example Questions

• What is the effect of providing the Classroom Supports intervention vs not providing it at week 4?

• What is the effect of starting individual-level intervention at week 8 with Parent-mediated social skills intervention vs with Peer-mediated social skills intervention?

• Is there a synergistic effect between CS and Peer vs Parent?
Example Multi-level SMART

PI: Connie Kasari, UCLA
Organizational-level AIs and SMARTs

*Open Methodological Problems*

• Interventions science for organizational-level AIs is in its infancy
• The methodological & statistical science for clustered SMARTs also is in its infancy
• For most designs with clustered outcomes, methods are needed:
  • Estimating optimal adaptive interventions for any type of clustered SMART
  • Estimating embedded AI effects in multi-level SMARTs
  • Sample size or power in multi-level SMARTs
  • Estimating spill-over effects in multi-level SMARTs
• This is an active area of methodological research at d³lab
References


Outline

• Organizational-level Adaptive Interventions and Clustered SMART Studies

• **Pilot Studies in Adaptive Interventions Research**

• Seemingly-restricted SMART Studies

• Business-as-usual “control” conditions in SMARTs
Prerequisite for any Pilot Study

• A clear set of scientific questions related to the evaluation or optimization of an intervention

• A clear (tentative) rationale for the educational or clinical significance of these scientific questions

• A (tentative) randomized trial design to answer these questions

• Acknowledgement that the research team or PI is not yet fully prepared to conduct the proposed randomized trial to answer these questions
  • More on this on the next slide
What are the Goals of any Pilot Study?

- Pilot studies are about preparing for a randomized trial
- **Success is defined** by
  - Being better prepared to justify the significance/design of the proposed randomized trial
  - Having an AI (or multiple AIs) that is (are) well-operationalized and manualized
  - Having an AI (or multiple AIs) that is (are) acceptable and feasible to key stakeholders (e.g., students, parents, teachers, or clinicians, etc.)
  - Ability to justify that the proposed trial design is feasible (i.e., the researchers are able to conduct the trial)
- **Success is not defined** in terms of whether the pilot
  - Provides “proof of concept evidence” of a treatment effect
Early References on the Goal of a Pilot


Kraemer HC et al. (2006). Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry.*


Multi-phase Optimization STrategy
MOST Framework: Linda Collins and colleagues

Experimental Designs for Building An Adaptive Intervention (e.g., SMART)

Pilot Studies (e.g., Pilot SMART)

Confirmatory Randomized Trials of an Already-known Adaptive Intervention
# Methodological Toolbox for Pilot Studies

## Goal of the Pilot

<table>
<thead>
<tr>
<th>Objective</th>
<th>Preliminary Data Analysis</th>
<th>Iterative or Formative Research</th>
<th>Small-scale Proposed Trial (with focus groups)</th>
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<tbody>
<tr>
<td>Better justify significance/design of the proposed trial</td>
<td>✓✓</td>
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<td>✓</td>
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<tr>
<td>Well-operationalized and Manualized AI(s)</td>
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<td>✓✓</td>
<td>✓</td>
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<tr>
<td>Acceptability and feasibility of the AI(s)</td>
<td>✓</td>
<td>✓</td>
<td>✓✓</td>
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<tr>
<td>Better justify feasibility of proposed trial</td>
<td>✓</td>
<td></td>
<td>✓✓</td>
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Common Data Sources for Preliminary Data Analyses

- Previous randomized trials
- Previous pilot data
- Administrative data
- Electronic medical record data
- Observational study data
Preliminary Data Analyses Can be Used to

- Examine longitudinal treatment effects using previous data
  - e.g., an inverted U-shape could justify the need for introducing a subsequent-stage treatment(s) for maintaining response
- Analyses that quantify heterogeneity in treatment effects
- Analyses that shed light on early predictors of ultimate failure/success to a particular treatment (e.g., ROC analyses)
  - Based on response to treatment, change in response, non-adherence to treatment, or a combination of outcomes
  - Could inform the choice of a tailoring variable
  - Could justify the need for a “salvage” treatment for specific students
- Examine reliability or validity of potential tailoring variables
- Potential usefulness of subsequent stage intervention options
- Analyses that help build/support a **dynamic** theory of change
Less Common (but Useful) Data Sources for Preliminary Data Analyses

• Qualitative concerns raised by experts/stakeholders (e.g., students, parents, teachers, other researchers) from a previous trial

• Experts/stakeholder elicitation surveys with questions related to
  • the ideal components to include in an adaptive intervention
  • the feasibility of adaptive intervention components
  • the acceptability of adaptive intervention components
## Considerations for a Small-scale Pilot Trial

### Acceptability and feasibility of the AI(s)
- Burden of the embedded tailoring variable
- Plan for common contingencies (e.g., missing value on a tailoring variable)
- Transitions between stages of treatment
- Concerns from clinical staff (e.g., interventionists insists on classifying student as non-responder)
- Concerns from students or parents

### Better justify feasibility of proposed trial
- Estimate of the response/non-response rate in a prototypical trial
- Collecting additional, candidate tailoring variables
- Distinction between research assessments and intervention assessments (tailoring variables)
- Fidelity to AI components
- Sequential randomization procedure
Example: Is this AI feasible? Is it acceptable?
PI: Connie Kasari, UCLA

Social engagement is measured on the playground at weeks 8 and 20 by the paraprofessional using the CGI (Clinical Global Impressions); the CGI is a 7-point scale (1=very much improved to 7=very much worse).
Example: Is this SMART feasible?

PI: Connie Kasari, UCLA
Primary Aim of the Pilot SMART

To examine acceptability and feasibility of

• Identifying children as early vs slower responders by the paraprofessionals in the context of Remaking Recess
• Transitioning children to Parent or Peer at week 8
• Providing augmented Peer + Parent to slower responders at week 20
• Not providing augmented treatment to responders at week 20
• Satisfaction with treatment sequences by children, parents, teachers, paraprofessionals, and school champions
• Teacher-rated measures of child progress during CS for deciding parent vs peer at week 8
• Conducting the SMART in the school setting
Sample Size for a Pilot SMART

Approach 1

• Ensure research team has the opportunity to implement and assess feasibility and acceptability of all aspects of the the SMART (and within each “treatment path” with a sufficient number)

• Scientists chooses
  • $m =$ number of students in each treatment path
  • $k = \Pr(\text{actual number of students in each path} \geq m)$
  • $q =$ anticipated non-response rate

• Method provides total sample size $N$
Sample Size for a Pilot SMART

**Approach 1**

- Scientists chooses
  - $m =$ number of students in each treatment path
  - $k = \Pr(\text{actual number of students in each path} \geq m)$
  - $q =$ anticipated non-response rate
- Method provides total sample size $N$
Sample Size for a Pilot SMART

**Approach 1**

- Scientists chooses
  - $m$ = number of students in each treatment path
  - $k = \text{Pr}(\text{actual number of students in each path } \geq m)$
  - $q = \text{anticipated non-response rate}$

<table>
<thead>
<tr>
<th>N</th>
<th>$q = \text{anticipated non-response rate}$</th>
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<td>$m = 5$</td>
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Sample Size for a Pilot SMART

**Approach 2**

- To obtain an estimate of overall non-response rate with a given margin of error (i.e., the goal is precision in the estimate)
  - Confidence interval method (point precision)
  - Typically requires larger $N$ than Approach 1
  - Use this if there is poor info about non-response rate
- Scientists chooses
  - $moe$ = margin of error
  - $1 - \alpha = \text{coverage probability for confidence interval}$
  - $q = \text{anticipated non-response rate}$
- Method provides total sample size $N$
Sample Size for a Pilot SMART

**Approach 2**

- To obtain an estimate of overall non-response rate with a given margin of error (i.e., the goal is precision in the estimate)
- Scientists chooses
  - \( moe \) = margin of error
  - \( 1-\alpha \) = coverage probability for confidence interval
  - \( q \) = anticipated non-response rate
- Method provides total sample size \( N \)
- Example:
  - \( 1-\alpha = 95\%, \; moe = 0.10, \; q=0.50, \) requires \( N=100 \)
References

  - Updated formulae (and for a variety of SMART designs)
  - Web-applet: [https://methodologycenter.shinyapps.io/PilotShiny/](https://methodologycenter.shinyapps.io/PilotShiny/)
  - On MOST: There are two back-to-back books by Collins.
Outline

• Organizational-level Adaptive Interventions and Clustered SMART Studies
• Pilot Studies in Adaptive Interventions Research
• **Seemingly-restricted SMART Studies**
• Business-as-usual “control” conditions in SMARTs
An Example Restricted SMART

First-stage intervention

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Intermediate outcome

Second-stage intervention

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Experimental Conditions

Subgroups

Beginning of school year
Week 8
End of school year
An Example Unrestricted SMART
Example SMART
PI: Nathan Clemens & Greg Roberts, UT Austin & Meadows Institute

1. Screening identifies students with reading/math difficulties
2. Pre-Test
3. Academic Intervention + Self-Regulation
   - weekly progress monitoring of academic skills and behavior
4. Academic Intervention only
5. 10-week assessment
6. Adequate academic response
7. Core instruction
   - monthly progress monitoring of academic skills and behavior
8. Core instruction + self-regulation intervention
9. Inadequate academic response
10. Intensified, individualized academic intervention
11. weekly progress monitoring of academic skills and behavior
12. Intensified, individualized academic + self-regulation intervention

R = Randomization
Let’s Identify One of the Four Embedded Adaptive Interventions in this SMART
The components of this adaptive intervention focus primarily (perhaps solely) on academic performance.

Label this AI “Academic Adaptive Intervention”
All students in this study are provided the “Academic Adaptive Intervention”
This study investigates the effect of the “Self-regulation” intervention component within the “Academic Adaptive Intervention”
Example SMART
PI: Nathan Clemens & Greg Roberts, UT Austin & Meadows Institute
Seemingly-Restricted SMART Design
PI: Nathan Clemens & Greg Roberts, UT Austin & Meadows Institute
Why is this such powerful insight?

- Trial is easier to explain to reviewers and other audiences
- Research question(s) are more clear
- Analyses are simple!
- This is nothing more than a 2x2 factorial design

De-coupling the purpose of the trial from other features may allow for greater novelty in design
Outline

• Organizational-level Adaptive Interventions and Clustered SMART Studies
• Pilot Studies in Adaptive Interventions Research
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• **Business-as-usual “control” conditions in SMARTs**
Review the Goal of a SMART

- Goal is to build an effective adaptive intervention design
  - Result in an “optimized adaptive intervention”
- The goal of a SMART is not to evaluate an adaptive intervention
- To evaluate whether an already-developed adaptive intervention is superior to usual care, a standard confirmatory randomized controlled/clinical trial may be the most appropriate trial design

Absolutely, SMARTs are not an alternative to the standard randomized clinical trial design
Multi-phase Optimization STrategy
MOST Framework: Linda Collins and colleagues

Experimental Designs for Building An Adaptive Intervention (e.g., SMART)
SMARTs can and often do include “business-as-usual” conditions

- Having optimization as a goal does not imply that a SMART cannot have a business-as-usual control condition
- In fact, researchers often include a business-as-usual intervention as one of the embedded (adaptive) interventions in the SMART
- For example, the investigator may seek to answer questions about how best to optimize an AI that includes a BAU intervention component or a BAU adaptive intervention
SMARTs can and often do include “business-as-usual” conditions

Researchers often include a “business as usual” intervention as one of the embedded interventions in a SMART
SMARTs can and often do include “business-as-usual” conditions

Another way is via a “monitoring only BAU” condition.

This is an intervention option where we operationalize the monitoring schedule (i.e., means by which intervention could be tailored subsequently) but do not otherwise provide treatment.
Switch Gears: A special type of BAU in RCTs is “research assessment only BAU”

We define a “research assessment only BAU” condition as one in which participants

• Are offered whatever usual care is available to those participants (i.e., **business as usual**)
  • i.e., intervention is not well-operationalized
• Are tracked for their **research assessments only**

This is a special type of BAU condition. For example, in this condition, it is unknown *a priori*

• what interventions may or may not be offered, or
• whether participants are monitored for non-response or other possible tailoring variables
Switch Gears: Confirmatory (or Replication) RCTs often include “research assessment only BAU”

Example Replication Trial in Education (not AI research)

JOURNAL OF RESEARCH ON EDUCATIONAL EFFECTIVENESS
2018, VOL. 11, NO. 1, 83–108
https://doi.org/10.1080/00224891.2017.1327625

INTERVENTION, EVALUATION, AND POLICY STUDIES

The Impact of Teacher Study Groups in Vocabulary on Teaching Practice, Teacher Knowledge, and Student Vocabulary Knowledge: A Large-Scale Replication Study

Madhavi Jayanthi, Joseph Dimino, Russell Gersten, Mary Jo Taylor, Kelly Haymond, Keith Smolkowski, and Rebecca Newman-Gonchar

ABSTRACT
The purpose of this replication study was to examine the impact of the Teacher Study Group (TSG) professional development in vocabulary on first-grade teachers’ knowledge of vocabulary instruction and observed teaching practice, and on students’ vocabulary knowledge. Sixty-two schools from 16 districts in four states were randomly assigned to treatment and control conditions. A total of 182 first-grade teachers and their 1,811 students formed the sample. Treatment teachers received the TSG professional development from October to March. Teachers in the business-as-usual control condition received school/district professional development. A multilevel analysis was conducted to detect impacts. Significant impacts were found for teacher knowledge and observed teaching practice. No impacts were found at the student level.

KEYWORDS
RCT
teacher study groups
vocabulary
professional development
Switch Gears: Confirmatory (or Replication) RCTs often include “research assessment only BAU”

*Same Example*

*Teacher Measures Used in the Analysis*

*Measure of Teacher Knowledge*
A set of vocabulary items from the Content Knowledge for Teaching Reading (CKTR) assessment (Phelps & Schilling, 2004) was used to assess the impact on teachers’ knowledge of research-based vocabulary instruction. Phelps and Shilling assessed the CKTR on several different samples and reported coefficient alphas ranging from .67 to .82. For each sample, estimated IRT reliabilities were above .70, which is acceptable for an outcome measure (Nunnally, 1978, p. 245). The 10 items in the measure focus on the contextual understanding of vocabulary instruction. Teachers are given classroom scenarios or instructional examples and are asked questions that relate to instructional decisions based on research-supported practices.
Switch Gears: Confirmatory (or Replication) RCTs often include “research assessment only BAU”

*Same Example*

*Documenting the Counterfactual*

Teachers in the control condition did not engage in the TSG or have access to the materials made available to teachers in the TSG condition during the course of the study. However, they did attend other PD activities related to literacy. In order to document the counterfactual and understand how the PD received by teachers in the TSG condition differed from “business as usual,” all teachers in the study recorded any PD activities they attended in reading on online logs monthly. Teachers were asked to provide information on the type of PD activities made available to them (e.g., coaching, seminars), the amount of time they spent participating in those activities, and the focus of those activities (e.g., vocabulary comprehension). Several of the items were drawn from the Grade 1 Teacher Survey used in the Reading First Implementation Study (Moss, Jacob, Boulay, Horst, & Poulos, 2006).

Table 4 provides details of PD involving vocabulary instruction received by teachers in both the TSG and control groups based on the online monthly logs. All 94 treatment teachers and 49 control teachers (56%) attended PD in vocabulary during the course of the study. Over half of the treatment teachers (52%) also attended additional PD sessions in vocabulary over and beyond the TSG intervention. The vocabulary PD that both groups of teachers attended addressed many of the same topics and activities. However,
SMARTs can be blended with a “research assessment only BAU” evaluation condition

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Advantages of adding a “research assessment only BAU” condition to a SMART

• Enables researchers to optimize and evaluate in a single study

• The investigator’s primary aim may, in fact, be *evaluation* and a secondary aim *optimization*
  
  • Thereby necessitating a hybrid-type of trial
  
  • More likely when this is the case, the primary aim is not evaluation of a more deeply-tailored AI vs BAU
Disadvantages of adding a “research assessment only BAU” condition to a SMART

• Recall, secondary aims generate hypotheses about *optimal* AIs
• An “assessment only” condition may take away resources (sample size) that could be used to address such aims
  • **Reduced power for optimization**
• When evaluating the estimated optimal AI vs “research assessment only BAU,” relatively fewer individuals will be consistent with the estimated optimal AI (relative to a confirmatory RCT)
  • **Reduced power for evaluation**
    • By contrast, in a subsequent confirmatory RCT, we decide how many individuals are offered the estimated optimal AI
• The SMART controls many expectancy effects that are not part of the optimized AI vs “research assessment only” treatment effect
  • Typically, these are positive (beneficial) expectancy effects
  • Could be part of “soft touch” components during delivery
Summary of BAU Discussion

• It is possible to include BAU conditions as part of a SMART
  • Allows investigator to build an AI that “optimizes around” (and therefore improves) a well-operationalized BAU intervention option
• It is also possible to design a trial that blends a SMART with a “research assessment only BAU”
  • There are advantages and disadvantages to doing this in terms of the optimization vs evaluation tradeoff

Be thoughtful and deliberate about the choice of BAU
Do not include a BAU because you cannot “let go” of evaluation