SYSTEMS NAVIGATION AND PSYCHOSOCIAL COUNSELING (SNaP) (HPTN 074)

Evidence-Based Structural Intervention

INTERVENTION DESCRIPTION

Goal of Intervention

- Improve antiretroviral (ART) uptake
- Improve medication-assisted treatment (MAT) for persons who inject drugs (PWID)
- Improve viral suppression

Target Population

- HIV positive PWID and their non- infected injection partners

Brief Description

The HIV Prevention Trials Network (HPTN 074): Systems Navigation and Psychosocial Counseling (SNaP) intervention is designed to reduce HIV transmission from PWID with HIV to their non-infected injection partners in Kyiv, Ukraine, Thai Nguyen, Vietnam, and Jakarta, Indonesia. The intervention integrates 1) systems navigation services that includes negotiating logistics and costs of any required laboratory testing and transportation; 2) psychosocial counseling including motivational interviewing, problem solving, skills building, and goal setting to facilitate initiation and adherence of ART and MAT; and 3) ART initiation, regardless of CD4 cell count. Participants also received the standard harm reduction services that were provided to participants in the comparison group (note: see details of these services under the "Comparison" section). Index participants who are PWID with HIV can select up to 5 concurrent non-HIV infected injection partners for participation in the study. Index participants can also bring a social support person (e.g., family member, sexual partner, friend) to counseling and systems navigation sessions to help with ART initiation and MAT use.

Theoretical Basis

- Motivational Interviewing

Intervention Duration

- Two systems navigation sessions, either in person or over the phone, followed by subsequent sessions as needed according to the participant or observed by the systems navigators.
- Two psychosocial counseling sessions, with 1 booster session at 1 and 3 months after enrollment. Additional counselling sessions could be requested by participants as needed.
- Duration of counseling sessions were typically 16-60 minutes.

Intervention Setting
- Community-based organization
- District health centers
- HIV and MAT clinics
- Hospital site
- Telephone

Deliverer
- Systems navigator
- Psychosocial counselor
    - Note: One person with addiction care experience served as both systems navigator and psychosocial counselor at all sites

Delivery Methods
- Counseling
- Goal setting
- Harm reduction
- Patient navigation
- Problem solving
- Skills building
- Text messages

Structural Components
- Access
    - Provided ART at study onset, regardless of CD4 cell count
    - Provided navigation services to facilitate HIV care and MAT
    - Provided psychosocial counseling
- Physical Structure – Integration of Services
    - Integrated systems navigation, psychosocial counseling, and ART initiation with existing standard harm reduction services

INTERVENTION PACKAGE INFORMATION

The intervention manual is available online in **Appendix B:**
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6299325/#SD1

Please contact **William C. Miller** for details on interventions materials.
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EVALUATION STUDY AND RESULTS

Study Location Information
The original evaluation study was conducted in Kyiv, Ukraine; Thai Nguyen, Vietnam; and Jakarta, Indonesia between February 2015 and June 2017.

Key Intervention Effects
- Increased ART uptake
- Increased viral suppression

Recruitment Settings
- Community outreach
- HIV testing sites
- Referrals from the injection networks of index participants

Eligibility Criteria
Participants were eligible as a PWID network unit (i.e., PWID with HIV and up to 5 HIV non-infected partners). Participants were eligible if they were between the ages of 18 and 45 years with the upper age limit increased to 60 years 8 months after study initiation, had no plans to move outside of the study area for at least 1 year after study enrollment, and were actively injecting drugs (initially defined as self-report of injecting drugs approximately 2 or more times per week in the past 3 months and the ability to identify the anatomical location of the most recent injection site, confirmed by study staff). Eight months after study initiation, the criteria were revised to self-report of injecting drugs 12 times or more in the past 3 months and at least 6 times in the past month and considered a 'PWID' by site staff).

Participants were defined as index participants if they had HIV infection at screening based on local HIV test procedures; a viral load of ≥1000 copies per mL at screening based on local testing with or without self-reported current ART use; and were willing and able to identify, recruit, and enroll at least one network injection partner who was not infected with HIV. Eight months after study initiation, a CD4 cell count of over 50 cells per µL was added to eligibility criteria for index participants.

Injection partners of index participants were a confirmed injection relationship with the index, based on referral identification cards or matching physical description, and no HIV infection.

Study Sample
The baseline study sample of 502 index participants is characterized by the following:
- *85% male, 15% female*
- *Median age of 35 years*
- *80% ART naïve, 11% currently on ART, 9% previously on ART*
- *22% currently on MAT*
- *Median viral load of 4.6 log_{10} copies per mL*
- *Median CD4 count of 293 cells per* µL

The baseline study sample of 806 injection partners is characterized by the following:
- *89% male, 11% female*
- *Median age of 33 years*
- *19% currently on MAT*

Assignment Method
Index participants were randomly assigned by a computer-generated sequence accessed through a secure web portal to either the standard of care or intervention group (3:1): standard of care (n = 376) or intervention (n = 126). Randomization was stratified by site and used a permuted-block design.

Comparison
Index participants in the standard of care group received referrals to existing HIV and MAT clinics where they were given primarily methadone since buprenorphine had little availability in Ukraine and Indonesia and no

availability in Vietnam. Index participants also received a standardized harm-reduction package, consistent with in-country guidelines, and the WHO package of care for PWID that included HIV testing and counseling; referrals to ART according to national guidelines, and diagnosis and treatment of STIs, hepatitis B, hepatitis C and tuberculosis. Harm reduction services also included referrals to standard substance misuse or addiction treatment, and syringe-service programs, injection risk reduction counseling, and sexual risk reduction counseling, including access to condoms.

Relevant Outcomes Measured

- ART uptake was measured as self-reported initiation and use of ART at 26 and 52 weeks.
- Viral suppression was measured as less than 40 copies per mL and less than 1000 copies per mL at 26 and 52 weeks.

Participant Retention

Because participant retention is not a criterion for the Structural Interventions (SI) chapter, the Prevention Research Synthesis (PRS) project does not evaluate that information.

Significant Findings on Relevant Outcomes

- A significantly greater percentage of intervention index participants than comparison index participants reported uptake of ART at 26 weeks (73% vs. 36%; Probability Ratio (PR) = 1.9, 95% CI = 1.6-2.3) and at 52 weeks (72% vs. 43%; PR = 1.7, 95% CI = 1.4-1.9). Additionally, a significantly greater percentage of intervention index participants than comparison index participants reported uptake of ART at 26 weeks and at 52 weeks for the following sites:
    - Ukraine
        - 26 weeks (71% vs. 17%; PR = 4.1, 95% CI = 2.7-6.2)
        - 52 weeks (73% vs. 34%; PR = 2.1, 95% CI = 1.6-2.9)
    - Vietnam
        - 26 weeks (88% vs. 51%; PR =1.7, 95% CI = 1.4-2.1)
        - 52 weeks (88% vs. 56%; PR = 1.6, 95% CI = 1.3-1.9)
- A significantly greater percentage of intervention index participants than comparison index participants achieved viral suppression (<40 copies per mL) at 26 weeks (36% vs. 16%; PR = 2.2, 95% CI = 1.6-3.0) and 52 weeks (41% vs. 24%; PR = 1.7, 95% CI = 1.3-2.2). Additionally, a significantly greater percentage of intervention index participants than comparison index participants achieved viral suppression (<40 copies per mL) at 26 weeks and at 52 weeks for the following sites:
    - Ukraine
        - 26 weeks (41% vs. 11%; PR = 3.7, 95% CI = 2.0-6.8)
        - 52 weeks (49% vs. 26%; PR = 1.9, 95% CI = 1.2-2.9)
    - Vietnam
        - 26 weeks (48% vs. 26%; PR = 1.9, 95% CI = 1.2-2.9)
        - 52 weeks (50% vs. 30%; PR = 1.7, 95% CI = 1.1-2.5)

Strengths

- None identified

Considerations

Additional significant positive findings on non-relevant outcomes

- Time to ART initiation was significantly faster for intervention index participants than comparison index participants overall over the 52-week follow-up period (HR=3.6, 95% CI=2.7-4.8) as well as for Ukraine (HR=4.9, 95% CI=3.2-7.6) and Vietnam (HR=4.7, 95% CI=2.8-7.8).
- Time to viral suppression was significantly faster for intervention index participants than comparison index participants overall over the 52-week follow-up period (HR=1.8, 95% CI=1.3-2.4), as well as for Ukraine (HR=2.3, 95% CI=1.5-3.8) and Vietnam (HR=1.7, 95% CI=1.1-2.7).
- Time to MAT use was significantly faster for intervention index participants than comparison index participants overall over the 52-week follow-up period (HR=2.4, 95% CI=1.6-3.7), as well as for Ukraine (HR=2.6, 95% CI=1.3-5.3) and Vietnam (HR=2.9, 95% CI=1.7-5.0).
- A significantly greater percentage of intervention index participants than comparison index participants overall reported MAT use at 26 weeks (38% vs. 24%; PR=1.7, 95% CI= 1.7-2.2) and at 52 weeks (41% vs. 25%; PR=1.7, 95% CI=1.3-2.2). Additionally, a significantly greater percentage of intervention index participants than comparison index participants reported MAT use at 26 weeks and at 52 weeks for the following site:
    - Vietnam
        - 26 weeks (62% vs. 30%; PR=2.1, 95% CI= 1.4-3.0)
        - 52 weeks (67% vs. 35%; PR= 1.9, 95% CI= 1.4-2.7)
- Mortality was significantly lower among intervention index participants than comparison index participants (5.6 deaths per 100 person-years vs 12.1 deaths per 100 person-years; HR=0.47, 95% CI=0.22-0.90).
- Mortality was significantly lower among intervention injection partners than comparison injection partners (0.46 deaths per 100 person-years vs 2.6 deaths per 100 person-years; HR=0.17, 95% CI=0.01-0.84).

Non-significant findings on relevant outcomes

- There was no significant intervention effect for ART uptake or viral suppression at 26 or 52 weeks among participants in Indonesia.

Negative findings

- None reported

Other related findings

- There were no significant intervention effects on MAT use or time to MAT use among injection partners overall and by study site.
- Seven new HIV infections were seen, and all were in injection partners in the standard of care group. The study was not designed with sufficient power to confirm an effect of the intervention on HIV acquisition, but the absence of any HIV infection among the 187 partners in the intervention group supports the possibility that the intervention could reduce HIV incidence among injection partners.

Implementation-related findings

- Fidelity — No meaningful differences in implementation and uptake of systems navigator sessions were identified across sites.
- Fidelity — There were differences in implementation of psychosocial counseling sessions across sites.
    - In Vietnam, 86% of intervention index participants completed 2 psychosocial counselling sessions within 4 weeks, compared to 64% of intervention index participants in Ukraine and 50% of intervention index participants in Indonesia.

  - More counseling sessions were conducted with a support person present among intervention index participants in Vietnam (100%) and in Ukraine (74%) compared to intervention index participants in Indonesia (50%).
- Adoption — The intervention was designed to be scalable, focusing on assisted engagement in care through systems navigation and flexible, brief psychosocial counseling. The intervention should be implementable in many settings that serve PWID, including HIV counseling and testing centers and nonprofit organizations. The role of systems navigator can be fulfilled by peers, social workers, counselors, or clinicians – the key feature is that navigators understand the local health-care system and are able to facilitate entry and retention in care.

Adverse events
None Reported

Funding
National Institute of Allergy and Infectious Diseases (NIAID) (grant number UM1AI068619)
National Institute of Mental Health (NIMH) (grant number UM1AI068617)
National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) (grant number UM1AI068613) (grant number P30 AI50410)

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