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

IMPAACT Protocol 2016 Update

Complications & Co-Morbidities Scientific Committee

May 31, 2017

Protocol Team

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Significance and Rationale

- AIDS is the #1 cause of death among adolescents in Africa.
- HIV+ youth experience significant mental health problems (Dow, 2016; Suad, 2011)
- Mental health problems contribute to long-term morbidity, poor ART adherence, and mortality.
- Few evidence-based mental health interventions for HIV+ youth.
- Evidence-based interventions adapted for low-resource settings is a public health priority.
- Building in-country capacity to deliver effective programs is essential for sustainability.
- The Indigenous Leader Outreach Model has high potential to strengthen local capacity to improve mental health.

Hypotheses

- Compared to the Discussion Control group, TI-CBT will:
  1. be feasible, acceptable, and result in reduced symptoms of depression, anxiety, and traumatic stress; changes will be maintained throughout the follow up period.
  2. improve and maintain ART adherence leading to improved rates of virologic suppression (HIV-1 RNA < 200 copies/mL).
  3. improve structural factors (caregiver HIV knowledge, stigma, support for adherence; GBV; gender roles).
  4. improve behavioral outcomes (alcohol/drug use; sex-risk).
- IYL will demonstrate strong implementation fidelity to TI-CBT with careful supervision and monitoring.

Overall Study Design

- Two Stages
  - Stage 1: Feasibility/Acceptability Pilot
  - Stage 2: 2-arm, individually randomized group study
- Sample Size
  - Stage 1: n=5 theater testing; n=8 pilot test
  - Stage 2: n=200 (100 per arm)
- Duration
  - 48 months
- Participants
  - 15-19 years old; HIV+; ART ≥24 weeks; no involvement in a mental health or adherence intervention
  - Caregivers (where available and with youth permission)

Methods (Stage 1)

- Screen for mental health symptoms on one of three indicators
  - Depression: PHQ-9 $\geq$ 10 (range 0-27)
  - Anxiety: GAD-7 > $\geq$ 10 (range 0-21)
  - Trauma: UCLA PTSD-RI $\geq$ 35 (range 0-68)
- Baseline assessment (w/in 3 weeks of first intervention session)
  - Ensure measures are feasible, understandable
- Ineligible to participate in efficacy study

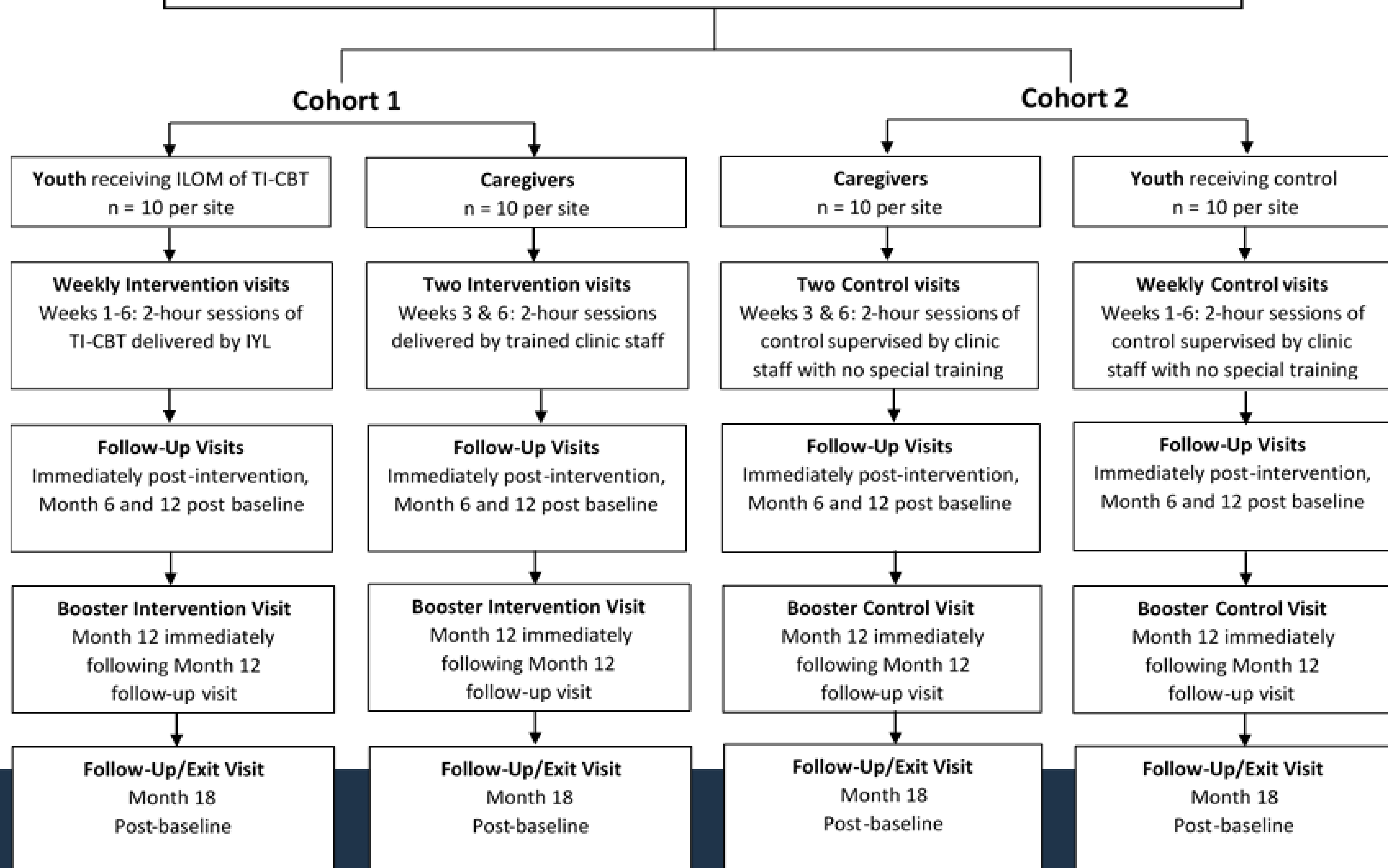
Methods (Stage 1)

- ADAPT-ITT: 8-step approach to contextualize an intervention for a local population (Wingood & DiClemente)

1) **A**ssess unique risk and protective factors
2) **D**ecide on the intervention to adapt based on findings in step 1
3) **A**dminister intervention components to small focus groups for feedback and identify new material/activities/content that will increase relevance;
4) **P**roduce or revise the curriculum based on feedback;
5) **T**opical expert feedback where team lacks expertise;
6) **I**ntegrate the various inputs;
7) **T**rain personnel to deliver the intervention; and
8) **T**est the final revised program in a pilot study.

Methods (Stage 2)

- Screen for mental health symptoms
- Train Indigenous youth leaders (≥21 years old) and local supervisors
- Randomize to study arms on intervention day 1
  - TI-CBT – IYL led
  - Discussion Control Group – clinic staff led
- IYL observations and fidelity checklists
- Youth and caregiver participant evaluations


Stage 2: Two-arm, randomized study of the efficacy of Indigenous Leader Outreach Model (ILOM) of Trauma-Informed Cognitive Behavioral Therapy (TI-CBT)
(n = 180 youth & 180 caregivers)
New cohort of youth living with HIV 15-19 years of age with mental health problems and their caregivers enrolled to evaluate the efficacy of ILOM of TI-CBT and its delivery by Indigenous Youth Leaders
Cohort 1: TI-CBT delivered to youth (n = 90) / Caregivers of Cohort 1 youth (n = 90)
Cohort 2: Control delivered to youth (n = 90) / Caregivers of Cohort 2 youth (n = 90)
Cohort 1
Cohort 2
Youth receiving ILOM of TI-CBT
n = 10 per site
Caregivers
n = 10 per site
Caregivers
n = 10 per site
Youth receiving control
n = 10 per site
Weekly Intervention visits
Weeks 1-6: 2-hour sessions of TI-CBT delivered by IYL
Two Intervention visits
Weeks 3 & 6: 2-hour sessions delivered by trained clinic staff
Two Control visits
Weeks 3 & 6: 2-hour sessions of control supervised by clinic staff with no special training
Weekly Control visits
Weeks 1-6: 2-hour sessions of control supervised by clinic staff with no special training
Follow-Up Visits
Immediately post-intervention, Month 6 and 12 post baseline
Follow-Up Visits
Immediately post-intervention, Month 6 and 12 post baseline
Follow-Up Visits
Immediately post-intervention, Month 6 and 12 post baseline
Follow-Up Visits
Immediately post-intervention, Month 6 and 12 post baseline
Booster Intervention Visit
Month 12 immediately following Month 12 follow-up visit
Booster Intervention Visit
Month 12 immediately following Month 12 follow-up visit
Booster Control Visit
Month 12 immediately following Month 12 follow-up visit
Booster Control Visit
Month 12 immediately following Month 12 follow-up visit
Follow-Up/Exit Visit
Month 18
Post-baseline
Follow-Up/Exit Visit
Month 18
Post-baseline
Follow-Up/Exit Visit
Month 18
Post-baseline
Follow-Up/Exit Visit
Month 18
Post-baseline

TI-CBT – Youth Sessions

Session	Content
Session 1	• How stress affects the body • Stresses of living with HIV • Coping with stress • HIV education
Session 2	• Stress related to HIV & adherence • Healthy/helpful or unhealthy/unhelpful coping strategies • Identifying alternatives and problem solving unhelpful responses
Session 3	• Connection between thoughts, feelings, and behaviors • Cognitive triangle • Learning about unhealthy/unhelpful patterns
Session 4	• Cultural gender roles and gender expectations • How gender and HIV influences thoughts, feelings, and behaviors
Session 5	• Interpersonal relationships in the context of pressure (peers & authority), medication logistics, and safe sex practices • Communication styles and solutions to difficult situations related to living with HIV
Session 6	• Review how stress, coping strategies, the connection between thoughts feelings and behaviors and the influence that thinking has on making healthy/helpful choices or unhealthy/unhelpful choices while living with HIV • Problem solving skills
Booster Session	• Review original intervention material • Primary goals of the program (how feelings and thoughts drive behavior, coping effectively with stress and trauma) • Reflect on using learned strategies and skills • Problem solve barriers to skill and strategy implementation

TI-CBT – Caregiver Sessions

Session	Content
Session 1 (youth session 3)	• Knowledge of HIV • HIV stigma • What is adherence and why is it important? • Obstacles to youth ART adherence
Session 2 (youth session 6)	• Why is adherence important? • How to help youth adhere to ART and health care • Caregiver communication about adherence
Booster Session	• Review original intervention material • Primary goals of the program • Emphasize the importance of youth ART adherence and how to assist youth in adherence efforts

Discussion Control Groups

- Led by clinic employees with no special training
- Mimic environment, transport reimbursement, etc., but without the scripted TI-CBT content
- Topics at the discretion of participants and facilitator
- Separate time and date to minimize contamination
- Control for non-specific group therapeutic factors

Intervention Schedule

- Each Study Arm:
  - Six 2-hour sessions for youth
  - Two 2-hour caregiver sessions
    (co-occur with youth sessions 3 and 6)
  - Booster session at 12-months for youth and caregivers

Assessments

- Time points
  - Baseline, immediately post-intervention, and 6-, 12-, and 18-months post baseline
- Method
  - ACASI
- Measures
  - Mental health, quality of life
  - ART adherence (self-report and biological), barriers
  - Gender-based violence, gender roles
  - HIV knowledge, stigma
  - Sexual behavior and drug/alcohol use

Accomplishments to Date

- Bi-weekly meetings
- In-person meeting of protocol team
- Input about screening measures for mental health from experts
- Site surveys and site implementation plan
- Sites selected
- Planned protocol submission mid-July

Sites

- Selection criteria
  - Minimal mental health resources and other adolescent support services in comparison to competing sites
  - Projected accrual feasible
  - Staff available to support the project and IYLs
  - Sufficient number of potential IYLs
- Four countries
  - Malawi (2 sites: Blantyre & Lilongwe)
  - South Africa (1 site: Soweto)
  - Botswana (2 sites: Gaborone & Molepolole)
  - Zimbabwe (3 sites: St. Mary's, Seke North, Harare)

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THANK YOU

Questions?