



Dorothy Dow^{1,2,3}, Jennifer Libous⁴, Emma Davies Smith⁵, Rebecca Dirschberger⁶, Olga Varchtchouk⁷, Sonia Lee⁸, Tichaona Vhembo⁹, Lynda Stranix-Chibanda^{9,10}, Teacler Nematadzira¹⁰, Ponego Lloyd Ponatshego^{11,12}, Limbika Maliwichi¹³, Tisungane Mvalo¹⁴, Janice Buckley¹⁵, Nicole Montañez¹⁶, Geri Donenberg¹⁷, on behalf of the entire IMPAACT 2016 Study Group

¹Duke University Medical Center, Durham NC, United States; ²Duke Global Health Institute, Durham, NC, United States; ³Kilimanjaro Christian Medical Centre-Duke Collaboration, Moshi, Tanzania; ⁴FHI 360, Washington DC, United States; ⁵Harvard T.H. Chan School of Public Health, Center for Biostatistics in AIDS Research, Boston MA, United States; ⁶Frontier Science & Technology Research Foundation, Inc, Buffalo NY, United States; ⁷Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda MD, United States; ⁸Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda MD, United States; ⁹University of Zimbabwe Clinical Trials Research Centre, Harare, Zimbabwe; ¹⁰University of Zimbabwe, Faculty of Medicine and Health Sciences, Harare, Zimbabwe; ¹¹Botswana Harvard Health Partnership, Molepolole, Botswana; ¹²Botswana Harvard Health Partnership, Gaborone, Botswana; ¹³Johns Hopkins Research Project-Kamuzu University of Health Sciences, Blantyre, Malawi; ¹⁴University of North Carolina Project Malawi, Lilongwe, Malawi; ¹⁵Perinatal HIV Research Unit (PHRU), University of Witwatersrand, Johannesburg, South Africa; ¹⁶UCLA Fielding School of Public Health, Los Angeles, CA, USA; ¹⁷University of Illinois at Chicago, Center for Dissemination and Implementation Science, Chicago IL, United States

BACKGROUND

- Symptoms of depression, anxiety, and post-traumatic stress can negatively impact HIV outcomes and quality of life.
- Despite increased risk of mental distress among youth with HIV (YWH), mental health (MH) resources are limited in many countries.
- IMPAACT 2016 evaluated whether a group-based, peer-led, manualized Trauma Informed-Cognitive Behavioral Therapy (TI-CBT) intervention can improve MH symptoms compared to a Discussion Control Group (DCG).



Left: Example of the Bright Futures Manual and Youth Leader practicing the TI-CBT triangle



FIGURE 1. Location of trial sites

METHODS

IMPAACT 2016 (Bright Futures Intervention)

- A two-arm, individually randomized group treatment trial
- Enrollment across four African countries (Figure 1) from March to September 2024
- **Inclusion criteria:** 1) 15-19 years of age; 2) aware of their HIV status; 3) prescribed antiretroviral therapy (ART) for >6 months; 4) moderate-to-severe symptoms of depression (PHQ-9 ≥10), and/or anxiety (GAD-7 ≥10), and/or post-traumatic stress (UCLA PTSD-RI ≥35).
 - Youth had an unscorable PTSD-RI if they did not report a traumatic event.
 - YWH were recruited from adolescent HIV clinics and screened by self-report on an electronic tablet.
- Enrolled participants were randomized (1:1) to receive 6 group sessions over 8 weeks of either TI-CBT or DCG, both led by trained and locally supervised youth leaders.
- **Primary MH outcomes** (PHQ-9, GAD-7, UCLA PTSD-RI, and a three-measure composite) were assessed at Month 6.
- **ART adherence** was measured with a validated 3-item self-report measure and viral suppression defined as **HIV RNA <200 copies/mL**.

Youth with HIV demonstrated a clinically meaningful reduction in mental distress in both trial arms. Treatment adherence and viral suppression were strong in both arms. There was no statistically significant difference between trial arms at 6 months.

RESULTS

- Of 365 youth screened, **254 (70%) enrolled**, resulting in 15 groups of 6-10 youth per group in the TI-CBT and 15 groups of 6-10 youth per group the DCG arm.
- Mean age was 17.3 years and 57% were female.
- Attendance to all six group sessions was 89%.
- In both arms, group-level means suggest clinically meaningful improvement from moderate-to-severe symptoms at baseline to asymptomatic-to-mild symptoms at Month 6.
- There was no statistically significant difference between arms in PHQ-9, GAD-7, or Composite scores at Month 6.
- There was no statistically significant difference in self-reported adherence nor viral suppression at Month 6.

Measure	Baseline		Month 6		Treatment Effect	
	TI-CBT (N=15)	DC (N=15)	TI-CBT (N=15)	DC (N=15)	Unadjusted Est. (95% CI)	Imputed Est. (95% CI)
PHQ-9	12.2 (2.0)	12.6 (2.3)	5.4 (2.8)	5.4 (1.9)	-0.1 (-1.8, 1.7)	-
GAD-7	9.9 (1.8)	10.1 (1.3)	4.5 (2.1)	4.3 (1.7)	0.2 (-1.2, 1.7)	-
PTSD-RI	41.1 (7.8)	42.4 (6.8)	21.7 (11.0)	15.9 (8.7)	5.8 (0.5, 11.1)	2.3 (-1.3, 6.0)
Composite	-0.1 (1.1)	0.2 (0.8)	-3.2 (1.8)	-4.1 (1.4)	0.9 (-0.2, 1.9)	0.2 (-0.6, 0.9)
Adherence	72.7 (7.6)	76.4 (7.2)	77.9 (5.8)	78.3 (4.5)	-0.4 (-4.6, 3.8)	-
Suppression	91% (8%)	88% (12%)	85% (17%)	88% (15%)	-4% (-18%, 11%)	-

N: number of groups. Group size: 5-10 youth (avg=8.5). Youth randomized: 128 TI-CBT, 126 DC. Est: estimate. Group-level summaries reported by arm, compared using paired t-test (15 pairs). Treatment effect: difference in paired group-level summaries. Composite: Sum of baseline standardized PHQ-9, GAD-7, and UCLA PTSD-RI scores. Adherence score: 0 = worst, 100 = best. Suppression: HIV RNA < 200 copies/mL. Asymptomatic-to-mild MH symptoms: PHQ-9 < 10; GAD-7 < 10; PTSD-RI < 35. Predictive Mean Matching used to multiply impute PTSD-RI score for 95 unscorable assessments (53 TI-CBT, 42 DC).

RESULTS (CONT)

- The PTSD-RI was unscorable for 1% (3/254) of participants at baseline; 37% (95/254) of participants at Month 6.
- Unadjusted (complete case) analysis indicated higher mean Month 6 PTSD-RI scores for TI-CBT v. DCG; however, with imputation, the difference was attenuated and not statistically significant.

CONCLUSIONS

- Rapid enrollment underscores the high rate of mental distress and desire for MH care by YWH.
- No difference in arm efficacy suggests that simply offering symptomatic YWH a safe space to discuss challenges in small peer groups led by a youth leader with supervision may lead to improved MH outcomes.

ACKNOWLEDGEMENTS

We sincerely thank the youth participants who gave of their time and shared life experiences; the caregivers, the passionate youth leaders and site study staff, the dedicated protocol team, the support of the IMPAACT network, and the dedicated NIH funders, all of whom made this work possible.

PLAIN LANGUAGE SUMMARY

The majority of youth with HIV screened for symptoms of anxiety, depression and/or post traumatic stress were symptomatic. With peer-led groups, their symptoms improved. There is an urgent need to screen and provide mental health care for youth with HIV. Task sharing to trained and supervised youth leaders can be an effective strategy.