Designing, Implementing, and Understanding School-Based Randomized Trials

Wendy M. Reinke
Keith C. Herman
University of Missouri

Mark D. Weist
University of South Carolina
Overview

- Learner Objectives
- Research Cycle
- Intervention and Sample Considerations
- Recruitment and Retention of Subjects
- Randomization
- Measurement Plan
- Analytic Plan
- Lessons Learned
Learner Objectives

This session will help participants:

- Understand the prevention science research cycle in the context of school-based trials,
- Understand the complexities of applied research in the areas of school mental health and social–behavioral interventions, and
- Be effective consumers of research when making decisions about using evidence-based programs and practices in schools.
Research Cycle

What is the problem?

Risk Factor Identification: What is the cause?

Intervention Evaluation: What works?

Implementation: How do you do it?
Two Group RCTs

  - R305A100342, Funded by the Institute of Education Sciences, U.S. Department of Education

  - R305A130143, Funded by the Institute of Education Sciences, U.S. Department of Education
Intervention & Sample Considerations
Where to begin?

- **Step 1:** What is the intervention to be evaluated?
- **Step 2:** What is the target population?
Level of intervention

- **Universal Interventions**
  - Target general or whole population

- **Selective Interventions**
  - Target population subgroup whose risk is higher than average for developing problem

- **Indicated Interventions**
  - Target high-risk individuals who are showing detectable signs of symptoms but do not meet full diagnostic criteria
Minimal Detectable Effects

- Step 3: How many participants do you need to find an effect if one exists?
  - Use Power analysis tools that account for nested data
  - **PowerUp!**
    - [http://web.missouri.edu/~dongn/](http://web.missouri.edu/~dongn/)
Recruitment

Step 4: Develop a plan to recruit participants

Partnerships are key to a successful project
Top 10 List for Recruitment

#10: Develop a plan of recruitment

- Who will do the recruiting?
- How will you recruit?
- When will you recruit?
- Where will you recruit?
Top 10 List for Recruitment

#9: Choose recruiters with care

- What are some important qualities of those who do the recruitment?
- Match recruiter to participant
#8: Brainstorm ideas for maximizing recruitment

- How to overcome potential barriers?
  - Parental consent process
    - Build in facilitators into consent forms or written documents

- How to compensate for involvement in supporting recruitment?
  - Teachers supports for gaining parent consent
    - Pay teachers to help
  - Reinforce students for gaining parent consent
    - Pizza Party or other reinforcer
Top 10 List for Recruitment

#7: Use strategies that are sensitive to diversity by gender, age, culture, education, and SES

- Consider the population you target
  - Get feedback on strategies from individuals
- Utilize liaisons
- Use endorsement from similar individuals
#6: Develop a tracking system and monitor carefully

- Shoot for a high percentage of participants (e.g., 100%; 85%) and get there~
#5: Principal Investigators need to be involved
- Building relationships with agencies/schools
- Answering questions that arise
- Taking the fall as needed
Top 10 List for Recruitment

#4: Keep relationships with collaborators healthy

- Building rapport
- Demonstrating usefulness
- Having a mutually beneficial relationship
Top 10 List for Recruitment

#3: Keep research team happy and healthy

- Positive atmosphere
- Solution focused versus Problem focused
- Celebrating successes
- Listening to viewpoints
- Reminding team of big picture
#2: Identify & Overcome barriers to participation as they arise

- Overwhelmed with other responsibilities
- Unhealthy organization factors
- Misperceptions of the project
#1: Know when a strategy is not working and quickly do something different!
Step 5: Randomization

Logic

Examples
Randomization: Logic

- Participants are randomly assigned to treatment or control conditions.

- Thus, we can reasonably assume that treatment and control groups were equivalent before Tx.
  - With a coin toss or a random number chart to assign participants.
  - Characteristics of treatment participants are statistically similar to those in the control condition.

- Differences in mean scores can be attributed to treatment with confidence.
CONSORT Statement 2010 Flow Diagram

**Enrollment**
- Assessed for eligibility (n = )
  - Excluded (n = )
    - Not meeting inclusion criteria (n = )
    - Declined to participate (n = )
    - Other reasons (n = )
- Randomized (n = )

**Allocation**
- Allocated to intervention (n = )
  - Received allocated intervention (n = )
  - Did not receive allocated intervention (give reasons) (n = )
- Lost to follow-up (give reasons) (n = )
  - Discontinued intervention (give reasons) (n = )

**Follow-Up**
- Allocated to intervention (n = )
  - Received allocated intervention (n = )
  - Did not receive allocated intervention (give reasons) (n = )
- Lost to follow-up (give reasons) (n = )
  - Discontinued intervention (give reasons) (n = )

**Analysis**
- Analyzed (n = )
  - Excluded from analysis (give reasons) (n = )
- Analyzed (n = )
  - Excluded from analysis (give reasons) (n = )
Group Randomization

- Randomly assign groups rather than individuals
- “Unit of Implementation”

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Randomly Assign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual social skill training</td>
<td>Student/child</td>
</tr>
<tr>
<td>Coach teachers to manage classroom</td>
<td></td>
</tr>
<tr>
<td>Coach schools to improve student behavior</td>
<td></td>
</tr>
<tr>
<td>School-based teams to increase parent involvement</td>
<td></td>
</tr>
</tbody>
</table>

- Consider contamination risk when deciding on level
IY TCM Randomization
Participant Flowchart

Enrollment

Assessed for eligibility
Teachers (n=109)
Students (n=2168)

Excluded (declined to participate)
Teachers (n=4)
Students (n=350)

Classrooms Randomized
Teachers (n=105; 96%)
Students (n=1818; 84%)

Allocation

Allocated to IY TCM
Teachers (n=53)
Students (n=901)

Allocated to Wait-List Control
Teachers (n=52)
Students (n=917)

Follow-Up

Lost to follow-up
Teachers (n=0)
Students (n=63; moved)

Lost to follow-up
Teachers (n=0)
Students (n=57; moved)

Analysis

Analyzed
Teachers (n=53)
Students (n=896)
Excluded Students (n=5; missing x and y)

Analyzed
Teachers (n=52)
Students (n=910)
Excluded Students (n=7; missing x and y)
Retention

- **Step 6: Develop a Retention Plan**
  - Recruitment and randomization are only useful if you can successfully retain participants.
  - High rates of attrition can undermine any confidence in your findings.
  - Retention is an everyday priority.
Top 10 List for Retention

#10: Be considerate of participants’ time
Top 10 List for Retention

#9: Determine cost-benefit of measures versus compensation to participants

- Avoid fatigue with unnecessary questions
- If asking a lot, pay enough to make it worth it
- Keep it simple
Top 10 List for Retention

#8: Develop and maintain good relationships with your participants

- Get to know them as individuals
- Have fun and meaningful interactions with participants
- Make yourself useful
Top 10 List for Retention

#7: Use strategies that are sensitive to diversity by gender, age, culture, education, and SES

- Consider the population with whom you target
- Use liaisons
- Get feedback from your participants on how you can improve the process
Top 10 List for Retention

#6: Give special attention to reluctant subjects
- Demonstrate your appreciation
- Show them they are important
- Give them the big picture
- Tap into their values
#5: Avoid burning out your research team

- Set goals and celebrate meeting goals
- Keep it positive
- Don’t forget the big picture
- Process challenges together
#4: Make sure to build retention activities into your budget

- Incentives at all levels of participation
- Small gifts and tokens of appreciation
Top 10 List for Retention

#3: Make expectations for participation very clear
- Group meetings
- Individual meetings
- Emails
- Written documents

**What’s going to happen in my classroom and with my students?**

- **Is that a phone?**
  - During observations, we strive to minimize disruptions as possible.
  - We use iPads to gather data reliably and silently.
  - Using these devices, we can code quickly and upload the data with less risk of user error.

- **Why is there more than one observer in a classroom?**
  - There may be 1 to 3 observers in your classroom.
  - There are two reasons for more than one observer in the classroom:
    1. It speeds up the process. For instance, it can take about 2 hours one researcher to observe 20 students (5 minutes/student). This is reduced with multiple observers.
    2. Two individuals may have to do the same observation to ensure that all of the observers are doing the observations the same way.

- **What are the observers saying when they whisper to each other?**
  - Sometimes observers need to briefly check with each other to confirm the following:
    1. They are starting their observations at the exact same time.
    2. They are coding correctly.
  - All comments should be brief. Please let us know if this causes any distractions.

- **Why are you putting stickers on my students?**
  - Using number tags ensures that we only observe those who are consented to be in the study and enhances the efficiency of the observations.
  - At the start, the observers will briefly confer with you and your class to distribute the students’ number tags. We will give you a roster. You will need to read the student names and numbers, while put on the students’ number tags. Then, please instruct the class not to play with the stickers.
  - Then, the observers will quietly move around the room being as invisible as possible.
  - At the end, the observers will remove the stickers from your students.

- **What about those math and reading activities?**
  - For the Woodcock-Johnson III Test of Achievement assessment, a data collector will take students to a quiet room and ask the child questions about math and reading.
  - These activities can last from 30-45 minutes, and the student is free to stop at any time for any reason.
  - We will ensure that the students are present for lunch, special periods, etc.
  - The child may be pulled more than once if the activities cannot be completed for any reason.
  - Please let us know if it is not good time to assess. We will come back at a time or day that is more convenient.

**Additional Information**

- Observations will be scheduled by Dr. Newcomer. Please ensure that your availability is accurate.
- Observers are aware of the whether teachers are or are not in the intervention. Please do not disclose this information to them.
- Please tell us of special circumstances that require any students to be out of the room for certain periods.
#2: Keep your promises

- Follow through with all you say you will do
Top 10 List for Retention

#1: Make your participants feel special!
- Thank you notes
- Small tokens
- Tell them they are important
Step 7: Measurement Plan

Fidelity
Consorts
Theory of Change
Timing of Assessments
Measuring Fidelity

1) Quality: Interventionist competence
   Interventionist skill level of using the training methods, processes and learning principles employed in the original program model

2) Differentiation:
   Implementation of the program for the population for whom the program was designed

3) Adherence:
   Delivery of core program content and intervention dosage (number of hours of training) in the recommended sequence

4) Participant Engagement:
   Level of the participants’ engagement in the intervention

   (Gresham, 2009; Power, et al., 2005)
Multidimensional Approach to Fidelity and Implementation

**Fidelity to Teacher Training**

**Content**
- **Adherence** to 6 Training Workshops
  - Positive relationships, praise, proactive teaching, ignoring, decreasing inappropriate behavior, and social/emotional coaching
- **Quality** of Implementing Workshops
  - Workshop leader effectiveness

**Process**
- **Engagement** in Workshops
  - Participant enthusiasm, attention, understanding, and participation in workshops
- **Exposure** to Workshops
  - Participant attendance and dose of workshop received

**Coaching Supports**
- **Differentiation** of supports tailored to each teacher

**Teacher Implementation Skill**
- Teacher Use of Targeted Skills in Classroom
  - Improved relationships, positive classroom climate, increased praise and proactive teaching, reduced reprimands

**Student Outcomes**
- Reduced disruptive behavior
- Increased time on task
- Improved academic performance

Reinke, Herman, Stormont, Newcomer, & David, (2014).
Measuring Constructs

- Measurement strategies are guided by your theory of change
- Theory of Change (ToC)
  - The model underlying your research
  - A source for generating research questions
  - **NOTE:** Logic Model or Logical Framework are related terms and similar to a Theory of Change
Develop your Theory of Change

**Figure 2. Theory of Change**

- **District Wide Training**
  - Train all school behavior support teams
  - Train all school personnel in EBPs

- **Coordinated Care**
  - Autonomous data based decision making
  - Competencies to provide effective environments
  - Assessing risk and protective factors
  - Relational supportive participation in system

- **Develop and Implement Shared Ecological Assessment System (SB-MAP)**
  - Form and train county-wide assessment team

- **Proximal Targets**
  - Enhanced Student Competence & EnviroFit
  - Increased Home/School Relational Supports
  - Structured, Predictable Environments

- **Distal Outcomes**
  - Reduced behavior problems
  - Increased time for instruction
  - Improved Academic Performance

- **Ongoing Supervision**
Table 1. Primary Hypotheses Related to Teacher and Students Outcomes

<table>
<thead>
<tr>
<th>Target</th>
<th>Hypothesis</th>
<th>How Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teacher (n=40)</td>
<td>1a. Teachers receiving the CCU will demonstrate greater increases in the use of effective classroom management practices relative to the control group.</td>
<td>1a. Increased use of praise and opportunities to respond, and decreased use of reprimands by frequency count during 20 minute BCIO-R classroom observation using MOOSES.</td>
</tr>
<tr>
<td></td>
<td>1b. Teachers with increased rates of effective classroom management practices will rate themselves higher on a measure of self-efficacy in classroom behavior management.</td>
<td>1b. Increased rating of self-efficacy on the TSSES.</td>
</tr>
<tr>
<td></td>
<td>1c. Teacher receiving the CCU will find the intervention to be effective, feasible, important, useful, and efficient.</td>
<td>1c. High rating on Social Validity measure.</td>
</tr>
<tr>
<td>Student (n=560)</td>
<td>2a. Students in classrooms in which teachers receive the CCU will demonstrate decreases in disruptive and aggressive behavior.</td>
<td>2a. Reduction of disruptive/aggressive behavior on the TOCA and ST-CIO observation.</td>
</tr>
<tr>
<td></td>
<td>2b. Student in classroom in which teachers receive the CCU will demonstrate increases on task behavior.</td>
<td>2b. Increased on task behavior on the ST-CIO observation.</td>
</tr>
<tr>
<td></td>
<td>2c. Students in classroom in which teacher receive the CCU will demonstrate improved academic performance.</td>
<td>2c. Improved score of academic performance on SAT-10.</td>
</tr>
</tbody>
</table>
### Table 4. Schedule of Data Collection by Condition

<table>
<thead>
<tr>
<th></th>
<th><strong>IY TT Classrooms</strong></th>
<th><strong>Control Classrooms</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>School Information Form</td>
<td>May</td>
<td>May</td>
</tr>
<tr>
<td>School Profile</td>
<td>May</td>
<td>May</td>
</tr>
<tr>
<td>School Record</td>
<td>May</td>
<td>May</td>
</tr>
<tr>
<td><strong>Student Academic and Social Behavior</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WJ-III reading/math</td>
<td>Oct/May &amp; May following year</td>
<td>Oct/May &amp; May following year</td>
</tr>
<tr>
<td>BIRS</td>
<td>Oct/May &amp; May following year</td>
<td>Oct/May &amp; May following year</td>
</tr>
<tr>
<td>Classroom Observations</td>
<td>Oct/May &amp; May following year</td>
<td>Oct/May &amp; May following year</td>
</tr>
<tr>
<td>TOCA-R</td>
<td>Oct/May &amp; May following year</td>
<td>Oct/May &amp; May following year</td>
</tr>
<tr>
<td>T-COMP</td>
<td>Oct/May &amp; May following year</td>
<td>Oct/May &amp; May following year</td>
</tr>
<tr>
<td>SWIS</td>
<td>May and May the following year</td>
<td>May and May the following year</td>
</tr>
<tr>
<td>School Records</td>
<td>May and May the following year</td>
<td>May and May the following year</td>
</tr>
<tr>
<td><strong>Mediators</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instructional Time</td>
<td>Oct/May</td>
<td>Oct/May</td>
</tr>
<tr>
<td>TSSES</td>
<td>Oct/May across two years</td>
<td>Oct/May across two years</td>
</tr>
<tr>
<td>Teacher Knowledge</td>
<td>Pre-Post IY TT Workshops (Oct, Dec, Feb)</td>
<td></td>
</tr>
<tr>
<td>INVOLVE-T</td>
<td>Oct/May</td>
<td>Oct/May</td>
</tr>
<tr>
<td><strong>Fidelity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classroom Observation</td>
<td>Oct/Nov/Jan/May &amp; Oct/May following year</td>
<td>Oct/May</td>
</tr>
<tr>
<td>Classroom Ecology</td>
<td>Oct/Nov/Jan/May &amp; Oct/May following year</td>
<td>Oct/May</td>
</tr>
<tr>
<td>Session Checklist</td>
<td>Post IY TT Workshops (Oct, Dec, Feb)</td>
<td></td>
</tr>
<tr>
<td>SET (PBIS fidelity)</td>
<td>Oct across all years</td>
<td>Oct across all years</td>
</tr>
<tr>
<td><strong>Teacher Implementation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBI</td>
<td>Oct/May across two years</td>
<td>Oct/May across two years</td>
</tr>
<tr>
<td>OCDQ-RE</td>
<td>Oct/May across two years</td>
<td>Oct/May across two years</td>
</tr>
<tr>
<td>IY TT Workshop Evaluation</td>
<td>Post IY TT Workshops (Oct, Dec, Feb)</td>
<td></td>
</tr>
<tr>
<td>TPIA-PRI</td>
<td>Oct (Pre-IY TT Workshop)</td>
<td></td>
</tr>
<tr>
<td>TPIA-PSTI</td>
<td>Post IY TT Workshops (Oct, Dec, Feb), May, and Oct/May of the following year</td>
<td></td>
</tr>
</tbody>
</table>

Note: 100 Classrooms will be randomized by cohort into either the IY TT condition (n=15 year 1; n=20 in year 2, an n=15 year 3) or Control condition (n=15 year 1; n=20 in year 2, and n=15 year 3). Month is during the year in which cohort is assigned to condition. Across/following years indicates consecutive years (see Table 2).
Step 8: Analytic Plan

Use analytic methods appropriate to the structure of the design and the data
Conducting Appropriate Analysis

- Unit of Randomization
- Nested Subjects

- Intraclass correlation (ICC) may occur among observations nested within the same classroom, due to commonalities in selection, exposure, mutual interaction, or some combination of those factors.

- Ignoring ICC can jeopardize the Type I error rate.
Alternatives to RCT

- Regression Discontinuity Designs
- Quasi Experimental Designs

Figure 1. Pre-Post Distribution with No Treatment Effect.

Figure 2. Regression-Discontinuity Design with Tx Effect.
Other Lessons Learned

- Involved in 3 large randomized trials (as PI on 2, Co-Investigator on 1)

- Bigger lessons:
  - Build from smaller studies, and take a long view
  - As presented, strong relationships (including with project officers) and team functioning are essential
  - Stay within your expertise
  - Try to build a prominent strategic research avenue
Enhancing the Quality of SMH Services (NIMH, 2003-07)

- Theme – testing achievable strategy for high quality, evidence-based intervention in schools

- Collaborators – Eric Youngstrom (UNC); Sharon Stephan, Nancy Lever, Elizabeth Moore, Bryan Harrison, Ken Rogers, Bruno Anthony (UMD); Kimberly Hoagwood (NYU); Jenni Jennings, Glenn Pearson (Dallas Public Schools); Phyllis Hazel, Nancy Bearrs (School-Based Health Centers in Delaware)

- Evaluating proximal impacts of three-component framework (Family Engagement Empowerment, Quality Improvement, EBP) on clinicians and distal impacts on students seen by clinicians
Enhancing Quality, lessons learned

- Can move a grant from one federal agency to another
- Managing error variance and promoting fidelity of intervention across sites is very challenging
- Hard to control diffusion of innovation and compensatory rivalry
- On target group side, intervention demands were way too intensive for clinicians
- Key missing component of within-school implementation support
- Collecting psychosocial measures from families through the mail does not work
Strengthening the Quality of School Mental Health Services (NIMH, 2010-15)

- Theme – testing achievable strategy for high quality, evidence-based intervention in schools with lessons learned and method advances from prior R01
- Collaborators – Eric Youngstrom (UNC); Sharon Stephan, Nancy Lever (UMD), Kimberly Hoagwood (NYU); Heather McDaniel, Leslie Taylor, Johnathan Fowler, Abby Bode, Melissa George (USC); Lori Chappelle, Samantha Paggeot, Eryn Bergeron (Waccamaw Center for Mental Health)
- Evaluating proximal impacts of four-component framework (Family Engagement Empowerment, Quality Improvement, EBP, Implementation Support) on clinicians and distal impacts on students seen by clinicians
Strengthening Quality, lessons learned

- Relationship with the community partner is essential and bi-directional
- Creating rules about only research staff collecting measures is expensive and highly problematic
- Try to avoid having clinicians as subjects
- Collecting measures and providing implementation support in 30 plus schools in a large county is almost prohibitive
- Diffusion of innovation and compensatory rivalry again difficult to manage
- Staff regardless of treatment condition want to do well, and comparison interventions can be effective
Strengthening Quality, lessons learned 2

- Academic record data are messy and very laborious to code
- Post-only research designs are less expensive but present other problems:
  - Tracking down families and collecting post-assessment in a timely manner (move to all phone interviewing)
  - Varying times of effectiveness for clinicians (e.g., beginning of to after 1 year of training and IS), varying dose and timing of intervention, and varying latency from intervention to measurement
“Baskets” of types of cases

- Reasonable dose (e.g., > 6 treatment sessions), no change in circumstance for client, post data collected close to treatment end
- Sporadic dose (e.g., 4 sessions spread over 3 months) and longer latency between end of treatment and post data
- Case seen by two clinicians within the same condition in a school
- Case moved from one school to another seeing clinicians from different study arms, ETC
Training and implementation support is insufficient/Need this and two other components – accountability and incentives.

Intent-to-treat framework is a very conservative approach to analyses.

Can we be out-of-the-box, and consider “super performers” or even better, super performers matched to cases of higher need?
Theme — testing achievable student and classroom (and family) support and focused intervention strategies for high school students presenting challenging emotional/behavioral problems

PIs — Lee Kern (Lehigh University), Steve Evans (Ohio University), Tim Lewis (University of Missouri) and collaborators from 5 states (PA – Talida State; OH – Ali Cloth; MO – Nicholas Cage; KS – Deborah Kamps, Howard Willis; SC – Mark Weist, Melissa George, Elaine Miller) and the University of Houston (for analyses, Paras Mehta)

Multiphase study with 64 high schools from 5 states (around 640 students) randomly assigned to intervention versus comparison (information to schools on Wellness) in the final efficacy evaluation
CARS, lessons learned (USC perspective)

- One school principal can almost take down a study
- Schools, staff are reserved/reticent about involvement when there is no history of collaboration and no relationship broker (as in the two NIMH funded R01s)
- Southern culture may make this challenge even more intense
- Relationships with all in the building are key
- Relying on SMH professionals and teachers to deliver interventions is fraught with many difficulties
CARS, lessons learned cont.

- Intensive measurement demands create multiple challenges (time; resource allocation; relationships with schools, school staff and families)
- Challenge of working with high school students with history of problems, and stigma and hopelessness that may be encountered
- Value of university connections and using trainees to support study implementation
- With excellent leadership and using technology (e.g., well-timed conference calls/in person meetings, Sharepoint) a 5 state, 6 university collaboration can work remarkably well
Summary

- Know where you are in the knowledge development cycle
  - Group RCT’s contribute a particular type of information to knowledge development
    - It is a primary, heavily favored way for most funding agencies to evaluate causal inferences
  - Not all Group RCTs are equal
    - Causal inferences are only warranted with high quality design and conduct of these trials
- Understand the strengths, limitations, challenges, and appropriate uses of group randomized trials as well as alternatives