



IMPAACT 2016

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

Guidance Document: Preparation and Adaptation of Trauma- Informed Cognitive Behavioral Therapy (TI-CBT) Intervention

**12 September 2023
Final Version 2.0**

**IMPAACT 2016 Guidance Document:
Preparation and Adaptation of TI-CBT Intervention
Overview of Section Contents and Identification of Current Section Versions**

Section	Current Version	Comments
Section 1 Guidance Overview	Version 2.0 12 September 2023	<ul style="list-style-type: none"> Clinical Trials Specialist changed to Clinical Research Manager
Section 2 Study-Specific Personnel	Version 2.0 12 September 2023	<ul style="list-style-type: none"> Clarified that ideally, male and female IYL will be represented in each group [TI-CBT vs Discussion Control Groups]
Section 3 Adaptation of the TI-CBT intervention	Version 2.0 12 September 2023	<ul style="list-style-type: none"> Clarified that the manuals will be revised as needed by the Adaptation Team [not by the site staff] and translated as needed by site staff. Clarified steps for training IYL and Adult Study Staff Clarified steps for concluding the Pilot Test
Appendices Supplies List Indigenous Youth Leader Criteria Adult Study Staff Criteria Local Study Supervisor Criteria Adaptation Feedback Forms	Version 2.0 12 September 2023	<ul style="list-style-type: none"> Supplies lists updated to align with updates to the intervention manuals Pilot Test Adaptation Feedback Form updated to reflect additional consideration for feedback requested.

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1.0 Guidance Overview

Prior to delivering the Trauma Informed Cognitive Behavioral Therapy (TI-CBT) intervention in the Pilot Tests and Randomized Trial, a systematic approach is taken to assess the acceptability and feasibility of the TI-CBT intervention and adapt the intervention manuals. The systematic approach used is the ADAPT-ITT model, an eight-step process outlined in [Section 3.0](#) below and summarized in [Section 3.1](#) of the protocol.

The intervention manuals will be adapted by sites by engaging with community stakeholders and the target population in Focus Groups and then by Pilot Testing the intervention. This document provides operational guidance for sites in preparing, conducting, and completing the community stakeholder engagement and Focus Groups as well as operational guidance on adapting feedback from the Pilot Testing.

1.1 Study-Specific Definitions

A definition list for personnel is included below. Refer to [Section 2.1](#) for details on recruiting, selecting and designating personnel.

Personnel	Definition
Adult Study Staff	Study staff designated to facilitate or observe the caregiver TI-CBT group sessions OR the caregiver Discussion Control group sessions.
Indigenous Youth Leader (IYL)	21-30 year-old IYL from local HIV clinics designated to facilitate or observe the youth TI-CBT group sessions OR the youth Discussion Control group sessions.
Facilitator	An individual <u>leading</u> community engagement, a Focus Group, or TI-CBT or Discussion Group sessions (Pilot Test and Randomized Trial) as follows: <ul style="list-style-type: none">• Facilitators leading community stakeholder engagement or a Focus Group may be an adult study staff (not designated to the Discussion Control Arm), local study supervisor, site Investigator of Record (IoR), or other designee – excluding IYL.• Facilitators leading a youth group session or caregiver group session will be an IYL or adult study staff, respectively.
Observer	An individual <u>observing</u> a Focus Group, or an individual <u>observing</u> a youth group session or caregiver group session who will be an IYL or adult study staff, respectively.
Local Study Supervisor	An individual (e.g. psychologist, nurse, IoR, other) with a working relationship with the site who is designated to supervise IYL or adult study staff.

A definition list for forms and manuals is included below. Refer to [Appendix II](#) to [Appendix VII](#) for copies of each form. Manuals are distributed separately.

Forms and Manuals	Definition
IYL Criteria Form	<ul style="list-style-type: none"> Each form outlines criteria expectations for the specified study-specific personnel (i.e. IYL, adult study staff, local study supervisor). Used by site study staff to document expected criteria met by each site-recruited potential study-specific personnel. Refer to Section 2.1 for instructions.
Adult Study Staff Criteria Form	
Local Study Supervisor Criteria Form	
Community Stakeholder Engagement Adaptation Feedback Form	<ul style="list-style-type: none"> Used by site staff to document feedback and recommended changes to the Youth Intervention Manual and Caregiver Intervention Manual and intervention delivery logistics. Used by site staff to document the identified component(s) to be delivered in the Focus Group (only for Community Stakeholder Engagement Adaptation Feedback Form) Refer to Sections 3.3.1, 3.3.2 and 3.6 for instructions.
Focus Group Adaptation Feedback Form	
Pilot Test Adaptation Feedback Form	
Caregiver Intervention Manual	<ul style="list-style-type: none"> Outlines how each caregiver group session will proceed as follows: 1) an overview of the main goals, supplies, and activities; 2) language for facilitators to deliver the curriculum; and 3) each session begins and ends with a relaxation exercise. Used by adult study staff designated to lead caregiver group sessions in the TI-CBT Arm. Adapted for each site from Focus Group and Pilot Test feedback per Sections 3.3, 3.4, and 3.6.
Youth Intervention Manual	<ul style="list-style-type: none"> Outlines how each youth group session will proceed as follows: 1) an overview of the main goals, supplies, and activities; 2) language for facilitators to deliver the curriculum; and 3) each session begins and ends with a relaxation exercise. Used by IYL designated to lead youth group sessions in the TI-CBT Arm. Adapted for each site from Focus Group and Pilot Test feedback per Sections 3.3, 3.4, and 3.6.
TI-CBT Training Manual	<ul style="list-style-type: none"> The backbone to the TI-CBT intervention, providing an introduction to TI-CBT and the training modules, psychoeducation and relaxation techniques. Used by the expert trainer to train local study supervisors, and IYL and adult study staff designated to lead group sessions in the TI-CBT Arm. Statistics and other supporting resources may be provided separately based on cultural relevance Will not be adapted.

1.2 Adaptation-Related Information and Communications

This section specifies the resources available to IMPAACT 2016 study site staff, including study-related communication and informational resources and other essential documents.

On behalf of the full Protocol Team, the Adaptation Team will oversee the adaptation of the intervention along with the local study supervisor and site staff at the specific site. The following Protocol Team members comprise the Adaptation Team: Co-chairs, Protocol Investigator(s), and Clinical Research Managers. The Protocol Team and Adaptation Team has developed study-specific contacts for various types of issues and questions specific to a Focus Group, as shown in [Figure 1-1](#). For issues and questions directed to the Protocol Team or Adaptation Team, a response from the appropriate team member can generally be expected within 24 hours. Always retain a copy of correspondence with the team in the relevant participant's study chart.

- **General questions:** Questions related to protocol interpretation or study implementation, including administrative, ethical, regulatory, counseling and data operations should be emailed to the IMPAACT 2016 Protocol Team as listed in [Figure 1-1](#). Any questions that are not answered by the protocol or this document should also be emailed to the IMPAACT 2016 Protocol Team.
- **Study-specific personnel:** Questions related to the recruitment, selecting and supervision of IYL and adult study staff should be emailed to the IMPAACT 2016 Adaptation Team as listed in [Figure 1-1](#). Additional detail is listed in [Figure 1-1](#).
- **TI-CBT Intervention Adaptation questions:** Questions related to adapting the intervention manuals should be directed to the IMPAACT 2016 Adaptation Team as listed in [Figure 1-1](#).
- **Community Stakeholder Engagement:** Questions related to preparing, conducting and concluding the community stakeholder engagement should be directed to the IMPAACT 2016 Adaptation Team as listed in [Figure 1-1](#).
- **Focus Group implementation questions:** Questions related to participant eligibility and management for the Focus Group should be directed to the IMPAACT 2016 Adaptation Team as listed in [Figure 1-1](#).

Figure 1-1
IMPAACT 2016 Study-Related Communications

Topic	Contact
User Support	
Adding site staff to protocol email group (IMPAACT.prot2016@fstrf.org)	User Support user.support@fstrf.org (include the protocol number in the subject line of your email message)
Recruitment, Selection, Training and Supervision of Study-Specific Personnel	
Consultation on recruitment and selection criteria; submission of criteria forms	IMPAACT 2016 Adaptation Team impaact.adapt2016@fstrf.org
Consultation on IYL and Adult Study Staff training, supervision, and roles	
Consultation on local study supervisor training and roles	
Adaptation Procedures	
Consultation on Community Stakeholder Engagement	IMPAACT 2016 Adaptation Team impaact.adapt2016@fstrf.org
Consultation on Focus Group	
Consultation on adaptation feedback documentation and reporting for Community Stakeholder Engagement, Focus Group and Pilot Test; submission of adaptation feedback forms	
Consultation on how to access Pilot Test eCRF data for adaptation feedback	IMPAACT 2016 Protocol Data Managers impaact2016.dm@fstrf.org
Focus Group Implementation	
Consultation on Focus Group participant eligibility	IMPAACT 2016 Adaptation Team impaact.adapt2016@fstrf.org
Consultation on any other aspect of Focus Group participant management, protocol interpretation, or study implementation not listed above	

2.0 Study-Specific Personnel

2.1 Recruitment and Selection of IYL, Adult Study Staff and Local Study Supervisors

Only individuals who have not and will not be exposed to TI-CBT material should be recruited as IYL or Adult Study Staff. Exposure includes but is not limited to: translating and/or back-translating TI-CBT manuals and/or handouts, participation in community stakeholder engagement or focus groups, and facilitating community stakeholder engagements or focus groups. Email the Adaptation Team at impaact.adapt2016@fstrf.org for additional guidance on types of exposure that may disqualify an individual from being recruited and randomly designated to a study arm as an IYL or Adult Study Staff.

Indigenous Youth Leaders (youth group sessions)

Recruitment: Site staff will complete the **Criteria Form for Selecting Potential Indigenous Youth Leaders for each recruited IYL found in Appendix II**. The Adaptation Team will work with site staff to recruit a minimum of six IYL from the local HIV clinic who are 21 years-old to 30 years-old for training to lead or observe the TI-CBT or Discussion Control youth group sessions. Candidates will be assessed by local study site staff using specific criteria in Appendix II around age, clinic attendance, ARV adherence, communication, dedication, and alcohol/drug use. Ideally, male and female IYL will be represented in each group.

Note: Site staff will also evaluate the mental health of IYL candidates using the same instruments as the participants for the purpose of determining appropriateness of selecting the IYL but will not exclude youth who report mental health problems unless such problems would interfere with program delivery (for example, psychosis, violent tendencies, etc.). If IYL report severe mental health problems, the same procedures will be followed as with participants – referral to appropriate clinic staff for evaluation and treatment within the local standard of care.

Selection and Randomization: Site staff are to email all completed IYL Criteria Forms to the Adaptation Team at impaact.adapt2016@fstrf.org. Mental health instruments will not be emailed to the Adaptation Team. The Adaptation Team will review the forms to confirm individuals qualify to serve as IYLs. Confirmed IYLs will be given an identification number by the Adaptation Team (site#-IYL#, e.g.: 1234-IYL1) and identification numbers will be provided to the Protocol Statistician(s) to be randomly designated to a study arm. At least three IYL will be randomly designated to the TI-CBT Intervention group sessions and at least three IYL will be randomly designated to the Discussion Control group sessions; a designation list from the Protocol Statistician (s) will be emailed to the CRMs, and the CRMs will email the designation outcome to site staff and IoRs. Site staff should update the appropriate Delegation of Duties log to reflect the IYL designations.

Adult Study Staff (caregiver group sessions)

Recruitment: Site staff will complete the **Criteria Form for Selecting Potential Adult Study Staff for each recruited adult study staff found in Appendix III**. The Adaptation Team will work with site staff to recruit a minimum of six adult study staff from the clinic or community for training to lead or observe the TI-CBT or Discussion Control caregiver group sessions. Candidates will be assessed by local study site staff using specific criteria in Appendix III around mental health experience, work experience, communication, dedication, and alcohol/drug use.

Selection and Randomization: Site staff are to email all completed Adult Study Staff Criteria Forms to the Adaptation Team at impaact.adapt2016@fstrf.org. The Adaptation Team will review the forms

to confirm individuals qualify to serve as adult study staff. Confirmed adult study staff will be given an identification number by the Adaptation Team (site#-Adult#, e.g.: 1234-Adult1) and identification numbers will be provided to the Protocol Statistician(s) to be randomly designated to a study arm. At least three adult study staff will be randomly designated to the TI-CBT Intervention group sessions and at least three adult study staff will be randomly designated to the Discussion Control group sessions; a designation list from the Protocol Statistician(s) will be emailed to the CRMs, and the CRMs will email the designation outcome to site staff and IoRs. Site staff should update the appropriate Delegation of Duties log to reflect the adult study staff designations.

Local Study Supervisor

Site staff will complete the Criteria Form for Selecting local study supervisors for a local study supervisor found in Appendix IV. Although there is no formal recruitment and selection process for the local study supervisor, ideally, this member of the team would have a background in mental health and a working relationship at the study site. The person serving as the local study supervisor could be, but is not limited to, a psychologist, nurse, or the IoR (or designee). The local study supervisor can also serve in the capacity of the on-site study clinician to evaluate and intervene as needed to address a safety concern.

To serve as the local study supervisor, the individual must be available for the following:

- 1) be onsite during TI-CBT and Discussion Control group sessions at all times to assist in the event that an issue arises during group sessions that requires professional attention
- 2) be available by phone during off hours
- 3) meet weekly with the expert trainer
- 4) meet twice weekly with the IYL assigned to the TI-CBT arm to review fidelity checklist and session observations notes respectively per Figure 3 in Section 5.3.1 of the protocol
- 5) meet before and after the caregiver session with the adult study staff assigned the TI-CBT arm to practice content for upcoming session and review fidelity checklist and session observation notes, respectively.

During the twice weekly meetings with the IYL and meetings with the adult study staff, the local study supervisor will use fidelity checklists completed by IYL and adult study staff, observer group session notes, and youth and caregiver attendance, participation, and self-reported amount of “fun had” and “learned” to help guide supervision discussions. Local study supervisors will evaluate IYL and adult study staff during these meetings and take notes documenting impressions about IYL and adult study staff engagement, empathy, and comfort in sharing difficulties that arose in session. The local study supervisor will be responsible for the following:

- 1) In the first of the two weekly supervision meetings, IYL will share their experiences and challenges conducting the group sessions and together with the local study supervisor troubleshoot and come up with solutions to issues that arose in the previous week’s sessions. The local study supervisor will repeat this process in the meeting with adult study staff.
- 2) In the second of the two weekly supervision meetings, IYL will practice delivering the next session and local study supervisors will evaluate IYL knowledge and session content. Where IYL need additional training before session delivery, the local study supervisor will provide it. The same will occur for adult study staff before the caregiver session is delivered.
- 3) Summarize and describe IYL and adult study staff evaluations to the expert trainer as well as to IYL and adult study staff, respectively.

Site staff DO NOT need to email all completed Local Study Supervisor Criteria Forms to the Adaptation Team alias.

2.2 Replacing/Adding Indigenous Youth Leaders, Adult Study Staff or Local Study Supervisors

To replace or add IYL, adult study staff or local study supervisors following initial recruitment and selection, the same recruitment, selection and as applicable randomization steps are followed as outlined above (i.e., submit completed relevant criteria forms to impaact.adapt2016@fstrf.org).

Sites should make every effort to identify two or more replacements or additional individuals for a given role (i.e., IYL or adult study staff) to allow for randomization and equal number of IYL or adult study staff in each group.

For alternative training options for IYL and adult study staff selected following the initial training, see [Section 3.5.2](#).

3.0 Adaptation of the TI-CBT intervention

3.1 Step 1: Assessment

Possible interventions for 15-19 year-olds living with HIV were assessed through literature reviews, focus groups, and information interviews. This step was completed prior to IMPAACT 2016 to inform protocol development; **no action is required to be completed by study sites.**

3.2 Step 2: Decision

Using the data derived from Step 1, the protocol team decided to use TI-CBT as the intervention for this study; **no action is required to be completed by study sites.**

3.3 Step 3: Administration

Administration will involve identifying components of the Youth and Caregiver Intervention Manuals that may be adapted to support local context through community stakeholder engagement. Components identified will be delivered in Focus Groups to the target population (youth and caregivers) in each country having participating sites. Refer to [Sections 3.3.1](#) and [3.3.2](#) below for guidance on preparing for and conducting the community stakeholder engagement and Focus Groups.

Webinar trainings will be conducted by the Operations Center:

Stakeholder Engagement and Focus Group Overview: The training will take place prior to the community stakeholder engagement and Focus Groups. The training will include the protocol chairs, Operations Center, and site study staff who will be involved coordinating the community stakeholder engagement and Focus Groups. The webinar will include guidance on scheduling and conducting the engagement and Focus Groups, logistical considerations for identifying youth and caregivers for the Focus Groups, forms for documenting community stakeholder engagement and Focus Group feedback, and questions from the site. Refer to [Section 3.3.1](#) for more details.

Focus Group Conduct: The training will take place following the community stakeholder engagement and prior to the Focus Groups. The training will include the chairs, Operations Center, Focus Group facilitators (who will be administering the Focus Groups, e.g. adult study staff not designated to the Discussion Control Arm, local study supervisor, site IoR, or other designee), and expert trainers. The

webinar will guide the facilitators on how to run the Focus Group based on the components chosen in the community stakeholder engagement. Refer to [Section 3.3.2](#) for more details.

3.3.1 Community Stakeholder Engagement

Preparing for the Community Stakeholder Engagement

The process of identifying components for possible adaptation is completed through community stakeholder engagement. The community stakeholder engagement will be conducted as at least one in-person meeting to include but not limited to community and youth advisory boards, site study staff, adult study staff/local study supervisors (who will be administering the Focus Groups), and other key stakeholders at the discretion of the IoRs (or designee). Any potential IYL and adult study staff who could lead Discussion Control group sessions should not attend the community stakeholder engagement, because these individuals should not be exposed to the manuals.

A minimum of one meeting is required within a country. Sites within a country may conduct a joint meeting, and multiple meetings may be necessary. The purpose of the meeting(s) is to review all content in the Youth and Caregiver Intervention Manuals to identify component(s) that are found to be confusing or culturally questionable and need to be delivered in the Focus Group. Site study staff will be responsible for identifying and inviting stakeholders as well as scheduling and facilitating the meeting(s).

The Adaptation Team will provide sites with the Youth and Caregiver Intervention Manuals for review during the stakeholder meeting(s). *At a minimum* for each meeting, the table of contents of the Youth and Caregiver Intervention Manuals **MUST BE TRANSLATED** into the local language with approved back translation, and a translator who has read and is familiar with the manuals' content must be present. Key concepts within the manuals may require discussion and deliberation for the appropriate translation at the discretion of the IoR or designee.

Conducting the Community Stakeholder Engagement

At the sites' discretion, manuals may be printed and/or electronically projected during the meetings for attendees to review. Refer to [Appendix I](#) for a list of supplies.

Using the manuals, facilitators – who may be an adult study staff (not designated to the Discussion Control Arm), local study supervisor, site IoR, or other designee excluding IYL – will describe the overall program, the logistics, and content; provide some data/justification for the need for and importance of the program; and read through each activity in the manuals.

Stakeholders will be asked to provide feedback on strengths and weaknesses of each component and will be prompted for feedback around feasibility, acceptability, wording for local context, concepts, and possible barriers to administering each component as well as recommend a component(s) for delivery in the Focus Group for further review.

One site study staff will be designated to document the discussion in meeting minutes and complete a Community Stakeholder Engagement Adaptation Feedback form for each the Youth Intervention Manual and Caregiver Intervention Manual per [Appendix V](#).

Concluding Engagement and Confirming Components

Site staff will email the completed Community Stakeholder Engagement Adaptation Feedback forms to the Adaptation Team alias (impaact.adapt2016@fstrf.org). The Adaptation Team will review the forms and along with the local study supervisor and relevant site staff, and discuss the recommended

component(s) for delivery in the Focus Group. Confirmation by the Adaptation Team to proceed with the identified component(s) for delivery in the youth and caregiver Focus Groups will be emailed to the site staff and IoRs.

3.3.2 Focus Groups (Youth and Caregivers)

Preparing for Focus Groups

As indicated in Section 3.1.1 of the protocol, one youth Focus Group and one caregiver Focus Group will be conducted in Botswana, South Africa, and Zimbabwe. A host site within each country will conduct the Focus Groups; the host site by default is the first site within a country to receive all IRB/EC approvals and protocol registration unless otherwise indicated. In Malawi, the local context is sufficiently different between the two sites and necessitates that Focus Groups be conducted at each site.

To help ensure readiness for the Focus Group, the Protocol Team has specified a set of Focus Group requirements that must be met prior to implementation of the Focus Group. These requirements are listed on the IMPAACT 2016 Site-Specific Study Activation Checklist.

On a site-by-site basis, when all implementation requirements have been met, the Operations Center will issue an Implementation Notice. At each site, no Focus Group activities may be performed prior to receipt of this notice.

The full intervention is not provided in the Focus Group. Once components for the Focus Group per country are identified by stakeholders and confirmed by the Adaptation Team, facilitators at a host site will be trained to deliver the identified components in the youth and caregiver Focus Groups; see “Conducting Focus Groups and Adaptation Following Focus Groups” for details on identifying facilitators.

A site must be protocol registered, complete the implementation requirements for the Focus Group, and receive an Implementation Notice prior to proceeding with the following Focus Group activities.

Recruiting Youth and Caregiver participants

Recruitment methods may vary across sites but are generally expected to rely on outreach to youth living with HIV in care at participating study sites and local clinics. Sites will recruit from the target population for the Pilot Test and Randomized Trial to meet the following minimum criteria:

- At time of Focus Group, 15-19 years old
- Living with HIV as confirmed by the youth
- Signed informed consent or assent per protocol eligibility criterion 4.1.2 and Appendix III.

Conducting Focus Groups and Adaptation Following Focus Groups

Four facilitators will lead two separate Focus Groups – two facilitators will lead a group of youth (up to 8 participants) and two facilitators will lead a group of caregivers (up to 8 participants) – and deliver the identified component(s) to the respective groups. Facilitators may be an adult study staff (not designated to the Discussion Control Arm), local study supervisor, site IoR, or other designee. Another site study staff member will be designated to observe and document each focus group discussion in meeting minutes to capture immediate reactions. Any potential IYL and adult study staff who could lead Discussion Control

group sessions should not facilitate nor attend the Focus Groups, because these individuals should not be exposed to the manuals.

After the delivery of a component, the facilitators will lead a discussion with participants about the component's acceptability, utility, relevance, mixed-gender appropriateness, and need for change as part of the adaptation feedback from participants. Use the Focus Group Adaptation Feedback Form in [Appendix VI](#) to document participant responses.

Site staff will complete a Focus Group Adaptation Feedback Form for each component discussed during the Focus Groups (summarizing the participants' feedback for adaptation) found in [Appendix VI](#). Feedback from the youth and caregivers will be audiotaped as facilitators lead the discussion so that the observers can refer to the audiotapes for clarity as needed. This process will be repeated for each component identified as requiring review in the Focus Group. The Focus Group is complete once all of the pre-identified components are delivered and feedback is obtained and documented in the Focus Group Adaptation Feedback Form.

Concluding the Focus Groups

Site study staff are to email the Focus Group Adaptation Feedback forms for all components discussed during the youth and caregiver Focus Groups to the Adaptation Team alias (impaact.adapt2016@fstrf.org). The Adaptation Team will review the form and discuss the feedback and recommended changes for adaptation. As needed, the Adaptation Team may request to discuss the feedback with sites by phone or email.

3.4 Step 4: Production, Step 5: Topical Experts, and Step 6: Integration

The Adaptation Team will make a final determination of adaptations to be incorporated into the site-specific Youth and Caregiver Intervention Manuals. For adaptations which members of the Adaptation Team are not experts on, topical experts may be required to provide input. An example of this would be additional support regarding cultural context and wording within the manual. Final determination of adaptations at each site will be emailed to the site staff and IoRs. The adaptation(s) will be incorporated into site-specific Youth and Caregiver Intervention Manuals by site staff.

Each site will designate site staff to revise and finalize the Youth and Caregiver Intervention Manuals per the community stakeholder engagement, Focus Group and topical expert feedback. Revisions will be emailed to the designated site translators for translation and back translation.

The site translators are to email the full Youth and Caregiver Intervention Manuals, with the new back translations included in each, to the Adaptation Team at impaact.adapt2016@fstrf.org for review and approval.

The Adaptation Team will distribute the final approved English and translated versions of the site-specific Youth and Caregiver Intervention Manuals to the respective site.

3.5 Step 7: Training

3.5.1 Initial Expert Trainer Training

Training will involve IYL, adult study staff, and local study supervisors. Site staff will work with the protocol chairs, the Operations Center, and the designated expert trainer per site to plan the training logistics. This training will take place after Step 6 is completed, as described in [Section 3.4](#).

Sites in Botswana, Zimbabwe, and South Africa will have one combined training per country; the two sites in Malawi may each have their own training, due to cultural variances. The trainings are expected to last 2 weeks of 8-hour days or 3 weeks of 4-hour days to be determined by the study staff and expert trainer. Not all IYL and adult study staff are required to be present for the entire training session; for example, the IYL will not need to attend the training component for adult study staff sessions focused on caregiver group sessions. The components of the training and who will be trained on which components are specified below and further in Sections 5.1.1.1, 5.2.2 and 5.3 of the protocol.

Pre-Expert Trainer Training

TI-CBT Intervention and Discussion Control Arm

All IYL and adult study staff will be trained on how to manage safety concerns among participants; however, the trainings will occur in two separate groups. Those randomized to deliver the discussion control group will train together and those randomized to deliver the TI-CBT intervention will train separately. Content will include:

- a) how to manage safety concerns that may arise during the group sessions, including how to refer youth with significant mental health distress to the local standard of care;
- b) how/when to consult local study supervisors and the IMPAACT investigators if a participant reports suicidal ideation or abuse or intention to harm others;
- c) how to identify safety concerns during a session (e.g., youth exhibiting risk of harming themselves or others, youth exhibiting a mental health risk) that require the IYL to consult with a designated on-site medical professional who will address the safety concern and intervene as needed to maintain safety of youth and IYL.

The IMPAACT 2016 Protocol Team will provide suggested content for delivery, and the local study supervisors and site staff will be responsible for delivering the training ideally prior to the Expert Trainer Training.

Expert Trainer Training on TI-CBT

TI-CBT Intervention Arm

IYL and adult study staff randomized to deliver the TI-CBT intervention will be further trained separately on how to deliver TI-CBT groups sessions to youth and caregivers, respectively, using the TI-CBT Training Manual. Content will include:

- a) the project's goals and objectives including the importance of trauma-informed cognitive behavioral programs for HIV-infected youth;
- b) the advantages and challenges of manualized interventions and the importance of following guidelines in order to evaluate if the intervention is effective;
- c) the facts of HIV and AIDS, depression, trauma, gender-based violence, ART regimens, adherence challenges, and consequence of non-adherence to health and well-being
- d) the content of all youth sessions (for IYL only) and content of all caregiver sessions (for adult study staff only), highlighting key themes and session goals.

Upon successful completion of training, the expert trainer and local study supervisor will designate a minimum of two certified IYL and two certified adult study staff to facilitate (lead) the group sessions, and designate a minimum of one certified IYL and one certified adult study staff to observe group sessions during the Pilot Test and Randomized Trial. Should an IYL or adult study staff facilitator be unavailable to deliver a TI-CBT or Discussion Control group session, the observer designated to that study arm will take his/her place as a facilitator.

Site study staff are to email a list of all IYL and adult study staff with their designation (facilitator or observer) to the Adaptation Team at impaact.adapt2016@fstrf.org.

3.5.2 Additional Training of Additional Indigenous Youth Leaders or Adult Study Staff

Upon confirmation of group designation per [Section 2.2](#), sites should await confirmation of training option to implement for individuals designated to the TI-CBT group, as options may vary on a case-by-case basis. Generally, the following training options may be considered based on timing in relation to the status of the Pilot Test and Randomized Trial.

All IYL and adult study staff regardless of group designation should complete the pre-expert trainer training outlined in Section 3.5.1 above.

Training post initial Expert Trainer Training and Prior To First Pilot Test Group Session

If training occurs following the initial expert trainer training and prior to the first Pilot Test group session, the general training approach may be considered:

- a) Additional new IYL or adult study staff will observe the Pilot Test group sessions in a training capacity and not as the official “observer” of the group session.
- b) During and after the Pilot Test, the IYL or adult study staff will attend all practice and supervision meetings.
- c) Local study supervisors will evaluate if the IYL or adult study staff understand the TI-CBT material and curriculum.
- d) Per local study supervisors’ availability and discretion of need, local study supervisors may conduct a “refresher for all” review of the TI-CBT training manual and TI-CBT intervention manual, to include all IYL or adult study staff previously trained and newly added IYL or adult study staff.
- e) At the start of the Randomized Trial, local study supervisors will confirm if the IYL or adult study staff are prepared to lead the group sessions or should serve as an official observer of the group sessions.

Training post initial Expert Trainer Training and Post First Pilot Test Group Session

If training occurs following the initial expert trainer training and post initiation of the first Pilot Test group session, email impaact.adapt2016@fstrf.org.

3.6 Step 8: Pilot Test

The full TI-CBT intervention is provided in the Pilot Test. The Pilot Test will include the delivery of the complete TI-CBT intervention over the course of six group sessions for youth and two group sessions for caregivers. For step-by-step instructions for accruing participants, study visit procedures, and delivering the intervention in the Pilot Test, refer to the protocol and study-specific MOP. Instructions of how to further adapt the TI-CBT intervention per feedback provided during the Pilot Test are described in this guidance document below.

As described in [Section 3.4](#), the Adaptation Team will distribute to each site the final approved English and translated versions of the site-specific Youth Intervention Manual and Caregiver Intervention Manual that have been adapted per community stakeholder and Focus Group feedback to use in the Pilot Test.

Adaptation Following the Pilot Test

Following the completion of the Pilot Test at a given site, designated study site staff, site IoRs, and group facilitators (e.g. IYL and adult study staff) will meet to discuss the site-specific data on feasibility and acceptability collected in the EVW10047 eCRF (IMPAACT 2016 Intervention Evaluation for Pilot Test) and EVW10048 eCRF (IMPAACT 2016 Group Session Feedback for Pilot Test), and other feedback. Designated site staff will access the EVW10047 and EVW10048 eCRF data from Medidata Rave. Sites should email the Protocol Data Managers (impaact2016.dm@fstrf.org) if unable to access the data. At the sites' discretion, the Youth and Caregiver Intervention Manuals may be printed and/or electronically projected during the meeting(s) for attendees to reference. Refer to [Appendix I](#) for a list of supplies.

The core constructs of the intervention and the questionnaires planned to be used in the Randomized Trial will not be changed, but the meeting attendees can propose changes to the Youth and Caregiver Intervention Manuals and ways to alter how the intervention is delivered (e.g. the timing or sequence of procedures) based on the Pilot Test findings for use in the Randomized Trial.

One study site staff will be designated to document a summary of Pilot Test findings and proposed changes by completing the Pilot Test Adaptation Feedback Form in [Appendix VII](#).

Concluding the Pilot Test

Study site staff are to email the Pilot Test Adaptation Feedback form to the Adaptation Team alias (impaact.adapt2016@fstrf.org). The Adaptation Team will review the form and discuss the feedback and recommended changes for adaptations with the IMPAACT 2016 CMC. As needed, the Adaptation Team may request to discuss the feedback with sites and/or additional stakeholders by phone or email. The Adaptation Team will make a final determination of adaptations to be incorporated into the site-specific Youth and Caregiver Intervention Manuals as described in [Section 3.4](#) above.

The manuals will be revised as needed by the Adaptation Team and back translated as needed by site staff following the guidance in [Section 3.4](#). The Adaptation Team will distribute the final approved English and translated versions of the site-specific Youth and Caregiver Intervention Manuals to each respective site for implementation in the Randomized Trial.

In addition, study site staff will be asked to complete a survey to collect information on implementation of the Pilot Test. The IMPAACT 2016 CMC will review the survey results with the purpose of identifying logistical concerns across sites. Questions will include information on accrual, pre-screening, screening, enrollment, and conduct of the intervention.

Appendix I: Supplies for TI-CBT Adaptation

(Community Stakeholder Engagement, Focus Groups and Post-Pilot Test)

Item	Quantity	Source	Initial to confirm on site
Community Stakeholder Engagement			
Community Stakeholder Engagement Adaptation Feedback Form	1	Appendix V (site print)	
Notepad for meeting minutes	Site discretion	Site purchase	
Youth Intervention Manual	Site discretion	Adaptation Team (Site print and/or electronically project)	
Caregiver Intervention Manual	Site discretion	Adaptation Team (Site print and/or electronically project)	
Focus Groups and Adaptation Following Focus Groups (only host site conducting Focus Groups)			
Focus Group Adaptation Feedback Form	1	Appendix VI (site print)	
Audiotape recorder	1	Site purchase	
Notepad for meeting notes	Site discretion	Site purchase	
Youth Intervention Manual (for youth Focus Group only)	1 per facilitator and observer	Adaptation Team (Site print)	
Caregiver Intervention Manual (for caregiver Focus Group only)	1 per facilitator and observer	Adaptation Team (Site print)	
See session specific supplies checklist below for supplies needed for selected components to be delivered in a Focus Group.			
IYL and Adult Study Staff Training (all sites for use in training IYL and Adult Study Staff)			
Youth Intervention Manual - adapted as needed	1 per IYL	Adaptation Team (Site print)	
Caregiver Intervention Manual - adapted as needed	1 per adult study staff	Adaptation Team (Site print)	
See session specific supplies checklist below for supplies needed for training IYL and Adult Study Staff.			
Adaptation Following the Pilot Test (all sites for use in reviewing Pilot Test outcomes and adaptations)			
Pilot Test Adaptation Feedback Form	1	Appendix VII (site print)	
Notepad for post-Pilot Test meeting notes	Site discretion	Site purchase	
Youth Intervention Manual	Site discretion	Adaptation Team (Site print and/or electronically project)	
Caregiver Intervention Manual	Site discretion	Adaptation Team (Site print and/or electronically project)	
EVW10047 eCRF (IMPAACT 2016 Intervention Evaluation for Pilot Test)	Site discretion	Medidata Rave (email Protocol Data Managers with access issues per Figure 1-1)	
EVW10048 eCRF (IMPAACT 2016 Group Session Feedback for Pilot Test)	Site discretion	Medidata Rave (email Protocol Data Managers with access issues per Figure 1-1)	
See session specific supplies checklist in the study-specific MOP for supplies needed for conduct of Pilot Test.			

Session-specific supplies for Group Sessions

(Notes: Sites hosting the Youth and Caregiver Focus Groups only need to acquire supplies required for the identified session(s) delivered during the Focus Groups. All other supplies for all other sessions not delivered during the Focus Groups may be acquired at a later time prior to the Pilot Test and Randomized Trial.

Youth Group Sessions (IYL should bring their Youth Intervention Manual to all youth group sessions)			
Session Part	Supply Item (handouts, worksheets, diagrams, certificate template located in the Youth Intervention Handout file)	Quantity	Check box if on site for session
Session 1 Supplies (review Session 1 Supplies Checklist in Youth Intervention Manual)			
A – Ice breaker	Beach or soccer ball with written questions on the ball	1	
B – Group Rules (pre-written by IYL)	Write Group Rules on flip chart (confidentiality, attention, respect, acceptance, attendance, silence cell phones) and Display on wall or flip chart	1	
D – Introduce Stress	Flip chart, markers	Minimum 1 of each item	
D – HIV Knowledge	HIV Knowledge Handout (print copies)	1 per youth, 1 poster size	
D – Introduce Stress	Stress Reaction Cycle Handout (print copies) and Display poster size on wall or flip chart	1 per youth, 1 poster size	
F – Body Awareness	Body size paper (large enough to draw an outline of each youth's body)	1 per youth	
G – Mark Sensations and Feelings	Box of assorted colored markers for youth to share	Multiple boxes at site discretion	
Session 2 Supplies (review Session 2 Supplies Checklist in Youth Intervention Manual)			
A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
C – Review Stress	Stress Reaction Cycle Handout (print copies) and Display poster size on wall or flip chart	1 per youth, 1 poster size from previous session	
D – Small groups for Stressors and Responses	Group Worksheet: Stress Response (print copies)	2 (1 per small group)	
E – Stressors and Responses, H – Health Response	Flip chart, markers	Minimum 1 of each item	
I – Assignment	Assignment: Stress and Happiness Worksheet (print copies)	1 per youth	
Session 3 Supplies (review Session 3 Supplies Checklist in Youth Intervention Manual)			
A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
B – Review Session 2 assignment, D – Stressful/ Pleasant Events	Flipchart, markers	Minimum 1 of each item	
C – Thoughts-Feelings-Behaviors (T-F-B)	Thoughts-Feelings-Behaviors Cognitive Triangle Handout (print copies)	1 per youth, 1 poster size	

E – Small groups for T-F-B	Plain white piece of paper and markers	1 set per youth	
I – Assignment	Assignment: Thoughts-Feelings-Behaviors (T-F-B) Blank Cognitive Triangle Worksheet (print copies)	1 per youth	
Session 4 Supplies (review Session 4 Supplies Checklist in Youth Intervention Manual)			
A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
C and D – Small groups for Gender Roles/Expectations	Flip chart paper and markers	2 sets per small group	
F – Family and Community Roles	Basket	1	
F – Family and Community Roles	Small pieces of paper (write each of the following roles on a piece of paper - parent, aunt, uncle grandparent, teacher, church leader, community authority, male friend, female friend, neighbor, female elder, male elder, doctor, nurse, counselor)	15 (At site discretion if more roles)	
G – Large Group Discussion	Local statistics on Gender-Based Violence (identify and prepare current local Gender-Based Violence statistics to share during the session)	Verbalize or print handout	
G – Large Group Discussion	Flip chart with markers	1	
H – Assignment	Assignment: Gender-based Messages Worksheet (print copies)	1 per youth	
Session 5 Supplies (review Session 5 Supplies Checklist in Youth Intervention Manual)			
A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
C – Interpersonal Interactions	Plain white piece of paper and pens or markers	2 sets	
D – Role Play for Interactions	T-F-B Cognitive Triangle Diagram Handout (use copy from Session 3)	1	
D – Role Play for Interactions	Flipchart with markers	1	
E – Small Group Safe Sex Demonstration	External (male) and Internal (female) Condoms	1 per youth	
E – Small Group Safe Sex Demonstration	Plain white piece of paper and pens or markers	1 set per small group	
H – Assignment	Assignment: Thoughts-Feelings-Behaviors T-F-B Unhealthy Interactions Worksheet (print copies)	3 per youth	

Session 6 Supplies (review Session 6 Supplies Checklist in Youth Intervention Manual)

A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
B – Review Homework, C/G – Small Groups, H – T-F-B	Flip chart sheet with markers	1 set per small group	
B – Review Assignment	T-F-B Unhealthy Interactions Worksheet (print copies)	1 per youth	
C – Small Groups for lessons learned	Flip chart paper and pens or markers	1 set per small group	
F – Body Drawings	Box of assorted colored markers for youth to share	Multiple boxes at site discretion	
F – Body Drawings	Body maps from Session 1	1 per youth	
G – Small Groups for Reflecting on Sessions	T-F-B Cognitive Triangle Diagram Poster (use copy from Session 3)	1	
Celebration	Certificates (print personalized copy with youth name)	1 per youth	
Celebration	Supplies per site discretion		

Caregiver Group Sessions (Adult study staff should bring their Caregiver Intervention Manual to all caregiver group sessions.)			
Session Part	Supply Item (handouts, worksheets, diagrams, certificate template located in the Caregiver Intervention Handout file)	Quantity	Check box if on site for session
Session 1 Supplies (review Session 1 Supplies Checklist in Caregiver Intervention Manual)			
B – Group Rules	Write Group Rules on flip chart (confidentiality, attention, respect, attendance, silence cell phones) and Display on wall or flip chart	1	
B – Group Rules, C – HIV Knowledge, D – Stigma, E – Adherence Obstacles	Flip chart, markers, tape, and scissors	Minimum 1 of each item	
C – HIV Knowledge	HIV Knowledge Handout (print copies)	1 per caregiver, 1 poster size	
C – HIV Knowledge, D – Stigma, E – Adherence Obstacles	Plain white piece of paper (or notepad) and pens or markers	1 set per small group	
E – Adherence Obstacles	Adherence Care and Treatment Meaning Handout (print copies) and Display poster size on wall or flip chart	1 per caregiver, 1 poster size	
G – Assignment	Assignment: Adherence Support Worksheet (print copies)	1 per caregiver	
Session B Supplies (review Session 2 Supplies Checklist in Caregiver Intervention Manual)			
A – Group Rules	Display pre-written Group Rules on wall or flip chart	1 from previous session	
D – Adherence Importance	Adherence Care and Treatment Meaning Handout (print copies), and Display poster size on wall or flip chart	1 per caregiver, 1 poster size	
D – Adherence Importance	Flipchart, markers	Minimum 1 of each item	
E – Role Plays	Adherence Plan Handout (print copies), and Display poster size on wall or flip chart	1 per caregiver, 1 poster size	
F – Celebration	Certificates (print personalized copy with caregiver name)	1 per caregiver	
F – Celebration	Supplies per site discretion		

Appendix II: Criteria Form for Selecting Indigenous Youth Leaders (IYL)

Suggested criteria for selecting Potential IYL to lead or observe the youth group sessions listed in table below (target is a minimum of 6 IYL): **complete this form for each potential IYL and email to the Adaptation Team** (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential IYL: _____

Sex (male or female): _____

Relation to clinic study staff (example daughter/son/niece/nephew/none):

Criteria	Description	Yes	No	Explanation if No
Age	... is between 21 and 30 years of age			
Clinic attendance	...Missed no more than one clinic appointment over the last 12 months			
Adherence	...Self-reports excellent ART adherence			
	...Viral load available and undetected or < 40 copies?			
Communicationable to read and write?			
experience standing and teaching in front of a group (perhaps at school for a presentation?)			
Dedication	...committed to attending all training sessions and leading all intervention/discussion control sessions?			
Alcohol/Drugs	...Does NOT have a problem drinking alcohol or taking illicit drugs (marijuana, cocaine, heroin, etc.)			
Mental health	...has been assessed using the same instruments as the participants			

Appendix III: Criteria Form for Selecting Adult Study Staff

Suggested criteria for selecting Potential Adult Study Staff to lead or observe the caregiver group sessions list in table below (target is a minimum of 6 adult study staff): **complete this form for each potential IYL and email to the Adaptation Team** (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential Adult Study Staff: _____

Sex (male or female): _____

New hire, or currently part of IMPAACT site team?: _____

Criteria	Description	Yes	No	Explanation if No
Mental Health experience	...prior training in mental health work? (if yes please provide training experience)			
Work experience	...prior work with caregivers of youth living with HIV?			
Communication	...able to read training materials and write notes?			
	...experience standing and teaching in front of a group?			
Dedication	...committed to attending all training sessions and leading all intervention/discussion control sessions?			
Alcohol/Drugs	...does NOT have a problem drinking alcohol or taking illicit drugs (marijuana, cocaine, heroin, etc.)			

Appendix IV: Criteria Form for Selecting Local Study Supervisor

Suggested criteria for selecting Potential Local Study Supervisor to supervise IYL and adult study staff in their facilitation of the youth and caregiver group sessions, respectively, listed in table below (target is a minimum of 1 Local Study Supervisor): **complete this form for each potential Local Study Supervisor and email to the Adaptation Team** (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential Local Study Supervisor: _____

Sex (male or female): _____

Does the Local Study Supervisor have credentials to serve as the on-site clinician?: _____

If yes, list credentials: _____

New hire, or currently part of IMPAACT site team?: _____

Criteria	Description	Yes	No	Explanation if No
Available	...to be onsite during group sessions at all times to assist in the event that an issue arises during group sessions that requires professional attention			
	...to be available by phone during off hours			
	...to meet weekly with the expert trainer			
	...to meet twice weekly with the IYL			
Evaluation and Mentor skills	...to help guide supervision discussions with IYL, provide support, answer questions, relate well to youth, guide IYL if issues arise, and evaluate IYL knowledge and session knowledge			

Appendix V: Community Stakeholder Engagement Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual, facilitators (e.g. local study supervisor, adult study staff not designated to the Discussion Control Arm; excluding IYL) will describe the overall program, the logistics, and content. The facilitator will provide some data/justification for the need and importance of the program (e.g., high rates of mental health problems, low adherence). Then, the facilitator will read through each activity in each session one at a time and ask the community stakeholder attendees to provide feedback on the activities, including their strengths and weaknesses; clarity, feasibility, acceptability and barriers of each activity; and component(s) needing improvement. The facilitator will request feedback about the components that might benefit from Focus Group testing.

Complete this form to document feedback on both the Youth Intervention Manual and Caregiver Intervention Manual, and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Community Stakeholder Engagement Date: _____

Number of Attendees, and their affiliation (e.g. youth cab, site staff, etc.) and demographics (e.g. age, gender, etc.): _____

Summary list of recommendations for adaptation:

--

Adaptation Team Review Date: _____

Adaptation Team Comments:	
Adaptation Team Approval:	

Use the following pages to document notes summarizing stakeholder responses, key outcomes, and recommendations for adaptation.

Clarity: Does everyone understand the points and activities in each session?

Stakeholder (e.g. youth CAB)	Summary	Key Outcomes/Recommendations

Feasibility and Acceptability: Do you feel youth or caregivers will like the material? Will they reject the material, or will the material be too hard to understand? Do you feel the wording, the concepts, and the processes are feasible and acceptable? Did you have fun and learn something?

Stakeholder (e.g. youth CAB)	Summary	Key Outcomes/Recommendations

Barriers to understanding manuals: Do you feel there are any barriers to communicating the information in the manuals to youth and caregivers? Do you feel youth and caregivers will like the session? Do you feel youth and caregivers will have fun and learn something from each session? Do you feel IYL and adult study staff can be trained on the manuals and to effectively deliver the manual information?

Stakeholder (e.g. youth CAB)	Summary	Key Outcomes/Recommendations

Barriers to delivering the group sessions: Do you feel there are any barriers to delivering the group session? Do you feel youth and caregivers will be ok attending a session for a minimum of two hours? Do you feel there is sufficient space to run both a TI-CBT group session and a Discussion group session and keep both groups separated to prevent sharing of information between the groups?

Stakeholder (e.g. youth CAB)	Summary	Key Outcomes/Recommendations

Appendix VI: Focus Group Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual, facilitators (e.g. adult study staff not designated to the Discussion Control Arm, local study supervisor, IoR) will deliver separately the selected components and activities to the youth group and caregiver group. Youth and caregiver participants will be asked to provide feedback on the components' and activities' acceptability, utility, relevance, and need for change.

Complete this form to document Focus Group outcomes, and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Focus Group Date: _____

Youth or Caregiver Focus Group: _____

Session Delivered: _____

Summary list of recommendations for adaptation (if session activities changes proposed, indicate updates to be made to the list of session activities on the fidelity evaluation form):

--

Adaptation Team Review Date: _____

Adaptation Team Comments:	
Adaptation Team Approval:	

Use the following pages to document notes summarizing participant responses, key outcomes, and recommendations for adaptation.

Acceptability/Relevance: What are your thoughts about this session? How does it fit within the [country in which it is delivered] culture? Are there changes you would suggest to make it more relevant for families in [country/culture]? What are your thoughts on the group structure (e.g. gender composition); are there changes you would make to enhance acceptability and feasibility?

Summary	Key Outcomes

Other: Facilitators may ask any additional questions depending on the specific session delivered to the participants.

Summary	Key Outcomes

Appendix VII: Pilot Test Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual (use revised manuals if adapted per the Focus Group outcomes), IYL and adult study staff facilitators will deliver separately the full TI-CBT intervention to the youth group and caregiver group, respectively. The observers will be in the sessions.

Complete this form to document Pilot Test outcomes, and email to the Adaptation Team
(impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Pilot Test Group Session Dates: _____

Youth or Caregiver Pilot Test Group: _____

Summary list of recommendations for adaptation (if session activities changes proposed, indicate updates to be made to the list of session activities on the fidelity evaluation form):

--

Adaptation Team Review Date: _____

Adaptation Team Comments:	
Adaptation Team Approval:	

Use the following pages to document notes summarizing Pilot Test outcomes, key outcomes, and recommendations for adaptation.

Feasibility and Acceptability: Review data collected in the EVW10047 eCRF (IMPAACT 2016 Intervention Evaluation for Pilot Test) and EVW10048 eCRF (IMPAACT 2016 Group Session Feedback for Pilot Test) and provide feedback on if there are ways to improve feasibility and acceptability.

Do you think the wording, concepts, and the sequence of procedures are feasible and acceptable?
Do you think delivering intervention in English is appropriate or is use of translated intervention manuals needed?

Topic	Summary	Key Outcomes

