



**eKISS**  
**electronic KIOSK Intervention**  
**for Safer-Sex:**

A pilot randomized controlled trial of an Interactive Computer-Based Intervention for Sexual Health in Adolescents and Young Adults

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Taraneh Shafii, MD, MPH, Samantha Benson, MPH,  
 Diane Morrison, PhD, James Hughes PhD,  
 Matthew Golden, MD, MPH, King Holmes, MD, PhD

## Disclosure

- Gen-Probe provided Aptima Combo 3 Assay test kits for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* for this study.



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## Background

- Sexually transmitted infections (STIs), unintended pregnancy rates disproportionately high in adolescent, young adult populations
- We need effective, scalable strategies to promote sexual health and reach young people in real-world settings
- Interactive Computer-Based Interventions (ICBI) are promising tools to meet these goals



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## Purpose of Study

- Test the feasibility and acceptability of an ICBI for sexual health
- Assess the effectiveness of the intervention in reducing unprotected sex
- Pilot test biomarker outcomes of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), and unintended pregnancy



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## Methods

- Pilot randomized controlled trial
- Participants recruited from
  - Public Health STD Clinic
- Recruitment flyers posted
  - Family Practice Clinic, Pediatric Clinic
  - 2 clinics serving homeless youth
  - Center serving homeless youth



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## Eligibility Criteria

- Males and females
- Age 14-24 years
- One episode of unprotected vaginal sex in the last 2 months: no condom or no birth control
- Self or partner not pregnant nor actively trying
- English language speaking, reading



## Study Procedures

- Screened for eligibility and consented via computer
- Randomization computer generated, stratified by gender, age (14-18, 19-24 yrs), visit type (expedited, clinician)
- Investigators and participants blinded to allocation arm



## Study Procedures

- Baseline visit
  - Sexual history computer assisted self-interview (CASI) +/- ICBI
  - Urine testing for GC/CT with NAAT
  - Incentive \$25 and bus ticket
- One follow-up visit at 3 months
  - Interim sexual history via CASI
  - Urine testing GC/CT; pregnancy (females only)
  - Incentive \$50 and bus ticket
- Approved by U. of Washington HSD



## Intervention

- Concept from Options Project
  - Jeffrey Fisher, PhD, U of Connecticut
  - Theoretical model: Information, Motivation, Behavioral Skills; motivational interviewing
  - Brief clinician-delivered to high-risk adults
- Adapted to computer-delivered
  - Designed to mimic clinician encounter
  - Client-centered, elements of motivational interviewing
  - Population adolescent and young adults



Now we'd like you to meet two of our doctors.



Dr. Turner

Dr. Rob

Which doctor would you like to talk with today?

- Dr. Turner
- Dr. Rob
- I choose not to have a doctor

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Hi, I'm Dr. Turner. I would like to talk with you for a few minutes about safer sex.

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I see you are keeping yourself healthy because... You and your partners use condoms SOME of the time. You and your partners use birth control like birth control pills, OrthoEvra Patch, NuvaRing, Depo-Provera Shot, IUD (Mirena), or Implanon SOME of the time. Your NEW partners get tested for STDS SOME of the time before you have sex together for the first time. You came into the clinic today. That is great! Keep it up!

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**But I am worried that you and your partners are at risk for getting STDs/HIV or pregnant because ...**  
 You and your partners don't always use birth control (like Birth Control Pils, OrthoIn-14 Patch, DepoProvera Shot, NuvaRing, the IUD) PLUS condoms.  
 Your partners have sex with other people beside you.  
 You and your partners don't always get tested for STDs/HIV before you have sex together for the first time.  
 You had sex with 4 or more people in the last 12 months.

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**I'd like to talk with you more about safer sex. You get to choose-what do you want to discuss more?**

- Condoms and how to avoid an STD/HIV
- Birth control and how to avoid an unplanned pregnancy.

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**How important is it for you and your partners to use condoms?**  
 0 means it is NOT at all important for you and your partners to use condoms.  
 10 means it is EXTREMELY important for you and your partners to use condoms.

Please choose the number that describes you:

Not at all important 0	1	2	3	4	5	6	7	8	9	Extremely important 10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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**How SURE are you that you and your partners could use condoms more than you do now?**  
 0 means you are NOT at all sure you and your partners could use condoms more than you do now.  
 10 means you are EXTREMELY sure you and your partners could use condoms more than you do now.

Please choose the number that describes you:

Not at all sure 0	1	2	3	4	5	6	7	8	9	Extremely sure 10
<input type="radio"/>										

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**You gave yourself a 5 for importance which tells me that using condoms is IMPORTANT to you. Why didn't you give yourself a lower number for importance like 4 or 3 or even a 0?**

Choose ALL that describe you:

- I don't want to get an STD/HIV from my partners
- I don't want to give an STD/HIV to my partners
- I've had an STD before and don't want to get one again
- I'm not trying to get pregnant right now
- I've gotten pregnant unexpectedly before
- Other: Please Specify:

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**What makes it difficult for you and your partners to use condoms?**

Choose ALL that describe you:

- Sometimes I don't feel comfortable talking with my partners about using condoms
- Sometimes I don't feel comfortable getting condoms from the clinic or pharmacy
- Sometimes I don't plan ahead and have condoms with me if I have sex
- Sometimes I have difficulty using condoms, especially in the heat of the moment
- Sometimes the condoms break or slip off while we are having sex
- Other: Please Specify:

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Which strategy would you like to know more about?

Please choose one:

- Condoms and how to avoid STDs/HIV
- Condoms PLUS birth control and how to avoid STDs/HIV and unplanned pregnancy

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Condoms and How to Avoid STDs/HIV

Please click the play button to watch this video of Theresa and Luis talking about condoms.  
Theresa and Luis: How to talk about condom use. *By Safe in the City*



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Please click the play button to review how to use condoms.

How to Use Condoms. *By Planned Parenthood*



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Which strategy do you want to focus on as a personal goal?

- I will talk with my partners about using condoms
- I will use condoms the next time I have sex
- I will carry condoms with me more than I do now
- I will only have sex with my partners if we use condoms
- I will only have sex with my partners if we use condoms and I am on birth control
- Other: Please specify: \_\_\_\_\_

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Good luck with your personal goal of "I will carry condoms with me more than I do now"

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## Outcomes

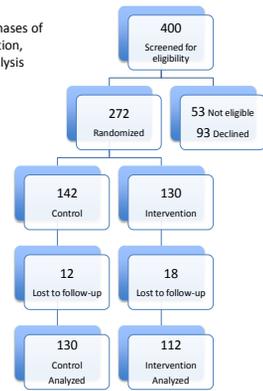
- Primary
  - Number of unprotected (no condoms) sex events in last 2 months
- Secondary
  - Number of unprotected (no birth control) sex events in last 2 months
  - Number of partners in the last 2 months
  - Incident GC/CT, pregnancy



## Statistical Methods

- T-test and Chi-square used to assess for differences between allocation arms at baseline
- Poisson regression with robust error variance to model outcome count variables: unprotected sex (condoms, birth control), number of partners
- Binomial regression used to model outcomes: incident CT/GC and unintended pregnancy

Flow diagram of phases of enrollment, allocation, follow-up, and analysis



Yielded follow-up rate 89%



Demographics	Total n=272 No. (%)	Control n=142 No. (%)	Intervention n=130 No. (%)
Age 21 yr (15-24)			
Female	176 (65)	89 (63)	87 (67)
Race/ethnicity			
White	101 (38)	56 (40)	45 (35)
Black	92 (34)	47 (33)	45 (35)
Asian/PI	27 (10)	15 (10)	12 (9)
Hispanic	19 (7)	8 (6)	11 (8)
Native American	6 (2)	4 (3)	2 (2)
Other	25 (9)	11 (8)	14 (11)
Health insurance			
Private	32 (12)	18 (13)	14 (11)
Medicaid	35 (13)	19 (13)	16 (12)
None	156 (58)	82 (58)	74 (57)
Education (19-24 yr)			
High school - some	52 (22)	30 (25)	22 (19)

Baseline Sexual Behavior	Total n=272	Control n=142	Intervention n=130
Age (yr) first vaginal sex	Mean (range) 15.6 (9-23)	15.4 (9-22)	15.9 (9-23)
No. sex partners	Median (range)		
12 months	3 (1-120)	3 (1-120)	3 (1-15)
2 months	1 (1-25)	1 (1-25)	1 (1-15)
New 2 months	1 (0-15)	1 (0-15)	1 (0-12)
Unprotected vaginal sex in last 2 months	3 (0-100)	4 (0-100)	3 (0-75)
No condom	5 (0-80)	4 (0-80)	5 (0-75)
No birth control (F)			
Most recent sex	No. (%)		
Used Condom	99 (36)	49 (34)	50 (38)
Used Birth control	92 (34)	55 (39)	37 (28)
Sex while drunk or high, ever	227 (84)	120 (84)	107 (82)
Exchanged sex for drugs/money, ever*	21 (8)	14 (10)	7 (5)*

Baseline Sexual Behavior	Total n=272 No. (%)	Control n=142	Intervention n=130
Last 2 months			
Anal sex	40 (15)	21 (15)	19 (15)
Oral sex, given	204 (75)	102 (72)	102 (78)
Oral sex, received	220 (81)	113 (80)	107 (82)
STD testing before most recent partner	87 (32)	50 (35)	37 (28)
Most recent partner have other partners			
Yes	60 (22)	34 (24)	26 (20)
No	98 (36)	55 (39)	43 (33)
Don't know	114 (42)	53 (37)	61 (47)
Pregnant, ever self or partner	109 (40)	59 (42)	50 (38)
Diagnosed STI, ever *(p<0.05)	145 (53)	84 (59)	61 (47)*
Baseline STI testing			
+ Chlamydia	32 (12)	17 (12)	15 (12)
+ Gonorrhea	7 (3)	3 (2)	4 (3)

Primary Outcome	Incident Rate Ratio (95% CI) Unadjusted model Adjusted model*
Unprotected vaginal sex (no condoms) in last 2 months	0.67 (0.44-1.02) p=0.05 0.67 (0.44-1.01) p=0.06

\*Statistical model adjusted for baseline differences of self-reported history of STI and ever transactional sex

- At 3-month follow-up those intervention arm reported 33% lower rate of unprotected sex (no condoms)
- No difference in unadjusted and adjusted models



Secondary Outcomes	Incident Rate Ratio (95% CI) Unadjusted model Adjusted model*
Number of sex partners in last 2 months	0.71 (0.50-1.03) p=0.07 0.80 (0.61-1.05) p=0.11

\*Statistical model adjusted for baseline differences of self-reported history of STI and ever transactional sex

- At 3-month follow-up those intervention arm reported 20% fewer sex partners
- Effect size attenuated in adjusted model



Secondary Outcomes	Incident Rate Ratio (95% CI) Unadjusted model Adjusted model*
Incident CT (no GC) (biomarker, self-report)	0.52 (0.25-1.08) p=0.08 0.55 (0.26-1.13) p=0.10

\*Statistical model adjusted for baseline differences of self-reported history of STI, ever transactional sex

- At 3-month follow-up those intervention arm had 45% fewer CT infections
- No difference in unadjusted and adjusted models
- Rare outcome: CT Positive: Control n=26; Intervention n=13



Secondary Outcomes Females only	Incident Rate Ratio (95% CI) Unadjusted model Adjusted model*
Unprotected vaginal sex (no birth control) in last 2 months	0.80 (0.47-1.35) p=0.40 0.78 (0.46-1.32) p=0.35

\*Statistical model adjusted for baseline differences of self-reported history of STI, ever transactional sex, baseline use of birth control

- At 3-month follow-up females in intervention arm reported 22% lower rate of unprotected sex (no birth control)
- No difference in unadjusted and adjusted models



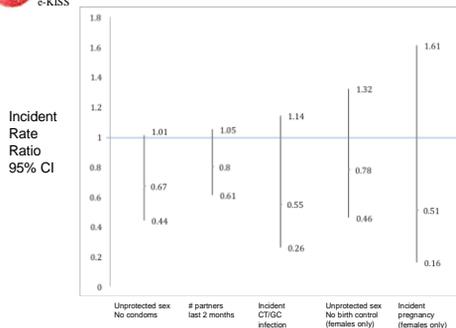
Secondary Outcomes Females only	Incident Rate Ratio (95% CI) Unadjusted model Adjusted model*
Incident pregnancy (biomarker and self-report)	0.51 (0.17-1.58) p=0.25 0.51 (0.16-1.61) p=0.25

\*Statistical model adjusted for baseline differences of self-reported history of STI, ever transactional sex

- At 3-month follow-up females in intervention arm reported 49% fewer pregnancies
- No difference in unadjusted and adjusted models
- Rare outcome: Pregnancy Control n=10; Intervention n=5



### Adjusted Outcome Models



Adjusted for baseline differences of ever STI and ever transactional sex

Exploratory Analysis Females	Incident Rate Ratio (95% CI) Adjusted model*
Unprotected vaginal sex (no condoms) last 2 months	0.50 (0.30-0.85) p=0.01
Number of sex partners in last 2 months	0.71 (0.50-1.00) p=0.05

\*Statistical model adjusted for baseline differences of condom use; birth control use and ever transactional sex

- At 3-month follow-up females intervention arm reported
  - 50% lower rate of unprotected sex (no condoms)
  - 29% fewer sex partners





## Limitations and Strengths

- Limitations
  - Did not reach planned sample size
    - Time needed to program and test the computer intervention
    - Lower than expected clinic volumes in age group
- Strengths
  - Computer intervention provides personalized confidential feedback, self-paced
  - Scalable with potential to reach high-risk populations
  - Collected biomarkers for STI and pregnancy



## Conclusions

- ICBI feasible to execute and acceptable to study population
- Although did not reach statistical significance, trend in effectiveness of the intervention at 3 month follow-up:
  - Reducing unprotected vaginal sex (no condoms)
  - Reducing number of partners
  - Reducing incident CT, GC, unintended pregnancy
- Statistical significance reached in females only
  - Reducing unprotected vaginal sex (no condoms)
- Next steps larger study to definitively test effectiveness for behavioral and biomarker outcomes



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