Re-Engaging Persons with HIV who are Out of Care: Is a New Approach Needed?

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STUDY QUESTION

- Does the structural intervention of rapid restart of antiretroviral therapy combined with the behavioral intervention "60-Minutes-For-Health" improve virologic suppression and re-engagement with care compared to rapid restart of ART with a diet and nutrition time-and-attention control?

BACKGROUND

- Persons with HIV who are out of care (PWH-OOC) are at risk of the complications of untreated HIV. The majority of new HIV transmission events in the U.S. are associated with this group [1].
- "60-Minutes-For-Health" is a brief, one-session behavioral intervention that improved re-engagement in a small pilot study [2].
- We evaluated the acceptability of rapid restart of ART and the impact of "60-Minutes-For-Health" on virologic and engagement in care outcomes

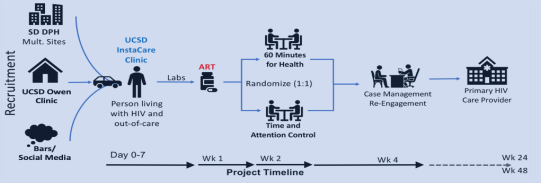
METHODS

- The study was an open label randomized controlled trial of "60-Minutes-For-Health" compared to a diet and nutrition time and attention control among PWH-OOC receiving rapid restart ART.
- Rapid restart ART was defined as the restart of ART within 7 days of re-engagement contact.
- The acceptability of rapid restart ART was evaluated via questionnaire administered at week 4.
- The protocol and primary outcomes are summarized in **Figure 1**.
- Services available through study or primary care are shown in **Table 1**. The "60-Minutes-For-Health" intervention is described in **Table 2.**

Population: PWH not on ART for the past 2 weeks **AND**:

- Had no HIV care visit in the past 6 months; **OR**
- 2 or more viral loads >200 separated by at least 4 weeks in the past 18 months; **OR**
- Had missed 2 or more HIV care visits in the past 18 months.

Figure 1: Study recruitment, randomization and primary outcomes



Primary outcomes

- Viral load </= 50 copies/ml (cpm) at week 24
- Two HIV provider visits at least 90 days apart by week 24
- ART acceptability at week 4 via ART acceptability survey

Maximum healthcare support for persons with HIV out of care in San Diego resulted in just 31.5% having 2 HIV provider visits and 37.5% having suppressed viral load after 24 weeks

Table 1: HIV services provided to all participants either through study or primary care

	Service available
Free transport	✓
Adherence counseling	✓
Case management	✓
Social work	✓
Medication assisted treatment (MAT)	✓
Free ART as needed	✓
Specialist pharmacy input	✓
Financial incentives	✓
Intensive peer navigator support	✓
In-clinic mental health services	✓

Table 2: 60-Minutes-For-Health. One-session brief behavioral intervention

Focusing on my physical health	Normalize retention, identify/correct retention-related misinformation and faulty heuristics. Elicit health priorities to improve retention.
Focusing on my emotional health	Explore emotions and how these may facilitate or impeded routine care. Build behavioral skills for coping.
Building on my HIV care history	Identify previous care gaps and explores motivations, behavioral skills and contexts affecting retention history. Leverage personal strengths to promote retention.
Personal health motivation	Support identification of personal health motivators. Develop targeted action plans to build motivation, skills and resources.

RESULTS

- 52 PWH-OOC were enrolled between November 2020 and September 2022.
- Demographics and baseline questionnaires are shown in **Table 3** and **Figure 2**.

Table 3: Participant demographics

	60-minutes for Health, N (%)	Control, N (%)
Cisgender man	25 (96.2)	22 (84.6)
Cisgender woman	0 (0.0)	3 (11.5)
Transgender woman	1 (3.8)	1 (3.8)
Age, Median (IQR)	46 (39-54)	41.5 (32-57)
Race		
Black	3 (12.0)	9 (36.0)
Multi-racial	4 (16.0)	0 (0.0)
Native American	2 (8.0)	2 (8.0)
White	16 (64.0)	14 (56.0)
Ethnicity		
Hispanic	11 (42.3)	6 (23.1)
Non-Hispanic	15 (57.7)	19 (73.1)
Household monthly Income		
<$500	9 (34.6)	18 (69.2)
$500-999	4 (15.4)	1 (3.8)
>$1000	13 (50.0)	7 (26.9)
Years since HIV diagnosis, median (IQR)	13 (6-26)	15 (6-23)
Previous years on ART, median (IQR)	10 (4-12)	6.5 (4-15)

Figure 2: Baseline Self-reported substance use, depression, anxiety, barriers to care and HIV care perceptions at week 0 enrollment

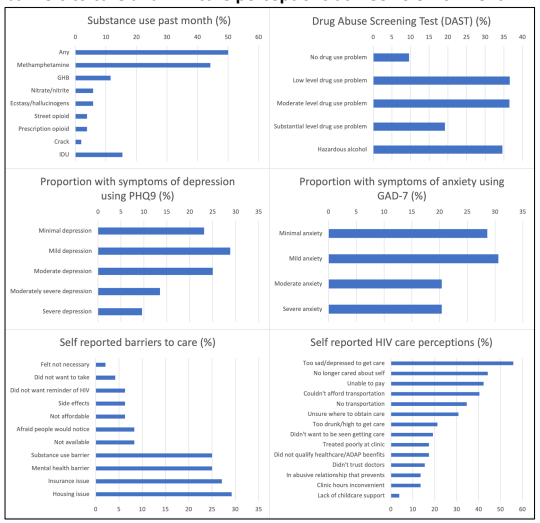
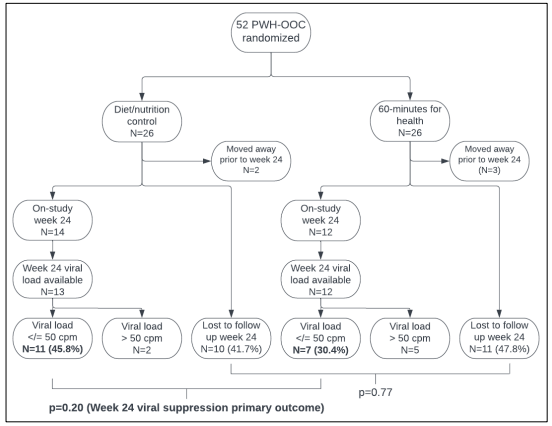


Figure 3: Summary of randomization, loss-to-follow-up and primary viral suppression outcome



Viral suppression outcome (Figure 3)

- Week 24 viral suppression was 37.5% among all participants: 30.4% among "60-Minutes-For-Health"/rapid restart ART compared to 45.8% among control/rapid restart ART (p=0.20).

Engagement in care outcome

- From 48 persons eligible for week 24 follow-up, 15 (31.3%) had attended 2 primary care visits at least 90 days apart. Among "60-Minutes For Health" 7/24 (29.2%) were engaged in care vs. 8/24 (33.3%) among control group participants (p=1.00).

Rapid restart ART acceptability survey outcome

- 77% reported high or very high acceptance of HIV medications
- 94% reported low or very low emotional distress associated with restarting ART

CONCLUSIONS

- **Despite extensive support services and financial incentives, we observed very low rates of engagement in care (31.3%) and viral suppression (37.5%) at week 24 among PWH-OOC highlighting an urgent need for structural reform.**
- **Rapid restart of ART among PWH-OOC was acceptable to most participants.**
- **"60-Minutes-For-Health" in the context of the structural intervention of rapid restart ART did not improve viral suppression or engagement in care outcomes.**

ADDITIONAL KEY INFORMATION

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References:
1. Z. Li, D. Purcell, S. Sansom, D. Hayes and I. Hall. **Vital Signs: HIV Transmission Along the Continuum of Care - United States, 2016.** MMWR 2019 Vol. 68 Issue 11 Pages 267-272
2. L. R. Smith, K. R. Amico, J. D. Fisher and C. O. Cunningham. **60 Minutes for health: examining the feasibility and acceptability of a low-resource behavioral intervention designed to promote retention in HIV care.** AIDS Care 2018 Vol. 30 Issue 2 Pages 255-265