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

IMPAACT 2016

Complications & Co-Morbidities Scientific Committee Meeting

June 12, 2019

Protocol Chairs: Geri Donenberg and Dorothy Dow

IMPAACT
International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Background and Rationale

- AIDS
  - number one killer of youth in Africa
  - incidence rising in adolescents vs. others
- High mental health distress in adolescents living with HIV
- Low ART adherence related to poor mental health
- Need evidence-based mental health interventions in Africa
  - Trauma-Informed Cognitive Behavioral Therapy (TI-CBT)
- Sustainability depends on capacity development
  - Few resources to deliver interventions
  - Supplement with Indigenous Youth Leaders (e.g., Rwanda)

Primary Objective

- **Objective:** Evaluate whether a TI-CBT Intervention is associated with improved depression, anxiety, and/or traumatic stress symptoms for youth living with HIV compared to a Discussion Control at 6 months.

- **Outcome measures:** Mental health at 6 months as measured by scores for depression (PHQ-9), anxiety (GAD-7), PTSD (UCLA-RI), and a composite measure

- **Hypothesis:** *TI-CBT will reduce depression, anxiety, and/or traumatic stress compared to a discussion control group*

Main Secondary Objectives

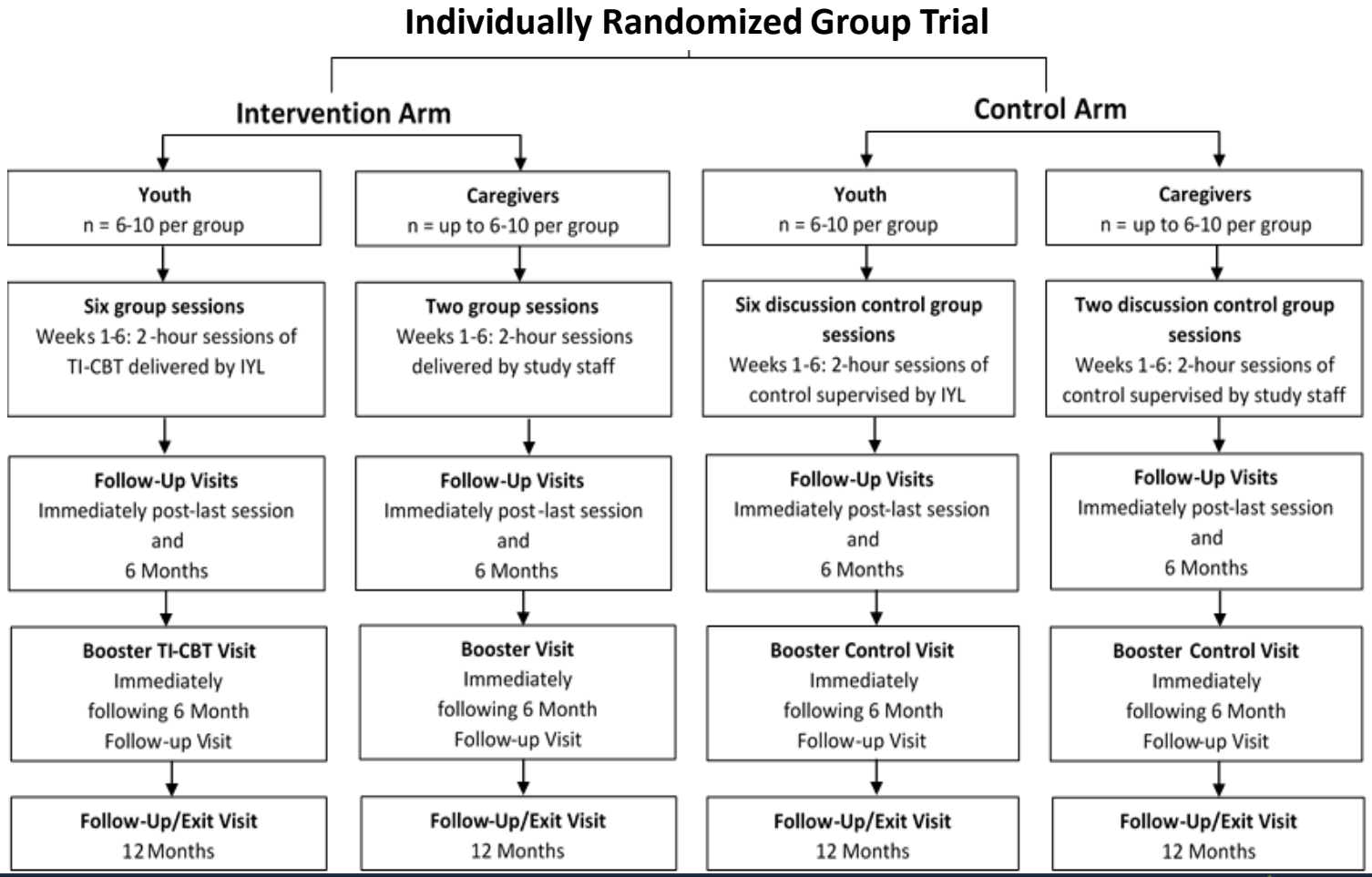
- Evaluate whether TI-CBT improves:
  - **Depression**, **anxiety**, and/or **traumatic stress** at 12 months;
  - **ART adherence** (hair samples, self-report) and **viral suppression** (HIV RNA plasma) at 6 and 12 months;
  - **Structural factors** (HIV stigma, support for adherence, adherence barriers, gender-based violence, gender roles) at 6 and 12 months; and
  - **Behavioral outcomes** (alcohol/drug use, sex-risk behaviors, caregiver report of youth behavior) at 6 and 12 months.

Study Design

8 Study Sites: Zimbabwe, Botswana, Malawi, South Africa

Community Engagement and Focus groups: Adapt TI-CBT for local context

Pilot test: Check feasibility/logistics at each site



Eligibility Criteria

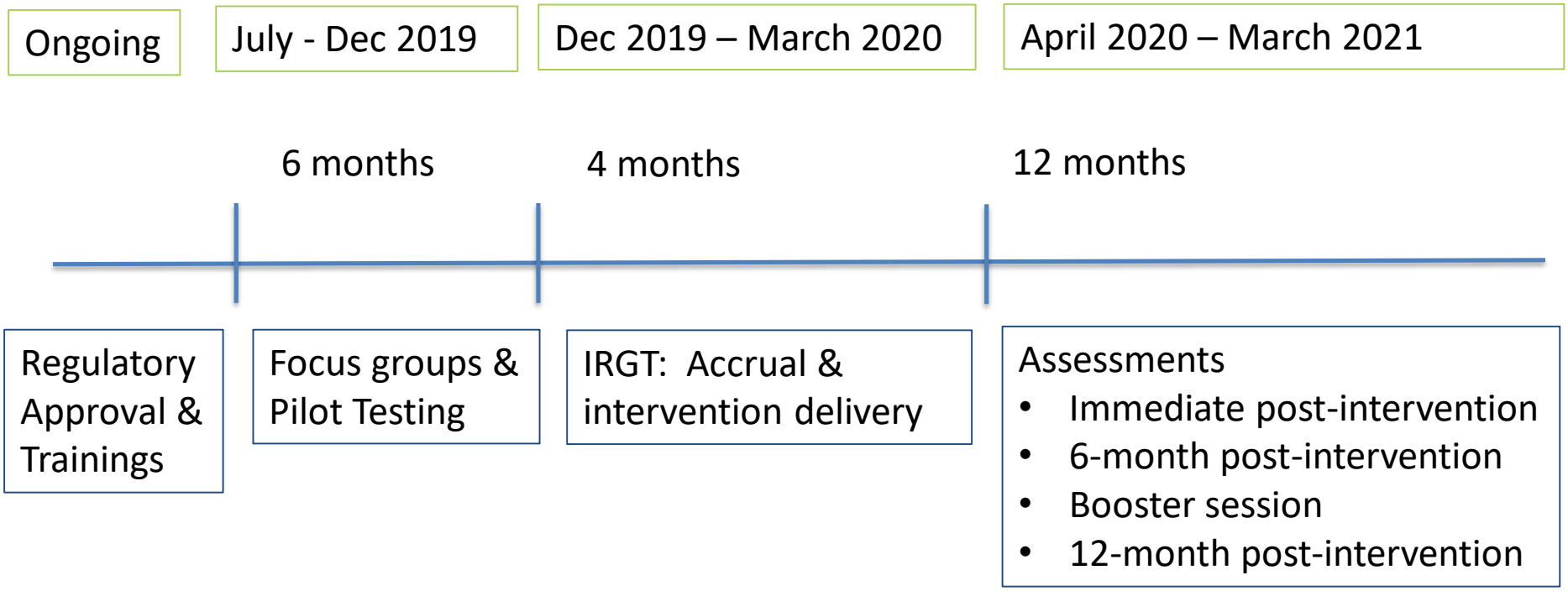
Inclusion:

- 15-19 years-old
- Confirmed HIV-infection
- Aware of HIV status
- Prescribed ART ≥ 24 weeks
- Mental health distress defined as one of the following:
  - General Anxiety Disorder-7 (GAD-7) score ≥ 10,
  - UCLA Post-Traumatic Stress Disorder-Reaction Index (UCLA PTSD-RI) score ≥ 35, or
  - Patient Health Questionnaire-9 (PHQ-9) score ≥ 10

Exclusion:

- Participating in a mental health or ART adherence intervention study
- Prior participation in the focus group or pilot test
- Unable to understand consent/assent

Proposed Study Timeline (22 months)



Study Milestones

Number of sites that have:

- **Received IRB Study Approval**: 1 site; 7 remaining sites expect approvals in June/July 2019.
- **Attended Community Stakeholder Engagement and Adaptation Training:** All sites.
- **Conducted Community Stakeholder Engagement meetings**: 5 sites; 3 planning this month
- **In-person Focus Group Training** will be held 13 June with a refresher webinar to follow.
- **Focus Groups** are on target to begin starting with South Africa CRS 8052 in July 2019.

Community Stakeholder Engagement Feedback

- Sites completed a Community Stakeholder Engagement Adaptation Feedback Form
- IMPAACT 2016 Adaptation Team (sub-group of Protocol Team) review forms and discuss adaptations needed to improve clarity and cultural acceptability
- Example Areas of Feedback:
  - Ensuring terms such as depression and stress are well understood and translatable
  - Adapting Activities for Varying Abilities
  - Topic Duration and Flexibility in Scheduling Sessions
  - Gender Composition of Group Sessions
  - Confidentiality and challenges with social media

Next Steps

- Focus Groups
- Adaptation of TI-CBT Intervention for Pilot Testing
- Youth Leaders, Adult Study Staff and Local Supervisor Training on TI-CBT Intervention Content by Expert Trainers
- Regional Study-Specific Training by Protocol Team
- Pilot Testing followed by Final Adaptations of TI-CBT Intervention
- Randomized Trial

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Acknowledgements & Protocol Team

Co-Chairs: **Geri Donenberg** and **Dorothy Dow**
Medical Officers: **Ellen Townley** (NIAID); **Sonia Lee** (NICHD); **Susannah Allison** (NIMH)
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Protocol Data Managers**:** **Christina "Tia" Reding** and **Lindsey Miller (formerly Linda Marillo)**
Laboratory Data Manager: **Katelyn Hergott**
Laboratory Technologist: **Natasha Samsunder** and **Amy James Loftis**
Laboratory Center Representative: **Sara Zabih (formerly Dale Dayton)**

NIH National Institutes of Health

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Extra Slide

Community Engagement Feedback

- **Culturally-Appropriate Content/Terms/Activities**: Sites may want/need to revise content and/or activities to ensure culturally-appropriate and relevant, such as type of ice breakers, terms (e.g. homework vs assignment, stress vs depression).

- **Confidentiality:** Carefully differentiate between 'keeping things to self' vs 'keeping study and session proceedings within the group' and differentiate between 'confidentiality' vs 'stigma' (e.g. participants failing to disclose issues due to fear of stigma).

- **Adapting Activities**: Sites may want/need to alter how activities are conducted to ensure participants of varying physical abilities are comfortable and fully engaged in activities.

- **Topic Duration:** Requested more time dedicated during session to explore stigma, relationships and connection between thoughts, feelings and behaviour.

- **Flexibility in Scheduling Sessions:** Mixed preference on combining multiple sessions into one day vs keeping sessions on separate days.

- **Gender**: Sites can use mixed gendered groups or split up genders for specific sessions as needed (with youth identifying as neither choosing which group they feel comfortable in)