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SYV: A Mental Health and Life Skills Intervention to Improve HIV Outcomes of Young People Living with HIV in Tanzania

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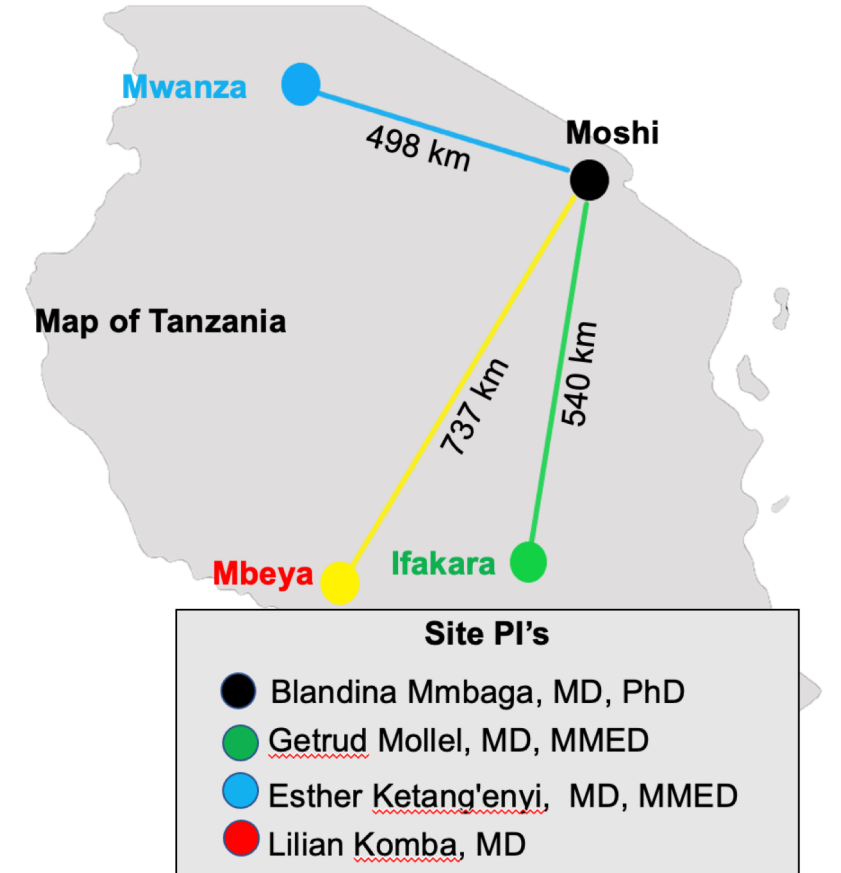


Background

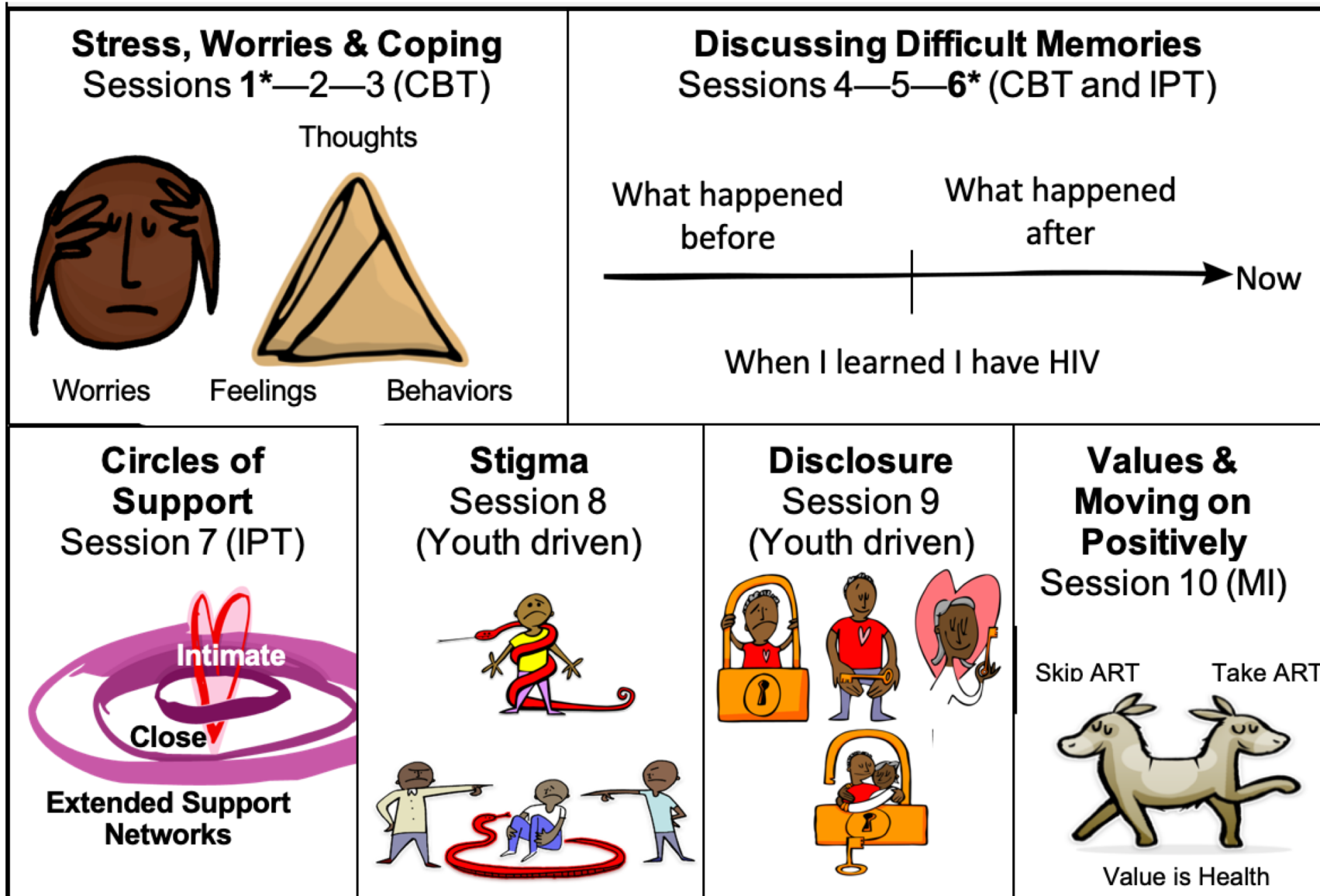
- Sauti ya Vijana (SYV:The Voice of Youth) is a peer-led, group-based mental health and life skills intervention for adolescents and young adults (10-24 years of age) living with HIV (AYALWH) in Tanzania.
 - SYV uses components of evidence-based psychotherapy in 10 weekly sessions (2 include caregivers) and 2 individual sessions.
 - Session content was designed with AYALWH to address common challenges and worries.
 - The original study showed promise to improve mental health, antiretroviral therapy adherence and HIV outcomes in the Kilimanjaro region, and is now being scaled in a fully powered effectiveness-implementation trial.
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Hybrid type-1 implementation Science design

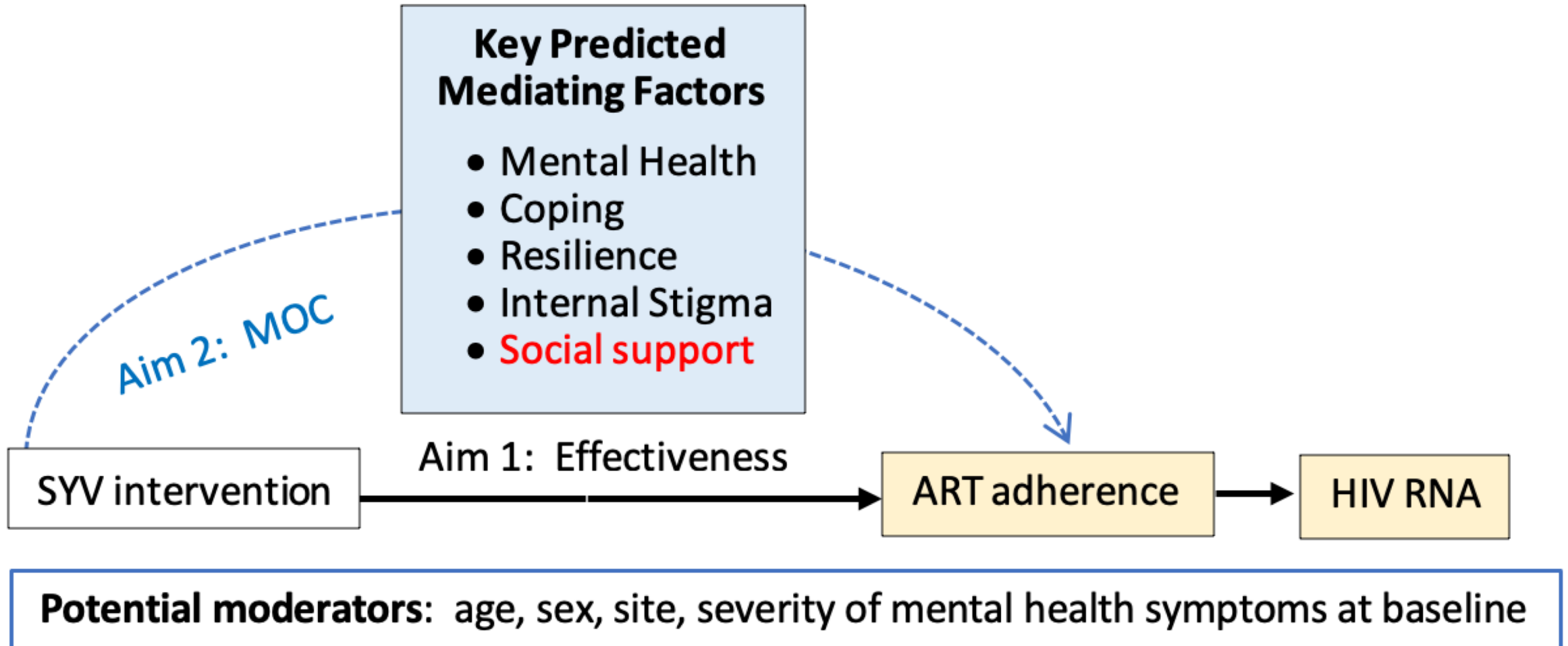
- Aim 1: Effectiveness (N=750)
 - Can SYV improve HIV RNA (viral suppression) in the intervention arm compared to the control arm?
- Aim 2: Mechanism of change
 - If it works, how does it work?
- Aim 3: Barriers and facilitators to implementation
 - Acceptability
 - Feasibility
 - Sustainability
 - Cost-effectiveness



SYV: Manualized Protocol



Hypothesized Mechanism of Change (MOC)



Sessions Format (~90 minutes)

- Greetings: (~10 minutes)
- Review last week's session (~10 minutes)
- Review the home practice and hear what the youth accomplished over the week (~10 minutes)
- New topic (~40 minutes)
- Assign home practice for the week (~10 minutes)
- Fun time/ Tea and bites (~10 minutes)

Methods

- Young people living with HIV recruited from local adolescent HIV clinic
- Participants will be consented (or assent with caregiver consent if <18 years)
- Consenting participants meet with research assistants to provide information:
 - about themselves (in school/work; engaging in high-risk behaviors)
 - about their ARV adherence,
 - response to different mental health questionnaires (PHQ-9, SDQ, UCLA trauma, GAD 7),
 - stigma (Berger's 10 question stigma scale)
 - Resilience
- Provide a hair sample from the occiput of the head to measure amount of ARV in the body
- Provide a blood sample to measure the viral load



Methods



Those randomized to the SYV intervention will be meeting with the group leaders to receive the content. If youth miss more than two consecutive sessions they cannot continue in the program as they get too far behind

Youth not randomized to the SYV intervention, those who remain in the standard of care arm, should not be hearing or seeing SYV content!

Group leaders are asked to not use the skills learned for all youth just yet. We first need to be able to understand if SYV is helpful. We think it will be and then we hope that all youth can receive the content in the program.

Lessons learned from training peer group leaders October 2021

- **Confidentiality:**

1. It is a group leader's decision to disclose their own HIV status to youth participants;
2. Groups must feel safe to share their stories

- **Boundaries:**

1. Group leader may already be friends with participants in the group they are leading;
2. Consideration of how to handle after hours calls from participants in distress led to the formation of a standard of care list of health professionals at each site and practice in handling personal contact outside the intervention.

Lessons learned from training peer group leaders October 2021

- **Secondary Trauma:**

1. It can be complicated for group leaders to hear intimate life details from participants and maintain professional distance;
2. Group leaders needed time to process their own stories before they were able to support others;
3. Hearing the other youth trauma narratives about learning they live with HIV often brought up hard memories for group leaders;
4. Having mental health experts on site to support PGLs during training and subsequently during intervention supervision was important, and ultimately successful.

Results from the scaled pilot across four sites

Attendance for all regardless of whether they were dropped “intention to treat”

	Total (N=69)	Ifakara	Mbeya	Moshi	Mwanza
Female	81.8%	100% (15-19 y/o)	87% (13-14 y/o)	71% (20-24 y/o)	72% (13-15 y/o)
Male	82%	73% (20-24 y/o)	82% (15-19 y/o)	98% (14-19 y/o)	77% (15-19 y/o)

Attendance based on those who “could attend” i.e. not counting those who never came or the sessions missed for those who were dropped “per protocol”

	Total (N=57)	Ifakara	Mbeya	Moshi	Mwanza
Female	92%	100% (15-19 y/o)	95% (13-14 y/o)	85% (20-24 y/o)	84% (13-15 y/o)
Male	91%	88% (20-24 y/o)	91% (15-19 y/o)	98% (14-19 y/o)	90% (15-19 y/o)

*12 participants dropped.

Other outcomes in the pilot and trial enrollment

- Fidelity to the manual was good, but documentation on the fidelity checklist required improved training and supervision discussions
- Mental health distress was found in about 10% of youth
- Suicidality was seen in the pilot and in the enrollment for the trial.
- One serious adverse event occurred when a participant attempted suicide and immediately received in patient care with close follow up resulting in enhanced training planned for May 2023

Table 1: Study Timeline

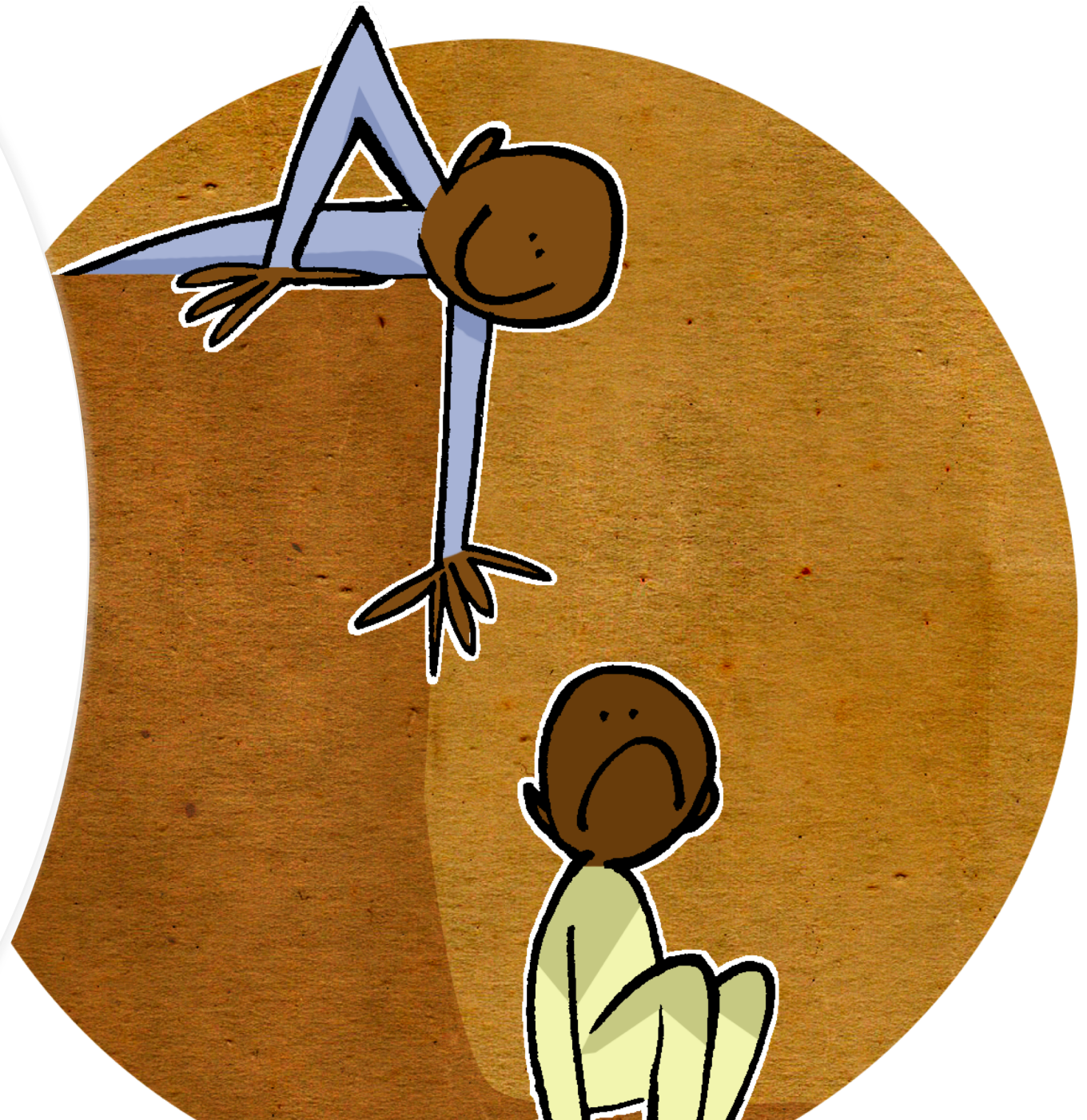
		Preparation: Training and Pilot		Randomized Controlled Trial														Wrap Up					
		Year 1		Year 2 (Feb 2022)		Year 3 (Feb 2023)					Year 4 (Feb 2024)					Year 5							
		April to Jan 22		Oct-Dec	Jan	Feb	Mar -May	Jun	Jul-Sep	Oct-Dec	Jan	Feb-Apr	May	J	July	Au	Se	Oct	Feb -Jan				
Month		1-6	Oct/Nov		1-3	12	1	4	5	6-8	9-11	12	1-3	4	5	6-8	1-5	6	7-12	1-6	7-12		
AIM 1*																							
Implementation and Analyses		Training		Pilot SYV		Adapt; Recruit		Data Cleaning & Analyses (primary endpoint at T ₂ ; secondary analyses; exploratory analyses)															
Wave* 1	SYV					T ₀	SYV	T ₁	T ₂		T ₃ *					T ₄							
	SOC					T ₀		T ₁	T ₂		T ₃					T ₄							
Wave 2	SYV						T ₀	SYV	T ₁	T ₂			T ₃ *				T ₄						
	SOC						T ₀		T ₁	T ₂			T ₃				T ₄						
Wave 3	SYV								T ₀	SYV	T ₁		T ₂				T ₃ *		T ₄				
	SOC								T ₀		T ₁		T ₂				T ₃		T ₄				
Wave 4	SYV											T ₀	SYV	T ₁		T ₂	T ₃ *		T ₄				
	SOC											T ₀		T ₁		T ₂	T ₃		T ₄				
Aim 3** (See Section C.7, Qualitative Implementation Outcome Measures and Table 4)																							
Characteristics of the Intervention				Costing and cost effectiveness analysis; monitoring adaptations using FRAME will be ongoing from end of Y1 to Y4.														Ongoing Analysis Y5					
Outer Setting						IDI (N=5)																IDI (N=5)	
Inner Setting						IDI (N=4)																IDI (N=4)	
Key Individuals								FDG, site 1		FDG, site 2		FDG, site 3		FDG, site 4									
Process				Monitoring fidelity throughout intervention delivery																			

*In Aim 1, each wave represents 2-3 groups; Each timeline represents one research site;

**In Aim 3, FRAME: framework for reporting adaptations and modifications expanded⁹⁶; IDI: In-depth Interview; FDG: Focus Discussion Groups

SYV pilot participant December 2022

“In 2022 I stopped using medicine again because I had given up and thought it was better to die. But when the Voice Of Youth project came, I attended the sessions and changed my decision of stopping my medicines. The session on handling stress made me feel valuable, now I am enjoying peace and taking my medicine every day.”



Questions?

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