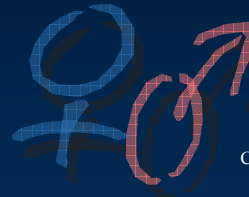




Project Connect: A Relationship-Based HIV/STI Intervention for Heterosexual Couples

Nabila El-Bassel
Louisa Gilbert
Susan Witte
Elwin Wu
Mingway Chang
Jennifer Hill
Peter Steinglass



Social Intervention Group
Columbia University School of Social Work
<http://www.Columbia.edu/cu/ssw/sig/>

2

Project Connect

- Randomized, controlled clinical trial
- 4-year study funded by the National Institute of Mental Health (NIMH, R01A140883)
- Carried out 1997 – 2001
- Combines stage I and stage II

3

Project Connect

This presentation will cover:

- The rationale for designing an HIV/STI prevention intervention for couples
- Stage I developmental phase
- Design and findings of the efficacy trial
- Implications of the findings for research in order to advance the science of HIV behavioral prevention intervention for couples

4

Project Connect

Why the HIV field needs to design HIV/STI prevention intervention models for women and their intimate sexual partners?

5

WHO Worldwide Prevalence of HIV/AIDS Among Women

- Number of women living with HIV/AIDS has increased
- 16 million women are living with HIV/AIDS
- Women account for 49.5% of adults living with AIDS
- 80% of adult HIV infections have resulted from heterosexual intercourse
- HIV infections continue to rise among racial and ethnic minorities and women

6

Prevalence of HIV/AIDS in the U.S.

- AIDS remains a crisis in the United States, despite the introduction of antiretroviral therapies in the mid 1990's
- In 2002, 26% of people living with HIV/AIDS in U.S were women
- In 2002, 72% of newly reported HIV infections among women occurred through heterosexual intercourse (among cases where the exposure category was known)
- Women are less likely to use condoms or protect themselves from HIV with their main sexual partner

7

Science of HIV/STI Intervention for Women in Long-term Relationships

Progress has been made in the science of HIV/STI prevention interventions for women:

- Early HIV/STI prevention interventions were less effective in helping women in long-term relationships to initiate safer sex practices
- Early interventions focused on either men or women as individual targets of change

8

Science of HIV/STI Interventions for Women in Long-term Relationships

- Were often provided through a group modality
- Rarely considered relationship dyadic contexts (intimacy, length of the relationship, love, commitment, closeness)
- Couple-based HIV prevention intervention is in its early stages and most studies conducted outside US
- HIV field in urgent need for evidence-based HIV prevention intervention for couples

9

Project Connect: Design & Implementation

- Developmental(Stage I)
- Clinical Trial Phase (Stage II)

10

Design & Implementation

Developmental/Stage I

- Designed a new theory-driven HIV/STI prevention intervention protocol consisting of six sessions
- Created assessment tools
- Developed training manuals for recruitment, assessment and intervention

11

Design & Implementation

Developmental/Stage I

- Designed data safety procedures to ensure participants' safety and confidentiality
- Created quality assurance procedures to assess fidelity of the implementation of the study protocols
- Developed process measures: 1) Facilitator Implementation and Evaluation Form, 2) Facilitator Competence Questionnaire, 3) Participant Evaluation Questionnaire

12

Design & Implementation

Developmental/Stage I

- Piloted recruitment strategies and the intervention using a small sample size
- Refined all protocols and manuals

13

Developmental/Stage I

Conducted focus groups and in-depth interviews with couples, community members

- Focus Groups
 - 4 cohorts; 3-4 couples each
 - Simultaneous, single sex focus groups, twice, one week apart
 - One couple focus group
 - In-depth interviews

14

Developmental/Stage I

- Elicited feedback from experts and community members
- Refined the protocols (assessment, recruitment, intervention)
- Trained assessment and intervention staff

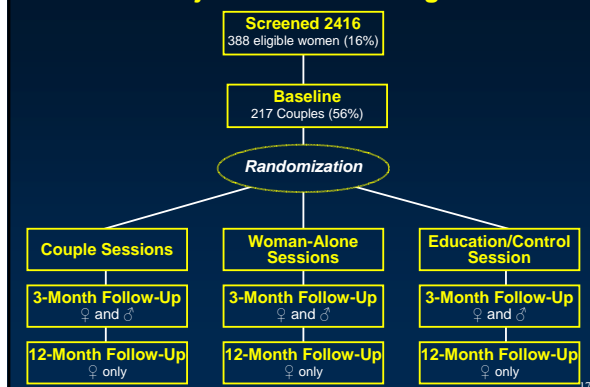
15

Project Connect: (217 couples)

1. Six sessions of relationship-based HIV/STI prevention intervention provided conjointly to couples ($n = 81$ couples)
2. Six sessions of relationship-based HIV/STI prevention intervention provided to women without their partners ($n = 73$ couples)
3. One HIV/STI information session provided to women without their partners ($n = 63$ couples)

16

Project Connect: Design



17

Follow-up Rates

- 84% for three month follow-up
- 80% for one year follow-up

18

Project Connect: Aim #1

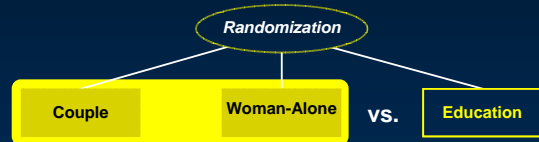
- To determine whether the relationship-based prevention intervention is more effective when both members of the couple receive the intervention together than when women alone receive it



19

Project Connect: Aim #2

- To examine the efficacy of the relationship-based HIV/STI prevention intervention



20

Project Connect

- Study site:
 - Hospital-based outpatient clinic in New York City
 - Community catchment area is predominantly low-income, minority (55% Latino, 35% African American) with high prevalence of HIV

21

Inclusion Criteria for Women

- Between 18 and 55 years old
- Has main, regular sexual partner (“study partner”) with whom she has been involved for at least 6 months
- Is confident that she will stay with this partner for at least one year
- Has had sex with this partner in the prior 30 days
- Has not used condoms consistently with this partner in the prior 90 days
- Reports no life-threatening abuse (per CTS2) by this partner in the prior 6 months

22

Inclusion Criteria for Women: Partner Risk

- Woman reports that she knows or suspects that her main, regular partner:
 - had sex with other men or women (prior 90 days),
 - contracted or had symptoms of an STI (prior 90 days),
 - injected drugs (prior 90 days), or
 - is living with HIV.

23

Recruitment Protocol

- Women approached and screened for study
- If eligible, she presented with a choice of ways to engage her male partner:
 - Mail an official invitation to him from PC
 - Send an official invitation with her to give him as she invites him herself
 - Project Connect staff called to invite him and answer questions
 - Some combination of the above

24

Sociodemographics

	Total Sample	Women	Men
Mean age	38 yrs.	36 yrs.	39 yrs.
< 25 years of age	9%	9%	8%
African American	55%	54%	55%
Latino/a	39%	40%	38%
High school or GED	49%	44%	53%
Never married	58%	60%	55%
Employed	24%	14%	35%
	<i>N</i> = 434	<i>n</i> = 217	<i>n</i> = 217

25

Risk Characteristics (at Baseline)

	Prevalence
	Total Sample
Both HIV-	60%
Mixed HIV Serostatus	13%
Both HIV+	13%
Partner's Status Unknown	14%
>1 Partner ^a	18%

^a In the prior 90 days

26

Theoretical Background for the Relationship-Based Intervention

- Cognitive/Behavior Theories
- Feminist Theory/Gender Roles
- Ecological Framework
- Marital and Family Therapy

27

Empirical Bases for the Relationship-Based Intervention

- Earlier experiences with HIV/AIDS prevention trials with men and women recruited from multiple settings
- Findings from the prior NIMH Multisite HIV Prevention Trial
- Findings from focus groups and in-depth interviews with men, women, and couples recruited from the community

28

Intervention Goals

To increase couples':

- Motivation to stay healthy as a couple
- Perceived vulnerability for HIV as a couple
- Shared responsibility for safer sex
- Awareness of gender roles and expectations related to safer sex practice and negotiation of safety

29

Intervention Goals

To increase couples':

- Safer sex communication, sexual comfort, and problem-solving skills around safer sex
- Male and female condom use
- Joint HIV testing
- Safer sex promotion among family, friends, and the community

30

Intervention Goals

- Focuses on the woman and her “study” partner
- Focuses on relationship contexts:
 - joint responsibilities
 - couple’s strengths and support system
 - couple’s decision making
 - couple’s problem solving
 - gender roles – couple’s expectations

31

Session 1: Orientation

- Enhance motivation of participant
 - Normalize need for HIV prevention for couples
 - Reduce anxiety, misperceptions, or stigma
 - Address concrete barriers to attendance
 - Sign contract of commitment

32

Session 2: Couples

- Review pros and cons of participation, and clarify roles and expectations
- Increase perceived vulnerability
 - HIV/STI information
 - Identify personal HIV and STI risk
- Identify positive reasons to stay healthy
- Discuss and promote joint HIV testing
- Learn safer sex communication skill: Speaker/Listener technique

33

Session 3: Couples

- Identify HIV risks among steady partners
 - Impact of HIV on family and community
 - Myths and facts of partner fidelity and honesty
- Explore individual and couple strengths related to safer sex practices and mutual protection
- Explore gender differences related to sexuality
- Introduce safer sex as a sign of love, caring and joint responsibility

34

Session 4: Couples

- Safer sex decision-making among couples
 - Unwritten rules about sex and power dynamics within the relationship
 - Decision-making process for condom use
- Discuss male and female anatomy, and male and female sexual health issues
- Identify safest condom and lubricant types
- Demonstrate and practice male and female condom use
- Introduce “menu” of safer sex options and ordering

35

Session 5: Couples

- Identify triggers for unprotected sex
- Identify and practice steps of problem-solving related to HIV risk reduction
- Review HIV joint testing as a prevention strategy
- Discuss how the couple can share HIV prevention knowledge and skills with their family, friends and community

36

Session 6: Couples

- Identify relapse to unsafe sex situations
- Practice skills to deal with relapse: self talk, speaker/listener, problem-solving
- Maintaining a mutually-satisfying and safe relationship; renewing couple commitment
- Identifying ways to make safer sex more fun as a reward for each other
- Delivery of effective prevention messages
- Graduation: presentation of certificates

37

Procedure in Each Session

- Review goal from previous session, exploring successes or barriers to success
- Review skills from earlier session
- Introduce new content
- Model and practice skills
- Set a couple-oriented safer sex goal for coming week
- Give out male and female condoms

38

Facilitators Qualifications

- All sessions delivered by female facilitators
- Two –hour intervention sessions provided by one facilitator
- Social work or public health degree
- Facilitators were trained to conduct intervention sessions in all three arms of the study

39

Facilitator QA

- Weekly facilitator meetings
- Review of weekly tape selection bringing highlights to meeting
- Expert consultation/supervision with Peter Steinglass, Executive Director of Ackerman Institute for the Family

40

Primary Outcomes

- Number of unprotected acts of intercourse with the study partner in the prior 90 days
- Proportion of protected acts of intercourse with the study partner in the prior 90 days
- Number of STI symptoms in the prior 90 days

41

Secondary Outcomes (Mediators)

- Condom use self-efficacy
- Safer sex communication
- Sexual comfort
- Joint HIV testing
- Condom use with casual partners
- Joint safety agreements

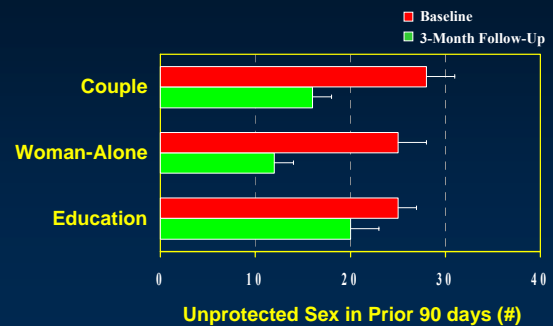
42

Data Analysis: Treatment Effects

- Intention-to-treat approach
- Regression using contrast coding derived from each aim
 - Regression appropriately matched to outcome variable
 - Poisson regression for count/rate outcomes
 - Tobit regression for censored data (e.g., proportion of acts)
- Unit of analysis was the individual
 - Random effects regression was employed to account for within-couple dependencies
- Multiple imputation to handle missing data

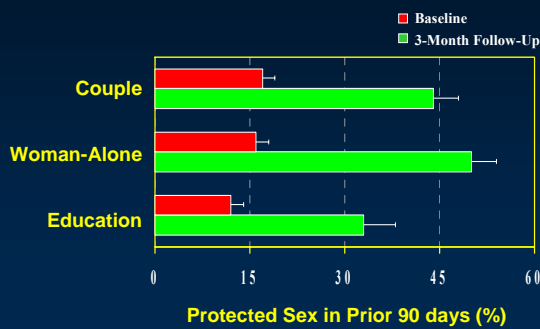
43

Unprotected Sex: Baseline & 3-Month Follow-Up



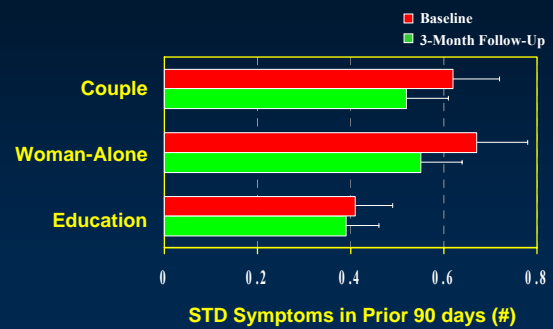
44

Protected Sex: Baseline & 3-Month Follow-Up



45

STI Symptoms: Baseline & 3-Month Follow-Up



46

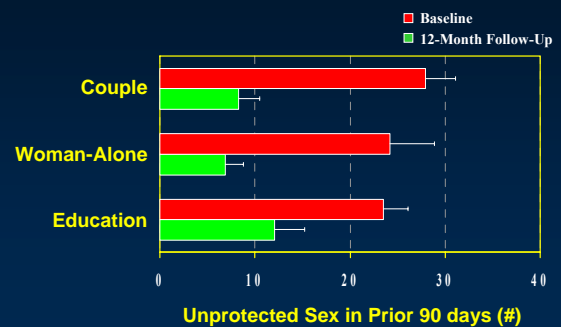
Primary Aims: Results at 3-Month Follow-Up

	Unprotected Sex [#] ^a	Condom Use [proportion]	STI symptoms [#] ^a
Intervention Effect [Intervention vs. Control]	.63* (.03)	.67* (.03)	1.0 (.81)
Modality Effect [Couples vs. Woman-Alone]	1.6 (.06)	-.52 (.09)	.97 (.86)
Gender^b	1.0 (.61)	.05 (.85)	.38 (.00)**
HIV+ vs. HIV-	.59** (.01)	1.01** (.01)	2.4** (.00)
HIV unknown vs. HIV-	1.2 (.37)	-.31 (.53)	1.2 (.63)
Baseline	1.0** (.00)	3.3** (.00)	1.4** (.00)

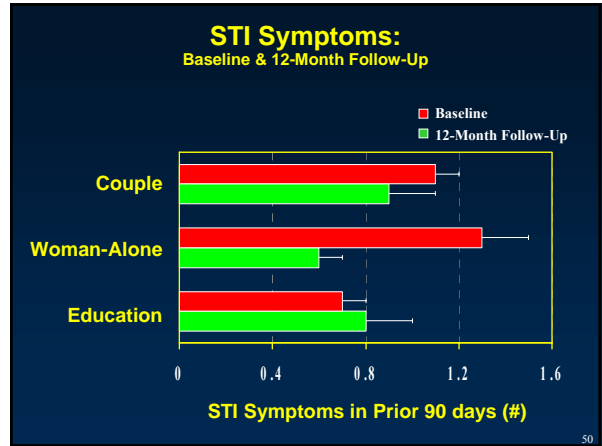
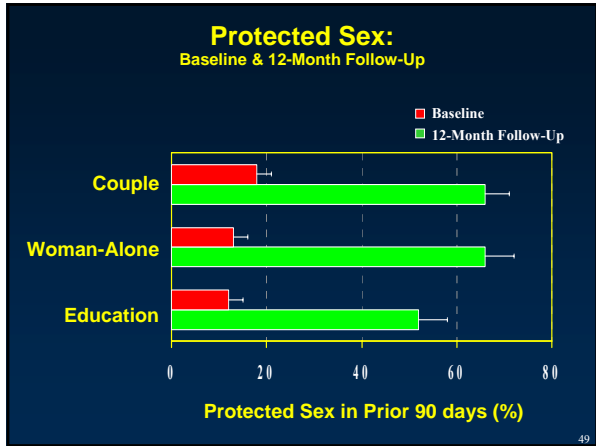
^a Incidence Rate Ratio ^b Male = 1, Female = 0 * p ≤ .05; ** p ≤ .01
(actual p-values are indicated in the parentheses)

47

Unprotected Sex: Baseline & 12-Month Follow-Up



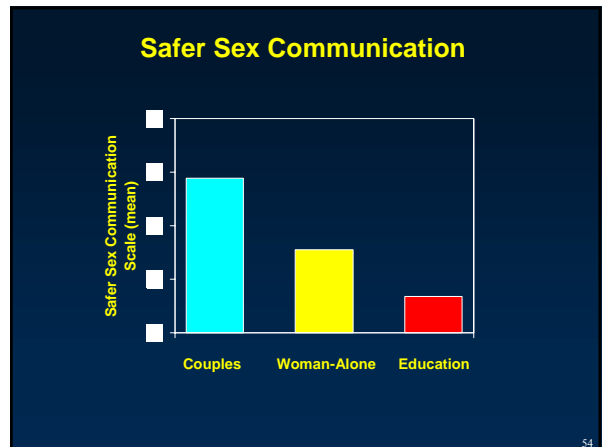
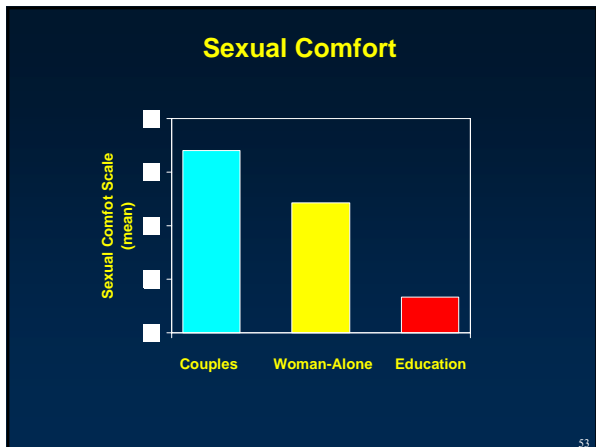
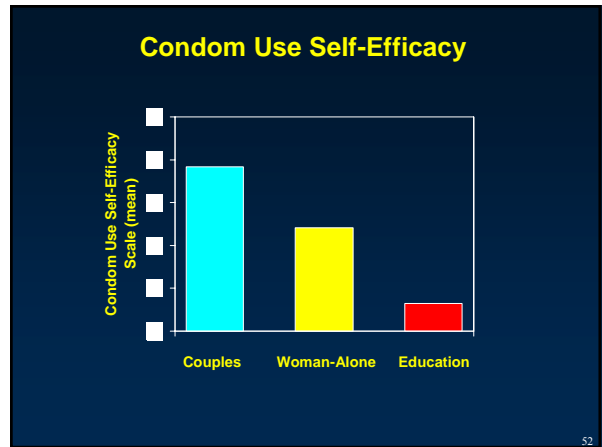
48



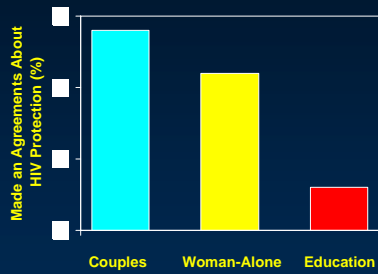
Primary Aims: Results at 12-Month Follow-Up

	Unprotected Sex [#] ^a	Condom Use [proportion]	STD symptoms [#] ^a
Intervention Effect [Intervention vs. Control]	.57* (.05)	.62 (.25)	.30 (.12)
Modality Effect [Couples vs. Woman-Alone]	1.2 (.32)	-.12 (.84)	2.7** (.01)
HIV+ vs. HIV-	15** (.00)	1.7* (.03)	1.9** (.01)
HIV unknown vs. HIV-	1.5 (.20)	-1.3 (.17)	1.5 (.16)
Baseline	1.0** (.00)	3.0** (.01)	1.3** (.00)

^a Incidence Rate Ratio * p ≤ .05; ** p ≤ .01 (actual p-values are indicated in the parentheses)



Making Agreements About HIV Protection



55

Conclusions from Project Connect

- Recruitment and retention of African American and or Latino couples in HIV prevention intervention research is feasible
- The relationship-based HIV/STI prevention intervention for African American and Latina women and their male sexual partners is effective in reducing HIV/STI risk behaviors
- Behavioral change on HIV risk maintained over time (12 months)

56

Conclusions from Project Connect

- Differences in the efficacy of the intervention as a function of delivery modality (i.e., couples vs. woman-alone) were not significant
- The study provides two alternative effective modalities to reduce HIV risk among women and their main sexual partners

57

How We Explain the Lack of Differences Between the Two Active Conditions

- The sample was self-selected – sexual partners were recruited by the female partner
- The content of sessions in both conditions focused on the women and one sexual partner (study partner)
- All exercises, role plays, and homework assignments focused on the woman and her study partner
- Participants in both conditions were taught how to practice the skills with their partners

58

How We Explain the Lack of Differences Between the Two Active Conditions

- Male partners in the woman alone condition were aware of the intervention and receptive to learning the safer sex skills
- Relationship context addressed even when the woman received the intervention alone
- The same facilitators conducted the intervention in both conditions
- Female facilitators delivered the intervention

59

How We Explain the Lack of Differences Between the Two Active Conditions

- The study relied on self reports, not biological data for HIV and STIs
- Only the female partner was followed up at 12 months

60

HIV/STI Intervention With Couples

- More research on HIV prevention intervention targeting couples is urgently needed
- Project Connect should be replicated in clinical controlled trials with same and different populations before testing in effectiveness trials

61

Eban HIV/STI Intervention With Serodiscordant African American Couples

- Multi-site randomized clinical trial
- 5 year study funded by the National Institute of Mental Health 2002-2006
- CUSSW (PI - Nabila El-Bassel)
- Emory -School of Public Health (PI - Gina Wingood)
- UCLA-Department of Psychiatry (PI - Gail Wyatt)
- University of Pennsylvania (PI - John Jemmot)
Annenberg School of Communication

62

Eban HIV/STI Intervention With Serodiscordant African American Couples

- Provides a bigger sample than Project Connect (n=800)
- Focuses on one target study population-African Americans -- which decreases heterogeneity and increases internal validity
- Couples are approached and recruited
- Experimental condition is tested against Health Promotion as a placebo condition

63

Eban HIV/STI Intervention With Serodiscordant African American Couples

- All facilitators and staff are African –American
- Sessions are delivered by a female and male facilitator
- Both female and male partners will be followed over time
- Use of biological markers for HIV and STIs
- Data points are collected through Audio Computer Assisted Self-Interview (ACASI)

64

Steps Taken in Testing the Efficacy of Connect

- Project Connect will be replicated with drug involved negative couples
- Increased sample size (400)
- Facilitators will be randomized to study conditions
- Testing Connect against a placebo condition instead of one information session

65

Steps Taken in Testing the Efficacy of Project Connect

- Project Connect is being adapted and replicated internationally in:
 - Colombia
 - Kazakhstan
 - South Africa

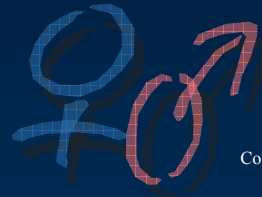
66

Implications for Research and Practice

- Our series of studies will improve the science of HIV behavioral risk reduction interventions for couples
- Findings of effective interventions are tested in real world settings
- Interventions are disseminated to agencies and community based organizations to improve evidence-based practice on HIV interventions for couples at risk

67

Project Connect



Social Intervention Group
Columbia University School of Social Work
<http://www.columbia.edu/cu/ssw/sig/>

68