

## Talking About Sex: A NIDA CTN Women's HIV Prevention Trial

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National Conference on Women,  
Addiction and Recovery:  
News You Can Use  
Anaheim, CA, July 12, 2006

## Workshop Objectives

- To gain knowledge of a 5-session HIV prevention intervention, including empowering women to assess HIV risk and HIV sexual risk behaviors, make safer sexual decisions, and put those decisions into action, through safer sex negotiation and (male and female) condom use.
- To be able to identify safeguards for protecting women from incurring added risk of partner abuse, and guidelines for safety planning when discussing safer sex behaviors.
- To gain knowledge of procedures for training and supervising counselors or other staff in a HIV safer sexual skills building group intervention.
- To begin thinking about potential benefits and challenges to adding a more extensive HIV prevention curriculum to their current treatment programs.

## Long Island Node Lead Team

- Susan Tross – Lead Investigator
- Aimee Campbell – Co-Project Director
- Jennifer Manuel – Co-Project Director
- Lisa Cohen – Protocol Manager
- Gloria Miele – Training Director
- Jim Robinson – Director, Data Management Center
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- Karen Loncto – QA Director
- Jen Lima – Regulatory Director
- Ned Nunes – Co-Investigator
- Nabila El-Bassel – Intervention Specialist
- Don Calsyn – Lead Investigator CTN0018: Men's Study
- Mary Hatch Maillette – Project Director CTN0018: Men's Study

## Community Treatment Program (CTP) Partners (N=12)

### Methadone Maintenance

- Thomas Jefferson (Philadelphia, PA, Delaware Valley)
- Consortium (Philadelphia, PA, Delaware Valley)
- Hartford Dispensary (Hartford, CT, New England)
- Staten Island University Hospital (Staten Island, NY, Long Island)
- Southlight Wakeview (Raleigh, NC, North Carolina)
- Bay Area Addiction, Research & Treatment (La Puente, CA, Pacific)
- Evergreen (Seattle, WA, Washington)

### Psychosocial Outpatient

- Southlight Life Plus (Raleigh, NC, North Carolina)
- Alcohol & Drug Services (Greensboro, NC, North Carolina)
- Compass (Toledo, OH, Ohio Valley)
- Presteria Center (Huntington, WV, Ohio Valley)
- Lexington Richland Alcohol & Drug Center (Columbia, SC, South Carolina)

## HIV /STD Risk In Women

- Heterosexual women are among the fastest growing subgroups of people with AIDS in the US
- While female AIDS cases due to injection drug use have declined (32%), cases due to heterosexual transmission have increased (66%)
- Rates of STDs are substantial among poor women
  - Family Planning Clinics: Chlamydia rates 2.4%-11.3%
  - US Job Corps: Chlamydia rates 4.6%-20.3%

Centers for Disease Control and Prevention, 2004

## Features Of Effective HIV Preventive Interventions

- Gender specificity
- Comprehensive skills building
- $\geq 4$  Sessions

Exner, Seal & Ehrhardt, 1997

## Skills Underlying Safer Sex

- Sense of self-efficacy about trying safer sex  
(Marin et al., 1998)
- Problem-solving skills
- Negotiation and refusal skills – in as much as male condoms are controlled by men
- Skills for using female condoms
- Eroticizing safer sex skills
- Partner abuse risk assessment and safety planning

## Theory

- Social Cognitive Learning Theory:  
Behavior is learned through the social processes of observation, modeling, skill rehearsal, and feedback, especially with one's peer group
- Empowerment Theory:  
Individuals are empowered to action by the processes of: skill mastery, peer support, and ability to impact on one's world

## Study Design

- Randomized Clinical Trial
  - 5 Session: Safer Sex Skills Building (WORTH - **W**omen **O**n **T**he **R**oad **T**o **H**ealth)
  - 1 Session: HIV/STD Education (Treatment-as-Usual)

## Assessment Timeframe

- Screening
  - (for unprotected sex with opposite sex partner in past 6 months)
- End of intervention follow-up
- 3-month post-intervention follow-up
- 6-month post-intervention follow-up

## Sample

### Eligible

- Participating in drug treatment at CTP
- Unprotected vaginal or anal sex in past 6 months
- Willing to participate in randomized trial
- Understand and speak English

### Ineligible

- Immediately planning pregnancy
- Major cognitive impairment ( $\geq 25$  MMSE)

## Outcomes

- Primary
  - # of unprotected penetrative (vaginal or anal) intercourse occasions in the past 3 months
- Secondary
  - proportion of unprotected occasions (of all occasions)
  - proportion of drug-with-sex occasions (of all occasions)
  - currently carrying condoms (yes or no)
  - perceived self-efficacy to carry out safer sex
  - gender role beliefs

## Assessment Measures

### Screen

- Risk Behavior Survey (RBS); Mini Mental Status Examination (MMSE); Demographic Questions

### Baseline & Follow Up

- Addiction Severity Index (ASI-Lite; drug & alcohol only at follow up)
- Composite International Diagnostic Interview for DSM-IV (CIDI; Baseline only)
- RBS (injection drug use only at follow up)
- Sexual Experiences & Risk Behavior Assessment Schedule (computer administered)
- HIV Safer Sex Attitude Questions
  - perceived HIV risk
  - perceived self-efficacy
  - perceived peer norms about safer sex
- BEM Sex Role Inventory
- Condom Use Skills Checklist
- Negotiation Skills Vignette Measure
- Abuse Experiences Questionnaire

## Recruitment

- |                        |     |
|------------------------|-----|
| • # Screened           | 807 |
| • # Eligible at Screen | 595 |
| • # Baselined          | 520 |
| • # Randomized         | 515 |

## Demographics

		M (SD) or %	Range
<b>Age</b>		38.8 (9.1)	34.1-44.0
<b>Education</b>	Less than HS	28.4	
	HS or higher	71.6	
<b>Race</b>	White	60.0	9.5-83.0
	Black	25.0	0-60.0
	American Indian	1.0	0-7.7
	Multi	8.0	0-15.4
	Other	7.0	0-85.7
<b>Ethnicity</b>	Hispanic	9.0	0-85.7

## Baseline Characteristics

Variable	%	Range (site)
Current Drug Use Disorder Diagnosis	50.7	
Current Alcohol Use Disorder Diagnosis	20.4	
Recent Sex Exchange	27.3	14.3-56.0
Childhood Abuse	58.3	
Adult Abuse	90.4	
Bisexual Sexual Partner	11.2	
Heterosexual Monogamy	53.0	32.0-79.0
Perceived Partner HIV Status (+)	4.0	0-16.0
Participant HIV Status (+)	2.7	0-7.7

## Baseline Outcome Measures

Variable*	M	SD	Range
Unprotected Vaginal Sex (MP)	15.5	27.3	7.7-23.8
Unprotected Anal Sex (MP)	0.9	3.9	0.6-2.4
Unprotected Vaginal Sex (OP)	2.1	6.9	0.8-4.9
Unprotected Anal Sex (OP)	0.2	1.7	0-1.0
Total Unprotected Sex	18.9	30.6	9.2-25.7
Sex with Drugs	9.2	20.3	6.1-12.8

\*Number of occasions in the past 3 months

## Safer Sex Skills Group Intervention WORTH Overview

- HIV/STD education
- HIV/STD risk assessment
- HIV/STD safer sex obstacle problem-solving
- Condom use skill-building
- Negotiation skill building
- Assertiveness training
- Partner risk assessment and safety planning

## **Men's Version REMAS: Real Men are Safe**

1. **HIV/AIDS Update: Identifying Risks**
2. **HIV/AIDS Update: Planning Prevention**
3. **Sex without drugs. Can it happen? Is it pleasurable?**
4. **Beyond the pick up line, communicating about sex**
5. **Communicating about Safe Sex II. Workshop Summary**

## **Counselor Certification**

- To achieve certification for the Safer Sex for Women intervention, counselors and supervisors were required to demonstrate proficiency in delivering 2 exercises from the treatment manual. These exercises were chosen at random.
- Each of the two exercises was separately rated by a trainer using the "Supervisor Rating Form – Safer Sex Skills Groups".
- Certification was based on an average score of "3" across both rating forms (range=1-5).

## Supervisor Certification

- Supervisors rated up to six of the counselor exercises, using the supervisor rating forms. A Lead Node trainer also rated these exercises.
- Certification was calculated by examining agreement across all forms rated. Agreement was defined as both supervisor and Lead Node trainer rating 3 or above, or both rating 2 or below.
- A percent agreement score was calculated based on the # of agreements over the total # of items. The cutoff for certification was a 70% agreement score.

## Rating Guidelines – General

- Make Independent Ratings
- Rate Overall Session - Not Individual Co-leaders
- Be Aware of Strengths & Weaknesses
- Rate Counselors, Not Participants

## Rating Guidelines – Meeting Goals

- Focus on Topic
- Accuracy - Completes All Exercises
- Accuracy of Information
- Familiarity and Readiness
- Clarity of Explanation and Follow-up
- Setting and Keeping Pace
- Maintains Neutral and Professional Stance

## Rating Guidelines – Style

- Appropriateness
- Warmth
- Interest and Constant Disposition
- Pays Attention to What Participants Say
- Responds Appropriately
- Limits Probing

## Rating Guidelines – Group Dynamic

- Modifying Inappropriate Behaviors
- Providing a Safe Environment
- Limiting Inappropriate Participant Disclosure

## Rating Guidelines – Modeling

- Use of Positive Reinforcement
- Appropriate Feedback
- Limits Use of Self as Example
- Non-judgmental
- Sets Classroom Tone
- Shows Respect and Keeps Confidentiality

## Supervisor Rating Form

Ability to meet the goals of the exercise:		Poor	Fair	Adq	Good	Excel	N/A
1.	Focus on topics	1	2	3	4	5	-3
2.	Introducing exercises	1	2	3	4	5	-3
3.	Accuracy (follows manual) – without introducing new material or exercises	1	2	3	4	5	-3
4.	Accuracy of information/data given to participants	1	2	3	4	5	-3

## Session 1: Introduction and HIV/STD Education\*

- WORTH (Women On The Road To Health)
  - Introduction
  - Purpose
  - Counselor and Participant roles and rules
- Warm-up: Why I Want to Take Care of Myself
- HIV Information
- STD Information
- HIV Testing and Counseling
- Living With HIV (Including HIV Treatment Information)
- Closing: Homework and WORTH Affirmation

\*HIV/STD Education Will Also Serve as Comparison Condition

## **Session 2: Making it Real: HIV/STD in Our Lives**

- Check-in
- HIV in Our Lives
- HIV Risk Rationalizations
- Challenging Rationalizations: Story of Jesse & Mathilde
- Challenging Rationalizations: Our Own
- Triggers for HIV/STD Risk Behavior: People, Places, Things
- Identifying Our Supports for Taking Care of Ourselves
- Closing: Homework and WORTH Affirmation

## **Session 3: Making It Real: Tuning Up Our HIV/STD Safer Sex Skills**

- Check-in
- Getting Smart about HIV/STD Risk: Stop Light Behaviors
- Condom Use Practice and Feedback
  - Male
- Condom Use Practice and Feedback
  - Female
- Eroticizing safer sex
- Self-Talk in Tough Risk Situations
- Problem-Solving the SODAS Way
- Closing: Homework and WORTH Affirmation

## Stop Light Behaviors



- **GREEN LIGHT** means GO -- NO RISK, this is SAFE to do. No exchange of bodily fluids (blood, semen, vaginal fluids).
- **YELLOW LIGHT** means CAUTION -- LOW RISK. Condom (or dental dam) protected activities are safe, as long as the barrier isn't broken, stays in place, and is used properly.
- **RED LIGHT** means STOP -- HIGH RISK and should NOT BE DONE if you can at all help it. Activities during which body fluids are freely exchanged, without condoms or dental dams constitute high risk.

## Stop Light Instructions

- Read the list of behaviors. Have participants identify which behaviors go with each color. Use their answers to clarify any misinformation or myths still present in the group. The point of this exercise is to emphasize that there are more sexual behaviors that have low risk or no-risk than high risk.

## Stop Light Examples

1. Vaginal sex without a condom – RED
2. Vaginal sex with a condom – YELLOW
3. Not having sex with other people – GREEN
4. Massage/body rubbing – GREEN
5. Oral sex on a guy with a condom – GREEN

## The SODAS Model

- **The letter S**
  - STOP. DEFINE THE PROBLEM AND THE GOAL
- **The letter O**
  - OPTIONS AND OUTCOMES
- **The letter D**
  - DECIDE
- **The letter A**
  - ACTION
- **The letter S**
  - SELF - PRAISE

## Example Using SODAS

- I want to make love to the great man I met, but I know I can only have safer sex. If I have sexual intercourse without a condom, I'll be risking getting HIV or an STD. If I ask him to use a condom, I'll be risking turning him off and maybe losing him.

## Putting SODAS into Action

- *What's the problem? What's the goal?*
- *What are your options?*
- *What would you decide?*
- *What will you do – to act on your decision?*
- Once we decide and act, we deserve a pat on the back for taking care of ourselves!

## Session 4: Making It Real: Making HIV/STD Safer Sex Happen

- Check-In
- Identifying Barriers to Safer Sex
- Safer Sex Negotiation and Refusal: The Basics
- Safer Sex Negotiation: Demonstration and Discussion
- Safer Sex Negotiation: Pairing Up
- Assessing Risk of Partner Abuse and Making Safety Plans
- Closing: Homework and WORTH Affirmation

## Safer Sex Negotiation - Talking It Out

Latricia just met this guy James at this party. She kind of knew James before. Latricia and James go back to James's house. Latricia is feeling a little uncomfortable, but she is horny, and James is coming on to her, and he is looking real good. She wants to have sex with him, but she will only have safer sex, because she doesn't want to get anything.

What is Latricia's problem?

She wants to have sex with him, but she will only have safer sex and she is feeling unsure of herself and uncomfortable with James.

## Safer Sex Negotiation - Taking It Apart

### What are Latricia's options?

- 1) She can negotiate with him to use a condom
- 2) She can slip the condom on when she gives him "head"
- 3) She can have an alternative to intercourse that is safer, like giving him a hand job
- 4) She can refuse to have any sex: directly (saying no) or indirectly (make an excuse)

### What are the consequences or outcomes of each option?

- 1) She is feeling unsure of herself and she might not be able to hold up her "bottom line" of having safer sex and using a condom (he might be able to talk her out of it).
- 2) This might work best. She can avoid having to ask him directly. He may find this sexy, and he won't be able to talk her out of it.
- 3) She can avoid having to ask him directly. He may find this sexy.
- 4) This would protect her, but her goal of having sex would not be achieved.



## Safer Sex Negotiation - Taking It Apart

### Let's say she decides to refuse to have sex, how can she do this?

- **Direct Approach**
  - 1) Tell him she will not have sex with him
  - 2) Suggest they have sex another time
- **Indirect Approach**
  - 3) She can tell him she gets infections from sperm and Dr. told her she needs to use a condom
  - 4) She can tell him she has her period and gets infections if she does not use a condom or it grosses her out to have sex during her period without a condom
- **Consequences**
  - 1) She's not going to do this – she wants to have sex – and James might get violent.
  - 2) If Latricia's really horny, this will be hard to do and James might be able to easily persuade her.
  - 3) This takes the reason for use off James and he may not care about the consequences to her.
  - 4) Again, this takes the reason for use off James

## Partner Abuse and Safer Sex

- Knowing What Abuse Is
- Identifying Your Risk For Abuse
- Making A Safety Plan
  - Safety Plan Worksheet

## Safety Plan Worksheet

- Steps at the Time of Crisis
- Steps at the Time When You Feel You are in an Abusive Relationship
- Steps to Prepare for a Possible Crisis
- Keep things you will need for leaving in a safe place (i.e. ID Card, SS Card, insurance information, names and numbers, money, change of clothing)

## **Session 5: Keeping It Going**

- Check-in
- Where We've Been Together: Review
- Getting Ready: Common Slip Situations (Especially Involving Drugs & Alcohol)
- Slip Plans: The SODAS Way
- Program Evaluation and Feedback
- Graduation

## **Community Treatment Program (CTP) Experience - Case in Point**

- Description of CTP
- Involvement in CTN-0019

## Study Intervention vs. CTP Treatment as Usual (TAU)

### WORTH Intervention

- Voluntary
- Group
- 6-8 clients
- Co-leaders
- Gender specific
- Focus on HIV and STDs
- Exercises, practice, active, group support, self-efficacy, problem-solving, coping, tools

### TAU HIV Education

- Mandatory
- Group
- 10-35 clients
- Single leader
- Co-educational

## Clinician Experience

- Manualized intervention
  - Training and practice
- Meeting during intervention implementation
  - Supervision, post group process
- Maintenance of co-leader relationship
  - Sharing responsibilities
- Overall

## Participant Experience

- Recruitment
  - Group size
  - Participant characteristics
- Attendance
- Adverse Events
  - Drug affected behavior
  - Emphasis on heterosexual sexual activity

## Supervisor Experience

- Manualized intervention
  - Pre-implementation meetings
- Session review
  - Finding time!
- Feedback
  - Presentation
  - Focus
- Research responsibilities
  - Consistency cross-nationally
- Overall

## Highlights of Intervention

- HIV/STD information – risk and resources
- Practice exercises
  - Condom practice
  - Partner communication
  - Individualized
  - Strategies for real world situations
- Gender specific intervention

## Changes at CTP Post-Study

- Currently conducting 1 mandatory single session group
- Study clinician became HIV Education Services Coordinator
- HIV Group
  - Co-led
  - HIV/STD didactic information
  - Focus on demonstration and practice
  - Using flipchart and other materials
- Future plans

## CTP Considerations

- Reimbursement
- MMTP versus outpatient psychosocial
- Timing of intervention
- Bringing sex into drug treatment, comfort level
- Moving from “talk therapy” to psychoeducation
- Re-introducing HIV Prevention as a key component for drug treatment
- Use a template for other gender specific interventions
- Public Health partnerships
- Group Size – what’s ideal
- Mandatory versus voluntary

## Questions For Our CTP Partners

- How do clients feel about it?
- How do staff (i.e. people doing it/not doing it) feel?
- What’s your ‘standard’ and ‘threshold’ (i.e. stop rule) for group attendance?
- What would you do differently?
  - ‘Dose’
  - Format (e.g. rolling participation, make-ups, etc.)
  - Leaders
  - Clients
- Might you keep it going?
- How might you make it fiscally sustainable (e.g. fee-for-service, grants)?

## Questions For Our CTP Partners

- What does it really take to do CTN-0019?
  - Who needs what time and effort ?
  - What space and stuff do you need?
- How does it fit/not fit into CTP daily life?
  - What strain might it put on CTP daily operating?
  - What redundancy with CTP daily operating is there?
  - What service gaps might it fill?
  - What clinical problems might it open up?

## 'Exit' Sustainability Study

- Purpose
  - Understand the experiences of carrying out research among professional clinical staff and managers at the CTPs
  - Identify the promoters and barriers to successful adoption and use of the safer sex interventions in real-world treatment settings
- Assessment
  - Survey
  - Telephone interviews (random subsample)

## Sample Survey Questions

	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
8. The Safer Sex Studies met an important unmet HIV/STD education and prevention service need in our clinic.	1	2	3	4	5
9. The clinic's participation in the Safer Sex Studies increased my awareness of research procedures.	1	2	3	4	5
10. The clinic's participation in the Safer Sex Studies increased my awareness of sex education and HIV/STD prevention and counseling with clients.	1	2	3	4	5

## Dissemination of Intervention

- CTN-0019 Timeline
- Check NIDA's website for study findings: <http://ctndisseminationlibrary.org/>

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