"FREE TESTING AND PREP WITHOUT OUTING MYSELF TO PARENTS"

Barriers and Facilitators for Oral and Injectable Prep Clinical Trial Participation Among AMSM

Celia B. Fisher[1], Leah Ibrahim Puri[1], Adam L. Fried[2], Kathryn Macapagal[3] & Brian Mustanski[3]
Fordham University NY USA[1], Midwestern University AZ USA [2], Northwestern University, IL USA[3]

Funding: National Institute on Minority Health Disparities (#1 R01 MD009561)

Contact: Celia B. Fisher, Ph.D.
Marie Ward Doty University Chair in Ethics
Director, Fordham University
HIV/Drug Abuse Prevention Research Ethics Institute
Bronx, NY, USA
Fisher@Fordham.edu

Presentation can be downloaded at https://goo.gl/EnFQcV

ETHICS@FORDHAM
Center for Ethics Education

FORDHAM UNIVERSITY
THE JESUIT UNIVERSITY OF NEW YORK

BACKGROUND

- US AMSM at HIV risk, now have access to FDA approved oral PrEP (Truvada).
- Non-adherence to daily use of oral PrEP has led to tests of a longer-lasting injectable PrEP (Cabotegravir: CAB). Once approved, CAB vs Truvada RCTS will be conducted with AMSM.
- Understanding AMSM motivations for participation in these trials is needed to inform protections of their rights and welfare.

STUDY AIMS

This study examined the extent to which AMSM'S decision to participate in an oral versus injectable RCT is influenced by the following:

- PrEP preventive benefits and free access to sexual health services versus side effects, lack of STI protection, and need for condom use.
- Altruism, fear of sexual orientation disclosure, and attitudes toward randomization.

PARTICIPANTS

- 198 U.S. AMSM 14 – 17 years: The majority were non-Hispanic white and Hispanic; had more than one lifetime male sex partner (including unprotected anal sex) and had not received an HIV or STI test in the past year.
- AMSM completed an anonymous web-based survey including demographic questions and 26 Likert-type and one open-ended item on reasons for or against participation in a hypothetical oral/injectable PrEP RCT.

HYPOTHETICAL RCT STUDY

- Taking PrEP pills daily protects against HIV but not against STIs. Condoms provide additional protection. Taking pills daily can be difficult so a longer-term injection has been found to work for adults.
- HIV negative youth would be randomly assigned (like a coin toss) to either the daily pill or injectable PrEP (every 3 months) condition for one year.
- Common (headache, upset stomach) and rare reversible (reduced bone density, kidney health) are side effects of PrEP.
- Youth will also receive regular HIV and STI testing, medical checkups to monitor and treat side-effects, and HIV prevention counseling on how to use condoms.

RESULTS

62.6% WOULD PROBABLY OR DEFINITELY AGREE TO PARTICIPATE

Sexual behaviors. Condomless anal sex experiences increased likelihood of participation ($r = .15$, $p < .05$).

"I would not participate because I feel confident I won't get HIV" A composite score for worry about HIV (59%) and likelihood of HIV infection (14%) increased likelihood of participation ($r = .22$, $p < .01$).

Feeling safer and more protected" The majority saw increased HIV protection and **"Not having … to make sure [my partner] put a condom on**" as reasons to participate, 17% would be less likely to participate due to continued need for condoms; 42% - 26% would worry about **"Side effects and putting unnatural things in my body."** A positive benefit-risk composite score increased likelihood of participation ($r = .57$, $p < .001$).

"I need PrEP and my doctor won't give it to me. A Health Services composite score increased likelihood of participation $r = .62$, $P < .001$) and included: Regular medical checkups; "**talking to health counselors about my sexual orientation;"** and free HIV testing and PrEP. For 39% free access to PrEP would lead to participation even if they did not want to.

RESULTS

"I'm concerned about my family discovering my sexual orientation." Not trusting researchers, disclosure to others, and worry that taking pills daily would out them to parents decreased likelihood of participation (Confidentiality score = -.45, $p < .001$).

Random Assignment. 15% – 28% would not participate due to preference for pill or injection and concern about being used as a guinea pig. 57% thought random assignment was fair. However, 60% thought they would be assigned to a condition best for them. The Concerns about Randomization composite score decreased likelihood of participation ($r = -.57$, $p < .001$).

"I would like to be a part of a community with the goal of helping other teens." 93% AMSM endorsed altruism as a reason to participate. ($r = .36$, $p < .001$). 42% indicated **"getting to the check-ups without my parents finding out"** would be a logistic barrier ($r = -.49$, $p < .001$).

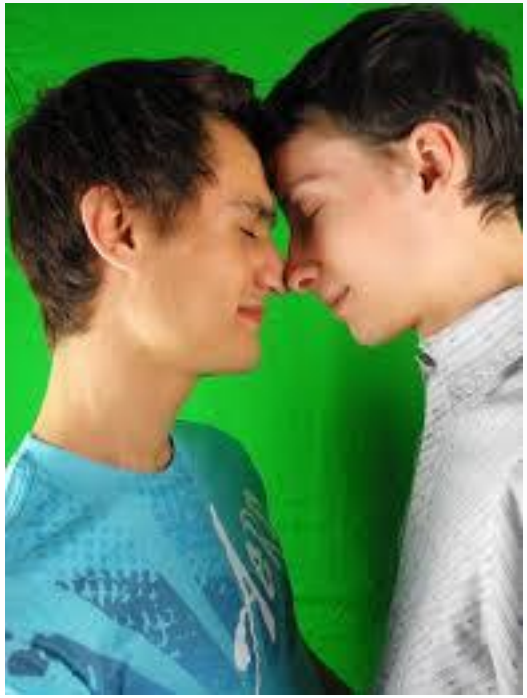
Multiple regression indicated the above variables accounted for 55% of the variance in participation choice.

DISCUSSION

- This is the first study to explore motivations of adolescent MSM to participate in future comparative oral/injectable PrEP RCTs.

- Our data suggest AMSM participation decisions will reflect a balancing of benefits and risks of PrEP medications, the value of access to free sexual health services, and a desire to help other sexual minority youth.

- The reasonableness of these motives is tempered by the potential for decrease in condom use, confusing random assignment with personal care, and potential undue influence of free sexual health services.



IMPLICATIONS FOR PARTICIPANT PROTECTIONS

- The increased risk of STI's and lack of condom use associated with PrEP are health risks observed in older MSM. Enhanced recruitment, informed consent, and monitoring procedures throughout the study should be implemented to encourage AMSM condom use and reduce the risk of STI's.
- Our data challenge the common use of the "coin-toss" as an adequate explanation of random assignment. Future research is needed to construct developmentally tailored explanations.
- "Outing" of sexual orientation to parents presents significant physical and social risk to AMSM. Investigators need to provide youth with privacy strategies they can use outside the research context.
- Lack of access to HIV services is a systemic problem in the US. Free HIV testing and health care is of significant research benefit to AMSM who do not have independent access to such services.
- Strategies to mitigate the potential undue influence of free services include: Recruitment, informed consent, and research visits that provide adequate referrals for youth and investigator advocacy to increase public assistance programs to serve AMSM sexual health needs.

RELATED PUBLICATIONS

Fisher, C.B. (2015). Enhancing the responsible conduct of sexual health prevention research across global and local contexts: Training for evidence-based research ethics. *Ethics &Behavior, 25 (2).* DOI: 10.1080/10508422.2014.948956

Fisher, C. B., Arbeit, M. Dumont, M., Macapagal, & Mustanski, B. (2016). Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Research on Human Research Ethics. 11, 3-14. first published online 3.7.16 DOI: 10.1177/1556264616633963.* PMID 26956988 and PMCID PMC4842126

Fisher, C. B., Fried, A. L., Desmond, M., Macapagal, K., & Mustanski, B. (2017). Facilitators and Barriers to Participation in PrEP HIV Prevention Trials Involving Adolescent and Emerging Adult Transgender Men and Women. *AIDS Education and Prevention, 29(3),* 205-217. doi:10.1521/aeap.2017.29.3.205 PMC5768197 PMID 28650227.

Fisher, C. B., Fried, A. L., Puri, L. I., Macapagal, K. & Mustanski, B. (2018). Patient-provider communication barriers and facilitators to HIV and STI preventive services for adolescent MSM. *Aids & Behavior, DOI: 10.1007/s10461-18-2081-x PMID: 29546468*

Fisher, C. B. & Mustanski, B. (2014). Reducing health disparities and enhancing the responsible conduct of research involving LGBT youth. *Hastings Center Report, 5,* 28-31. PMID 25231783. PMC4617525.http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4617525