Impact of Systems Navigation and Counseling on ART, SUT, and Death in PWID: HPTN 074

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FULL STUDY TITLE

HIV Prevention Trials Network 074: Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care.

BACKGROUND AND RATIONALE

In most settings, people who inject drugs (PWID) experience high HIV incidence, limited access to HIV and substance use treatment, and high mortality. HPTN 074 is a randomized, controlled vanguard study conducted in Kyiv, Ukraine; Jakarta, Indonesia; and Thai Nguyen, Vietnam – areas of the world with high HIV prevalence and incidence among PWID.



METHODS

HIV-infected PWID, "index participants", were enrolled with at least one HIV-uninfected injection partner. Index PWID were randomly assigned to standard of care (SOC) or a systems navigation and psychosocial counseling intervention. All HIV-infected PWID were referred to existing local antiretroviral therapy (ART) and medication-assisted treatment (MAT) services. Outcome measures included ART uptake, viral suppression, MAT uptake, mortality, and partner HIV incidence.

RESULTS

- 502 indexes and 806 partners were enrolled (**Table 1**) with good retention (**Figure 1**).
- Indexes in the intervention arm had better outcomes (**Table 2**):

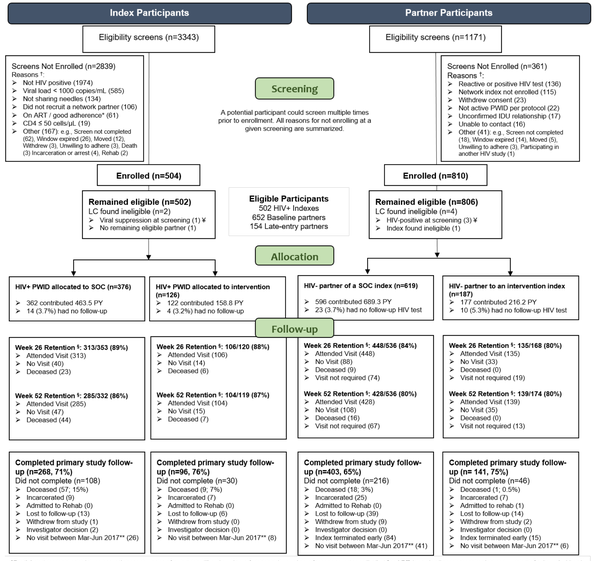
  Higher ART use (**Figure 2**), viral suppression (**Figure 3,4**), MAT use (**Figure 5**)
  Lower mortality (**Figure 6**).
- Partners in the intervention arm had no clear increase in MAT use (**Figure 7**), but had **reduced** mortality (**Figure 8**).
- **All incident HIV infections among partners occurred in the SOC arm**:.

  Intervention: 0 cases/215.6 person-years; incidence rate: 0.0 per 100 person-years (CI 0.00, 1.7)
  SOC arm: 7 cases/683.6 person-years; incidence rate : 1.0 per 100 person-years; (CI 0.41, 2.1)
  Incidence rate difference for HIV transmission, -1.0 per 100 person-years (CI -2.1, 1.1).

CONCLUSION

In this vanguard study of a scalable, integrated HIV intervention for PWID, ART and MAT uptake doubled, mortality was reduced by more than 50%, and no HIV incident cases were identified among HIV-uninfected partners of indexes receiving the intervention. Pending further studies, policymakers may wish to consider these striking results as they implement new programs.

Figure 1: CONSORT DIAGRAM



⁵Participant screens can have more than one reason for not enrolling (number of reasons ≥ number of screens not enrolled). *On ART / good adherence served as a surrogate for low viral load to reduce the site burden of viral load screening. ¥Confirmatory central laboratory testing indicated ineligible due to HIV viral load or HIV serostatus. ⁵Retention denominator excludes participants who are deceased and partners of the deceased index and non-required late entry partner visits. **Specific reason for premature termination of study follow-up was not provided. ART=antiretroviral treatment. IDU=injection drug use. LC=laboratory center. PWID=person who injects drugs. PY=person-years of follow-up. SOC=standard of care.

TABLE 2: STATUS AT 26 AND 52 WEEKS AND TIME TO EVENT FOR ART USE, VIRAL SUPPRESSION, AND MAT UPTAKE

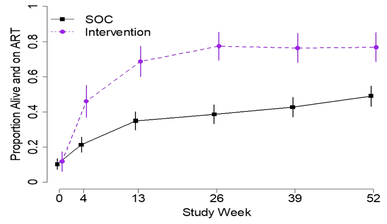
	Status at 26 weeks			Status at 52 weeks			Time to Event
	Intervention Percentage	SOC Percentage	PR (95% CI)	Intervention Percentage	SOC Percentage	PR (95% CI)	HR (95% CI)
Indexes							
ART use	67%	34%	2.0 (1.7, 2.4)	72%	43%	1.9 (1.6, 2.3)	3.6 (2.7, 4.8)
Viral suppression (<40 copies/ml)	36%	16%	2.2 (1.6, 3.1)	41%	24%	1.7 (1.3, 2,2)	1.8 (1.3, 2.4)
MAT use	38%	24%	1.7 (1.3,2.2)	41%	25%	1.7 (1.3, 2,2)	2.7 (1.8, 4.1)
Mortality			--			--	0.47 (0.22, 0.90)
Partners							
MAT use	30%	25%	1.2 (0.84, 1.6)	34%	26%	1.3 (0.96, 1.7)	1.3 (0.87, 2.0)
Mortality			--			--	0.17 (0.01, 0.84)

Abbreviations: SOC-Standard of care, MAT-medication-assisted treatment; PR-probability ratio; HR-hazard ratio; CI-confidence interval

TABLE 1: BASELINE CHARACTERISTICS OF INDEX AND PARTNER PARTICIPANTS, BY ARM

	Index Participants		Partner Participants	
Characteristic	Intervention n=126 n (%)	SOC n=376 n (%)	Intervention n=187 n (%)	SOC n=619 n (%)
Self-identified gender				
Female	16 (12.7%)	59 (15.7%)	17 (9.1%)	73 (11.8%)
Male	110 (87.3%)	317 (84.3%)	170 (90.9%)	546 (88.2%)
Age at enrollment (years)				
18-29	21 (16.7%)	61 (16.2%)	43 (23.0%)	191 (30.9%)
30-39	85 (67.5%)	243 (64.6%)	100 (53.5%)	302 (48.8%)
40+	20 (15.9%)	72 (19.1%)	44 (23.5%)	126 (20.4%)
Highest education level				
No schooling	1 (0.8%)	3 (0.8%)	1 (0.5%)	3 (0.5%)
At least some primary school	12 (9.5%)	43 (11.4%)	9 (4.8%)	32 (5.2%)
At least some secondary school	61 (48.4%)	195 (51.9%)	86 (46.0%)	332 (53.6%)
At least some technical training	33 (26.2%)	89 (23.7%)	51 (27.3%)	160 (25.8%)
At least some college/university	19 (15.1%)	46 (12.2%)	40 (21.4%)	92 (14.9%)
Relationship status				
Married	45 (35.7%)	126 (33.5%)	68 (36.4%)	225 (36.3%)
Living with sex partner, unmarried	17 (13.5%)	58 (15.4%)	15 (8.0%)	92 (14.9%)
Separated, divorced, widowed	24 (19.0%)	80 (21.3%)	40 (21.4%)	102 (16.5%)
Single	40 (31.7%)	112 (29.8%)	64 (34.2%)	200 (32.3%)
Unemployed (last 3 months)				
Yes	78 (61.9%)	227 (60.4%)	103 (55.1%)	348 (56.2%)
No	48 (38.1%)	149 (39.6%)	84 (44.9%)	271 (43.8%)
ART status				
Currently on ART	15 (11.9%)	39 (10.4%)		
Previously on ART	9 (7.1%)	37 (9.8%)		
ART naive	102 (81.0%)	300 (79.8%)		
	Median (IQR)	Median (IQR)		
Years since HIV diagnosis	1.2 (0.03,5.2)	0.7(0.09,4.2)		
HIV-1 RNA (log10 copies/mL)	4.6 (4.0, 5.0)	4.6 (4.0, 5.0)		
CD4 Count (cells/µL)	295 (174,492)	291(165,462)		

FIGURE 2. Proportion alive and on ART- Indexes



INDEXES

FIGURE 3. Proportion Alive with HIV RNA <40 cp/mL - Indexes

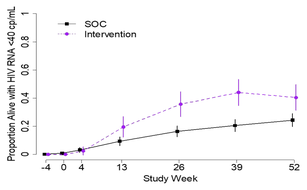


FIGURE 4. Proportion alive with HIV RNA Viral suppression <1,000 cp/ml Indexes

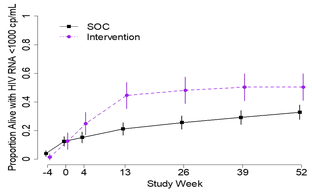


FIGURE 5. Proportion Alive and on MAT - Indexes

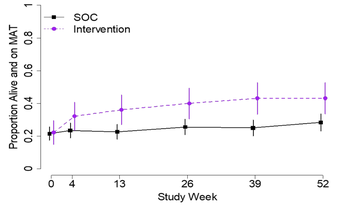
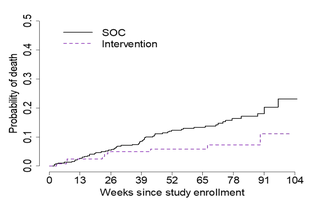


FIGURE 6. Probability of Death – Indexes only



PARTNERS

FIGURE 7. Proportion Alive and on MAT - Partners

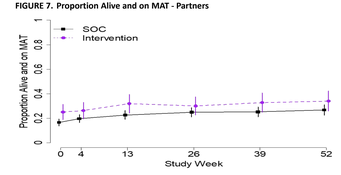
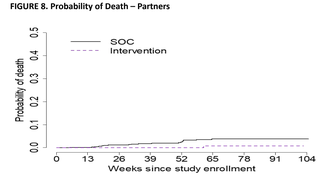


FIGURE 8. Probability of Death – Partners



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