Evidence-Based Medicine Journal Club

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Study

- HIV/STD Risk Reduction Interventions for African American and Latino Adolescent Girls at an Adolescent Medicine Clinic: A Randomized Controlled Trial
- Authors: Jemmott III JB, Jemmott LS, Braverman PK, Fong GT
- Archives of Pediatrics and Adolescent Medicine 2005 May;159:440-449.

Introduction

- ¼ of the 15 million new cases of STD's in the US occur in adolescents
- Sexually active adolescents have the highest rate of STD's of any age
- The number of cases of sexually transmitted HIV infection among adolescent females continues to rise

Protection from HIV/STD's

- Abstinence
- Correct and consistent use of condoms
- 50% report using condoms at last sexual intercourse

What can be done?

- Simple access to condoms doesn't prompt correct and consistent use
- Various educational interventions to promote safe sex have been used
- What works?

The Answerable Clinical Question:

- P = Adolescent clinic population of low-income, inner city adolescent girls have a high risk of HIV/STD
- I = Do skill-based interventions
- C = Compared to informational interventions
- O = Decrease the risk of HIV and STD's?

Study Goal

- To determine the efficacy of skill-based HIV/STD risk-reduction intervention in reducing self-reported unprotected sexual intercourse among African American and Latino adolescent girls.

Design

- Randomized controlled trial
- Philadelphia, PA
  - Family planning patients at an adolescent medicine clinic

Are the results of the study valid?

- Was the assignment of patients to treatments randomized?
- Were all patients who entered the study properly accounted for and attributed at its conclusion?
- Was follow-up sufficiently long and complete?

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- Were the groups similar at the start of the trial?
- Aside from the experimental intervention were the groups treated equally?

Was the assignment of patients randomized?

- Participants stratified by age
- Computer generated random number sequence
- Assigned patients to 1 of 3 interventions
  - Skills-based HIV/STD intervention
  - Information-based intervention
  - Health-promotion control intervention

Were all patients who entered the study properly accounted for and attributed at its conclusion?

Figure. Progress of participants through the trial. Those not randomized failed to appear for unknown reasons.

- X^2 and t tests were performed to analyze attrition
- Intervention conditions did not differ significantly in those attending follow-up

Was follow-up sufficiently long and complete?

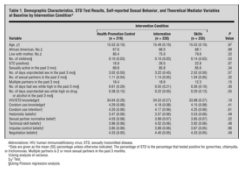
- 12-month follow-up
- Differences not seen at 3- and 6-month follow-ups were just beginning to be seen at the 12-month follow-up.

Were the patients, health care workers and study personnel "blind" to treatment?

- The patients obviously knew which intervention they were receiving.
- The proctors collecting questionnaires at the follow-up visits were blinded.

Were the groups similar at the start of the trial?

- Eligibility criteria same for all groups
- X^2 tests, analyses of variance, and Poisson regression analyses performed on demographic characteristics
- No statistically significant differences among conditions



Aside from the intervention, were the groups treated equally?

- The time allotted for each intervention, the group sizes and the follow-up visits were the same for each group.
- All groups were treated equally.

Are the results of the study valid?

- Was the assignment of patients to treatments randomized? **YES**
- Were all patients who entered the study properly accounted for and attributed at its conclusion? **YES**
- Was follow-up sufficiently long and complete? **PROBABLY NOT**

Are the results of the study valid?

- Were the patients, health care workers and study personnel "blind" to treatment? **NOT EVERYONE**
- Were the groups similar at the start of the trial? **YES**
- Aside from the experimental intervention were the groups treated equally? **YES**

What were the results?

- How large was the treatment effect?
- How precise was the estimate of the treatment effect?

How large was the treatment effect?

- Effect size is a measure of the strength of the relationship between two variables.
- Use of Cohen's d as a measure of effect size – How can it be interpreted?
- Most accepted opinion:
  - 0.2 = small effect
  - 0.5 = medium effect
  - 0.8 = large effect

Results

- Interventions did not differ significantly at the 3- or 6- months follow-up
- Unprotected Sexual Intercourse
  - At the 12-month follow-up, adolescents receiving the skill-based intervention reported less frequent unprotected sexual intercourse than those receiving the health-promotion control (d=0.28; P=.002) or the information-based interventions (d=0.19; P=.033).

Results – Other Sexual Risk Behaviors

- At the 12- month follow-up, those receiving skill-based intervention were less likely to report multiple partners than those in the health-promotion control group (d=0.25; P=.002). No significant difference was noted from the information-based intervention.

Results – STD Rates

- At the 12-month follow-up, adolescents in the skills-based intervention group were significantly less likely (d=0.18; P=0.05) to have an STD than were those in the health promotion control intervention. No statistical difference was found between the information-based intervention.

Results – Conceptual Mediator Variables

- Adolescents in skill-based interventions scored higher in post-intervention than health-promotion control:
  - HIV/STD knowledge (d=0.62; P<.001)
  - Condom use knowledge (d=0.59; P<.001)
  - Intentions (d=0.21; P=.008)
  - Hedonistic beliefs (d=0.28; P<.001)
  - Sexual Partner approval (d=0.20; P=.009)
  - Technical skills beliefs (d=0.20; P=.20)
  - Impulse control beliefs (d=0.19; P=.02)

Results – Conceptual Mediator Variables

- Skill based intervention caused significantly greater increases (d=0.30; P<.001) in condom use knowledge than did the information-based intervention.

How large was the treatment effect?

- For all but two outcome measures, d is close to 0.2 (small effect).
- For HIV/STD knowledge and condom use knowledge, d is of medium effect (d=0.62 and 0.59 respectively) when comparing skill-based interventions vs. health-promotion control.

How precise was the estimate of the treatment effect?

- The true risk-reduction can never be known, it is estimated based on confidence intervals.
- Confidence Interval not given
- Population size has effect on CI
- Power was considered when setting up this study
- 506 participants were needed to give the study a power of 80% to detect a 0.25 SD difference
  - 682 participants were in the study

What were the results?

- How large was the treatment effect? **SMALL EFFECT**
- How precise was the estimate of the treatment effect? **RELATIVELY PRECISE**

Will the results help me in caring for my patients?

- Can the results be applied to my patient care?
- Are the likely treatment benefits worth the potential harms and costs?

Can the results be applied to my patient care?

- Similar population in our adolescent clinic – low-income, inner city adolescents
- Patients in the adolescent clinic have high rates of HIV/STD's
- Adolescents in the study were paid ($120) to participate – it seems unlikely most adolescents in our patient population would spend 4 hours for health education on their own accord.

Are the likely treatment benefits worth the potential harms and costs?

- Drawbacks:
  - Expensive intervention
  - Trained facilitators
  - Time consuming
  - Only a small difference from controls; little difference between skills-based and information-based

Will the results help me in caring for my patients?

- Can the results be applied to my patient care? **MOSTLY**
- Are the likely treatment benefits worth the potential harms and costs? **PROBABLY NOT**

Conclusion

- Although the skills-based intervention method showed statistically significant results when compared to the control, the difference was not large considering the drawbacks to the intervention.
- Even less of a difference was seen in the results between the skills-based intervention and the information-based intervention.
- A less expensive, less time-consuming intervention method is needed for our clinics.