PROMISING RESULTS FROM A PILOT RCT MENTAL HEALTH INTERVENTION FOR HIV INFECTED YOUTH

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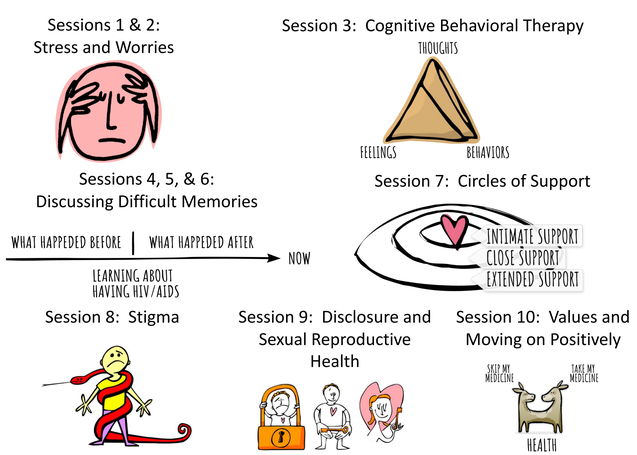
BACKGROUND

- There are increasing numbers of young people (10-24 years of age) living with HIV (YPLWH), many of whom have unaddressed mental health challenges.
- Mental health challenges are associated with poor antiretroviral therapy (ART) adherence, which leads to unacceptably high mortality.
- Few evidence-based mental health interventions exist to address mental health challenges and improve HIV outcomes specifically for YPLWH.
- This study reports the secondary outcomes from a randomized pilot study to evaluate change in mental health, antiretroviral therapy adherence (ART) and virologic outcomes of the Sauti ya Vijana (SYV) intervention arm compared to the standard of care arm.

METHODS

- This was an individually randomized group treatment pilot trial which used a stepped-wedge design.
- YPLWH who understood their HIV diagnosis and were receiving ART were recruited and enrolled from two clinical sites in Moshi, Tanzania.
- SYV consisted of ten group sessions (two joint with caregivers) and two individual sessions held weekly, delivered by group leaders (24-30 years of age).
- Demographics, mental health questionnaires (PHQ-9, SDQ, UCLA Trauma), stigma, self-report and objective measures of adherence (ART concentration in hair), and HIV RNA were obtained at baseline and 6-months (post-intervention).
- Trends towards effectiveness were assessed by comparing outcomes between arms in exploratory analyses using mixed effects modeling.

Table 1: Sauti ya Vijana (SYV) Intervention Session Content



Sauti ya Vijana (SYV: The Voice of Youth), a mental health and life skills intervention, designed with and for young people living with HIV in Tanzania shows promise to reduce mental health challenges through new coping strategies and to improve antiretroviral therapy adherence and viral suppression.

RESULTS

Table 2: Mental health and HIV measures at baseline and 6-month follow-up including only participants with data at both time points (N=93)[a]

		Standard of care (N=38)			SYV Intervention (N=55)		
		Baseline	6-month	Change	Baseline	6-month	Change
PHQ-9	Total score	6.3 (4.1)	5.1 (3.9)	-0.9 (3.7)	4.9 (3.3)	4.1 (3.4)	-0.8 (4.0)
	≥ 10[b]	10 (27.0%)	4 (11.1%)		4 (7.3%)	5 (9.1%)	
SDQ	Total score	7.1 (3.6)	7.3 (4.4)	0.1 (3.9)	7.3 (4.0)	6.7 (4.4)	-0.6 (3.9)
	≥ 17[b]	0 (0.0%)	2 (5.6%)		0 (0.0%)	2 (3.6%)	
UCLA Trauma	Total score	9.3 (6.9)	8.9 (6.3)	-0.3 (5.9)	8.6 (7.4)	8.6 (7.5)	0.0 (7.3)
	≥ 18[b]	5 (13.5%)	4 (10.8%)		9 (16.4%)	8 (14.5%)	
Composite Mental Health Difficulties[b,c]		12 (35.3%)	7 (19.4%)		13 (23.6%)	11 (20.0%)	
Stigma Mean (SD)	Total Score	23.5 (3.7)	21.5 (5.1)	-2.3 (4.7)	21.9 (5.1)	22.7 (5.3)	0.6 (4.2)
	Internal Score	8.1 (1.8)	7.1 (2.0)	-1.1 (1.7)	7.7 (1.9)	7.5 (2.1)	-0.2 (2.5)
	External Score	15.5 (3.7)	14.3 (4.2)	-1.2 (3.9)	14.4 (4.3)	15.1 (4.5)	0.7 (3.3)
Adherence ART concentration in Hair (ng/mg)	Self-report Score	57.7 (15.2)	57.7 (14.9)	-0.1 (12.4)	60.5 (11.6)	65.5 (12.3)	5.1 (17.0)*
	NVP (N=13)	44.2 (15.4)	49.7 (20.8)	5.4 (16.1)	47.1 (19.2)	45.9 (20.0)	2.4 (32.2)*
	EFV (N=29)	9.3 (7.3)	10.0 (8.2)	-1.1 (4.1)	6.0 (5.4)	5.7 (3.3)	-0.3 (4.8)
	LPV (N=15)	6.1 (5.9)	11.0 (11.7)	4.9 (9.2)	6.3 (6.6)	6.9 (5.9)	0.6 (6.5)*
	ATV (N=20)	4.7 (4.0)	4.4 (3.2)	-0.4 (2.3)	5.8 (3.8)	6.1 (3.1)	0.4 (1.7)*
	Standardized (N=77)[d]	-0.4 (2.0)	-0.5 (2.0)	-0.1 (1.5)	-0.7 (2.3)	-0.6 (1.7)	0.1 (2.1)*
Viral Load Copies/mL	Log_{10}	5.1 (2.8)	5.3 (3.3)	0.2 (1.8)	5.4 (3.3)	4.7 (2.6)	-0.7 (2.5)
	Total Score[b]	25 (65.8%)	25 (65.8%)		35 (64.8%)	41 (74.5%)	

[a] Means (standard deviations) unless otherwise noted; negative value favors the intervention except for adherence where a positive value signifies improved adherence.
[b] Reported as count (percentage)
[c] Scoring at or above the cutoff on one or more of the mental health measures
[d] ART concentration in hair available in 77/93; the lower limit of detection for EFV, LPV, ATV is 0.05 ng/mg and for NVP is 0.5 ng/mg. The standardized hair measure was created by collapsing the four anchor antiretrovirals (EFV, NVP, LPV, ATV) into a single measure using the log base 2 of the hair level minus the median log base 2 of the hair level for each drug and combined these "standardized" hair values into a single variable.

RESULTS

- Between June 2016 and July 2017, 128 YPLWH were enrolled; 105 were randomized to intervention versus control; (58 randomized to SYV); 93 came to the 6-month (post-intervention) study visit and were included in this analysis.
- Mean age of participants was 18.1 years; 51% were female; 84% were known to be infected perinatally.
- Exploratory analyses of effectiveness outcomes demonstrated change in mental health symptoms and internal stigma improved **in both arms** baseline to 6-months, but were **not significantly different between arms**.
- Self-reported adherence improved by 7.3 percentage points (95% CI: 2.2, 12.3) more in SYV compared to SOC
- Standardized levels of ART concentration in the body measured from hair samples increased by 0.17 ng/mg (95% CI: -0.52, 0.85) more in SYV compared to SOC.
- Virologic suppression (HIV RNA <400 copies/mL) at baseline was 65% in both arms, but increased to 75% in the SYV arm and stayed the same in the SOC arm (RR 1.13; 95% CI: 0.94, 1.36).

CONCLUSIONS

- YPLWH worldwide are an important population, but often have poor HIV outcomes due to stigma and mental health difficulties.
- Very few interventions exist to improve outcomes in this critical population.
- This pilot trial of SYV demonstrated trends towards improvement in ART adherence, measured objectively, and virologic outcomes among YPLWH in Tanzania supporting efforts to scale the intervention into a fully powered effectiveness trial.

ADDITIONAL KEY INFORMATION

Additional Resources

Video series on our work produced by Duke Global Health Institute can be viewed at:
https://spark.adobe.com/page/qn3TZ7866G23R/

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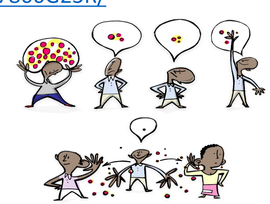

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