

Randomized Trial of Brief Alcohol Intervention for Viral Suppression and Alcohol Use

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BACKGROUND

- Unhealthy alcohol use is a major contributor to viral nonsuppression among persons living with HIV (PWH)
- It is unknown if brief behavioral interventions to reduce alcohol use can improve viral suppression among PWH with unhealthy alcohol use in sub-Saharan Africa

OBJECTIVES

- Compare the effectiveness of a brief, culturally-adapted skill-based alcohol counseling intervention with the standard of care for PWH and unhealthy alcohol use and a risk factor for viral non-suppression to:
 - 1. Improve viral suppression
 - 2. Reduce unhealthy alcohol use

METHODS

Study Population & Design:

- SEARCH SAPPHIRE Alcohol (NCT 04810650) was an individually randomized controlled trial in 3 Ugandan and 5 Kenyan communities
- PWH ≥18 years who self-reported unhealthy alcohol use (Alcohol Use Disorders Identification Test-Consumption [AUDIT-C] ≥3/female; ≥4/male) and had:
 - Unsuppressed HIV viral load (≥400 copies/mL) in past 12 months OR
 - Missed visit(s) OR
 - Out of HIV care OR
 - New HIV diagnosis
- · Randomized to:
- Intervention of in-person counseling sessions at baseline and 3 months with booster phone calls every 3 weeks in the interim with viral load and adherence counseling
- OR
- Control of brief advice on harmful effects of alcohol and safe levels of drinking and viral load feedback at their post-baseline regular clinic visit

Primary Outcome:

 Viral suppression (HIV RNA<400 copies/mL) measured at week 24

Secondary Outcome:

- Unhealthy alcohol use, defined by:
- AUDIT-C ≥3/female; ≥4/male prior 3 months <u>OR</u>
- Alcohol biomarker, phosphatidylethanol (PEth), ≥50ng/mL measured at week 24

Analytic Methods:

Targeted Minimum Loss-Based Estimation (TMLE) compared 1° and 2° outcomes between arms

A RCT of a brief alcohol counseling intervention vs. control showed **no effects on viral suppression**, but **did reduce unhealthy alcohol use** among PWH with unhealthy alcohol use and high risk of HIV viremia in East Africa

RESULTS

- · 400 adults living with HIV enrolled and randomized: 197 intervention, 203 control
 - 94% analyzed at week 24 (5% moved away from study area; 1 died)
- Viral suppression increased from 60% at baseline to 83% in intervention and 82% in control arms at week 24. No difference in viral suppression between arms: (aRR 1.01, 95% confidence interval [CI]: 0.93-1.10) at 24 weeks
 - Among PWH with baseline viral non-suppression (n=150), suppression 73% in intervention, 64% in control arms (aRR 1.15, 95%CI: 0.93-1.43)
- Unhealthy alcohol use declined from 98% at baseline to 73% in intervention, 84% in control (aRR 0.86, 95%CI: 0.79-0.94). Effects stronger in women than men (aRR 0.70, 95%CI 0.56-0.88)

Characteristics of participants

	Intervention (n=197)	Control (n=203)	Total (n=400)
Female, n (%)	60 (30)	71 (35)	131 (33)
Age, years, median [Q1, Q3]	37 [31,45]	37 [30,42]	37 [31,43]
Enrollment Criteria, n (%)			
Unsuppressed VL	70 (36)	71 (35)	141 (35)
Missed visit(s)	52 (26)	59 (29)	111 (28)
New to care	50 (25)	59 (29)	109 (27)
Re-engaging in care	25 (13)	14 (7)	39 (10)
Baseline VL>400, n (%)	79 (40)	82 (40)	161 (40)
Baseline AUDIT-C score, median [Q1,Q3]	6 [4,8]	6 [4,8]	6 [4,8]
Baseline PEth (ng/mL), mean [95% Cl]	492 [398-585]	481 [396-566]	486 [423-550]

RESULTS (cont.)

Comparison of HIV Viral Suppression and Unhealthy Alcohol use between arms at 24-weeks

	Intervention	Control	aRR
	% (95% CI)	% (95% CI)	(95% CI)
Viral suppression	83.3	82.4	1.01
	(78.1-88.6)	(77.5-87.2)	(0.93-1.1)
Unhealthy alcohol use	72.9	84.4	0.86
	(68-77.9)	(80.1-88.7)	(0.79-0.94)

SUMMARY

 In an RCT of 400 PWH with unhealthy alcohol use and risk for viral non-suppression, a brief alcohol intervention did not affect viral suppression at 24 weeks, but it did result in reduced alcohol consumption

CONCLUSIONS

 Brief alcohol interventions have the potential to improve the health of PWH in sub-Saharan Africa by reducing alcohol use, a significant driver of HIV and associated comorbidities

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