

**Project WORTH:
A NIDA CTN Women's HIV Prevention Trial
(Sister of REMAS)**

**CU-Partners/Long Island Regional
Node (NIDA U10 A 13035)
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- Don Calsyn – Lead Investigator CTN0018: Men’s Study
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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)
- Prestera Center (Huntington, WV, Ohio Valley)
- Lexington Richland Alcohol & Drug Center (Columbia, SC, South Carolina)

HIV 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%)
- Partner risk factors in heterosexual transmission:
IDU partner HIV infection (19.8%)
- Race/Ethnicity of AIDS cases: Black (59.5%); White (20.2%); Latina (19.1%)

(Centers For Disease Control and Prevention, 2004)

HIV /STD Risk In Women

- 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%

Factors Associated With HIV Sexual Risk Behavior In Women

- **Cocaine/Crack Use** (Booth et al., 1999; Edlin et al., 1995)
- **Recent Problem Drug or Alcohol Use** (Wingood & DiClemente, 1998)
- **Sex With Drugs or Alcohol** (McEwen et al., 1992; Robertson & Plant, 1998)
- **Sexual Partnership Types, Primary vs Casual, Multiple** (Bulterys et al., 1993; Wyatt et al., 2002; Hearn et al., 2005)
- **Survival Sex/Sex Trade** (Astemborski et al., 1994; DeHovitz et al., 1994)
- **Local HIV Seroprevalence** (Friedman et al., 2005)
- **Sociodemographics** (Kim et. al, 1993)
- **Intimate Partner Violence** (Bogart et al., 2005; Gilbert et al.. 2000)
- **Bisexual Behavior** (Young, 2002)

Features of Effective HIV Preventive Interventions For Women

- Gender specific
- Comprehensive skills building
- ≥ 4 sessions

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

Similarities To REMAS

- Structure: 5 sessions
- Approach: Active Skill Building and Processing
- Group Format: Relies on power of peer support and mutual coaching
- Drugs-with-sex blend is a theme

Differences From REMAS

- Personal empowerment
- Cognitive-affective skills for:
 - managing problem feelings
 - assessing pros and cons of risk situations
 - making personal choices
- Relationship skills for assertiveness, negotiation, and refusal
- Skills for assessing personal safety and safety planning
 - Assessing pros and cons of relationship situations

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

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

Session 1: Introduction and HIV/STD Education*

- WORTH (**W**omen **O**n **T**he **R**oad **T**o **H**ealth)
 - 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/STDs 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

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

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

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!

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 & 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)

Recruitment

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

Demographics

		M (SD) or %	Range
Age		38.8 (9.1)	34.1-44.0
Education	Less than HS	28.4	
	HS or higher	71.6	
Race	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
Ethnicity	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

Predictors of Unprotected Sexual Occasions

Variable	Est	SE	DF	t	p
Age	.31	.02	470	12.4	<.0001
Hetero Monogamy	1.73	.36	470	4.8	<.0001
Perceived Partner					
HIV Status	1.81	.35	470	5.1	<.0001
Sex with Drugs	1.02	.0003	470	74.3	<.0001
Het Monog - Perceived					
Partner Status	-2.05	.36	470	-5.7	<.0001

Predictors of Unprotected Sexual Occasions

- * **Age:** Lower Age is associated with more unprotected sex.
- * **Drugs-with-sex:** Drugs-with-sex occasions is associated with more unprotected sex (10 drug occasions associated with an increase in unprotected sex of 24%)
- * **Monogamy X Perceived Partner Status:** Among women who perceive their partners to be HIV negative, heterosexual monogamous women had 39% more unprotected sex occasions than non-monogamous women.

Perceived Male Partner Risk Factors

- Main Male Partners:

Monogamous: IDU (33%); Crack (46%); MSM (6%); Pay for Sex (11%); Jail (47%)

Non-Monogamous: IDU (34%); Crack (52%); MSM (3%) Pay for Sex (25%); Jail (55%)

- Other Male Partners:

IDU (35%); Crack (71%); MSM (16%); Pay for Sex (72%); Jail (70%)

'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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