

Stopping HCV in Its Tracks? A Behavioral Intervention to Reduce Transmission Behaviors among young HCV- positive injectors

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Overview

- Brief epidemiology of Hepatitis C Virus (HCV) in the USA
- The Drug Users' Intervention Trial – a behavioral intervention to reduce HCV among young HCV-negative IDUs
- STRIVE - a behavioral intervention to reduce HCV among young HCV-positive IDUs

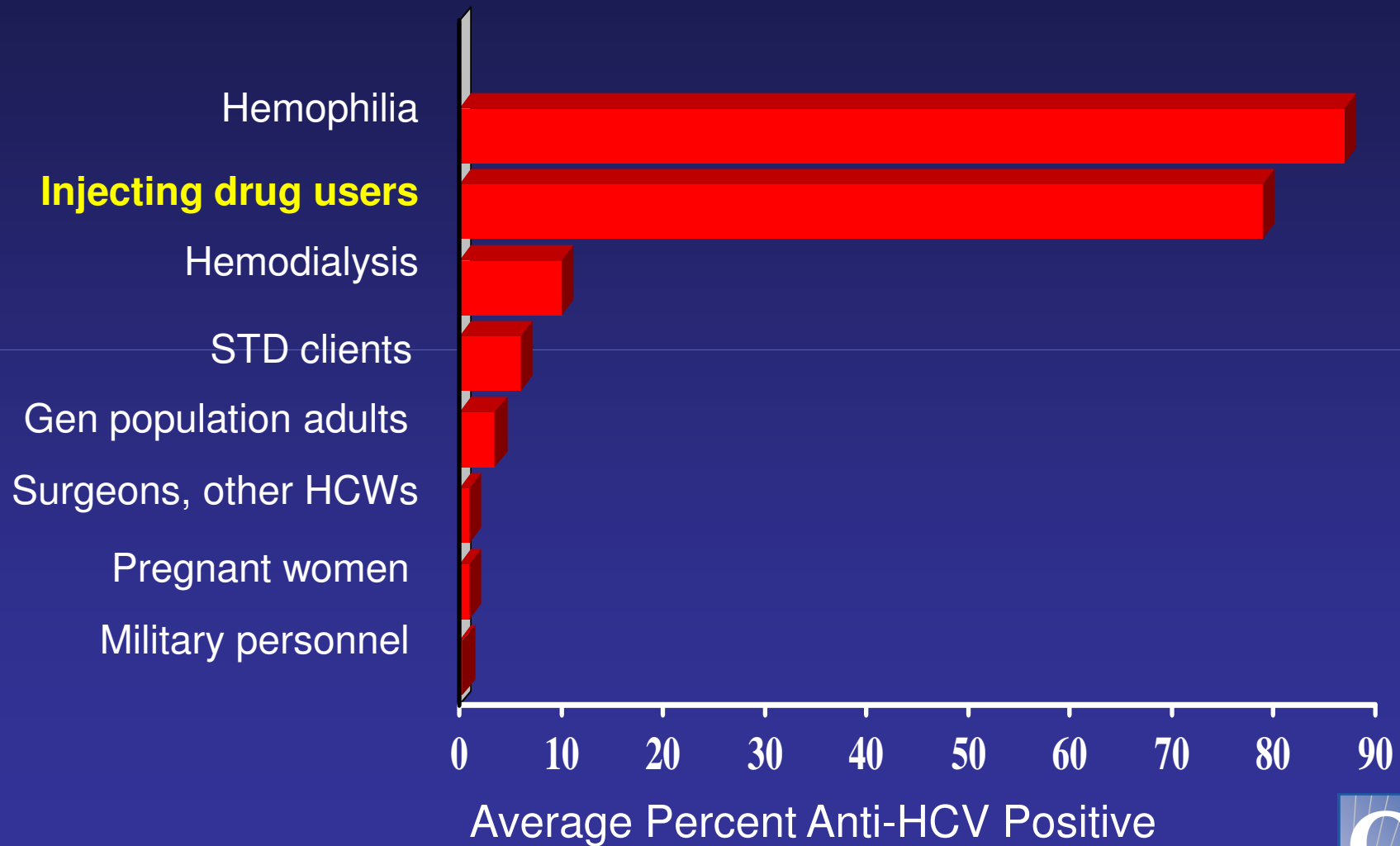


Hepatitis C Virus Infection United States

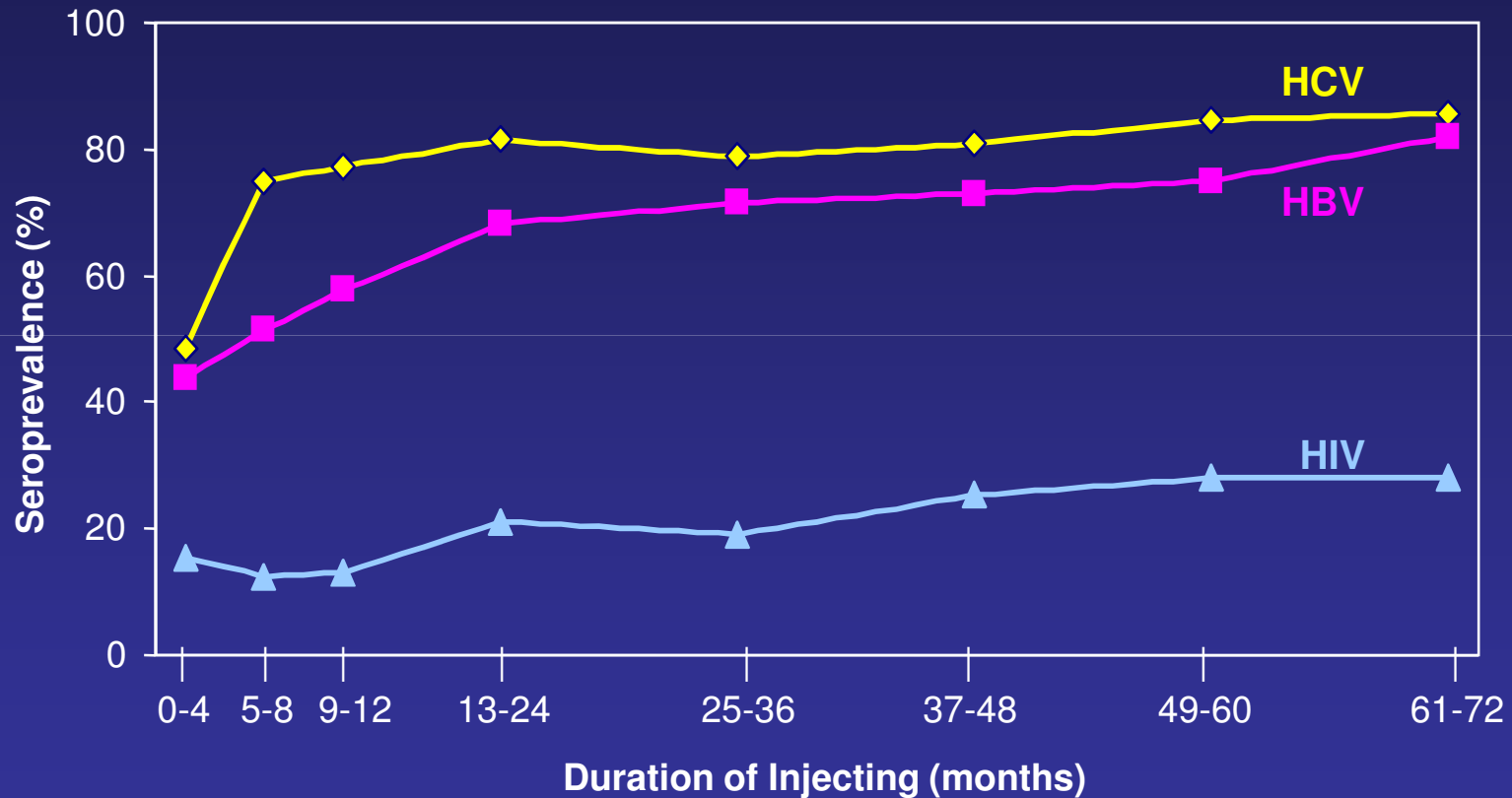
New infections (cases)/year 1985-89	242,000 (42,000)
1997	38,000 (6,000)
2001	25,000
Deaths from acute liver disease	Rare
Persons ever infected (1.8%)	3.9 million (3.1-4.8)*
Persons with chronic infection	2.7 million (2.4-3.0)*
HCV-related chronic liver disease	40% - 60%
Deaths from chronic disease	8,000-10,000/year

* 95% Confidence Interval

HCV Prevalence by Selected Groups United States



Seroprevalence of HCV, HBV, and HIV Infections among Serial Cohorts with Increasing Duration of Injection Drug use: ALIVE Study, Baltimore, MD 1988-1989



(Garfein et al., AJP 1996;86:655-661)



CIDUS II - Risk of Incident HCV Infection from Sharing Paraphernalia after Adjusting for Receptive Syringe Sharing among Young IDUS in Chicago

	Adjusted Relative Hazard*	95% Confidence Interval
Shared cookers	3.54	1.26-9.94
Shared rinse water	2.29	1.01-5.20
Shared cotton	1.98	0.88-4.46

* Adjusted for receptive syringe sharing, education, homelessness, residence, injection frequency, and cocaine injection.

(Thorpe, Ouellet, Hershov, Bailey, Williams, Williamson, Monterroso, Garfein, AJE 2002;155:645-53)



Drug Users Intervention Trial (DUIT) Primary Study Outcomes

- To decrease the proportion of injections involving HIV/HCV-associated risk behaviors (e.g., receptive syringe sharing, sharing paraphernalia, and split drugs or “backloading” with a previously used syringe).
- To decrease the number of times participants practiced unprotected vaginal or anal sex with main steady, other steady, and casual or sex trade partners.

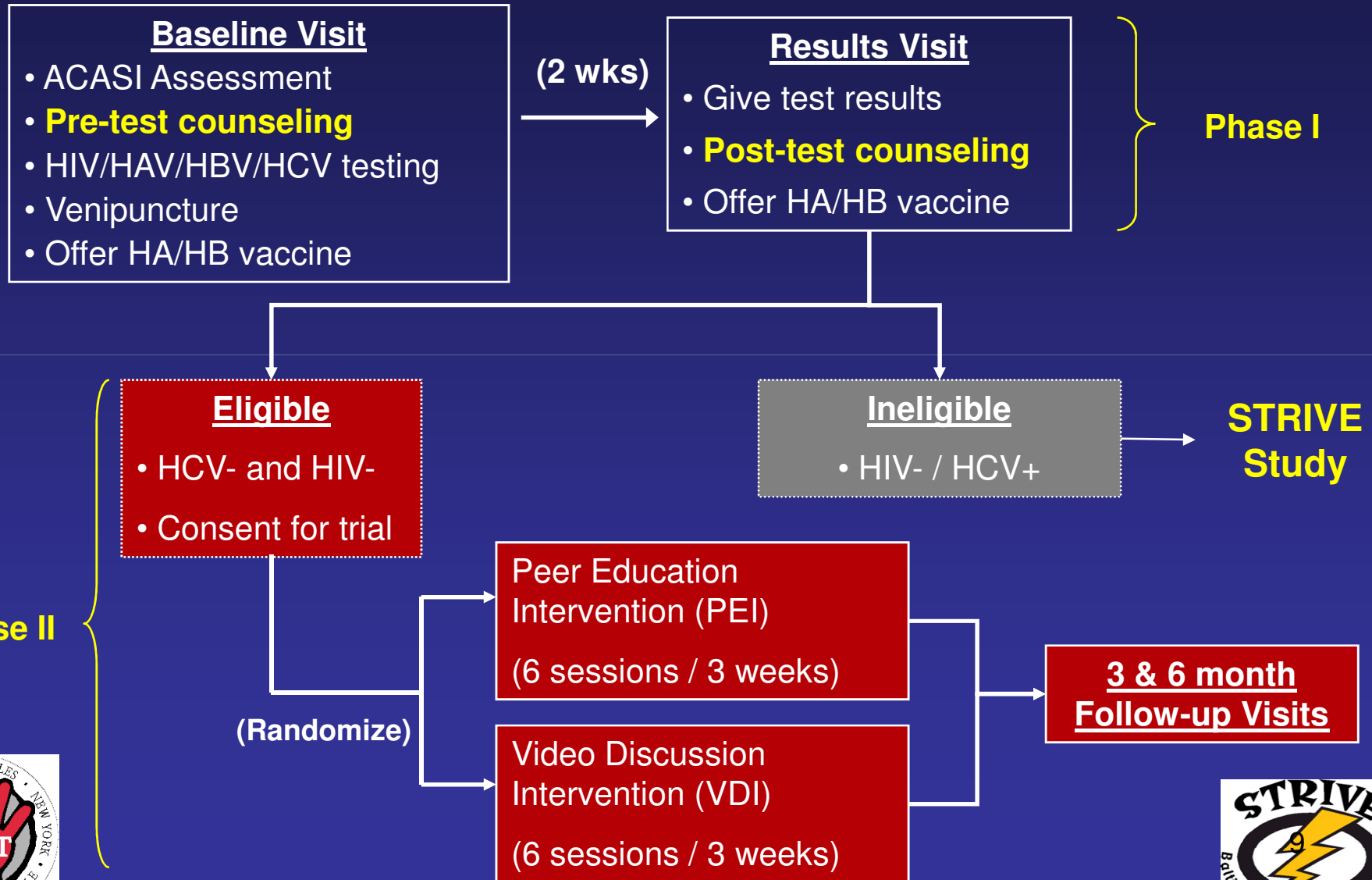


Study Design and Participants

- Multi-site, randomized controlled trial
- Eligibility:
 - 15-30 years old
 - Injected in the past 6 months
 - HIV and HCV seronegative at baseline
 - English speaking
- Recruited via street outreach, targeted advertising, and respondent-driven chain referral
- Behavioral and serologic assessments at baseline and 3 and 6 months post-intervention



Study Design



STRIVE Aims

To evaluate a behavioral intervention to:

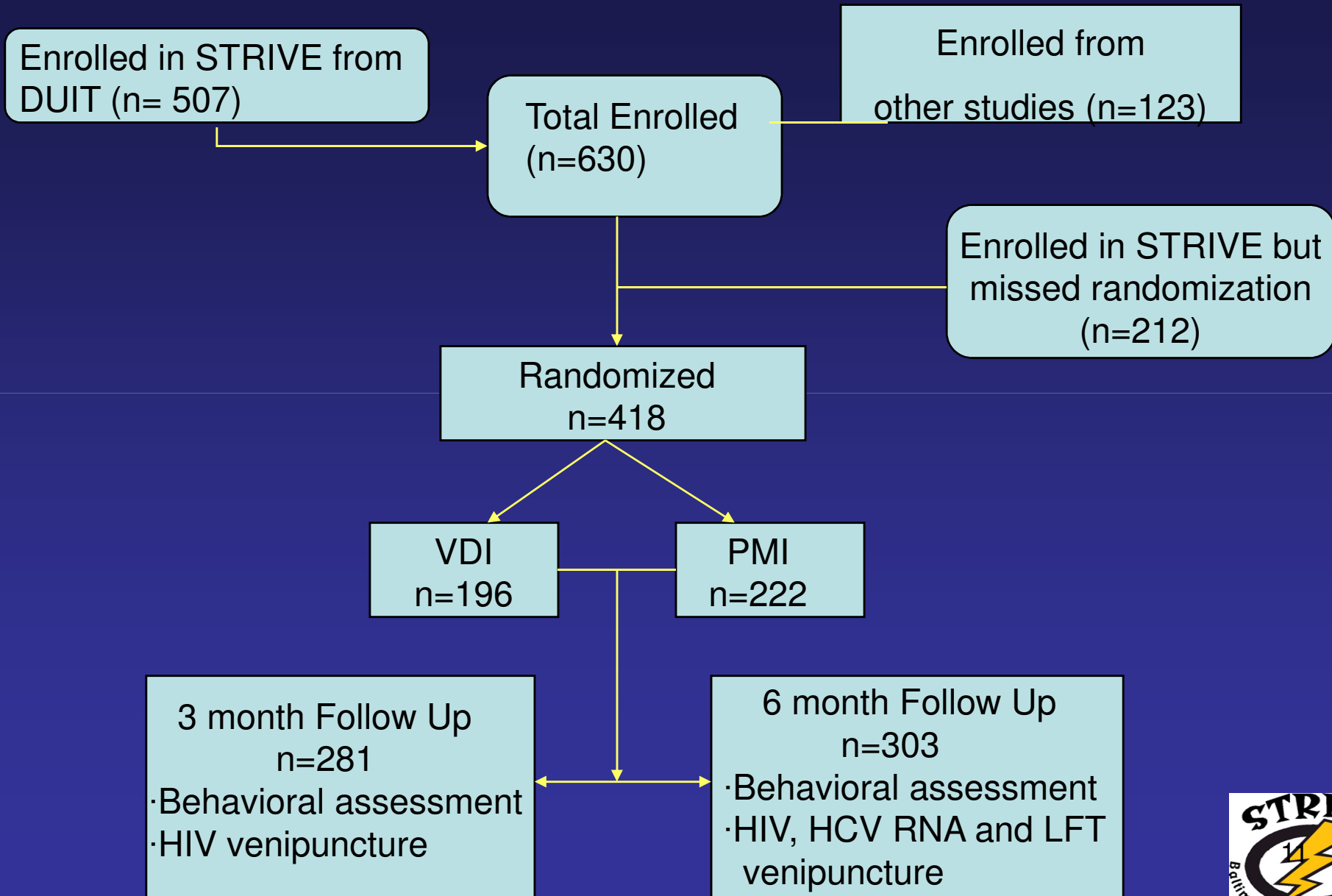
- 1) Reduce distribution of used injection equipment (needles, cookers, cottons and rinse water);**

- 2) Increase health care utilization among young HCV+ positive IDUs**

- 3) To estimate the proportion of IDUs eligible for IFN therapy based on:**
 - active infection (ALT and HCV RNA)
 - medical contraindications (depression, EtOH)
 - potential for re-infection from injection risks



Participant Enrolment and Randomization in STRIVE



STRIVE Peer-Mentoring Intervention (PMI)

- Six small-group peer-mentoring intervention workshops led by 2 facilitators at each site
- Sessions held 2X per week, 2 hours long, scripted
- Based on CBT, Social Learning and Empowerment Theory
 - information on HCV transmission risks
 - communication/skills to help reduce distributive equipment sharing
 - natural history of HCV and importance of HCV-related medical visits
 - effective communication techniques for getting the most out of a HCV medical visit.
- Activities were interactive, involving either guided discussions, small-team games or videos
- 5th session based in the community, involving practicing of peer mentoring skills
- 6th session was a 'graduation' ceremony



The STRIVE Video Discussion Intervention (VDI)

- Attention control condition, matched to intervention in terms of number and length of sessions (6 sessions, 2 hours each)
- Participants watched “The Corner” (HBO Miniseries)
- Two facilitators guided discussion away from intervention themes
- All sessions from PMI and VDI audio-taped; random 10% reviewed by other sites
>>96% fidelity



STRIVE baseline characteristics of 18-35 year old IDUs enrolled 5/02-6/04

Variable		All Baselined (N=630)	Randomized (N=418)
Age in years	Median (IQR)	26 (24-29)	26.5 (24-29)
Gender	Male	76.2%	75.8%
	Female	23.5%	23.7%
	Transgender	0.3%	0.5%
Race/ Ethnicity	Non-Hisp. Black	5%	7%
	Non-Hisp. White	60%	57%
	Hispanic	24%	27%
	Other/mixed	10%	10%



Baseline Injection Risk among Randomized STRIVE participants (n=418)

- 62% injected at least daily
- 23% injected less than 4 years
- 61% inject heroin most often

- 87% reported any injection risk behaviors in the past 3 months
 - 45% reported receptive syringe sharing
 - 47% reported distributive syringe sharing
 - 74% shared cooker, cotton, or water



Randomization Results

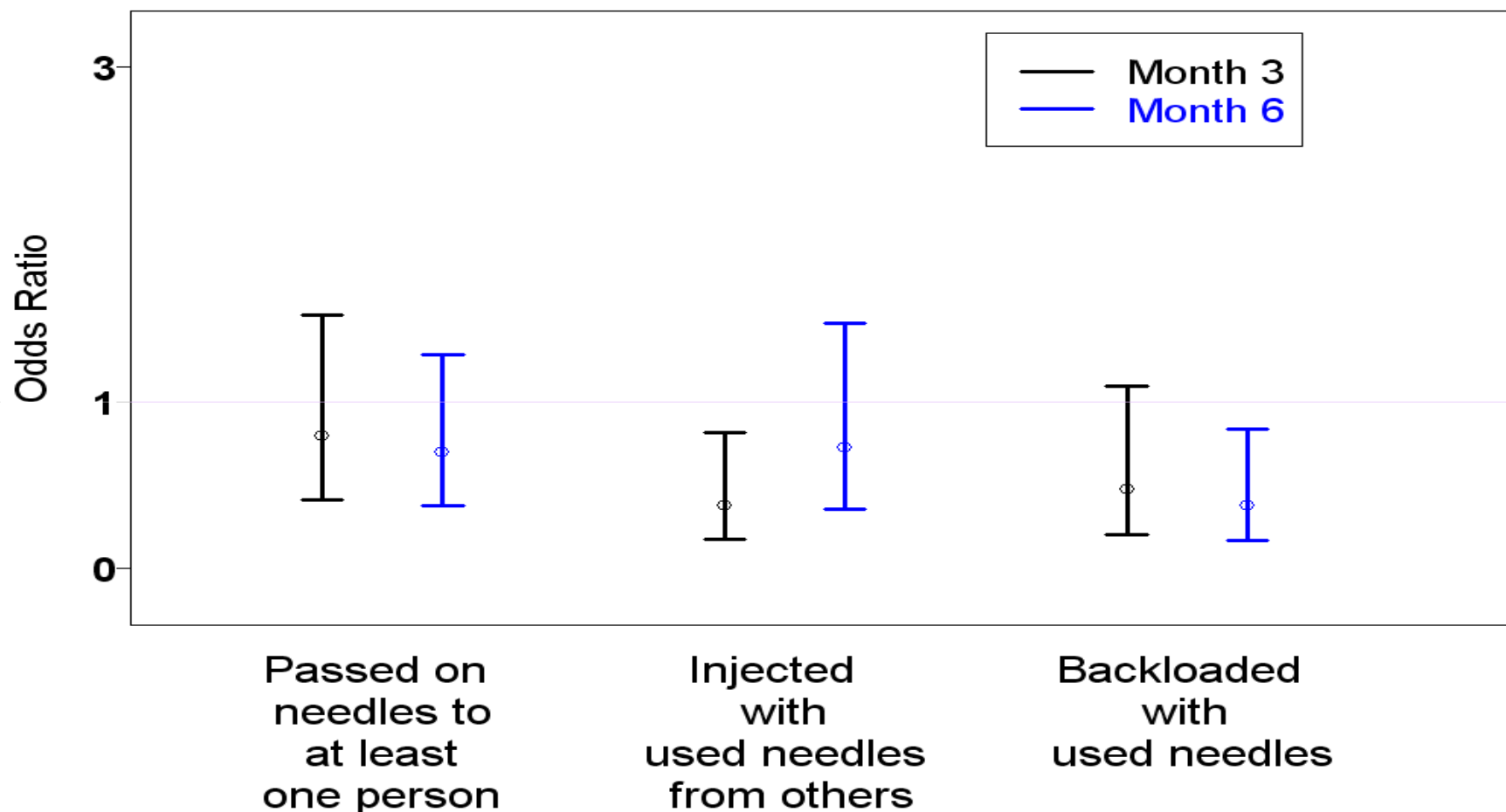
Randomization “worked”

Members of both trial arms were similar ($p>0.05$) in terms of:

- Sociodemographics
 - Primary outcome measures
 - All risk behaviors examined
- 86% attended at least one follow up visit; no difference between arms



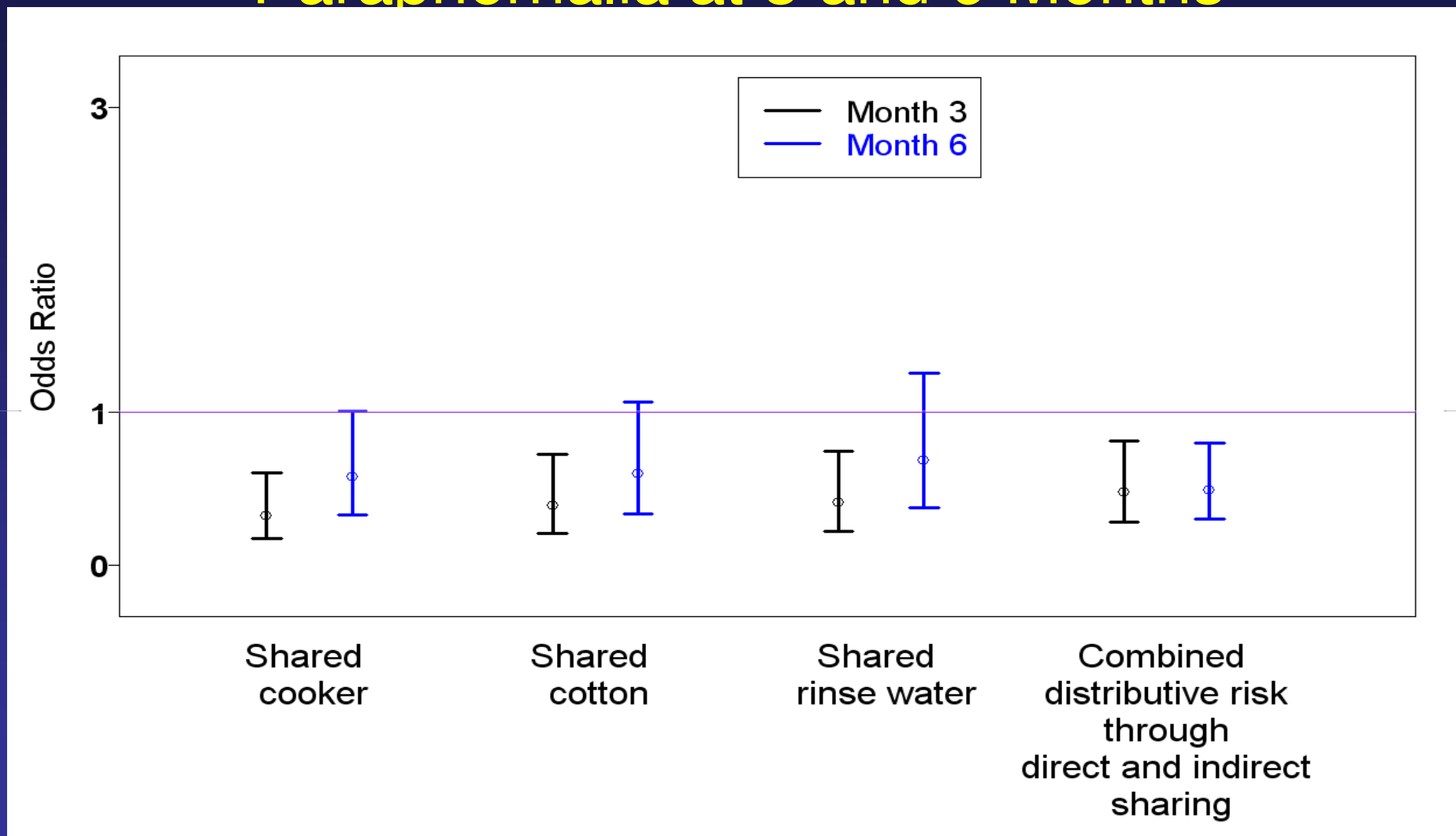
Between-arm Comparison in Needle Sharing Behaviors at 3 and 6 Months



• Adjusted for gender, race, age, city, cohort size, duration having known HCV+ status at BL; P-values based on comparisons between the 2 arms at 3/6 months adjusting for baseline



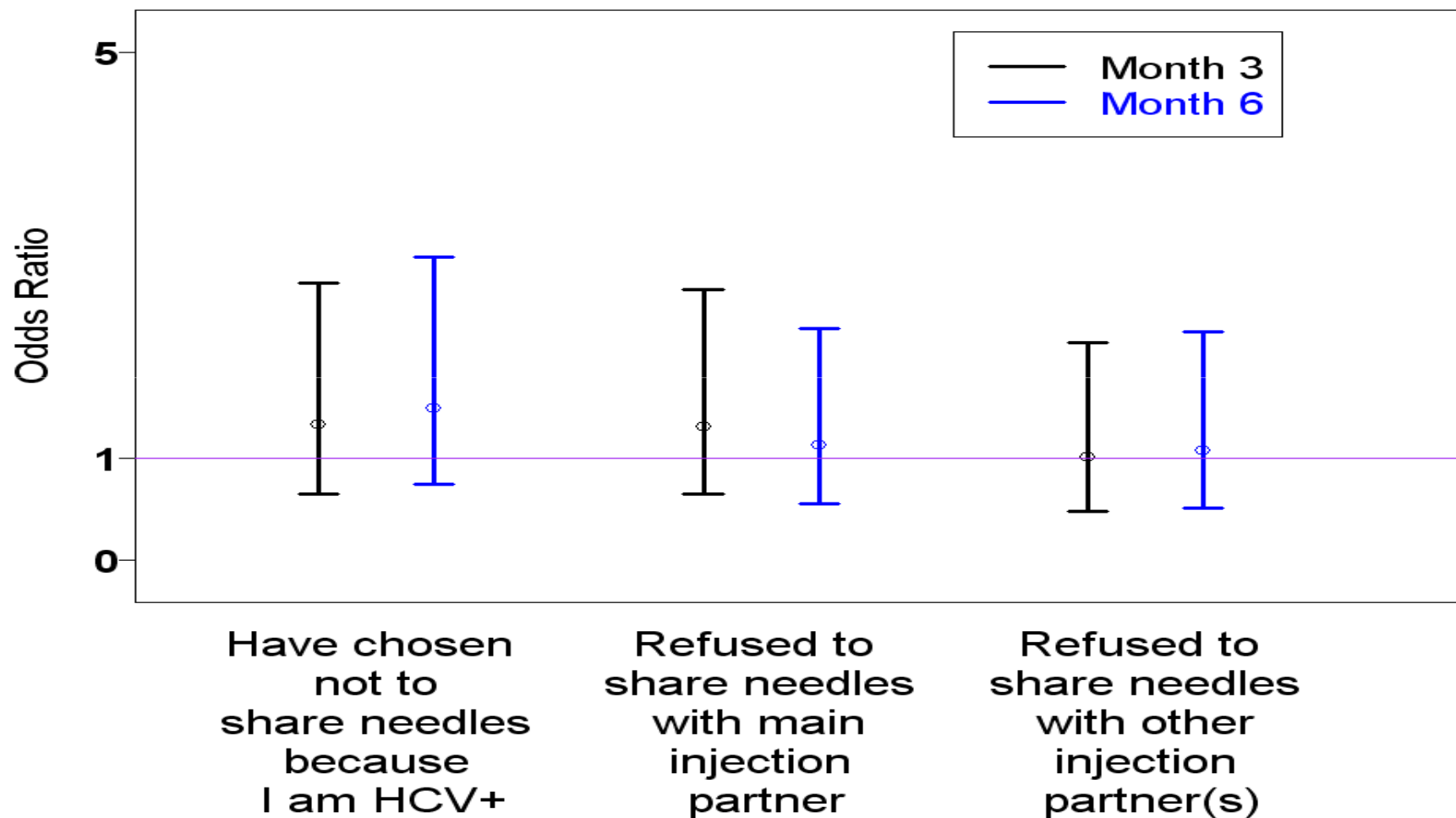
Between-arm Comparison in Sharing Injecting Paraphernalia at 3 and 6 Months



• Adjusted for gender, race, age, city, cohort size, duration having known HCV+ status at BL; P-values based on comparisons between the 2 arms at 3/6 months adjusting for baseline



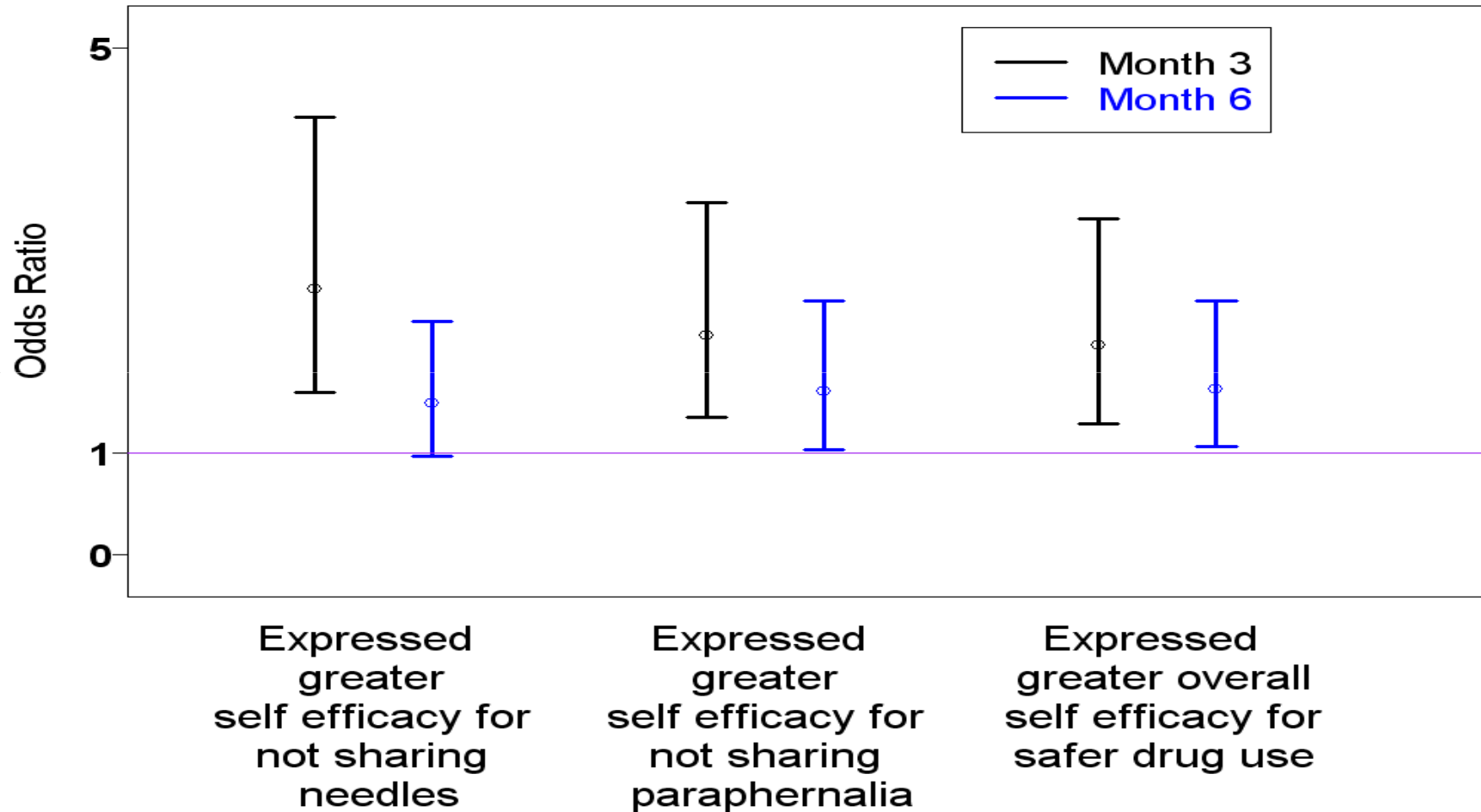
Between-arm Comparisons in Attitudes Related to Needle Sharing at 3 and 6 Months



• Adjusted for gender, race, age, city, cohort size, duration having known HCV+ status at BL; P-values based on comparisons between the 2 arms at 3/6 months adjusting for baseline



Between-arm Comparison in Self-Efficacy Related to Needle Sharing at 3 and 6 Months



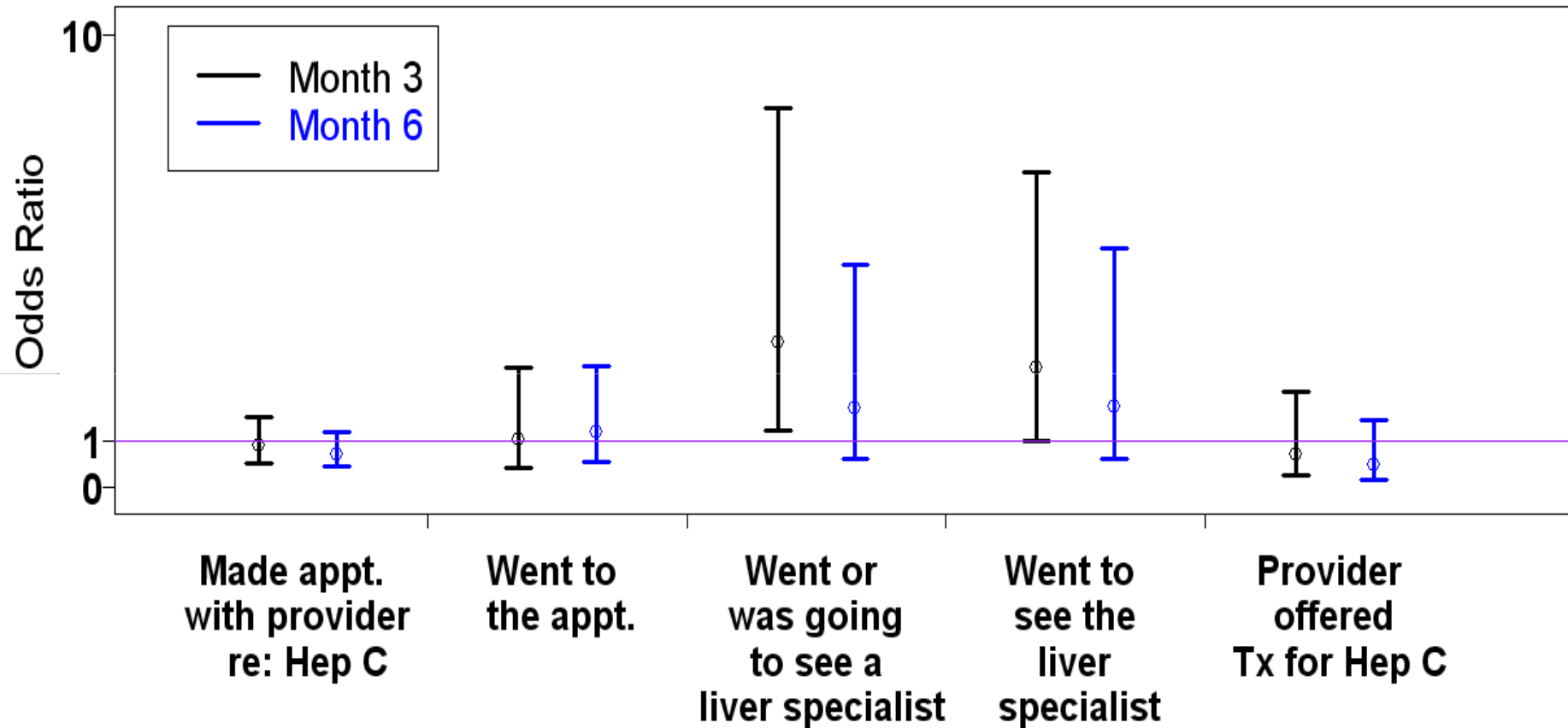
• Adjusted for gender, race, age, city, cohort size, duration having known HCV+ status at BL; P-values based on comparisons between the 2 arms at 3/6 months adjusting for baseline



Health Care Utilization



Results: Intervention Effect Health Care Utilizations at 3/6 Months



Adjusted for gender, race, age, city, cohort size; P-values based on comparisons between the two arms at 3/6 months.



Limitations

- Study was powered for twice the sample size, so power was suboptimal.
- Contamination across trial arms was difficult to avoid
- Ethically mandated counseling could have had a significant intervention effect.
- Repeat self-reported outcomes may be subject to reporting bias.
- Subjects lost to follow-up did not differ than those retained in terms of sociodemographic and behavioral data, but were more likely to:
 - Have CES-D scores >16
 - Report no health insurance
 - Report not having a usual source of health care



Conclusions

- Our peer mentoring intervention was significantly associated with reductions in HIV/HCV transmission-associated injection behaviors among IDUs in 3 U.S. cities.
- Overall risk reductions were maintained after 6 mo; behavior changes appeared to be mediated through increases in self-efficacy.
- Some evidence of increased uptake of HCV care at 3 mo, but not 6 mo, suggesting system-level barriers to care persist
- This intervention has significant promise in reducing the spread of HCV and HIV among young IDUs who continue to practice high-risk injection behaviors.



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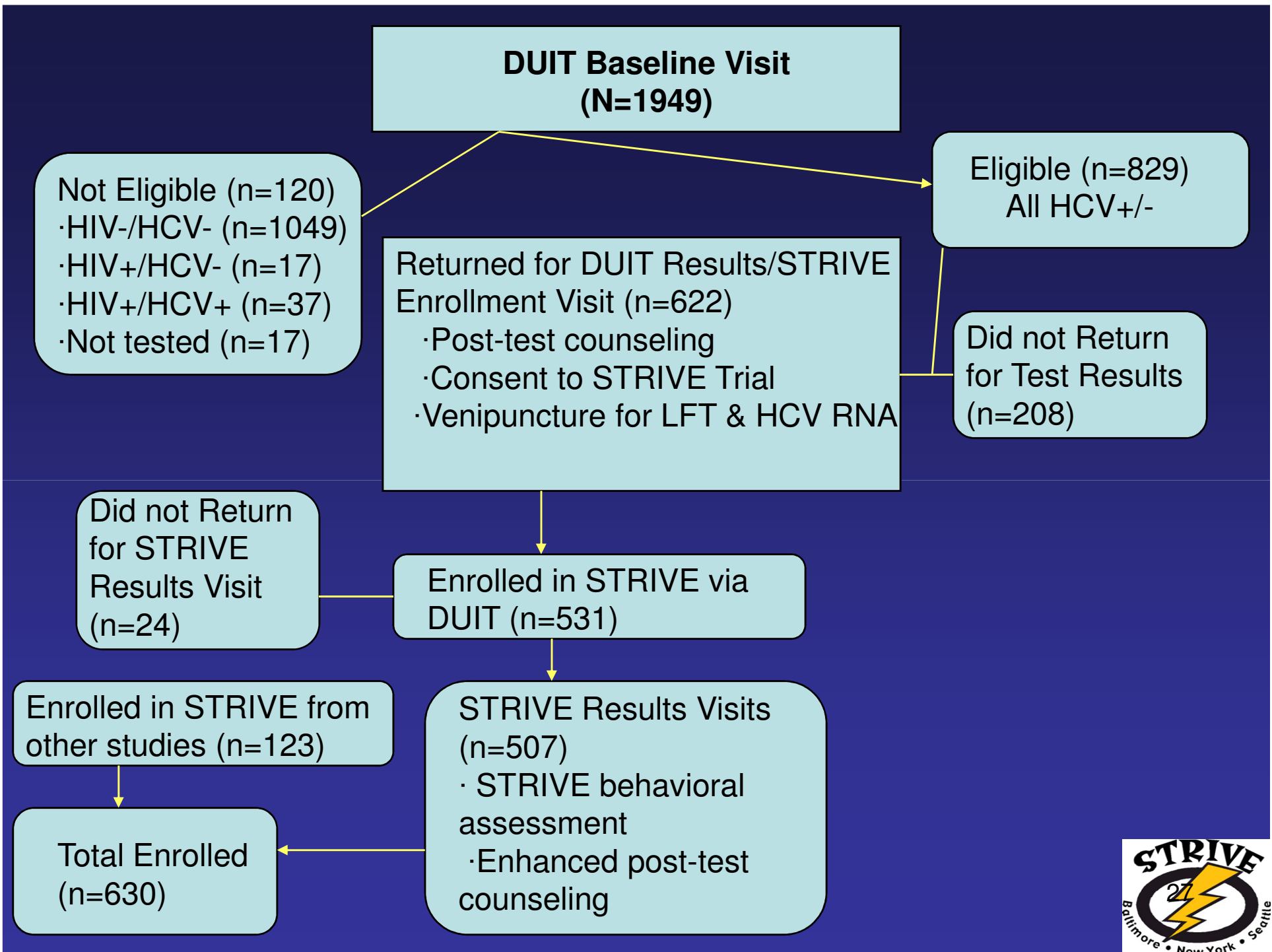
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Additional Slides





Analysis - Regression Methods

1. Logistic regression for binary outcomes (0/1). Compute odds of non-zero outcome.
2. Proportional odds models for ordinal outcomes. Compute odds of higher risky behaviors or greater self efficacy. Score tests were used to test proportional odds assumptions.
3. Baseline outcomes used as covariates.



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Percent of STRIVE Participants Attending Intervention and Follow-up Visits by Condition (n=418)

	Session #							Follow-up Visits		
	1	2	3	4	5	6	≥4 sessions	3M	6M	Either
PMI	100	83	80	75	76	74	78	66	81	86
VDI	100	78	73	73	68	70	74	66	80	87

Between arm comparisons $p > 0.1$



