

Structuring RCT Partnerships: Exploring Contrasts in Researcher-Practitioner Roles and Responsibilities when Implementing RCTs in Real-World Settings

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The project described was supported by the Office of Adolescent Health. Its contents are solely the responsibility of the authors and does not necessarily represent the official views of HHS.

Presentation Goals

- Illustrate pros and cons of partner and staffing structures
- Evaluator as grantee vs. subcontractor
- Provide lessons learned and strategies to improve:
 - Site recruitment
 - Participant recruitment
 - Participant eligibility screening and enrollment
 - Participant retention/minimizing attrition
 - Program implementation

Study Specifications

Implementation:	Locations:	Current sample:	Follow-up time points and rates:
High schools	NYC and NC	1,523	12 months: 71%
Reproductive health clinics	CA	1,716	3 months: 94% 9 months: 91%
Mental health settings	CA, NM, ME, MI, and LA	342	Post-program: 90% 9 months post-program: 76%
Juvenile justice services offices	NM and WV	227	3 months: 81% 6 months: 71% 12 months: 56%
Reproductive health clinics	LA	319	6 months: 87% 12 months: 90% 18 months: 82%
Youth summer job training programs	LA	850	Post-program: 92% 6 months post-program: 87%

Study Partnerships & Roles

Study Partners:

Funding agency	Primary grantee	Evaluator/ researcher	Intervention developer	Implementation partners
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Study Roles:

➤ Study design, analysis, reporting	➤ Participant recruitment	➤ Intervention implementation
➤ Implementation partner/site recruitment	➤ Eligibility screening and enrollment	➤ Fidelity monitoring
➤ Staff recruitment, training, management	➤ Participant retention/ minimizing attrition	➤ Reporting to funder (programmatic and fiscal)

Evaluator as Grantee vs. Subcontractor

	Evaluator as Grantee	Evaluator as Subcontractor
PROS:	<ul style="list-style-type: none">• Control selection of study partners and staff• Control study timelines• Quickly and creatively resolve issues	<ul style="list-style-type: none">• Access to target population• Community knowledge/trust• Understanding of population culture and preferences
CONS:	<ul style="list-style-type: none">• Responsible for administrative logistics• Building relationships within unfamiliar systems	<ul style="list-style-type: none">• Less control over quality/capacity of implementation partners• Less leverage in enforcing or improving implementation fidelity• Less able to quickly address issues that may negatively impact study

Assess Potential Site Implementation Fit

1. Sufficient numbers of target population?
2. Fit with site's existing services flow/interactions?
3. Other interventions or studies offered?
4. Strong relationships/community trust?
5. Understand what random assignment means?
6. Motivated to participate in/support the research?

Strategies for Site Engagement

- Shared document for site-specific study details
- Regular calls/meetings to finalize study details
- Build rapport with partners before study starts
- Ongoing use of shared document to clarify and confirm implementation details
- Tools:
 - Study Presentation
 - School Study Agreement
 - Implementation Site Plan

Participant Recruitment

- Brainstorm best methods to introduce study and motivate participation
- Train recruiter to provide clear and accurate information to potential participants
- Tools:
 - Study brochures, flyers, posters, informational letters
 - Study recruitment script
 - Recruiter training
 - Practice 'mock' recruitment sessions

Participant Screening & Enrollment

- Evaluator specifies study eligibility criteria
- Eligibility data may come from multiple sources
- Train staff on research protocols
- Monitor recruitment, screening, enrollment data
- Review and revise strategies as needed
- Tools:
 - Research Protocol (detailed step-by-step manual)
 - Training by evaluator and 'shadowing' existing staff
 - Data monitoring tables


Program Implementation

- Intervention developer specifies program:
 - Duration, facilitator qualifications, appropriate settings, and training requirements
- Delivery models:
 - Delivered by evaluator staff hired specifically to implement intervention and study tasks
 - Delivered by partner staff hired specifically to implement intervention and study tasks
 - Delivered by existing/current partner staff who allocate portion of time to intervention and study tasks

Participant Follow-Up

- Primary outcome data collection conducted by trained evaluator study staff
- Partners can assist with:
 - Locating study participants
 - Facilitating connections to outside organizations/facilities where participants may be reached

Key Takeaways

- Careful planning during start-up phase is crucial
 - Recognize the benefits and limitations of different partner structures
 - More direct oversight of partners and staff is ideal in order to quickly respond to study issues
 - Document partner responsibilities
 - Continuous, clear, and creative communications with partners and staff is essential
 - Strong relationships and being responsive and flexible is key!
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School Study Agreement Example

Agreement Sections:

1. Study Timeline
2. Points of Contact
3. Consent of Students and Parents
4. Setting a Master Schedule to Accommodate Program and Study
5. Determining Student Eligibility
6. Randomization of Students
7. Survey Data Collection
8. Student Administrative Data Collection
9. Fidelity Requirements
10. Outstanding Issues
11. Study Agreement Signatures

7. Survey Data Collection

Agreement:

[List all agreed upon responsibilities and details]

1. School representatives recognize that all study students (both those randomly assigned to PGC and those randomly assigned to 'class as usual') will respond to the survey in the beginning of the 9th grade, 10th grade, and 11th grade.
2. School representatives recognize that students will receive a \$10 gift card after completing each survey (\$30 total value if all three are completed).

[Include table to document school-specific study details]

QUESTIONS/REQUIRED INFORMATION	SCHOOL INFORMATION	DATE COMPLETED
1. Identify school point person to assist with coordinating survey data collection (name, position, phone, email):		
2. Identify type of \$10 gift card to provide to students at your school for completing surveys:		

Implementation Site Plan Example



YOUTH EMPOWERMENT STUDY IMPLEMENTATION SITE PLAN West Virginia Division of Juvenile Services Youth Reporting Centers (YRCs)

Address and hours	YRC name and contact information:	Days and hours of YRC operation:	Best days and hours for study recruitment:

Site contacts	[YRC director name] [Contact information]	[Other contact name] [Contact information]	[Other contact name] [Contact information]

	Questions/information needed:	Site details:
Space	1. Is there a private distraction-free space (room) at the YRC that can be designated for use by the study facilitator to recruit and enroll participants and hold program sessions?	
	2. List the days/times that these rooms are available for use by study facilitator.	
Site staff	1. Please list the staff positions within your YRC (case managers, therapists, JPOs, etc.)	
	2. List the YRC staff who conduct intake with youth and parents.	
	3. Who is responsible for organizing the daily programs and schedules for youth?	
Site services	1. Describe generally how and when youth receive services at your site (days of week, times of day, duration of normal visit).	
	2. What types of services are offered to youth at your site?	
Recruitment	1. Describe the intake process at the site.	
	2. Identify all staff who conduct intake with the youth at the site.	
	3. Can outside study staff have access to YRC appointment system or youth schedules in order to schedule eligibility screening appointments?	
Follow-up strategies	1. Are there certain site staff or service providers that regularly maintain contact with youth after they have completed their YRC Program Track? (e.g., social worker, counselor, JPO)	
	2. Can you think of other ways to maintain contact with youth after they complete services at your site? (Community programs or partners who serve them?)	

