



# TEEN VIDEO STUDY

(412) 329-TVS1 [www.TeenVideoStudy.com](http://www.TeenVideoStudy.com)  
[teen-video-study@andrew.cmu.edu](mailto:teen-video-study@andrew.cmu.edu)

## *Overcoming Evaluation Challenges*

### Communication & Consent: IRB & Clinic Perspectives

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# Agenda

- Teen Video Study Background
- Evaluation & Implementation Challenges
  - Experiences with multi-site IRBs
    - Lessons Learned
  - Development & Implementation of Video Consent
    - IRB issues
    - Clinic considerations

# Teen Video Study

- Randomized clinical trial comparing interactive, web-based educational videos on teen risky behaviors
  - Ford Motor Company's *Driving for Life* Video
  - *Seventeen Days*
- Funding
  - U.S. Department of Health & Human Services, Office of Adolescent Health
- Research Team
  - Carnegie Mellon University (Lead institution)
  - West Virginia University
  - University of Pittsburgh
  - Nationwide Children's Hospital
  - Adagio Health Inc.
  - WV County Health Departments

# Study Design

- Pilot Study
  - Test logistical needs of offering study
  - Assess expectations of IRBs
  - Identify needs of clinics used as recruitment sites
- Full implementation
  - 14-19 year old females
  - Longitudinal (Baseline, 3 months, 6 months, & 15 months)
  - Clinic-based enrollment
  - Individual study participants randomized into a video group
  - Intervention delivered remotely
  - Internet-based behavioral data collection, biological specimens done at home/clinic and sent by mail

# Research participation by minors

- Minors seeking reproductive care
  - Parent knowledge/consent not required
  - Consent for research NOT same as consent for care
- Code of Federal Regulations Title 45: Public Welfare, Part 46: Protection of Human Subjects
  - Parental waiver requirements
    - No more than minimal risk
    - Not feasible without waiver
    - Additional precautions are put into place
- Certificate of Confidentiality

**Carnegie Mellon**  
*PI: Julie Downs, PhD*

*PI: Elise Berlan, MD*

**Nationwide Adol. Clinic**

*Pitt PI: Robert McCall*

**External Evaluation**

*UPMC PI: Gina Sucato, MD*

**UPMC CHP Adol. Clinic**

**IBC protocol approval**

**West Virginia University**  
*PI: Pamela Murray, MD, MHP*

**WVU Pediatric & Adolescent Practice**

**Adagio Health, Inc.**

Aliquippa, PA  
Erie, PA  
Seneca, PA  
Uniontown, PA  
Washington, PA

**WV Health Departments**

Boone County (Danville, WV)  
Braxton County (Sutton, WV)  
Hancock County (New Cumberland, WV)  
Harrison County (Clarksburg WV)  
Marion County (Fairmont, WV)  
Marshall County (Moundsville, WV)  
Randolph County (Elkins, WV)

# TVS Expectations of IRB

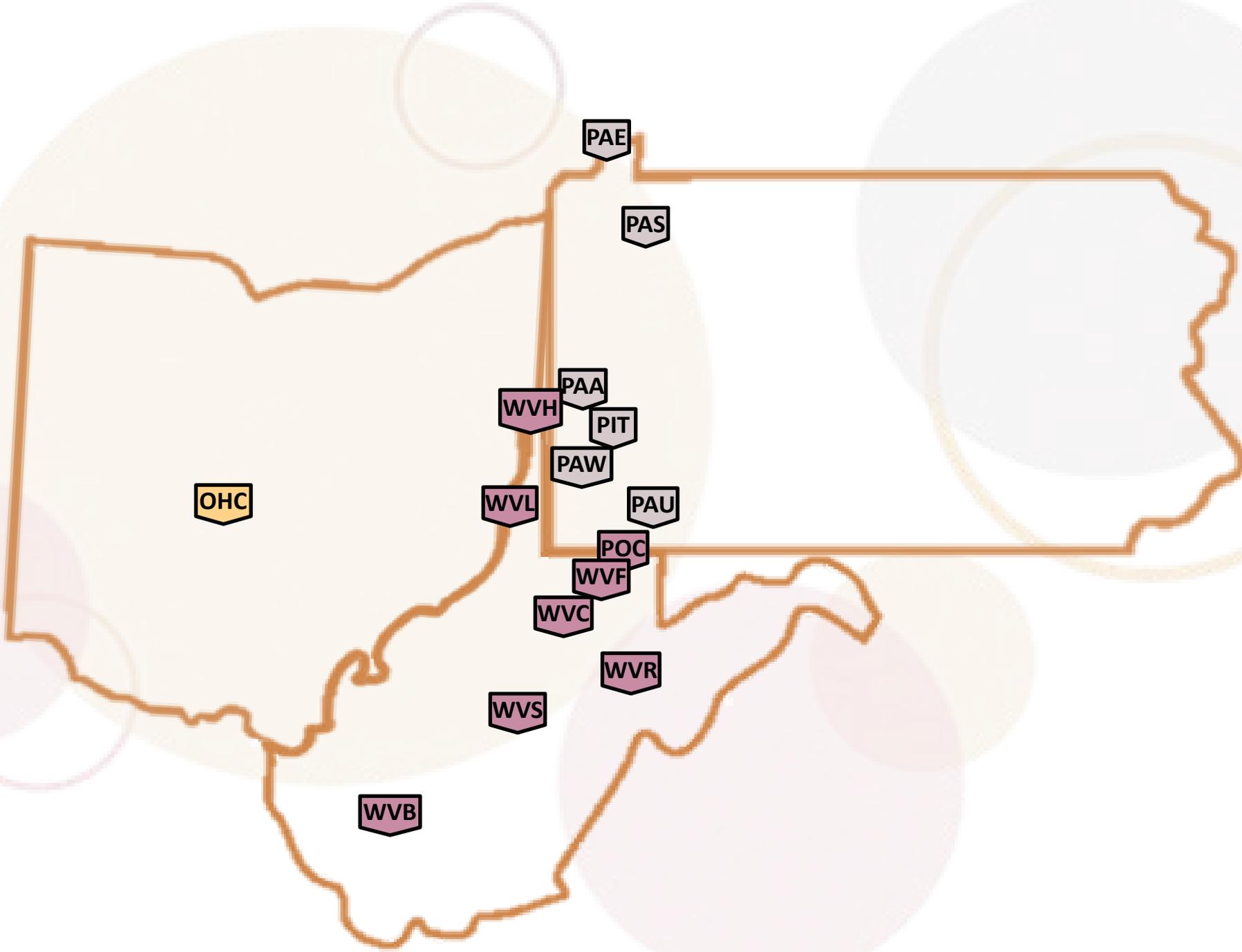
- Assigning clinics to appropriate oversight IRB
- Waiver of parental consent
  - Medical care vs. research consent
  - Family planning vs. primary care patient
  - Parent reactions
  - Guardianship issues
- Participant confidentiality
  - Waiting room
  - Statutory laws

# Site-specific IRB requirements

- CMU, lead institution
  - Separate protocols for 14-17 & 18-19
  - Partial parental waiver
    - What is a “present parent”?
- WVU
  - IBC approval for processing of clinical samples
  - Special IBC training required
  - Wording for assent forms identical to consent forms
- Pitt
  - Separate study advertisements for 14-17 & 18-19 year olds
- Nationwide
  - Parental consent and 18-19 consent used same forms

# Recruiter Training

- Ethics/CITI training
  - Social & Behavioral Research Investigators
  - Biosafety for Protocols Involving Blood, Body Fluids, Human Cells, & Human Tissues
  - Biosafety for Shipping and Receiving Biological Materials
- TVS Training
  - Recruiter-based consent & enrollment
  - Role-playing
  - “What do I do if...”
  - Video-based consent & enrollment



PAE

PAS

PAA

PIT

PAW

PAU

POC

WVH

WVL

WVF

WVC

WVR

WVS

WVB

OHC

# Video Consent

- Why necessary?
  - Recruitment sites geographically disperse
  - Small teen patient load in rural areas
  - Time demands of clinical staff recruiters
- Considerations
  - IRB approval
  - Acceptability to clinic staff
  - Clinic flow
  - Acceptability to teens

# Video Consent Process

- Teen invited to screen during check-in
- Recruiting bag
  - Study cell phone
  - Study tablet
  - Recruitment notebook
  - Test Kit
- Screening & review of consent/assent form
- Teen discusses study & forms with TVS recruiter by phone
- Clinic staff recruiter witnesses teen sign consent/assent form
- Teen completes enrollment with TVS staff by phone
- Teen access TVS website and completes baseline measures

# Clinic Considerations

- Development
  - Connectivity
  - Logistics
- Implementation
  - Clinic flow
  - Clinic staff resistance
  - Technology “sprouting feet”

# Take Home Thoughts

## IRB

- Adequate time for multiple approvals
- Each IRB officer interprets regulations differently
- Consider Centralized IRB option

## Video Consent

- Design communication
- Additional protections
- Logistics
- IRBs overall receptive
- Communication prior to filming

# Summary

- Prepare for expected challenges
- Be flexible and open to the unexpected
- Communication is critical



# Challenges and Strategies to Maintain Effective Implementation and Evaluation of School-Based Teen Pregnancy Prevention Programs

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# Today's Presentation Goals

- Describe challenges with implementing and evaluating longitudinal teen pregnancy prevention interventions in middle schools.
- Provide strategies used by two different Tier 2 programs in an attempt to maintain effective program activities and evaluation designs.



# About the Programs - Similarities

## Healthy Futures and PATH

- Age appropriate curriculum
- Targeting 6<sup>th</sup> – 8<sup>th</sup> grade in high-risk communities
- Follow-up in 9<sup>th</sup> grade
- Group cluster (32 schools)
- Randomized (treatment-control)



# About the Programs - Differences

## Healthy Futures

- 15 urban schools
- Northeast Massachusetts
- Demographics
  - Approximately 12 years old
  - 51% male, 48% female
  - 40% Hispanic
  - 27% White
  - 17% Asian
  - 5% Black

## PATH

- 17 rural schools
- Northwest Indiana
- Demographics
  - 47% 11 years old
  - 65% 12 years old
  - 47% male, 53% female
  - 90% White
  - 2% Black
  - 11 % Hispanic



# Planning a School-based Program and Evaluation

## Research Design

- Longitudinal
- Cluster (school) randomized
  - Treatment = Healthy Futures/PATH
  - Control = Placebo/Basic Health
- School as cluster
- Students as participants
- Survey development
  - Primary and secondary questions



# Planning a School-based Program and Evaluation

## School Selection

- Cultivating relationships
- Enrollment with MOU
- Matching/Randomization



# Planning a School-based Program and Evaluation

## Participant Recruitment

- Cultivating relationships
  - Teachers
  - Staff
- Consent/assent process
  - JSI/HF – Separate
    - Program (passive)
    - Evaluation (active)
  - ITMESA/PATH – Combined (active)



# Implementing a School-based Program and Evaluation

## Outcome Data Collection

- Scheduling
  - Overcoming unplanned events
- Securing necessary information
  - Rosters, missing participants, etc.
- Questionnaire administration
  - Paper-pencil vs. web-based
  - Ensuring confidentiality
- Follow-up over a four year period



# Implementing a School-based Program and Evaluation (cont'd)

## Process Data Collection

- Use of results for monitoring vs. opportunity for improvement
- Facilitator self-assessment
- Observer assessment



# Implementing a School-based Program and Evaluation (cont'd)

## Use of Fidelity and Implementation Data

- Monitoring vs. opportunity for improvement
  - Modification of instruction (teaching strategies)
  - Modification of curriculum
- Setting benchmarks
- Variability and drift
- Facilitator self-assessment
- Observer assessment
- Feedback to stakeholders
  - What to report and when



# Summary of Lessons Learned To Date

- Continue to cultivate relationships with school staff
- Be open and honest
- Maintain protocols, expect variability
- Have on-going meetings and conversations between program and evaluation staff
- Be flexible



# Disclaimer

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# **Fidelity Matters: The Impact of Positive Prevention Plus on Sexual Behaviors**

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Third Annual Teen Pregnancy Prevention Grantee Conference  
Ready Set Sustain: Continuing Our Success  
May 20-22, 2013

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# Overview

1. Characteristics of fidelity
2. Measuring fidelity
3. Results of exploratory analyses

# Implementation Fidelity

- The bridge between a promising idea and its impact on student behavior is implementation (Dusenbury et al., 2003)
- Programs are seldom implemented as planned (Type III error).
- Past research clearly demonstrates the link between fidelity and impacts (Berkel et al., 2011)

# Features of Implementation Fidelity

1. Dosage
2. Attendance
3. Adherence
4. Quality
5. Adaptation
6. Differentiation (treatment-control contrast)

# Adaptations

Green Light Adaptations	Yellow Light Adaptations	Red Light Adaptations
<ul style="list-style-type: none"><li>• Update data/statistics.</li><li>• Tailor learning activities and instructional methods to youth – culture development.</li><li>• Make activities more interactive.</li><li>• Customize role-play. (e.g., change names).</li></ul>	<ul style="list-style-type: none"><li>• Change sequence of activities.</li><li>• Add activities.</li><li>• Add activities to address additional risk and protective factors.</li><li>• Replace videos.</li><li>• Modify condom activities.</li><li>• Use other teaching strategies that cover same ground (e.g., lecture).</li></ul>	<ul style="list-style-type: none"><li>• Shorten the program.</li><li>• Remove, Reduce or eliminate activities</li><li>• Remove, Reduce or eliminate opportunities for skill practice (e.g., role-play).</li><li>• Remove condom activities.</li></ul>

# Facilitator Log

## POSITIVE PREVENTION TEACHER CURRICULUM LOG

Please complete this form **after each lesson for each class period you teach** so that your responses are accurate. Please answer honestly. The information you provide will only be presented in group form. The information you provide is completely confidential. Your name or other identifying information will not be disclosed to anyone.

**Name:** \_\_\_\_\_

**School Site:** \_\_\_\_\_

**Class Period:** \_\_\_\_\_

# Lesson Video Observation Form

**SBCSS Nutrition Education Lesson Observation Form**  
**Week #1 Power Survey & PUFL Energizer #1- GRADE 4**

Observer Name: _____	School Site: _____
Date: _____	Nutrition Educator Name: _____
	# of Students: _____
	Date & Time of Session : _____

**Part One:**

**Introduction:** The purpose of the observation form is to measure the fidelity and quality of implementation of the program delivery. Please use the guidelines below when completing the observation form and *do not* change the scoring provided; for example, do not circle multiple answers or score a 1.5 rather than a 1 or a 2.

**You should complete the observation form after viewing the entire session, but you should read through the questions prior to the observation.** It is also helpful to take notes during your viewing; for example, for Question 1, each time an implementer gives explanations, place a checkmark next to the appropriate rating.

# Exploratory Analyses

- Clustered RCT
- Examined condom use, psycho-social mediators, and factors related to fidelity for 30 day and 6 month follow-up data.
  - Adherence
  - Quality
  - Adaptations
- Examine effects using logistic and OLS regression
  - $posttest\ #1\_score = b_0 + b_1(pretest\_score) + b_2(Quality\_Group)$
- Adjusted for clustering effect
  - Used robust standard errors using Huber/White/sandwich estimates
  - Report means for marginal means for ease of interpretation

# Lesson Completion

Site	Average Percent of Activities Completed	# of Classes	Std. Deviation
1	0.94	4	0.010
2	0.91	9	0.052
3	0.88	24	0.056
4	0.87	13	0.043
4	0.87	30	0.066
5	0.84	9	0.063
6	0.78	5	0.035
7	0.75	3	0.051
8	0.75	25	0.140
9	0.59	10	0.278

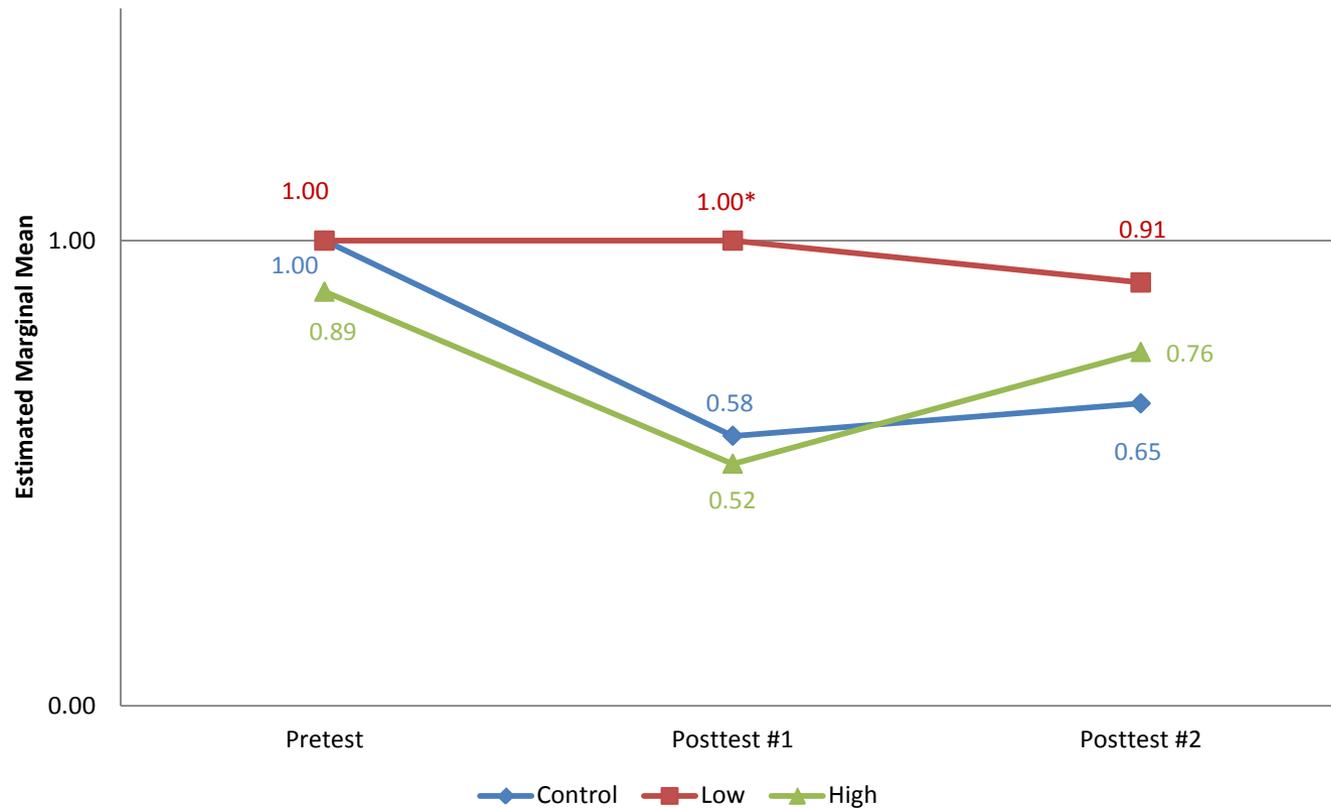
# Adherence and Adaptions

	Refusal Skills Practice	Condom Demonstration	Steps in Condom Use	Condom Use Negotiation Practice
Activity not conducted	25.2	29.5	15.2	25
Activity conducted with adaptations	6.1	11.4	16.6	7.6
Activity completed with fidelity	68.7	59.1	68.2	67.4

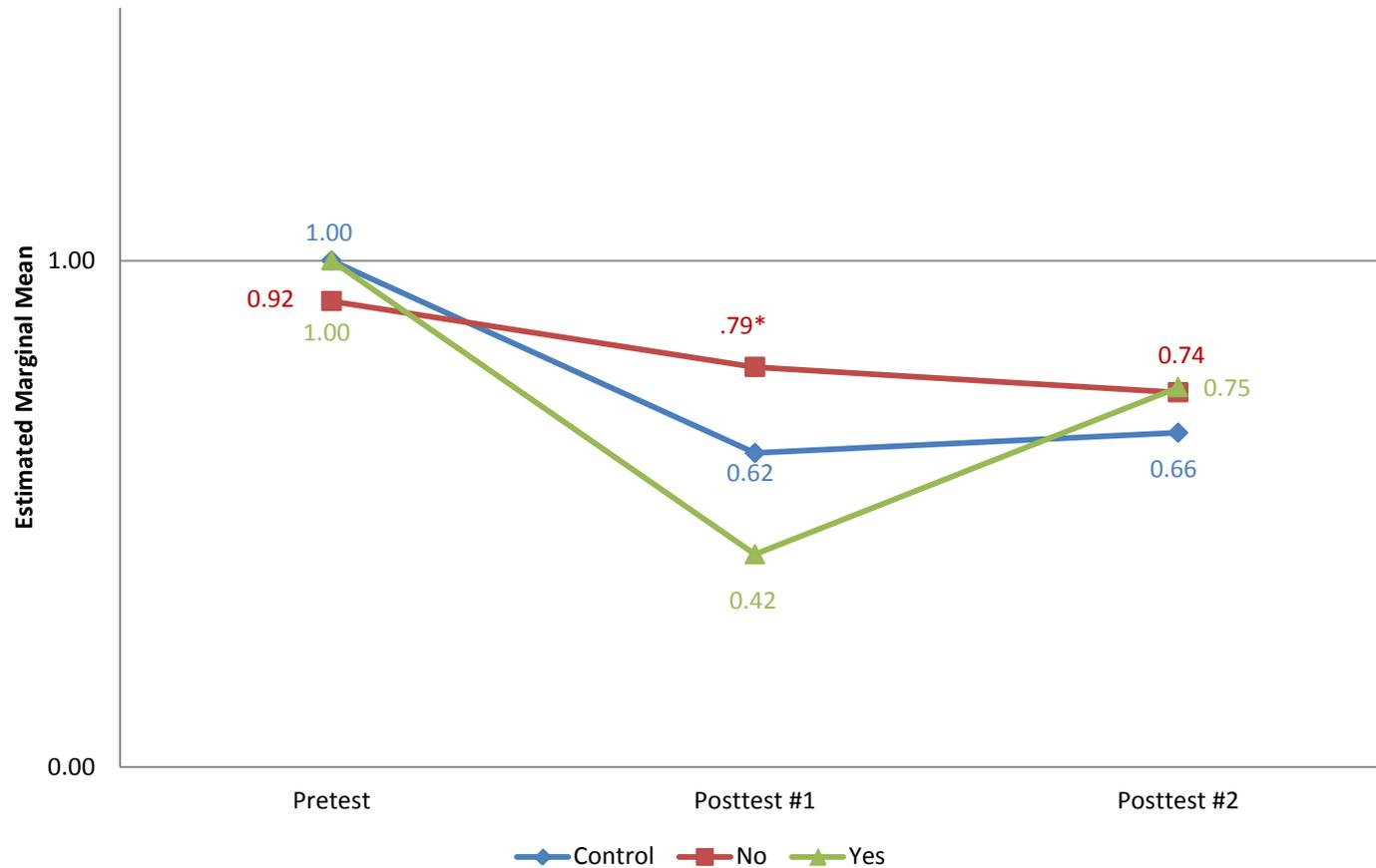
# Health Topics Covered

Topic		Treatment	Control
Pregnancy Prevention	Posttest #1	86.0	27.1
	Posttest #2	85.1	23.5
HIV/AIDS/STD's	Posttest #1	90.7	27.3
	Posttest #2	89.1	34.5
Dealing with Risky Situations	Posttest #1	61.0	37.2
	Posttest #2	61.6	57.9
Using Condoms or Birth Control	Posttest #1	76.7	9.5
	Posttest #2	74.9	8.1
Abstinence	Posttest #1	67.0	16.5
	Posttest #2	74.9	8.1
Human Sexuality	Posttest #1	65.6	16.3
	Posttest #2	61.8	20.1

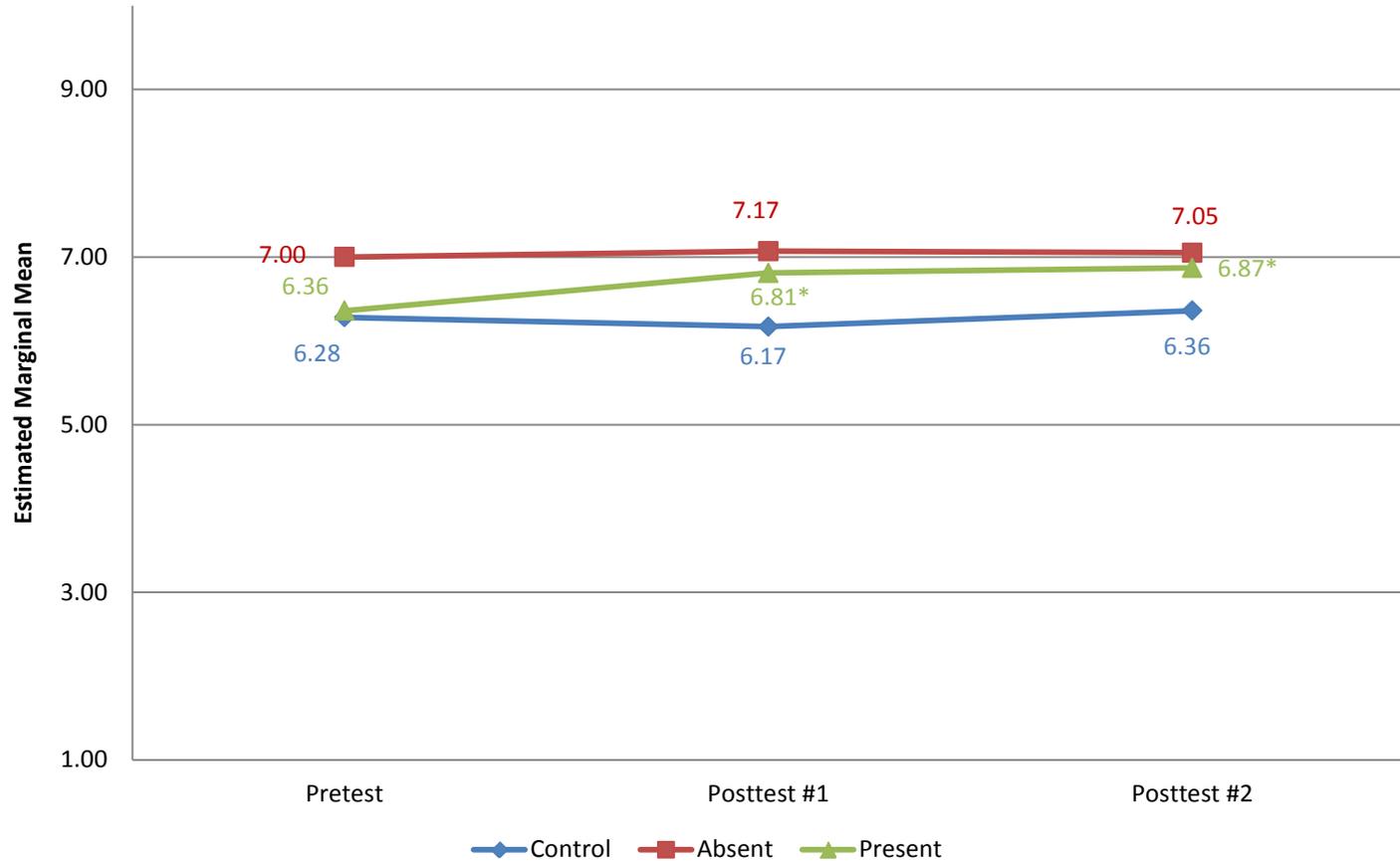
# Had Sex Without Condom in Past 30 Days by Quality



# Had Sex Without Condom in Past 30 Days and Did Condom Lesson



# Self-Efficacy to Use Condoms by Attendance



# Conclusions

- Need to measure fidelity
- Fidelity Matters
  - The use of an RCT alone doesn't make rigorous impact evaluation.
- Strategies to improve fidelity

# Thanks!

## Questions & Feedback

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