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

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

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

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

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

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

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
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

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Total n=272 No. (%)</th>
<th>Control n=142 No. (%)</th>
<th>Intervention n=130 No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 21 yr (15-24)</td>
<td>176 (65)</td>
<td>89 (63)</td>
<td>87 (67)</td>
</tr>
<tr>
<td>Female</td>
<td>101 (38)</td>
<td>56 (40)</td>
<td>45 (35)</td>
</tr>
<tr>
<td>White</td>
<td>92 (34)</td>
<td>47 (33)</td>
<td>45 (35)</td>
</tr>
<tr>
<td>Asian/PI</td>
<td>27 (10)</td>
<td>15 (10)</td>
<td>12 (9)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>19 (7)</td>
<td>8 (6)</td>
<td>11 (8)</td>
</tr>
<tr>
<td>Native American</td>
<td>6 (2)</td>
<td>4 (3)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>25 (9)</td>
<td>11 (8)</td>
<td>14 (11)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>35 (13)</td>
<td>19 (13)</td>
<td>16 (12)</td>
</tr>
<tr>
<td>None</td>
<td>156 (58)</td>
<td>82 (58)</td>
<td>74 (57)</td>
</tr>
<tr>
<td>Education (19-24 yr)</td>
<td>52 (22)</td>
<td>30 (25)</td>
<td>22 (19)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline Sexual Behavior</th>
<th>Total n=272 No. (%)</th>
<th>Control n=142 No. (%)</th>
<th>Intervention n=130 No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last 2 months</td>
<td>204 (75)</td>
<td>102 (72)</td>
<td>102 (78)</td>
</tr>
<tr>
<td>Oral sex, received</td>
<td>220 (81)</td>
<td>113 (80)</td>
<td>107 (82)</td>
</tr>
<tr>
<td>STD testing before most recent partner</td>
<td>87 (32)</td>
<td>50 (35)</td>
<td>37 (28)</td>
</tr>
<tr>
<td>Most recent partner have other partners</td>
<td>114 (42)</td>
<td>53 (37)</td>
<td>53 (37)</td>
</tr>
<tr>
<td>Pregnant, ever self or partner</td>
<td>109 (40)</td>
<td>59 (42)</td>
<td>50 (38)</td>
</tr>
<tr>
<td>Diagnosed STI, ever *p&lt;0.05</td>
<td>84 (30)</td>
<td>59 (42)</td>
<td>26 (20)</td>
</tr>
<tr>
<td>Baseline STI testing + Chlamydia + Gonorrhea</td>
<td>32 (12)</td>
<td>17 (12)</td>
<td>15 (12)</td>
</tr>
</tbody>
</table>

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<th>Intervention n=130 No. (%)</th>
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</thead>
<tbody>
<tr>
<td>Age (yr) first vaginal sex</td>
<td>15.6 (9-23)</td>
<td>15.4 (9-22)</td>
<td>15.9 (9-23)</td>
</tr>
<tr>
<td>No. partners 12 months</td>
<td>99 (36)</td>
<td>49 (34)</td>
<td>50 (38)</td>
</tr>
<tr>
<td>No. partners New 2 months</td>
<td>92 (34)</td>
<td>55 (39)</td>
<td>37 (28)</td>
</tr>
<tr>
<td>Unprotected vaginal sex in last 2 months</td>
<td>3 (0-100)</td>
<td>4 (0-100)</td>
<td>3 (0-75)</td>
</tr>
<tr>
<td>Unprotected vaginal sex</td>
<td>93 (34)</td>
<td>55 (39)</td>
<td>37 (28)</td>
</tr>
<tr>
<td>No birth control</td>
<td>150 (55)</td>
<td>77 (54)</td>
<td>73 (55)</td>
</tr>
<tr>
<td>Most recent sex used Condom Used Birth control</td>
<td>113 (42)</td>
<td>59 (42)</td>
<td>50 (38)</td>
</tr>
<tr>
<td>Sex while drunk or high, ever</td>
<td>227 (84)</td>
<td>120 (84)</td>
<td>107 (83)</td>
</tr>
<tr>
<td>Exchanged sex for drugs/money, ever</td>
<td>21 (8)</td>
<td>14 (10)</td>
<td>7 (5)</td>
</tr>
</tbody>
</table>

**Primary Outcome**

Incident Rate Ratio (95% CI)

Unprotected vaginal sex (no condoms) in last 2 months

- Unadjusted model
- Adjusted model

*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

<table>
<thead>
<tr>
<th>Incident Rate Ratio (95% CI)</th>
<th>Unadjusted model</th>
<th>Adjusted model*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of sex partners in last 2 months</td>
<td>0.71 (0.50-1.03) p=0.07</td>
<td>0.80 (0.61-1.05) p=0.11</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
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<th>Incidence Rate Ratio (95% CI)</th>
<th>Unadjusted model</th>
<th>Adjusted model*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident CT (no GC) (biomarker, self-report)</td>
<td>0.52 (0.25-1.08) p=0.08</td>
<td>0.55 (0.26-1.13) p=0.10</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Incidence Rate Ratio (95% CI)</th>
<th>Unadjusted model</th>
<th>Adjusted model*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprotected vaginal sex (no birth control) in last 2 months</td>
<td>0.80 (0.47-1.35) p=0.40</td>
<td>0.78 (0.46-1.32) p=0.35</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Incidence Rate Ratio (95% CI)</th>
<th>Unadjusted model</th>
<th>Adjusted model*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident pregnancy (biomarker and self-report)</td>
<td>0.51 (0.17-1.58) p=0.25</td>
<td>0.51 (0.16-1.61) p=0.25</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Incidence Rate Ratio 95% CI</th>
<th>Unadjusted model</th>
<th>Adjusted model*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprotected vaginal sex (no condoms) last 2 months</td>
<td>0.50 (0.30-0.85) p=0.01</td>
<td></td>
</tr>
<tr>
<td>Number of sex partners in last 2 months</td>
<td>0.71 (0.50-1.00) p=0.05</td>
<td></td>
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</tbody>
</table>

*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**

**Acknowledgements**

- Research mentors:
  - King Holmes, MD, PhD, Diane Morrison, PhD, Matt Golden, MD, MPH
- Research coordinator: Samantha Benson, MPH
- Public Health Seattle & King County STD Clinic and ALL STAFF!
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- Options Project: Jeffrey Fisher, PhD
- Adolescent Medicine Division Chief: Leslie Walker, MD, MPH
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  - U. of Washington Dept of Pediatrics, Seattle Children’s Hospital
  - GenProbe (GC/CT test kits)