

IMPAACT 2016

Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings

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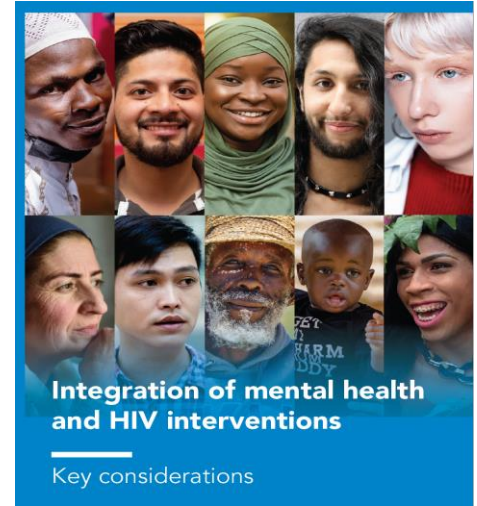
IMPAACT annual meeting June 30, 2022

Brief Outline

- ▶ Recap of IMPAACT 2016 rational, methodology, intervention content, timeline
- ▶ Updates since last presentation June 2019
 - ▶ Trainings
 - ▶ Publications
- ▶ Why IMPAACT 2016 remains a critical study
- ▶ Next steps

Rational

- ▶ Adolescents living with HIV
 - ▶ key population
 - ▶ high risk of virologic failure
- ▶ Mental health challenges
 - ▶ ~50% present by 14 years-old,
 - ▶ 75% present by 24 years-old
 - ▶ overlooked and unaddressed
- ▶ Improving mental health → ↑ ART adherence → better viral outcomes



Integration of mental health and HIV interventions. Key considerations. Geneva: Joint United Nations Programme on HIV/AIDS and the World Health Organization; 2022. License: CC BY-NC-SA 3.0 IGO

IMPAACT 2016

- Can trauma-informed cognitive behavioral therapy delivered by young adults living with HIV improve the mental health and ART adherence of 15-19 years-olds living with HIV?
- Eight sites in four countries: **South Africa**, **Botswana**, **Zimbabwe**, **Malawi**



Intervention Content

- ▶ Mental health literacy
- ▶ Cognitive Behavioral Therapy
 - ◆ Thoughts → Feelings → Behavior
 - ◆ Change unhelpful/unhealthy T-F-B to helpful/healthy T-F-B
- ▶ Coping with stress
- ▶ Relaxation techniques
- ▶ HIV education
- ▶ Adherence strategies
- ▶ Gender-based violence and gender roles
- ▶ Safe sex practices

- ▶ 6 sessions
- ▶ 120 minutes
- ▶ Group-based
- ▶ Peer-led
- ▶ 2 caregiver sessions

IMPAACT 2016 Timeline

2018

- IMPAACT 2016 approved
- Protocol to sites
- SMC review

2019

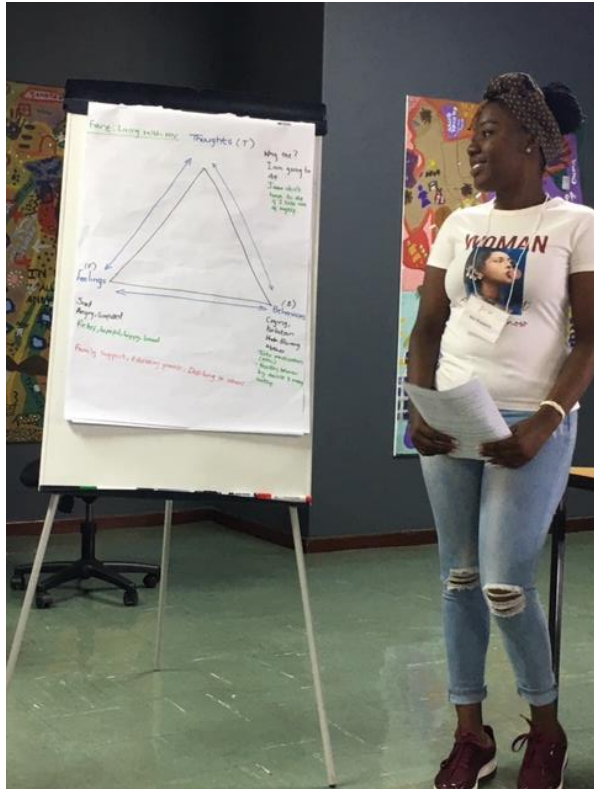
- IRB/regulatory approval at all sites
- DAIDS protocol registration
- Stakeholder engagement
- Focus groups
- Manual translations

2020 PAUSED

- Youth leader trainings
 - Regional trainings
 - Planned to start pilot and RCT
-
- Publications & presentations

2022 TODAY

- MOG approved study re-start pending funding
- Study team ready to resume trainings and move forward with pilot and RCT



January 2020, we conducted our first youth leader training in Johannesburg, SA.

March 2020, the study was paused until further notice just as the team was heading to Botswana for the second youth leader training.



IMPAACT 2016 Expert Trainer Training Underway



Four Indigenous Youth Leaders (IYL), ages 22-24 years old, from Soweto, South Africa living with HIV, as well as adult study staff, recently participated in a two-week training on the trauma-informed cognitive behavioral therapy (TI-CBT) intervention which they will provide to their younger peers living with HIV.



IMPAACT 2016: Operationalizing HIV Intervention Adaptations to Inform the Science and Outcomes of Implementation

Jennifer L. Libous¹, Nicole A. Montañez¹, Dorothy E. Dow², Suad Kapetanovic³, Janice Buckley⁴, Tebogo Jacqueline Kakhu⁵, Portia Kamthunzi⁶, Limbika A. Maliwichi⁷, Tichaona Vhembo⁸, Tariro Dianah Chawana⁹, Teacler Nematadzira¹⁰ and Geri R. Donenberg^{11*}

Libous, Front. Reprod. Health, 2021

Described the adaptation process (ADAPT-ITT)

- ▶ Community engagement (n = 108)
- ▶ Focus Groups (n = 5 - 8 participants per group)
 - ▶ AYALWH groups
 - ▶ Caregiver groups
- ▶ Strategic training of youth leaders

Results of the Kigali Imbereheza Project: A 2-Arm Individually Randomized Trial of TI-CBT Enhanced to Address ART Adherence and Mental Health for Rwandan Youth Living With HIV

Geri R. Donenberg, PhD,^{a,b} Jessica Fitts, PhD,^a Charles Ingabire, MPH,^c Sabin Nsanzimana, MD, MPH,^d Mary Fabri, PsyD,^e Erin Emerson, MA,^a Eric Remera, MPH,^d Olivier Manzi, MD,^f Bethany Bray, PhD,^a and Mardge H. Cohen, MD^{e,g}

J Acquir Immune Defic Syndr • Volume 90, Number 1, May 1, 2022

PMID: 35013089

- ▶ Rwanda
- ▶ Year 2014 - 2017
- ▶ Age 14-21 years
- ▶ No mental health inclusion criteria
- ▶ Mixed/co-ed groups
- ▶ Control group: Long-standing support groups

Summary of KIP Findings

- ▶ Feasible and acceptable
- ▶ YL-delivered with fidelity and competence
- ▶ Depression/anxiety symptoms
 - ▶ ↓ in all youth from baseline to 6- and 12-months, maintained at 18-months.
 - ▶ no difference between arms
 - ▶ Individuals w/lower levels of depression/trauma benefited more from the intervention
 - ▶ Individuals w/high levels of depression/trauma & females benefited more from support groups
- ▶ Self-reported adherence at baseline (75%) unchanged at follow-up
- ▶ Viral load
 - ▶ Extracted from medical record
 - ▶ Not time matched with study visit
 - ▶ 42% missing data
- ▶ Comparator arm was robust and contextually unique

Publications

Dow et al. *BMC Public Health* (2020) 20:1358
<https://doi.org/10.1186/s12889-020-09380-3>


BMC Public Health

RESEARCH ARTICLE

Open Access

A group-based mental health intervention for young people living with HIV in Tanzania: results of a pilot individually randomized group treatment trial



Dorothy E. Dow^{1,2,3*} , Blandina T. Mmbaga^{2,3}, John A. Gallis^{2,4}, Elizabeth L. Turner^{2,4}, Monica Gandhi⁵, Coleen K. Cunningham^{1,2} and Karen E. O'Donnell^{6,7}

- ▶ Tanzania
- ▶ Year 2016-2020
- ▶ Age 12-24 years
- ▶ No mental health inclusion criteria
- ▶ Single gender groups
- ▶ No time-matched control

PMID: 32887558 ; <https://Sites.duke.edu/sautiyavijana>

Summary of SYV findings



- ▶ Pilot RCT
 - ▶ Primary outcomes: Feasibility, acceptability, excellent fidelity
- ▶ Virologic suppression (HIV RNA <400 copies/mL)
 - ▶ Trend toward improvement in SYV vs. standard of care by 10% at 6 month follow-up
 - ▶ 10% increased suppression in the cross-over group pre- to post- intervention
- ▶ Self-reported ART adherence improved
- ▶ ART drug concentration improved more in SYV vs. SOC
- ▶ Mental health
 - ▶ Majority scored as mild or asymptomatic on screeners
 - ▶ Clinical change difficult to evaluate given low scores

How is IMPAACT 2016 different?



- ▶ **Population**
 - ▶ 15-19 years-old
 - ▶ Documented mental health distress
- ▶ **Primary outcome**
 - ▶ Change in mental distress
- ▶ **Secondary outcome**
 - ▶ Change in objective measures of ART adherence and HIV RNA

Lessons Learned:

Positioning IMPAACT 2016 for success

- ▶ Use rigorous inclusion criteria → Youth with mental health distress
- ▶ Implement a realistic SOC from LMICs → Open topic discussion control groups
- ▶ Increase generalizability → Multi-country/multi-site
- ▶ Employ validated measurement tools → PHQ-9, PTSD, GAD-7 are interpretable and harmonized
- ▶ Evaluate biological outcomes of adherence and HIV RNA → Hair samples, blood
- ▶ Provide consistent monitoring and supervision → Cascading supervision approach
- ▶ Improve methodological rigor → Detailed training manual for clarity and reproducibility
- ▶ Conduct comprehensive peer leader training → multidisciplinary team (mental health and ID/HIV expertise)
- ▶ Engage communities → focus groups to inform adaptations to the local context

Why should we still invest in IMPAACT 2016?

- ▶ Now more than ever, young people are suffering increased levels of mental health distress due to the COVID19 pandemic.
- ▶ IMPAACT 2016 is powered to show change in mental health distress.

Correspondence

Lancet HIV, Vol 9, June 2022

Mental health needs of adolescents with HIV in Africa

The mental health burden of people living with HIV by Tiffany Gooden and colleagues is very inspiring.¹ The comprehensive study shows how people living with HIV have an increased risk of developing composite mental illness, depression, anxiety, and severe mental illness compared with people without HIV.

We want to bring attention to an often neglected topic that we believe will influence global mental health epidemiology in the coming decades—mental disorders in adolescents and youth living with HIV in sub-Saharan Africa.² We particularly want to share our experience from field research in Mozambique, a country with the world's eighth highest HIV prevalence, and where 52% of the population is younger than 18 years.³ We did an observational study to evaluate anxiety, depression, post-

traumatic stress, and mental health needs of adolescents living with HIV to reduce stigma, to increase adherence to treatment, and to improve quality of life. Mental health programmes should promote awareness and include educational activities on mental health and HIV in schools and communities, and they should pilot the efficacy of alternative delivery modalities such as teleconsultations and telepsychiatry for screening and care. Given the higher prevalence of disorders among people living with HIV, when drafting the mental health international research agenda, solutions for prevention and care of these individuals should be prioritised in the hope of a trend reversal in the coming years.

Our call is directed to the scientific, academic, and policy-making communities. Let us not forget the mental health needs of this population. Please—we are asking loudly for them. We declare no competing interests.

*Francesco Di Gennaro, Claudia Marotta, Annalisa Saracino, Edoardo Occa, Giovanni Putoto
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Potential Global Impact

- ▶ IMPAACT 2016 will answer a distinct and critical question that remains unanswered in sub-Saharan Africa
 - ▶ Can a peer-delivered mental health intervention improve mental health outcomes for adolescents living with HIV?
- ▶ Improved mental health predicts increased ART adherence and better viral outcomes
 - ▶ Reduced transmission to others
 - ▶ Prevention of mother-to-child transmission as adolescents become mothers
 - ▶ Increased health and productivity for the community



Youth leader training, Johannesburg SA, Jan 2020

THANKS!

Any questions?

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Acknowledgments

THANK YOU to the....

Eight sites committed to the IMPAACT 2016 protocol.

Youth, caregivers, and community that have dedicated time and energy in the stakeholder engagements and focus groups.

Site teams for obtaining regulatory approvals and manual translations.

Protocol Clinical Research Managers

Entire **IMPAACT 2016 team** for your ongoing dedication and enthusiasm.

Pim Bowers, Susanna Allison, Sonia Lee, Ellen Townley, and IMPAACT Network leadership for your incredible commitment to moving this study forward

We sincerely thank you.

Overall support for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) was provided by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the National Institutes of Health (NIH), under Award Numbers UM1AI068632-15 (IMPAACT LOC), UM1AI068616-15 (IMPAACT SDMC) and UM1AI106716-09 (IMPAACT LC), and by NICHD contract number HHSN275201800001I. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

