

PROTECT & CONNECT (PACT)

Best Evidence – Risk Reduction

INTERVENTION DESCRIPTION

Goals of Intervention

- Reduce condomless vaginal and/or anal intercourse

Target Population

- Men in community supervision who use drugs and their main female sex partners

Brief Description

Protect & Connect (PACT) is a couple-based intervention that consists of HIV counseling, testing, and referral (CTR) as well as five HIV and sexually transmitted infection (STI) risk-reduction sessions delivered to each pair. These sessions emphasize the importance of couple communication; negotiation and problem-solving skills; technical condom-use skills; strategies for identifying and reducing personal risks, such as unsafe injection practices; biomedical HIV prevention strategies (e.g., HIV treatment as prevention, post-exposure prophylaxis, and pre-exposure prophylaxis); linkage to HIV, STI, and substance use treatment; reproductive health issues; risks for and experiences of sexual coercion; opioid overdose response and prevention; informal social support; and couple goal setting to increase protective behaviors.

Theoretical Basis

- Social Cognitive Theory
- Ecological framework
- Motivational Interviewing

Intervention Duration

- Five weekly sessions (1st session: 45 minutes; remaining 4 sessions: 90 minutes each) delivered over 5 weeks

Intervention Settings

- Community Supervision Program Site

Deliverer

- Social worker or master's level social work student who completed four days of training on the intervention

Delivery Methods

- Counseling
- Discussion
- Goal setting
- Skills building

Structural Components

There are no structural components reported for this study.

INTERVENTION PACKAGE INFORMATION

An intervention package is available. Please contact **Nabila El-Bassel**, Social Intervention Group, Columbia University, School of Social Work, New York, NY 10027.

Email: ne5@columbia.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS**Study Location**

The original evaluation study was conducted in New York, NY between July 2013 and July 2017.

Key Intervention Effects

- Reduced condomless vaginal and/or anal sex

Recruitment Settings

Community Supervision Programs

Eligibility Criteria

Participants were eligible to participate if they were 18 years or older; both partners identified each other as their primary sexual partner of the opposite sex; the relationship had lasted at least 3 months; at least one partner reported having had condomless vaginal and/or anal intercourse with the other in the past 90 days; at least one partner reported exposure to an outside HIV risk in the past year (i.e., engaged in unprotected sex with another partner, shared syringes, tested positive for HIV or other sexually transmitted infection (STI), or at least one partner suspected that their partner had exposure to an outside HIV risk); the couple planned to stay together for at least another year; and the male partner was mandated to community supervision, an alternative to incarceration or probation verified by court records. Additional criteria for the male partner included either (a) use of illicit drugs or binge drinking (i.e., drinking 5 or more alcoholic beverages on a single occasion) in the past 90 days or (b) attended substance abuse treatment in the past 90 days. Participants were excluded if they did not have sufficient fluency in English, had significant psychiatric or cognitive impairments, or identified safety concerns about participating with their partner.

Study Sample

The baseline sample of 460 participants (230 couples) is characterized by the following:

- 74% *black or African American, 19% Hispanic/Latino*
- 50% *male; 50% female*
- *Mean age of 35 years*
- 7% *HIV positive; 17% had an STI*
- 29% *reported binge drinking in the past 90 days*
- 58% *used illicit drugs in the past 90 days*
- 6% *injected drugs in the past 90 days*

Assignment Method

Participants (N = 460; 230 couples) were randomized to 1 of 2 study arms: Protect and Connect (PACT) Intervention (n = 230; 115 couples) or HIV Counseling, Testing, and Referral (CTR) condition (n = 230; 115 couples).

Comparison

The HIV CTR condition consisted of one session. Participants received rapid oral HIV testing, pretest/posttest counseling, and referral to HIV or STI care. Additional services included individualized health risk assessment, identification of current use of case management services and need for additional social health services, and a resource manual to assist in linkage to services needed as identified by the couple.

Relevant Outcomes Measured

- HIV and incident STIs (including gonorrhea, chlamydia, and trichomonas vaginalis) were measured at the 12-month follow-up.
- Sex behaviors (including the total number of times of condomless vaginal and/or anal intercourse, number of times of vaginal and/or anal intercourse with the study partner and all other partners, number of sexual partners during the past 90 days) were measured at 3-, 6- and 12-month follow-ups.
- Drug use behavior (including injection drug use during the past 90 days) was measured at 3-, 6-, and 12-month follow-ups.

Participant Retention

- PACT Intervention:
 - 77% retained at 3 months
 - 84% retained at 6 months
 - 88% retained at 12 months
- HIV CTR Condition:
 - 82% retained at 3 months
 - 84% retained at 6 months
 - 84% retained at 12 months

Significant Findings on Relevant Outcomes

- Across all follow-ups, intervention participants reported 33% fewer acts of condomless vaginal and/or anal intercourse with their study partners in the past 90 days than comparison participants (Incidence Rate Ratio [IRR] = 0.67, 95% CI: 0.45 - 0.99, p = 0.04). *
 - At the 6-month follow-up, intervention participants reported 33% fewer acts of condomless vaginal and/or anal intercourse with their study partners in the past 90 days than comparison participants (IRR = 0.67, 95% CI: 0.46 - 0.99, p = 0.04). *
 - At the 12-month follow-up, intervention participants reported 39% fewer acts of condomless vaginal and/or anal intercourse with their study partners in the past 90 days than comparison participants (IRR = 0.61, 95% CI: 0.41 - 0.91, p = 0.02). *
- Across all follow-ups, intervention participants reported 70% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR=0.30, 95% CI: 0.12 - 0.74, p = 0.009). *

- At the three-month follow-up, intervention participants reported 67% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR = 0.33, 95% CI: 0.13 - 0.86, p = 0.02). *
- At the six-month follow-up, intervention participants reported 69% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR = 0.31, 95% CI: 0.12 - 0.77, p = 0.01). *
- At the 12-month follow-up, intervention participants reported 74% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR = 0.26, 95% CI: 0.10 - 0.66, p = 0.004). *
- Across all follow-ups, intervention participants reported 40% fewer acts of condomless vaginal and/or anal intercourse with all partners in the past 90 days than comparison participants (IRR=0.60, 95% CI: 0.42 - 0.85, p = 0.005). *
 - At the three-month follow-up, intervention participants reported 36% fewer acts of condomless vaginal and/or anal intercourse with all partners in the past 90 days than comparison participants (IRR = 0.64, 95% CI: 0.45 - 0.92, p = 0.02). *
 - At the six-month follow-up, intervention participants reported 40% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR = 0.60, 95% CI: 0.42 - 0.86, p = 0.005). *
 - At the 12-month follow-up, intervention participants reported 47% fewer acts of condomless vaginal and/or anal intercourse with their non-study partners in the past 90 days than comparison participants (IRR = 0.53, 95% CI: 0.37 - 0.76, p = 0.001). *
- Across all follow-ups, intervention participants reported 26% fewer sex partners in the past 90 days than comparison participants (IRR = 0.74, 95% CI: 0.61 - 0.88, p = 0.001). *
 - At the three-month follow-up, intervention participants reported 31% fewer sex partners in the past 90 days than comparison participants (IRR = 0.69, 95% CI: 0.55 - 0.87, p = 0.002). *
 - At the six-month follow-up, intervention participants reported 27% fewer sex partners in the past 90 days than comparison participants (IRR = 0.73, 95% CI: 0.61 - 0.87, p = 0.001). *

Considerations

Additional significant positive findings on non-relevant outcomes

Condom use intentions:

- Across all follow-ups and at the three- and six-month follow-ups, condom use intentions were significantly higher among the intervention participants than among the comparison participants, respectively ($\beta = 0.71$, 95% CI: 0.15 - 1.26, p = 0.01; $\beta = 0.70$, 95% CI: 0.02 - 1.38, p = 0.04; $\beta = 0.71$, 95% CI: 0.14 - 1.27, p = 0.01).*

Condom use self-efficacy:

- Across all follow-ups and at the three-, six- and 12-month follow-ups, condom use self-efficacy was significantly higher among the intervention participants than among the comparison participants respectively ($\beta = 1.52$, 95% CI: 0.42 - 2.62, p = 0.007; $\beta = 1.35$, 95% CI: 0.03 - 2.67, p = 0.046; $\beta = 1.48$, 95% CI: 0.36 - 2.60, p = 0.01; $\beta = 1.74$, 95% CI: 0.34 - 3.13, p = 0.02).*

Number of times discussed with study partner on how to prevent HIV in the past 90 days:

- Across all follow-ups and at the three- and six-month follow-ups, intervention participants discussed with their study partner how to prevent HIV more often in the past 90 days than comparison participants (IRR =

1.89, 95% CI: 1.06 - 3.36, $p = 0.03$; IRR = 2.18, 95% CI: 1.22 - 3.89, $p = 0.009$; IRR = 1.93, 95% CI: 1.09 - 3.43, $p = 0.03$).*

Being under the influence of drugs or alcohol the last (most recent) time of vaginal and or anal intercourse with study partner in the past 90 days:

- Across all follow-ups and at the six- and 12-month follow-ups, a significantly lower proportion of intervention participants reported a being under the influence of drugs or alcohol during the last (most recent) time of vaginal or anal intercourse with their study partner in the past 90 days than comparison participants (OR = 0.55, 95% CI: 0.31 - 0.96, $p = 0.04$; OR = 0.56, 95% CI: 0.31 - 0.99, $p = 0.046$; 12 OR = 0.47, 95% CI: 0.23 - 0.99, $p = 0.046$).*

Non-significant findings on relevant outcomes

- There were no significant intervention effects at any follow-up on injection drug use or cumulative STI incidence.
- There was no significant intervention effect on condomless vaginal or anal intercourse with study partner in the past 90 days at the three-month follow-up.
- There was no significant intervention effect on number of sex partners in the past 90 days at the 12-month follow-up.

Negative findings

- None reported

Other related findings

- There were significant differences in illicit drug use and race between those lost to follow-up and those retained; however, both variables were included as covariates and controlled for in the analysis.

Implementation-related findings

- None reported

Process/study execution-related findings

- All sessions were digitally recorded for both arms. The recording sessions were used for quality control and supervision. After listening to each session recording, the supervisors used the information gained to provide feedback to the facilitators to improve the fidelity and delivery of the sessions.

Adverse events

- None reported

*Note: Multilevel models included random effects for couple, repeated measures, and covariate adjustments for baseline measures of the outcomes, and other covariate adjustments (i.e., sex, age, black or African American race/ethnicity, high school, single, homeless, not enough money for food, ever in prison, and illicit drug use).

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REFERENCES AND CONTACT INFORMATION

El-Bassel, N., Gilbert, L., Goddard-Eckrich, D., Chang, M., Wu, E., Goodwin, S., Tibbetts, R., Almonte-Weston, M., & Hunt, T. (2019). [Effectiveness of a couple-based HIV and sexually transmitted infection prevention intervention for men in community supervision programs and their female sexual partners: A randomized clinical trial](#). *JAMA Network Open*, 2(3), e191139.

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