DESIGN, IMPLEMENTATION, MONITORING, AND EVALUATION OF MENTAL HEALTH AND PSYCHOSOCIAL ASSISTANCE PROGRAMS FOR TRAUMA SURVIVORS IN LOW RESOURCE COUNTRIES:

USER'S MANUAL FOR RESEARCHERS AND PROGRAM IMPLEMENTERS

(ADULT VERSION)

MODULE 6:

USING CONTROLLED TRIALS TO ASSESS PROGRAM IMPACTS

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CONTENTS

ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AMHR	Applied Mental Health Research
BA	Behavioral activation
CBI	Components based intervention
CBT	Cognitive Behavior Therapy
CDC	Centers for Disease Control
CPT	Cognitive Processing Therapy
DIME	Design, implementation, monitoring and evaluation
DRC	Democratic Republic of Congo
FG	Focus Group
FL	Free List
HIV	Human immunodeficiency virus
JHU	Johns Hopkins University
LMIC	Low and middle income countries
MOH	Ministry of Health
NGO	Non-governmental organizations
POFO	Positive Outcome for Orphans Study
PPS	Probability proportional to size
PRA	Participatory rural appraisal
PTSD	Post traumatic stress disorder
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
SES	Social economic status
SOW	Scope of Work
USAID	United States Agency for International Development
TFCBT	Trauma Focused Cognitive Behavior Therapy
VOT	Victims of Torture Fund
WHO	World Health Organization

INTRODUCTION TO THE MANUAL

The Manual for Design, Implementation, Monitoring, and Evaluation of Mental Health and Psychosocial Assistance Programs for Trauma Survivors in Low Resource Countries: A User's Manual for Researchers and Program Implementers has been written to assist researchers and organizations developing and implementing programs among trauma-affected populations to 1) identify and measure the impact and prevalence of mental health and psychosocial problems in the populations they seek to serve; 2) develop or adapt appropriate interventions to address these problems; and 3) measure the impact of these interventions. The Manual consists of 6 modules. Collectively, the modules describe a process of program **d**esign, **i**mplementation, **m**onitoring, and ***e***valuation (DIME) that has been developed and used by the authors since 2000. The modules may be used sequentially, to follow the life of a project, or as a stand-alone unit to address a specific project need.

- **Module 1** describes procedures for a qualitative assessment to identify priority problems from the local perspective.
- **Module 2** provides guidance in the development and validity testing of tools to measure these priority problems.
- **Module 3** describes population-based assessments to gauge prevalence and severity of the priority problems using the instrument developed in module 2.
- **Module 4** describes a process for overall design of a program to address the priority problems, including design of program monitoring and evaluation.
- **Module 5** outlines the selection, adaptation, and implementation of interventions.
- **Module 6** describes procedures for assessing intervention impacts.

Definition Box:

Intervention(s)*:* Service(s)/activity(ies) directly benefitting the client

Program*:* The intervention(s) and all ancillary activities necessary to support the intervention(s): logistics, finance monitoring and evaluation, etc.

LAYOUT OF THE MANUAL

Modules are presented in narrative form, with extensive use of subheadings. With the exception of text boxes, each section and each paragraph is meant to be read sequentially. Additional material that is useful as examples of concepts or expansion on subjects discussed in the text has been included in text boxes. Examples of study materials that may be adapted for use in an actual study are placed separately as appendices.

TEXT SET OFF IN RED BOXES WITH THIS SYMBOL INDICATES THAT WHAT FOLLOWS IS A CRITICAL REQUIREMENT OR CONSTRAINT

TEXT SET OFF IN PURPLE BOXES WITH THIS SYMBOL CONTAIN REAL-LIFE EXAMPLES OF THE ACTIVITIES DESCRIBED IN THIS MODULE

TEXT SET OFF IN BLUE BOXES WITH THIS SYMBOL PROVIDE NOTES AND TIPS ON INFORMATION PRESENTED IN THIS MODULE

Throughout each module, you will encounter a series of symbols and boxes set off from the text. These are meant to draw your attention to an important concept, example or requirement:

INTENDED USERS

This manual is primarily intended for researchers and groups responsible for mental health and psychosocial interventions for trauma-affected populations, such as government providers and non-governmental organizations (NGOs).

The methods described in each module are intended to be within the typical budget, resources, and time constraints of organizations that normally focus on implementation rather than data

collection. The approach is designed to be used in a limited area among a population with a homogenous language, culture, and similar circumstances. In areas containing populations with a variety of languages, cultures, and environments, the approach described in this manual should be used separately with each group. For this reason, the authors have focused on developing a process that is rapid and relatively inexpensive.

This is meant as a **'**user**'** manual rather than a training manual. It is intended for use in the field by those who have previously received field-based training in its contents (or have similar training experience) and are now leading teams in their own sites. Such persons should either have some prior experience in qualitative and quantitative data collection methods (depending on the Module being used) or lead teams with persons who have such experience.

The authors have found that even with prior experience in data collection, individuals and organizations attempting to use the methods described here for the first time will have many important questions during the process that cannot be addressed in the manual itself. Answering these questions as they arise—and developing the skills required for using the approaches in different settings—is best done in a field-based training situation, with direct instruction in the course of supervised use of this approach among a local population. Even after training, organizations using this approach may want guidance and ad hoc assistance.

The authors would be pleased to discuss training and technical assistance with any interested organization or individual.

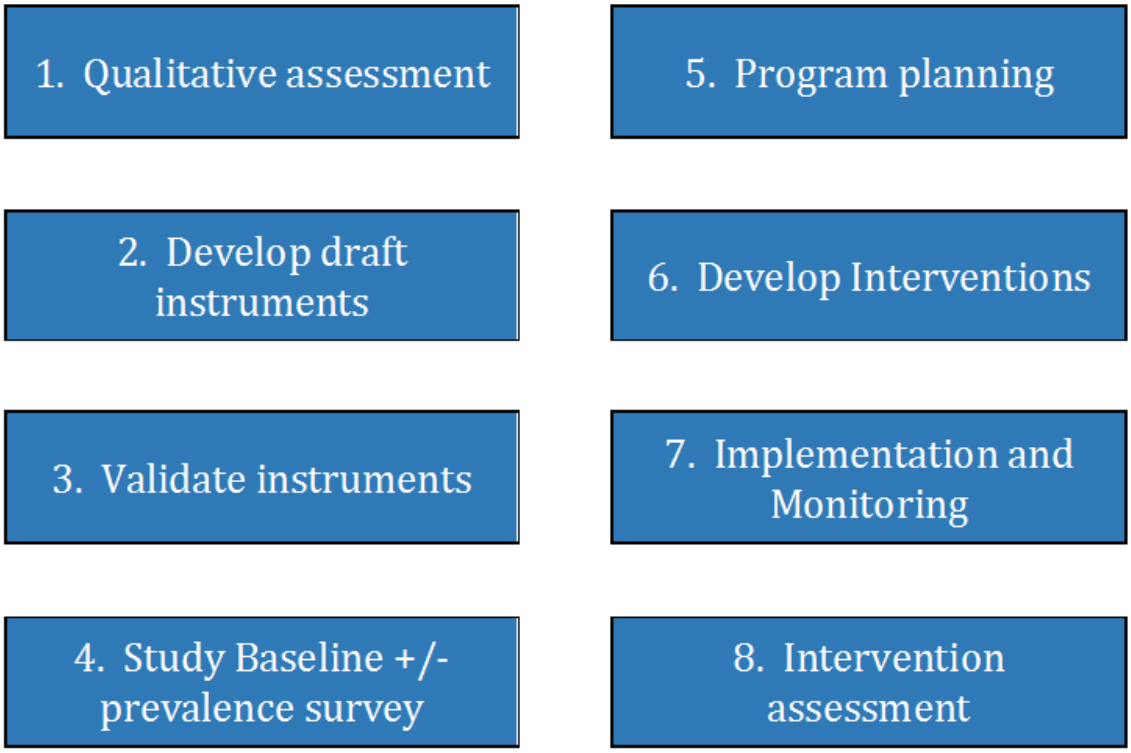
The manual does not contain detailed descriptions of commonly done research activities, such as quantitative interviewing, partly due to the expectation that organizations have persons experienced in these activities and partly because there are many other manuals available that describe these activities. Instead, the manual focuses on research activities or methods that are different from commonly used approaches. For example, Module 1 contains much more information on interviewing than the other modules because the qualitative methods used in Module 1 are less commonly used than quantitative methods.

THIS MANUAL IS NOT APPROPRIATE FOR 'OFF THE SHELF' USE WITHOUT PRIOR ON-THE-GROUND TRAINING OR SIMILAR EXPERIENCE. THOUGH WHAT IS PRESENTED HERE REPRESENTS WHAT THE AUTHORS HAVE FOUND TO WORK WELL TO DATE, FIELD SETTINGS VARY. USERS OF THE METHODS PRESENTED HERE NEED FIELD EXPERIENCE TO INTERPRET AND ADAPT THESE METHODS TO DIFFERENT SITUATIONS.

THE **DIME** MODEL

The diagram below outlines the steps of the **d**esign, **i**mplementation, **m**onitoring, and **e**valuation (**DIME**) process described in this manual. Qualitative data collection (Module 1) is the first step in the process and informs each of the subsequent steps. A brief description of each step follows.

Figure 1: Steps of the DIME Process



1. **Qualitative Assessment to identify and describe priority mental health and psychosocial problems of trauma survivors: (Module 1)**

   Variations in culture and environment affect how people understand the mental health and psychosocial problems related to experiencing trauma. By *understand,* we mean how these problems are described, how they are prioritized, their perceived causes, and how people currently cope with them. This information is vital in selecting problems that are important to local people, accurately communicating with them about these problems, and identifying interventions that are likely to be acceptable and feasible for local people and therefore effective and sustainable.

2. **Develop draft instruments to assess priority mental health and psychosocial problems of trauma survivors: (Module 2)**

   Having decided which problems the program will address, we then draft quantitative assessment instruments to address these problems. These instruments have various uses, depending on the program: conducting community or clinic-based surveys; screening persons for inclusion in a specific intervention program (for programs in which not all people will be served); identifying those with severe problems who may need specialized services including referral; and monitoring and evaluating the effectiveness of services by tracking changes in severity and/or prevalence of the problems identified.

   The process of drafting appropriate instruments includes reviewing the published literature for measures that have already been developed for the selected problems and comparing available measures with the qualitative data to select the measure or measures that best match how local people describe the problem. These measures are then adapted to better fit local concepts.

   Drafting includes translation. Terminology suggested by translators often differs from that used by local populations, particularly by poor and uneducated people. Therefore, qualitative data is preferred as the best source for translating key concepts. Employing the words and phrases that local people actually use (as identified in the qualitative data) will improve the clarity of the instruments, thereby improving their acceptability and accuracy. The translators are instructed to utilize the qualitative data to directly translate all signs, symptoms, problems and topics in the instruments that were mentioned by interviewees in the qualitative study using the same words found in the qualitative data. Only where concepts are not mentioned in the qualitative data do the translators themselves choose the appropriate terms.

3. **Validate draft instrument(s): (Module 2)**

Once translated, the draft instrument(s) must be piloted and tested for ease of use, clarity, acceptance (both by interviewers and interviewees), and accuracy in the field. Accuracy refers to reliability and validity, which in turn refer to whether the instrument gives the same result with repeated use or use by different interviewers (reliability), and whether it measures what it is supposed to measure (validity). Testing involves interviews with members of the target population using the assessment instrument and analyzing the results.

Validity and reliability testing are particularly important with psychosocial and mental health measures, where assessment is based on the interview alone (i.e., there are no laboratory or other tests). A tool that is not accurate can lead to inappropriate inclusion/exclusion of intervention participants as well as incorrect conclusions about need and program impact.

4. **Study baseline +/-prevalence surveys: (Module 3)**

Both baseline assessments and prevalence surveys are based on the instruments developed in steps 2 and 3. Baseline assessments refer to interviews done using the instrument in order to establish the eligibility of individuals for participation in an intervention program. Prevalence surveys perform the same function at the population level to measure the percentage and numbers of eligible (i.e., affected) persons in the population, and also provide some indication about the variation in severity of problems at the population level.

5. **Overall program planning: (Module 4)**

This includes planning the program goals and objectives and the strategy and the type of intervention(s) for achieving these. It also includes the development of process and impact indicators, and the overall program work plan.

6. **Develop interventions to address the identified mental health and psychosocial problems of trauma survivors: (Module 5)**

The qualitative data on the perceived causes of problems and how those affected cope with the problems are critical to intervention design. Interventions need to address the perceived causes of priority problems (or explain to participants why they do not) in order to make sense and therefore inspire both confidence and cooperation. The more closely interventions can match the ways in which people currently think about and

address the selected problems, the more likely the interventions are to be acceptable to them. Where there are differences, they need to be explained and agreed upon by the local population. For example, using counseling to address a problem that is thought to be caused by poverty will take some explaining.

7. **Implementation and monitoring: (Modules 4 and 5)**

   This refers to the implementation and monitoring of the intervention and the overall program. It includes procedures for iterative changes in the planned activities as needed, according to the monitoring data.

8. **Intervention assessment: (Module 6)**.

   Upon completion of the intervention, participants are interviewed using qualitative methods to identify potentially important unexpected impacts of the program. They are also re-interviewed using the baseline quantitative instrument, to measure changes in the outcome indicators such as problem severity and function. Where possible, the amount of change is compared with the amount of change experienced by a control group, to determine the true program impact. Module 6 describes the use of a randomized control trial design to evaluate interventions.

MODULE 6:

USING CONTROLLED TRIALS

TO ASSESS PROGRAM IMPACTS

6.A. INTRODUCTION TO MODULE 6

A.1. PURPOSE AND RATIONALE OF MODULE 6

Service organizations have a responsibility to use interventions known to be effective and beneficial for the populations that receive them. However, the current evidence base for psychosocial and mental health interventions in low and middle income countries (LMIC) is poor and most interventions are unproven for most populations. It is quite possible, particularly for counseling-based interventions, that the approach used for one culture may not be appropriate or acceptable for another, so adaptation and testing are indicated when introducing an intervention to a new population. It cannot simply be assumed that the new intervention will be acceptable and effective based on results elsewhere; however, it is not always feasible to wait for researchers to test the feasibility of a prior approach. Instead, service organizations themselves must take the lead in generating this evidence prior to, or as part of, implementing their programs.

The purpose of this module is to describe a process for assessing the impact of mental health programs on recipients. Recipient-based impact assessments of mental health and psychosocial programs are uncommon in LMIC due to a lack of accurate assessment methods and perceived high expense and difficulty. This may be especially true in the case of survivors of torture and traumatic experiences, who are often in settings with poor infrastructure due to political instability, war, or natural disaster. Where assessments are done, they typically consist only of comparing recipient measures conducted before and after interventions. While suggestive, the results of such assessments do not determine how much (if any) of the changes found are due to the program versus other factors. In this module we argue for impact assessments as a routine part of programming and, where possible, the use of a more scientific approach in the form of controlled trials. Controlled trials measure the amount of change due to the program and are therefore the best indicators of the program's worth. Accurate assessments of program impact inform the choice of interventions and of subsequent improvements. They inform calculations of cost effectiveness, which are important given the high cost of programs and the need to justify their support out of public funds, and in turn the formation of health policy.

In this module we present an approach to controlled trials in the program context that we have successfully used in collaboration with service organizations in low resource countries with trauma-affected populations. This approach uses scientific research methods, yet is designed to be low cost, to complement program activities, and to be largely conducted by the service

organizations themselves with external technical input. Such studies will achieve three important objectives:

1. To know whether or not specific programs are actually benefiting their recipients
2. To serve as a basis for ongoing improvement of those programs
3. To advance the field by building evidence of what works and what does not

As such, Module 6 represents the culmination of the activities described in the other modules. Module 1 describes the collection of data and other information to understand the important mental health priorities and how they might be addressed. Module 2 describes the development of instruments to quantify these problems and their effects on functioning. Module 3 describes the use of these instruments in population-based studies to quantify needs. Module 4 describes the use of the information from Modules 1-3 (and other available information) to plan services, including monitoring and evaluation. Module 5 describes specific mental health interventions that are likely to be effective given past experience and studies, as well as their how they may be implemented in programming. Finally, Module 6 describes procedures for testing the products of module 1-5, thereby determining whether the resulting services produce meaningful benefits in the lives of those who receive them.

All modules in this series refer to the adaptation of existing methods for the purposes described above. The focus is on adjustments and what is different about the methods in this context compared to how they are usually used, rather than providing complete descriptions of the basic methods where such descriptions can be found elsewhere. References to these resources are included in the text where appropriate.

A.2. INTENDED USERS

This module is intended for researchers, aid organizations, governmental and non-governmental organizations (NGOs), and other organizations providing psychosocial interventions. These groups should have experience in instrument-based quantitative data collection and basic data analysis, and in program monitoring and evaluation. For such organizations, Module 6 is intended to provide a feasible approach to measuring the impact of a psychosocial program; one that is within their budget, resources, and time constraints, and requires minimal outside technical assistance. The approach is designed for use in a limited geographic area among a population with a homogenous language and culture. In areas containing groups with multiple languages and cultures the approach described in this manual may need to be used separately with each group.

A.3. KEY ELEMENTS OF THE IMPACT ASSESSMENTS, AND THEIR RATIONALE

A.3.1. INCLUSION OF A CONTROL OR COMPARISON GROUP, PREFERABLY RANDOMIZED

Testing the impact of interventions requires more than a comparison of pre- and post-intervention assessments. This approach can determine if change has occurred but it cannot determine whether that change is due to the intervention/program. In the course of the intervention, the social, economic, political, or physical environment may have altered in ways that affect the program outcomes, making the intervention appear more or less effective than it actually is. Determining the impact of the intervention requires comparison of a group that receives the intervention with another group that does not but is otherwise as similar to the intervention group as possible. Only by comparing the change occurring among the intervention and control/comparison groups can the amount of change due to the intervention be ascertained. It is frequently argued that conducting such controlled studies is too difficult or simply inappropriate in low resource environments, particularly those that are unstable, such as areas impacted by conflict or natural disaster. However, these are the situations in which controlled studies are most needed because of the high likelihood that external changes will occur during the program/study that could affect project outcomes. Therefore, controlled studies should always be considered and conducted when possible.

A second objection is that controlled studies are unethical because the control group must wait for services. However, need normally exceeds service capacity, thus waiting for services is the program norm. Few, if any, service programs are equipped to immediately provide services to all who need them. Staffing and resources are routinely based on the expectation that those who need services are not going to present at the facility all at once. Where demand exceeds supply, controlled trials can be conducted in such a way that supply is fully engaged throughout the study. The number of people who wait, and how long they wait, is no different than it would be in the absence of the trial. Figures 2 and 2a illustrate how this can be done. Both figures reflect possible trials for an intervention where the program service capacity is 500 persons at a time. In Figure 2, 500 persons have been assessed and found to be in need. They are then randomly assigned to either the intervention or control group. At the end of the study they are reassessed and compared. Under this design 250 people who might have been treated immediately have had to wait for treatment because of the trial. Figure 2a illustrates the same design except that twice as many people are assessed and found to be in need. Randomly dividing them into intervention and control groups results in no more waiting than if the trial had not taken place, since treatment capacity is 500 at a time. **In this way, trials can avoid**

increasing the wait for services by assessing and identifying more people than the program can serve.

Figure 2

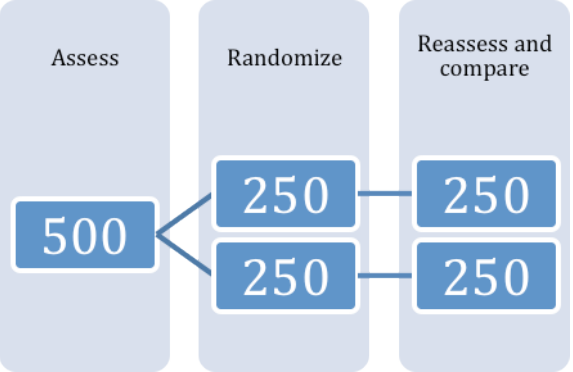
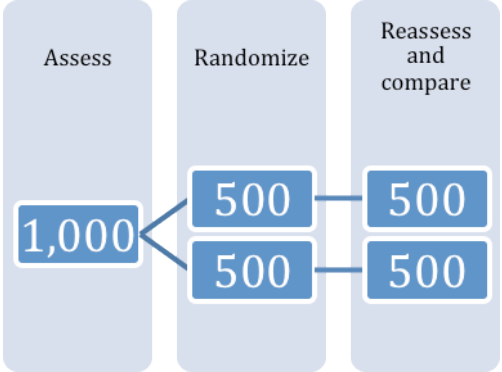


Figure 2a



A related concern is **identifying** a particular person in need of mental health services and then **asking** them to wait. Some program staff prefer not to identify people in need until they can be served by the program. However, identifying persons in need of services and making sure they do not come to harm until they can be helped would be a better option for the population. Controlled trials can be designed to incorporate this protection by regular checks between the study staff and those who have been identified as in need but have been asked to wait for services. If those persons are found to be in danger they can be removed from the study and either given the intervention immediately or referred to emergency services. In this way they are assisted by the program while they wait for services.

In controlled trials the preferred way of deciding who receives services first (the intervention group) is by random selection. For programs, this decision usually depends on who turns up first at the service facility or through community outreach. However, random selection is preferred for studies because it offers the greatest likelihood that the intervention and control groups are the same when they begin the study. It can also be argued that random selection is fairer than giving preference to those who have the quickest access to services.

If the intervention is to be given to eligible **individuals** regardless of where they live or receive services, then it is individuals who are randomly allocated to either intervention or control groups. If the intervention is provided at the **community or clinic level** or there is reason to believe that the benefits of the intervention are likely to spill over to other members of a community/neighborhood, then random allocation is done at the level of the community or clinic. Within each community or clinic, all persons taking part in the study either receive the

intervention or are controls, depending on whether the community was allocated to intervention or control.

Example: Wait-list Controls from a RCT in Eastern Democratic Republic of the Congo (DRC)

In this study, women who met eligibility criteria within nine participating villages in DRC were asked to form groups of approximately 15-20 women to participate in an evaluation of a Village Savings and Loan Association (VSLA) program. Once created, these groups were then either randomized to the treatment condition and enrolled in the VSLA program, or to a wait-list control, in which they were asked to wait until the next round of VSLA groups were started in Year Two. Importantly, as part of the informed consent process before enrollment and randomization, all of the groups were informed that they might be placed on the wait-list rather than beginning the VSLA program immediately, depending on the outcome of the randomization process.

The aim was to have four VSLA groups and four wait-list control groups in each of the 9 participating villages. All groups were formed simultaneously, and before randomization occured. Those groups that were randomized to receive VSLA began the program immediately. The intervention lasted for approximately 12 months and was facilitated by trained staff from the International Rescue Committee (IRC), our local partner for this research. The wait-list control groups were asked to not take part in VSLA activities during this time. After completing the intervention, the wait-list control groups were then invited to participate in the VSLA program. IRC staff also asked participants from the treatment condition (those who participated in the initial VSLA groups) to take the lead in training these new groups of participants who had been on the wait-list.

Example: Procedures for Monitoring Wait-list Controls in a RCT in Kurdistan, Iraq

Participants in this study were adults in Kurdistan, Iraq who had been tortured and/or imprisoned and had significant mental health symptoms. There were four study arms in this RCT: 1) Behavioral Activation; 2) Cognitive Processing Therapy; 3) General Supportive Counseling; and 4) Wait-list Control. Participants were randomized to receive either immediate therapy or to a wait-list control condition using a 3:1 ratio of immediate therapy to wait-list control. The type of therapy that a participant received depended upon which Community Mental Health Worker (CMHW) they consulted. Those who were randomized to the wait-list control arm were asked to wait for approximately four to five months before beginning the assigned intervention.

The participants were informed of their randomization assignment by the CMHW. If they were assigned to the wait-list control they were told to contact the CMHW immediately if their symptoms worsened during the waiting period. They were also asked to check-in with the CMHW on a regular basis, approximately every six to eight weeks, even if there had been no noted change in symptoms by the participant. During this assessment, the CMHW attempted to determine if there was any change in severity of symptoms. If there was no symptom change, the participant would remain on the wait-list and begin treatment after the waiting period had ended. As with those who started therapy immediately, the type of therapy received for the wait-list controls would be based on which CMHW to which they presented. If, however, symptoms had worsened at the check-in, the participant would begin therapy with the CMHW immediately, or if deemed an emergency (in which the participant may be in danger or a danger to someone else) they would be referred immediately to a treatment center.

A.3.2. ASSESSMENTS PRE- AND POST-INTERVENTION

Quantitative assessments of the key program outcomes are conducted among all participants at the beginning and end of their study participation, for both intervention and control groups. These assessments are done by trained interviewers using questionnaires (quantitative instruments) previously developed for this purpose (See Module 2: Develop Tools to Measure the Problem). Where possible, these interviewers should not be the program implementers since they are more likely to have a stake in the outcome and this bias may affect the assessment results. Using program staff, particularly the provider who treated the interviewee, may also affect how interviewees responds to questions. Study participants may desire to please program implementers by providing responses in assessment interviews that reflect what they think program implementers want to hear. Using interviewers who do not know the study participants also makes it easier to 'blind' them in the post-intervention assessment as to

whether the participant received the intervention or was a wait-list control, thereby reducing the potential for biasing the interview results.

Where programs must use program staff to conduct the assessments, they can still minimize potential biases by using interviewers who are not service providers. Where this also is not possible – the interview must be done by the provider – s/he might conduct the pre-intervention interview but the post-intervention interview should be done by a different provider who did not serve the participant they are interviewing. In this way someone who the participant does not know conducts both the pre- and post-intervention interviews. This at least reduces the risk that the participant, having come to know the provider, may give responses that please the provider.

A.3.3. CONDUCT OF INTERVENTIONS AS A NORMAL SERVICE PROGRAM

Interventions should be provided as they would be in a service program. The intervention should not be carried out with more resources, more highly qualified staff, or better supervision than would normally be provided. The training materials and training should be the same as are intended for future program use. Meeting these requirements ensures that the results reflect the true impact of the intervention under normal circumstances rather than under artificial experimental conditions.

Clearly these restrictions do not apply to the program monitoring or impact evaluation procedures, since the approach described here requires more resources and complexity than will be devoted to ongoing Monitoring and Evaluation during implementation after the trial is completed.

A.3.4. EVOLUTION OF THE INTERVENTION

Normally, in impact assessments, each person or group within the intervention group must receive the same intervention. This means that the intervention does not vary in ways which may affect its impact. If variation does occur it may be argued that the intervention group did not all receive the same intervention and that the results do not reflect its true impact.

While this approach may work for interventions that have already been implemented and adapted for local use, it does not work well when the impact assessment is being introduced to a new population or situation for the first time. In these situations, problems with the intervention, or simply ways in which it needs to be improved, become apparent during implementation. Rather than waiting until the end of the impact assessment period, these

changes are made as soon as they are identified. To not do so would mean that the impact results would be obsolete as soon as the impact assessment is completed.

Changes implemented in this way should not be made on essential intervention components, but refer to improvements in access, feasibility, and acceptability among the population. If fundamental changes to the intervention itself are required, this would suggest that the intervention is inappropriate, in which case it should be stopped and replaced with something more suitable.

A.3.5. MONITORING OF THE INTERVENTION

Monitoring consists of tracking the numbers of persons recruited into the intervention and control groups, their compliance, how often they are seen, what problems they present with at each treatment session, what is done for them, and their symptom progress. Much of this information should be collected as part of normal program monitoring (i.e., outside a controlled study) although it frequently is not. In the study context monitoring is done for three reasons:

1. To determine whether the intervention was provided as planned. Without this information it is not clear whether the study really refers to the intervention or not. For example, if an intervention fails to show an impact but in fact clients only received half the intended sessions, the conclusion that it is ineffective may be incorrect.

2. To identify problems affecting implementation in real time, so that appropriate changes can be made (See A.3.4, above). These problems often reflect additional adaptations to a new population that only become apparent during implementation. As such, the data is often as valuable to future programming as the impact results.

3. To determine whether changes resulting from these problems (#2) are effective.

Therefore, by the end of the study the intervention will already have improved in terms of access, feasibility, and acceptance.

A.3.6. ASSESSMENT OF IMPACTS BEYOND THE ORIGINAL STUDY GOALS

Assessment of program impacts is usually restricted to the program goals and/or objectives. These can be defined as important positive impacts that are expected to occur because of the program. They are therefore a subcategory of the expected positive impacts of the programs, as represented in the top left corner of the diagram below.

Diagram: Categories of Program Impacts

Positive Expected Impacts (including Pre-defined Goals & Objectives)	Negative Expected Impacts
Positive Unexpected Impacts	Negative Unexpected Impacts

This diagram illustrates that there are four categories of possible program impacts: expected positive and negative impacts, and unexpected positive and negative impacts. The original program goals and objectives form only a part of one of these categories, yet they are usually the only impacts that are measured. Impact assessments should identify and assess as many of the program impacts as possible in order to get a more comprehensive picture of a program's net benefit (or lack of it), and to identify and try to address negative impacts.

This module includes an approach to identifying and measuring unintended impacts. Further information about this approach has also been published elsewhere (Bolton et al., 2007b)

6.B. METHODS: DESCRIPTION OF THE IMPACT ASSESSMENT PROCESS

B.1. RECRUITMENT AND TRAINING OF INTERVIEWERS, SUPERVISORS, AND STUDY DIRECTOR

Wherever possible, persons conducting the assessment interviews should not be the same persons as those conducting the intervention. However, in practice this is often not possible due to logistic and financial reasons. In such cases, the initial assessments may be done by the providers if they are meeting the participants for the first time or at least do not know them well.

Although providers should not know participants well or should be meeting them for the first time, a trial in Thailand found that it was important for the interviewer (in the case of this study it was the providers doing the initial assessment interviews) to make at least one casual visit with the potential participants prior to coming with the actual consent forms and assessment instruments. The providers felt this was a critical step in building trust with potential clients and was useful for increasing the likelihood that potential participants would answer the questions honestly during the assessment.

At the end of the study providers may also conduct the interviews, but in this case they interview clients of another provider to reduce bias and, where possible, maintain blinding of interviewers.

Staff from the implementing organization, outside hires, or a combination of both may fill both interviewer and clinical supervisor roles. Staff may be used if there is an interest in building capacity (particularly if future studies are anticipated) and/or in order to save costs. Organizations often lack sufficient staff to cover all positions, so interviewers and supervisors may be a mix of staff and outside hires.

B.1.1 INTERVIEWER QUALIFICATIONS

Unlike the instrument validity studies and prevalence studies, in most cases intervention trial interviews are conducted on a part-time basis as persons to be screened become available. Where interviews are done by the providers, all providers do interviews. Where interviews are done independently, the number of interviewers and supervisors (and the amount of time they spend interviewing) depends on the rate of screening interviews and can be small.

Regardless of whether the interviewers are independent or are the intervention providers, the qualifications for being an interviewer are as follows:

- ✓ Fluent and literate in the language(s) of the local population where the study will be conducted
- ✓ Available to conduct interviews at times and places convenient to the clients (clinics, homes, other)
- ✓ In good health and able to travel to wherever interviews are conducted
- ✓ Acceptable to the target population (in terms of reputation, where they are from, gender, age, ethnicity)

Interviewers will be expected to prioritize the study over other work (an issue that often comes up when interviewers come from the implementing organization and are pulled in many different directions). However, it is understood that emergencies and/or unexpected but important events can occur that can oblige those involved to miss a day or more. Under such circumstances, an interviewer can leave briefly and return to the study as soon as possible. Trials should have a process in place to manage interviews if an interviewer or interviewers are away or unavailable, otherwise opportunities for conducting interviews may be missed.

It is important to ensure that the selected interviewers will be acceptable to the population being interviewed. This is particularly important for persons who are survivors of torture and other traumatic events, or are otherwise mistrustful of other sections of the population. For example, to enhance cooperation, we have used former drug users as interviewers in a study of HIV-related behaviors related to current drug use. Also, we have had interviewers who have a similar history with traumatic experiences or come from similar areas in a study of depression and trauma symptoms among torture and systematic violence survivors from Burma currently living in Thailand. Consultation with community leaders and stakeholders is useful in thinking through who would be appropriate interviewers.

An important step is to make sure that all providers, clinical supervisors, and project team members get to know the interviewers, approve of them, and find them suitable for this position. The providers and clinical supervisors, as well as the local program coordinator and field project director, will need to work closely with the interviewers and have a smooth working relationship with them.

B.1.2. SUPERVISOR QUALIFICATIONS

During the impact assessment there are two sets of supervision activities. One set refers to the supervision of providers in their conduct of the intervention. This is described elsewhere (see Module 5). The second set of activities refers to supervision of the research activities and is described here. This includes supervision of the screening and post-intervention interviews as well as randomization, follow up of wait-list controls, and follow up of refusals and drop outs. Both types of supervision activities may be conducted by the same person or different persons. This normally depends on whether the providers are also responsible for the assessment and recruitment activities and the availability of the supervisors, because they often have existing responsibilities with their organization. Where the provider and interviewer roles are combined, the supervision of providers and interviewers can also be provided by the same person. In most cases, though, it useful to have separate people for clinical supervision and supervision of the research activities.

Supervisors who will oversee the research activities need the following qualifications:

- ✓ Fluent and literate in language(s) of the interviewers and of the research team (to act as a liaison between researchers and interviewers where they do not share a common language)
- ✓ Available to meet weekly and as needed with both the interviewers and the research team (the latter usually by phone)

- ✓ Acceptable to and respected by the interviewers, providers, and clinical supervisors
- ✓ Can travel to study site locations
- ✓ Computer literate and able to use email as a consistent form of communication (or another form of communication appropriate for the site location)
- ✓ Able to work independently and maintain organization of research activity information

As described in other modules, research supervisors provide the link between the research team and the interviewers, counselors, and clinical supervisors. Like the interviewers, they need not have interviewing experience, although prior experience working on a study of any type is helpful. As a supervisor, they may need to conduct some interviews and/or sit in when an interviewer becomes unavailable or additional supervision is needed. Thus, they share the same qualifications as the interviewers, with the additional requirement that they are able to communicate verbally with both the interviewers and the study director. Supervisors meet with the interviewers on a regular basis, usually weekly although this depends on the rate of interviews. Supervisors also meet weekly with the field study director.

Variations may be made in how research activities are supervised, as long as the same monitoring and communication is taking place. For example, the supervision may be conducted by a single person or using a team approach. The box below briefly describes how a trial in Thailand structured the supervision of research activities.

Example from the Thailand-Burma Border RCT on setting up supervision of the research activities.

In the case of the Thailand-Burma border research project, supervision of the research activities was primarily done by the field study director, a doctoral student from the United States who lived at the project site and had extensive prior experience working in that setting. The field study director worked together with a local project coordinator to oversee the research activities. It was the responsibility of the field project coordinator to meet regularly with the clinical supervisors and counselors, maintain the tracking forms from the research activities, and keep the research team updated on the progress of activities. The local project coordinator assisted the study director by conducting the monthly phone/home-visit contacts with control clients, contacting counselors when needed, and meeting with the clinical supervisors when the study director was not available. Both the field study director and the local project coordinator spoke English and the local language. The task of communication with the counselors was a shared responsibility, but the director took responsibility for communications to the research team via phone and email.

B.1.3. FIELD STUDY DIRECTOR QUALIFICATIONS

One field study director is needed on-site to lead the study. This includes the period from the planning phase through the assessment, recruitment and randomization, the conduct of the intervention and tracking of controls, and the follow up assessments. This position is ideally full time. Requirements for field study directors are as follows:

- ✓ Preferably team leader or manager for the organization implementing the program, or someone with similar experience (research experience is desirable but not essential, since most challenges are logistic)
- ✓ Available to direct pre-study planning
- ✓ Available for the duration of the study itself (one to two years, depending on the rate of recruitment and treatment)
- ✓ Speaks the same language as the trainer and the supervisors (and interviewers if possible)

B.1.4. INTERVIEWER AND SUPERVISOR TRAINING

If available, interviewers from the previous qualitative and quantitative studies can be used since they already have training in general interviewing techniques. Supervisors and interviewers are trained together. Training consists of two to three days of didactic training including standardized interviewing methods and procedures as well as specific orientation and practice with the instrument among themselves. They also learn to determine whether the interviewee is eligible for the impact study and, if so, how to conduct the recruitment and randomization procedures. During the training, interviewers and supervisors also discuss any special considerations that need to be considered when interviewing vulnerable populations, such as HIV-positive adults, active drug users, survivors of torture or other traumatic experiences, etc. Special considerations may include issues such as how to conduct safety monitoring, when to stop or pause an interview, and when to call a supervisor for assistance or consultation.

If providers will be conducting interviews, it is best to plan for specific workshop time to review the assessment instrument and the procedure for conducting interviews. A trial in Thailand had providers conduct the initial assessment; the box below shows the workshop agenda with notes on the activities conducted.

Example: Provider training on screening assessments and randomization assignment from the Thailand-Burma Border RCT

For this study, providers (counselors and clinical supervisors) were deemed the most suitable to conduct the interviews with potential clients. After their clinical training, the providers received three days of training specifically on consent forms, use of the assessment instrument, and randomization. Other topics covered included review of the safety monitoring steps and discussions about recruitment.

Day one was spent introducing the assessment instrument and algorithms used to score subsections to assess eligibilty for the study. This was done by reviewing the assessment instrument in full as a large group and taking time to answer questions along the way. Information was also provided on how to correctly record the information (i.e., circling the answer choices versus placing a checkmark, and writing numbers clearly).

Day two focused on practice using mock interview. For this activity, the three clinical supervisors played the role of the interviewee, and were each given an identical, pre-completed assessment instrument with which to guide their responses. The supervisors were asked to sit with a group of counselors, who took turns asking each question on the assessment and writing in the response given by the clinical supervisor. Ideally, at the end of the mock interview each counselor would have filled out their assessment form in a uniform and standard way; however, when this was not the case the trainers reviewed the mistakes with the small group and then again with the whole group. The afternoon took time to review the steps for safety monitoring and interview consent forms. A flowchart of the safety monitoring steps is included in Appendix A. Each provider reviewed and agreed to the steps for responding to need outlined in the flowchart , as well as the separate safety response form (Appendix B). Finally, the process for randomization (in this case sealed envelopes with stickers stating the randomization) was reviewed and each provider received two mock envelopes with stickers.

Day three again used pre-scripted interviews and role plays, but unlike Day 2 activities, each counselor went through the complete process individually with a respondent (clinical supervisor) including consent to the screening, consent to participate in the study (if the individual being interviewed met criteria), the remaining questions on the assessment, opening of the randomization envelope andplacement of the stickers, and the explanation to the individual about the process for waiting or receiving treatment immediately. The trainers (which included the field project director) reviewed each of the assessment forms completed during the pre-scripted role plays and reviewed mistakes with the whole group (e.g., minor errors such as forgetting to fill in the date, or signing the consent form but not marking “yes” that consent was given).

IF A PERSON MISSES ANY OF THE TRAINING ACTIVITIES — EITHER THE REVIEW OF THE QUESTIONNAIRE OR THE PRACTICE SESSIONS — S/HE CANNOT CONTINUE AS AN INTERVIEWER OR SUPERVISOR REGARDLESS OF THE CAUSE. WITHOUT THE TRAINING S/HE CANNOT BE EXPECTED TO USE THE INTERVIEWING METHODS CORRECTLY.

B.2 OVERVIEW OF THE IMPACT ASSESSMENT PROCESS

The remainder of this module describes the steps in the impact assessment process. These are:

1. Development of eligibility criteria for inclusion and exclusion in the study/program
2. Screening into study and the pre-intervention assessment
3. Allocation of participants to immediate intervention or wait control
4. Monitoring
5. Post-intervention qualitative assessment
6. Additions to assessment instrument based on #5
7. Post-intervention interview using expanded instrument
8. Data analysis

If the intervention is found to be effective the following steps are also implemented:

9. Provision of intervention to the wait control group
10. Implementing subsequent screening, provision of intervention, monitoring, and post-intervention assessment as an ongoing service program

B.3. DEVELOPMENT OF ELIGIBILITY CRITERIA

Some eligibility criteria are similar for all trials and others vary according to the problems being addressed by the intervention and the nature of the intervention. One criterion that is common across controlled trials is that the participants should not currently be a danger to themselves or others. Those participants need to receive urgent monitoring and treatment with interventions already known to be effective, rather than being randomized to either a wait control or to an intervention whose effectiveness is currently unknown. Also, interventions that require significant cooperation from the participant normally require that the participant is capable of such actions. If a participant must return for multiple treatment visits, for example, they are generally required to live in the area during the study, be capable of following a schedule (which may exclude severe mental illness including uncontrolled psychoses or severe cognitive deficits, for example), or have someone that can ensure that they return.

Criteria that commonly vary are those based on the study outcomes. These are expressed as the presence or absence of a problem, or (more commonly) its severity. We normally include severity in dysfunction as well. As described in Module 2, symptom and dysfunction severity are measured using scales derived from individual questions. Eligibility criteria then consist of meeting a minimum severity cutoff score on one or more of these scales (depending on which scale(s) measures the main study outcome). Calculation of the appropriate cutoff score is

usually done using the data from the validity study described in Module 2. There are various methods of calculating the most appropriate score. Each attempts to provide a balance between scores that are high enough to exclude most persons who don't have significant problems (i.e., good specificity) but low enough to include most persons who do have significant problems (good sensitivity).

One method of doing this is to generate a Receiver Operating Characteristic (ROC) Curve to plot each score's sensitivity and specificity for identifying cases. Cases and non-cases are defined in the validity data based on reports by self and others as to whether an interviewee has the problem being assessed (See Module 2). The score which maximizes both sensitivity and specificity is usually chosen as the cutoff score. ROC Curve analysis is available with most health statistics software and should be done by an experienced data analyst. Therefore, it is not described further here.

Other approaches can also be used, particularly if the researchers are more concerned about specificity than sensitivity or vice versa. The box below briefly describes an alternative and more arbitrary approach to cutoff selection that was used in a trial in Uganda where sensitivity was the greater concern.

Eligibility Criteria from an RCT of Treatments for Depression Among Adolescents Living in Internally Displaced Person (IDP) Camps in Northern Uganda (Bolton et al., 2007a)

To be eligible for participating in the RCT, adolescents had to meet the following criteria based on a locally validated quantitative screening instrument: (1) be above a pre-determined threshold of symptom severity for a locally-defined, depression-like mental health problem; (2) have symptoms that lasted at least one month; and (3) have some degree of functional impairment. Additional inclusion criteria were being able to understand and speak the local language (*Acholi Luo)* and having lived in either of the two study IDP camps for at least one month prior to the screening. Exclusion criteria included the following: (1) having a severe cognitive or physical disability (leading to an inability to answer the questions); or (2) actively suicidal or having intent to hurt others (due to their need for immediate treatment).

The threshold for depression severity was determined based on data collected during the validity study of the quantitative screening instrument for depression. During the validity study, 72 youth (out of the 178 in the study) were identified by themselves and local informants as having significant depression-like problems (based on the local syndrome similar to depression) and therefore regarded as having significant depression. The average score on the composite depression score for this group was 48 points (sd 16.1). To ensure that we included many of the youth experiencing a significant amount of depression symptoms and not only the most severe, we chose a cut-off score of one standard deviation below this average score (32 points).

B.4. SCREENING INTO THE STUDY AND PRE-INTERVENTION ASSESSMENT

Persons are screened for entry into the study on the basis of the eligibility criteria. All criteria (see Section B.1) are built into the study instrument so that the research/program team can determine from these records whether a person was included or excluded correctly.

B.4.1. FINDING PERSONS TO BE SCREENED

Normally, a combination of approaches is used to enlist persons for screening interviews. These can include publicizing the availability of screening via local leaders or other influential persons, through local organizations or town hall meetings, or using available media sources such as newsletters and radio. Service providers frequently have such connections, including those created during previous steps in the DIME process. Publicity can either encourage all persons to be screened or specify those who feel they may have the problems being assessed and treated. If there has been a prior prevalence study using the instrument, participants who were interviewed at that time can be encouraged to return for screening, particularly those who felt that they had many of the problems described in the prevalence interview. If contact information was collected in the prevalence study, those persons found to be eligible could be contacted directly for re-interview. Similarly, persons who participated in the validity study (all interviewees or specifically those found to be eligible) could also be encouraged to return for screening. In some of our study sites the intervention was ready to proceed when the validity study was done and the validity testing produced only minor changes in the instrument. In those sites, screening interviews began immediately after the validity study, while those validity study interviewees who met the study criteria were invited to join the study without repeating the interview. However, this is possible only when the validity study results in few changes and the intervention begins within weeks of the validity study interview. Otherwise, the screening must be repeated.

A trial in Thailand found that publicizing the availability of screening through local leaders, posters flyers, and information provided on a radio program was not producing as many people for screening as had been anticipated. This was the case even though the posters and flyers were specifically designed for people with low literacy and acceptable to the community, and the radio program was widely listened to by their target population. After meeting together, the counselors and clinical supervisors, with support from other project team members including the local project coordinator and the field project director, decided to approach recruitment by holding informational meetings in the community where snacks were provided and providers went in small groups to discuss the project and mental health in general with those present. They found that this approach, compared to one-on-one recruitment and the

other approaches mentioned above, worked within the community because the community saw them as service providers instead of a single individual coming to speak with someone about the stigmatized topic of mental health. In addition to these informational meetings, the providers found that referrals from currently enrolled clients were especially helpful, and worked with their clients for introductions to others that they felt would be interested in, or could benefit from, the services being offered.

B.4.2. SAMPLE SIZE AND RECRUITMENT

The screening and recruitment process continues until the number of persons who meet the inclusion criteria and agree to participate in the study is at least as large as the number established by sample size calculations.[1]

In our research we have compared the mean change in the intervention group with the mean change among the control group, either for a symptom or function score (depending on which is considered to be the primary outcome). We have arbitrarily decided that a difference in mean change of 20% between groups is programmatically significant. Therefore, we have used this 20% difference to calculate sample sizes. We have also used the standard figures for power and alpha of .8 and .05, respectively. For most studies we have found that these figures and the local variance estimates have suggested a sample size of 80-100 persons per study arm. This means 80-100 clients who complete the intervention and 80-100 clients who complete the wait period, all 160-200 of whom complete the pre- and post-intervention assessments. To calculate the number of persons who need to be **recruited** into the study we typically estimate that approximately one third of the intervention group will not complete treatment (i.e., withdraw and be lost to follow up), therefore inflating the number of persons to be recruited into the intervention arm (i.e. found eligible, agreed to participate) to 110-130. Numbers for controls can be less, since there is not the same concern about dropping out of treatment. However some controls may also not be available for post-intervention assessment (they may have moved, decided they did not want to be re-interviewed, developed a health issue, died, or otherwise become lost to follow-up). For controls, we usually recruit approximately 90-110. The box below is an example of how a sample was recruited in Uganda.

[1] A discussion of the issues involved in sample size calculation, and references to sources of methods for doing these calculations can be found at http://www.consort-statement.org/consort-statement/3-12---methods/item7a_sample-size/

Example: Sample Recruitment from the RCT in Northern Uganda (Bolton et al., 2007a)

All participants in the instrument validity study conducted immediately prior to recruitment were considered for inclusion in the impact assessment (n=178). Of these, 98 (55%) met the inclusion criteria. With the goal of enrolling a total sample of 300 youth in the intervention study (100 in each study arm: a control and two interventions), additional youth were screened from the two IDP study camps. To increase the likelihood that those screened would be eligible, interviewers asked knowledgeable local people to refer adolescents they thought had the locally-defined depression-like problems described in the preliminary qualitative study (see Module 1). These referred youth were then interviewed using the validated screening instrument. In order to find more referrals, the interviewers also asked the interviewees if they knew of others their age that also have these problems.

Using this referral system, an additional 489 adolescents were referred and screened, resulting in a total of 667 adolescents being screened. From these 667, 300 youth met the cut-off criteria: a) a depression score greater than 32 points; b) symptoms lasting at least one month; and c) some degree of functional impairment.

Program staff visited the eligible youth and enrolled those who agreed to be in the study (289, or 96%). With 289 youth enrolled in the study, it was necessary to expand the number of participants in order to achieve the sample size of 300. We therefore reduced the depression cut-off score to 28 points, which resulted in an additional 39 adolescents being added to the study eligible sample. Of this 'extra' group, 15 were recruited into the study. The other 14 adolescents were not contacted for study inclusion because the target size of 300 youth for the trial had been met. The inclusion of this small number of youth with lower baseline depression scores was necessary to ensure a large enough sample to effectively evaluate the intervention effects, but slightly reduced the average depression scores in each study group. In the end, a total of 304 youth agreed to participate in the study.

Recruitment is done either as a single cohort or as rolling admissions. In a single cohort study, all persons begin and complete the intervention at the same time. This is typically done where there is sufficient capacity to recruit and treat the entire required sample size simultaneously. However, recruitment often occurs more slowly because there is not the capacity to offer services to the required numbers all at once. For newly trained providers of interventions it is often preferable to begin with a small number of clients and later expand as their abilities increase. Under these circumstances we use rolling admissions: providers begin to treat clients as they are recruited until reaching their capacity, which varies based on whether they are working full time (three to five clients seen at a time) or part time (two to three clients at a time). New clients are then recruited to replace those who finish treatment until the sample size is reached (although in a normal program, recruitment and treatment of clients will

continue beyond the research). Those allocated to the wait control begin to receive treatment once their designated wait period is completed, based on availability of a provider, if they request to receive the treatment offered after their wait period. Completion of a study takes much longer with this rolling admission approach. Wait time depends on the number and capacity of the providers and the sample size.

Example: Rolling Admissions in the RCT in Kurdistan, Iraq

Eligible participants for this study were randomized into either a treatment condition (1 of 3 possible therapies) or to a wait control condition. Recruitment of participants through our local partners in Iraq began immediately after 46 community mental health workers (CMHWs) were trained on the different types of therapies.

Participants who were randomized to the treatment condition started the intervention immediately. Participants who were randomized to the wait control were asked to wait approximately five months. They were reassessed at that time and then began one of the three therapies, whichever had been assigned to their respective CMHW. Participants did not all start their interventions (or wait period) at the same time, however. Instead, they were enrolled into the study as they were referred to us through our local partners and torture survivor networks in Iraq. We continued recruiting participants until we reached our desired sample size of 130 participants in each of the four study arms (three therapy types plus the wait condition), for a total of 520 participants. This rolling admissions process was necessary, in part, so as not to overburden the CMHWs, most of whom had only recently been trained on these new types of therapies. As participants finished their 12 intervention sessions and spaces opened up in the CMHW's course loads, new participants (or those whose five month waiting period had ended) took their places. Even outside the context of research, a typical course of treatment provided by a CMHW was 12 sessions over four to five months. This means that when CMHWs had full course loads, there may have been a waiting list of up to five months. This was further justification for rolling admissions, as well as using a wait-list control group.

B.5. ALLOCATION OF PARTICIPANTS TO INTERVENTION OR WAIT CONTROL

Allocation of participants to study arms should occur only **after** determining eligibility and securing their informed consent to participate in the study. Common methods for random allocation of participants to study arms include the following:

1. *Simple random allocation*: Participants names or ID codes are randomly assigned to a study arm
2. *Stratified random allocation*: Participants are first grouped into categories relevant to the setting and interventions provided. Categories might include gender, age group or

site where they live or receive services. In this process, the names of participants from a single category (e.g., age group, gender) are all put together and then names are picked at random from within the category and randomly assigned to a study arm

Stratified random allocation is the more commonly used approach, in order to ensure balance among various factors considered to be important. Examples of stratified randomization are provided in the boxes below.

Example of Stratified Random Selection from the RCT in Northern Iraq (unpublished)

This study assessed the impact of an intervention being provided by 20 Community Mental Health Workers (CMHWs). We wanted to ensure that the CMHWs each had the same number of both clients and controls, in order to equally share both the amount of work and the influence of each CHMW on the final results. The randomization process had the following steps:

1. We generated a patient list for each CMHW. This list included patient ID numbers in sequence (i.e. 1-20). Next to each patient ID number was an assignment to immediate therapy or wait control. For this study these assignments were generated at random and separately for each list by the study director using a computer random number generator. However, it could also be done by hand using a random number table: to generate equal numbers of intervention and controls, assignment can consist of reading a line of 20 single digit random numbers in the table. The first number could correspond to the first patient ID and each successive number corresponding to the next ID up to 20. Each odd number could indicate assignment to the intervention group and even numbers to the wait control group (or vice versa).

2. For each CMHW, individually sealed envelopes with a paper indicating the treatment assignment (immediate therapy or wait control) were stapled directly to consent forms that were pre-numbered with a patient ID number.

3. Once a patient consented to be in the study, the CMHW opened the envelope attached to the form and informed the patient whether they would begin the therapy immediately or be assigned to the wait control group.

The study investigators kept master lists indicating the appropriate treatment status (intervention/wait-control) for each patient ID number to ensure fidelity to the randomization model.

Example of Stratified Random Selection from the RCT in Northern Uganda (Bolton et al., 2007a)

The 304 eligible youth who agreed to participate were stratified into four strata: boys in camp A, girls in camp A, boys in camp B, and girls in camp B. Within each stratum participants were randomly assigned to one of the three study groups: (1) Creative Play; (2) Interpersonal Therapy – Group; and (3) Wait Control. This was done in order to achieve equal gender and camp distribution across the three interventions, as we suspected that gender and camp could affect how children responded to the intervention. Random assignment was done within each stratum by the study director. For each stratum the director formed a list of all participants. He then began reading from a random number table (the starting point is irrelevant) and when he reached a one, two, or three, he assigned the first child to the corresponding study group. He then continued reading the table, using the same system to assign each child in turn to one of the three study groups.

B.6. MONITORING

Three types of monitoring are conducted simultaneously during trials of mental health interventions:

1. Program monitoring using process and outcome indicators designed during the planning phase using a logframe and/or other design process (See Module 4).
2. Monitoring of the intervention itself with respect to quality and treatment fidelity. This is done as part of the clinical supervision process and focuses on service quality and fidelity to the treatment process (See Module 5).
3. Monitoring of adherence to the study design. This includes monitoring correct initial assessment and screening into the study, consent procedures, refusals, safety monitoring, dropouts, lost to follow up, monthly calls/regular contact with control clients, sessions with treatment clients, and follow up assessments with control and treatment clients.

Program monitoring is described in detail in Module 4 and therefore is not discussed in detail here. The same is true for intervention monitoring (See Module 5) except for one aspect which has important implications for impact assessment. This aspect of intervention monitoring, and the monitoring of adherence to study design (#3) are described below.

Example of Maintaining Fidelity During an RCT of Counseling Treatment Among Torture and Trauma Survivors from Burma Now Living in Thailand

For the majority of counselors in this project, providing systematic counseling was new at the start. In order to explain the issue of fidelity and the need to keep treatment for clients consistent between counselors and over the course of the study, the project team adopted the motto to "cook the curry in the same way". The research team director explained to the team, specifically to the counselors, that in order for the research to be able to be conducted all providers needed to follow the steps as they were trained to do so. This phrase was used often by the research team, trainers, and clinical supervisors to continually remind the counselors about the need to be consistent with how they provided the counseling.

In this case, the example was a light-hearted reminder to help the counselors understand the need for fidelity.

B.6.1. INTERVENTION MONITORING TO ITERATIVELY IMPROVE THE INTERVENTION AND PROGRAM

Module 5 describes how the clinical supervision system enables training to continue during implementation. In fact, most skills are developed during implementation in supervision, which is why this approach to clinical supervision is referred to as an 'apprenticeship' training model. Under this model, local clinical supervisors are trained with the providers and subsequently meet with them weekly to review their cases. The supervisors also communicate weekly with the trainers (to date these trainers are U.S.-based and have conducted these meetings by phone or Skype). In this way both the clinical supervisors and providers continue to receive training in their roles while maintaining treatment quality and fidelity through ongoing engagement with the trainers.

This ongoing interaction between the levels of client, provider, supervisor, and trainer/expert has important implications in conducting trials. People at these levels must also have close contact and cooperation with other project staff in the field (i.e. study director, research supervisors, or other project staff). Such contact facilitates the detection of problems at all program levels during implementation, collective problem solving through discussion between the various levels, and testing solutions. This allows for evolution of the intervention during the course of the trial.

Normally trials do not allow changes in the intervention once the trial has begun. This is to ensure that everyone receives the same intervention. Therefore, when the trial is completed it

is clear exactly what form of intervention the results refer to. Keeping the intervention constant in this way may work well for trials conducted in countries where the interventions have already been implemented and refined, often based on experience among many populations and over many years.

Where interventions are being introduced for the first time and tested at the same time, this approach does not work well. This is particularly true in low resource settings and in non-Western cultures, both of which are different from the settings where most existing interventions were developed. Despite our best efforts to seek out local advice, adapt interventions accordingly, and then pilot test them, subsequent implementation typically reveals new and important issues. Frequently these problems are clearly so important that failure to address them during the trial would render the trial irrelevant, since future implementers would have to address them anyway.

For this reason, we recommend that studies have a period following training where providers have an opportunity to meet with a real client, but the data from that client will not be included in the study. This allows the providers more practice and time to increase their confidence, and also allows the clinical supervisors, trainers, and other project team members to see problems that arise and address them as appropriate before enrollment into the study begins.

Example of Implementation Problems Emerging During Multiple RCTs

Below are examples of problems emerging at each of the four levels of implementation, and consequent changes in the Iraq RCT:

1. Clients: Between sessions, clients were typically required to complete self-assessment forms at home recording change in behaviors. Many could not do this because they were illiterate.

   Change: Visual representations were created of both the concept being assessed (in this case, activities) and the amount of change experienced.

2. Providers: Families of clients did not want them coming for treatment, and were angry with the providers. They believed that a non-medication treatment such as counseling could not be effective, and seeking treatment stigmatized the whole family.

   Change: Early psycho-education sessions were expanded to include family members.

3. Clinical Supervisors: Despite emphasis in the initial training, providers continue to have difficulty distinguishing between 'thoughts' and 'emotions' and explaining these differences

to clients.

Change: Additional training materials were created by the trainers. These materials were used in additional training sessions for the providers conducted by the supervisors.

4. Trainers: Clients were taking too long to complete the 12 weekly hour-long sessions. Instead of two to three months some clients required up to four to five months because they found it difficult to come to the clinics weekly.

   Change: Duration of sessions was expanded to 2 hours whenever possible, thereby reducing the number of visits required.

Below are examples of problems emerging at each of the four levels of implementation, and consequent changes in the interventions in the Thailand-Burma RCT:

1. Clients: Due to limited time for counseling, Clients expressed that the length of time to complete all sessions would be too long for them to commit to participating.

   Change: Counselors combined the topics of "encouraging participation" and "psychoeducation" into one session, which was not originally planned.

2. Providers: Community members were not familiar with counseling and mental health. They believed that providers were "looking for crazy people," and did not want to be associated with the providers.

   Change: Providers put enrollment activities on hold in order to develop awareness-raising posters and pamphlets in easily understood local language and with pictures to aid those with low literacy. In addition, they held small group community discussions to talk about their work and answer questions and produced a radio program on a station frequently listened to by the community.

3. Clinical Supervisors: Despite emphasis in the initial training, providers continue to have difficulty in distinguishing between 'thoughts' and 'emotions' and explaining these differences to clients.

   Change: Additional training materials were created by the trainers. These materials were used in additional training sessions for the providers conducted by the supervisors.

4. Trainers: Clients often cancelled appointments and reschedule for the next week, which meant that it was taking too long to complete the weekly hour-long sessions.

   Change: Providers started rescheduling appointments within the same week in order to try to keep the overall length of treatment as planned.

For these reasons, we allow changes in the intervention during the trial. These changes are made under the following conditions:

1. The changes are clearly important to the program's success, such as improvements to address poor access.

2. All changes occur at the same time for all participants/providers/supervisors. It is often helpful to distribute a written memo about the changes, translated into the local language, so that all providers, clinical supervisors, and project team members are clear about the changes and reasons for the changes.

3. Changes should not be fundamental to the type of counseling being provided, but instead refer to how the intervention is provided or changes in the relative emphasis of different content areas. If fundamental changes are required then the intervention is clearly inappropriate and the trial is not required. For example, enhancing the psychoeducation element of an intervention to help clients better understand the intervention would be a change in emphasis rather than a fundamental change. Similarly, providing treatment using fewer but longer sessions to make access easier would not be a fundamental change but a change in how the intervention is provided. On the other hand, removal of behavioral aspects of cognitive behavioral therapy (CBT) would be a fundamental change in that the remaining treatment would no longer be CBT.

Changes are made in response to problems that have emerged during the study, and are only retained if continued monitoring demonstrates that they have worked. Therefore, these changes increase the likelihood that the intervention will be found to be feasible and effective. Since final analysis will still include those who participated before the changes were made, the results will actually underestimate the impact of the intervention.

Once the trial is completed, the results refer to an evolving (but fundamentally the same) version of the intervention and how it is provided in the program context.

B.6.2. MONITORING CORRECT IMPLEMENTATION OF STUDY DESIGN

Monitoring correct implementation of the study design means following participants as they pass through the various stages of the trial, as well as finding and tracking those who are lost to follow up or who refuse to participate. This is done by means of various instruments that track, at the individual and group levels, assessment and screening into the study, consent procedures, refusals, adherence, safety monitoring, dropouts, lost to follow up, monthly

calls/regular contact with control clients, sessions with treatment clients, and follow up assessments with control and treatment clients.

Monitoring overall recruitment progress

Figure 3 shows part[2] of a tracking tool used in a study in Southern Iraq to monitor the status of recruitment on a weekly basis (Weekly Recruitment Form).

Figure 3: Weekly Recruitment Form

FIGURE 3. WEEKLY RECRUITMENT FORM

CMHW Identification		Week (19/03/11 – 25/03/11)				Week (26/3/11 – 01/04/11)			
ID	Name	Total Intake	Total Number Torture Survivors	Total Eligible	Total Agreed	Total Intake	Total Number Torture Survivors	Total Eligible	Total Agreed
		0	0	0	0	0	0	0	0
		0	0	0	0	3	3	3	3
		0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1
		0	0	0	0	2	2	2	2
		0	0	0	0	4	4	3	3
		0	0	0	0	4	4	3	2
		1	1	1	1	1	1	1	1
		3	2	2	2	0	0	0	0
		0	0	0	0	2	2	2	2
		0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
	Total for the week	5	4	4	4	17	17	15	14
	CUMULATIVE TOTAL	5	4	4	4	22	21	19	18

This tool has space to track the number of study participants recruited by each provider (called Community Mental Health Worker or CMHW) per week as well as the cumulative total. It is maintained and used by the field project director. Tracking the volume and pace of recruitment helps the director determine if the research is on track to meet participant number requirements given time and budget constraints. If not, study managers can make adjustments in activities or in personnel or other resources in order to meet study deadlines.

[2] Only 2 weeks are shown in this example; the complete form would include every week of the study.

A study in Thailand used a similar system, but did not track enrollment by week and instead used an overall recruitment tracking form. Appendix A shows this tracking form ("Study Recruitment"), which lists the names of all potential clients and their contact information. This form was then updated if the person was enrolled (or ineligible), refused (either refused the screening assessment of refused to be in the study), or could not be found to complete the assessment. When the "status" column was blank, this meant the person had not yet been contacted. This form was only viewed, and maintained, by the field project director because it included client name and contact information. Similar to the Southern Iraq study, however, the field project director in Thailand regularly counted and checked the enrollment numbers to monitor the progress for the overall study.

Figure 4: Study Recruitment Tracking Form

Figure 4. Study Recruitment Tracking Form

Number	Organization	Sex	Age	Name	Contact	Location	Assigned	Status
1	MTC	F	79		c/o Counselor 22	Central Market Area	22	Enrolled
2	AAPP	M	36		0824093899	Buffalo Farm	16	Refused
3	MTC	M	38		0827943800	Htung Htaung	24	Didn't meet
4	SAW	M	83		c/o Counselor 18	Mae Pa	18	Refused CBI
5	SAW	F	28		0824093800	Mae Tao	32	
6	AAPP	F	35		0719693800	Baan Tung	36	Enrolled

Monitoring individual participants' progress through the study

In order to have confidence that research procedures are being followed, it is important to track key events outlined in the research plan. Key events include the following:

- Screening of potential participants before trying to recruit
- Recruitment of participants following randomization procedures
- Obtaining consent of participants prior to enrollment
- Follow up with participants who do not comply with research or intervention procedures
- Monitoring participants for signs of danger (e.g., suicide).

Appendix B shows the client tracking form used in a Southern Iraq RCT. This form tracks events by study participant and is organized by provider (CMHW). The form tracks dates of key events such as intake, consent, sessions, calls to control clients, drop out of the study, exit interviews, etc. There is space for comments about the study participant. The random allocation of the client to intervention or wait control is also indicated (this is unknown to the therapist prior to

enrollment of the participant). For this study site in Southern Iraq, a photo of each provider was also inserted into the tracking form.

Appendix C ("Project Log") shows a completed version of the same type of form (for a few participants only). In this example, participants are grouped according to their provider (not shown). Each row represents a study participant, beginning with the client ID. Each week the progress of each participant was recorded through the various study stages (each row represents one participant) by entering the date of each event when it occurs. For those in the intervention arm most columns represent each of the intervention sessions, whereas for controls each column represents the date of a regular check-in to ensure their safety while they await treatment. The second-to-last column records the date of the repeat assessment, while the final 'comments' column records any current issues with the client that affects their participation and what is currently being done to address this. Comments here typically refer to problems in finding the participant and/or compliance. This column is also used to record who conducted the final assessment in case of problems with the assessment (all names of both clients and staff in the original document have been removed).

Dropouts from the study are highlighted in the log. Dropouts will often disappear or refuse to be contacted again. However, providers and/or supervisors make special efforts to contact these persons. The purpose of these contacts is primarily to find out why the person dropped out (in case this is something that is correctible for this person or relevant to the program overall), ask them to return to the study or, if they refuse, to conduct the repeat interview. When the final analysis is done these interviews are used as part of the post-intervention assessments regardless of whether the participant completed the intervention or control period.

A study in Thailand used a similar form for tracking individual participants' progress through the study. Minor changes were made, as can be seen in the example in Appendix D. For example, for security reasons, photographs of counselors were not included on the form. In addition, since gender was recorded on the master recruitment list mentioned above, the information was not included here. Tracking of the consent forms was not done on this form either. Additional information was recorded on the Thailand form, including more detailed information on the criteria and scoring on the criteria algorithms. Finally, this study modified the columns at the end to show status (recorded as "COMPLETE," meaning that initial assessment, wait period/sessions completed, and a follow up assessment completed), whether or not counseling services (in this case Components Based Intervention) were requested by control clients after their wait period, whether other services were received during the study, if monitoring forms were completed (weekly for treatment clients and monthly contact calls for wait control

clients), as well as the status of weekly forms and assessments for control clients who requested counseling after their wait period. Similar to the form used in Southern Iraq, this Thailand study had a comments area; however, this did not track who completed the follow up assessment (because each interviewer used a unique identification number written on the form at the time of the assessment, but did track additional notes on the status of the client.

For this site in Thailand, the field project director received the weekly forms by email and used these, in addition to information obtained through regular meetings with the clinical supervisors, to update the overall tracking form.

Because information on randomization for the assignments is included on this form, the form is only viewed by the field project team and other research team members not directly involved in providing services. This is so that service providers and their clinical supervisors remain blinded to the randomized assignments of future participants, to protect against potential bias.

Follow up assessment scores and information on status for meeting criteria are not included on these types of project tracking logs. This is so that all members involved in the study are blinded to the outcomes for both control and treatment clients.

Monitoring each contact with participants

In the Southern Iraq RCT, the research design submitted for approval to the institutional ethics review board (IRB) included making referrals for study participants deemed a danger to themselves or others. For example, if we identified a study participant who we believed was about to commit suicide, the study participant would be referred to a hospital or psychiatrist for care. For this reason, we developed a system to monitor study participants for these issues on a regular basis. Providers referred such participants to their clinical supervisor (a psychiatrist) who would help make the determination about where to refer the client. Appendix E is a client monitoring form that Cognitive Processing Therapy providers used at the beginning of each therapy session to screen for these dangers. A similar form was developed for the other intervention and for controls. Intervention participants were assessed at each weekly session, while controls were assessed by telephone or met briefly at the provider's clinic on a monthly basis.

A research site in Thailand used a similar system for monitoring each contact with participants. Appendix F shows the client monitoring form that Components Based Intervention providers used at the beginning of each session to track overall progress, and specifically screen for safety issues. Appendix G shows the client monitoring form that this same study used for follow up

with control clients. The local project coordinator attempted to contact each control client on a monthly basis (either by phone or in person) to complete this form.

For this study in Thailand, the counselors, clinical supervisors, and other members of the research team developed a safety monitoring system and response plan. Appendix H shows the flow chart used to explain the steps providers must take at every point of contact with clients.

Using Google Documents to monitor study procedures

In Southern Iraq, Google Documents was used as a workspace for the monitoring forms and processes described above. First, study tracking forms were created as Google spreadsheet documents and were located online only in a project Google Documents folder. Data entry and review of the tracking forms was done directly online. Comments or action items were indicated using coloring of cells in the spreadsheet and adding comments with questions or instructions for action.

Second, key documents were scanned into a *.pdf format (intake forms, consent forms, client monitoring forms) and uploaded to a Google Documents folder. This helped prevent loss of key project documents during transport. This also allowed us to double check that events documented on the tracking sheets actually occurred. For example, if the consent of a participant is indicated on the tracking sheet, we could verify if the signed consent form actually existed by checking the Google Documents folder for the scanned document. Tracking contact with clients and controls was facilitated by completing (and scanning) a unique Client Monitoring Form for each therapy session of intervention participants and for each call to a control participant.

The research site in Thailand also used Google Documents and created three separate files online:

1. Master Recruitment List: A list of all potential clients and information for each person regarding subsequent enrollment, refusal, or non-availability to be contacted. This document was only accessed and edited by the field project director. (Appendix I)

2. Project Log: A spreadsheet to track each study participant throughout the study, organized by provider. This document was only edited by the field project director, but was made available for viewing by others in the research team who were not living at the project site. (Appendices C-E)

3. Wait Control and Follow-Up Assessment List: Two pages were saved in the same spreadsheet. The first listed the names and contact information for all control clients and noted the date their wait period would end. The local project coordinator used this list to make the regular monthly calls to control clients and track completion of or attempts for these calls. The second page listed all clients (treatment and control) in order of their expected follow-up assessment date. This list was then used to give the interview assignments to the external interviewer responsible for conducting follow up assessments. When the list was used to create the interview assignment sheet, information on the randomization assignment for each client was removed. Only the field project director and local project coordinator has access to and ability to edit this file. (Appendix J)

B.7. POST INTERVENTION QUALITATIVE ASSESSMENT

B.7.1. QUALITATIVE ASSESSMENT AMONG STUDY PARTICIPANTS

At the start of a study, a qualitative assessment is conducted among a sub-set of study participants in each of the study intervention arms who have completed the study activities (completed treatment or the wait period) to identify positive and negative *unexpected effects* of the program (i.e., effects not assessed at baseline with the original study instruments).

The purpose of this assessment is to identify significant unexpected effects and add questions about these effects to the quantitative assessment instrument before it is used for future screening/enrollment and for the post-intervention interviews. Doing so provides a method to measure both the expected and unexpected effects of the program. We consider this important because unexpected effects, both positive and negative, can be significant.

About 20 participants are needed per intervention (therefore, 40 would be needed for studies with 2 intervention arms). They can either be a convenience sample or purposively selected to represent the range of important variables (e.g., age group, gender, site). In the case of rolling admissions, the qualitative study is conducted among the first 20 clients to finish each intervention. Since the interviews refer to effects of the intervention, controls are not included.

Data collection consists of Free Listing interviews (see Module 1). Normally, two Free Lists (FLs) are completed with each participant, although the number of FLs and the primary question(s) can vary (see example below). The primary question for the first FL asks about all the changes that have occurred for self, family, and community (if relevant) since the respondent began the intervention. The second FL primary question asks about all the changes to

self/family/community that are **due to** the intervention. The purpose of the first FL is to explore all changes the client is aware of including those which the participant many not recognize as due to the intervention (but may be so). The second FL acts as a specific follow up to the first FL. However, clients can give responses on the second list that do not appear on the first, simply because they did not think of them beforehand.

As with other FLs, a secondary question probes for more information about each change mentioned. Probing also includes specifically asking about both positive and negative changes in ways that demonstrate that the interviewer is expecting both to be present. Otherwise interviewees may be reluctant to mention negatives. Finally, interviews may include asking for suggestions about how to improve the program. See Appendix K for an example of a completed FL form.

Analysis of the FL forms is conducted in the same way as described in Module 1. The left and right columns on both FL forms are analyzed together to generate a single list of items. Using the FL analysis approach in Module 1, the final result is a list of changes in order of decreasing number of respondents who mentioned each change (which provides an indication of relative importance). The box below is an example of the process and summary of the results from a trial in Uganda.

Example: Results of a Post-intervention Qualitative Study from the RCT in Northern Uganda (Bolton et al., 2007a)

As part of the post-intervention assessment, a small qualitative study of intervention A and B participants and their caregivers was carried out to learn about unexpected effects of the interventions that were not assessed by the original study questionnaire. Ten of the interviewers from the pre-intervention qualitative study conducted the interviews. They received refresher training on qualitative interviewing methods and specific training on the questions used for this study. In order to get a variety of experiences, the intervention providers were asked to provide names of five to seven youth per camp whom they thought had substantially improved over the course of the intervention period and names of five to seven youth per camp whom they thought had not improved, or had not improved as much as others. These names were given to the interviewers without revealing the level of reported improvement, so as not to bias the interviews. The primary FL questions referred to changes in participants in general, rather than to just the respondent or any other specific participant. The specific questions and probes used to gather this information were developed by the researchers in consultation with the interviewers, all of whom had experience interviewing local youth.

For this study the research team decided to use the FL primary question: “Tell me something that children got as a result of the program.” Additional probes were used to generate information about

changes that affected the participant, their families, and other people in the communities in which they live. They were probed about positive and negative changes as well as for suggestions about how to improve the programs. A total of 25 youth (15 for intervention A and 10 for intervention B) and 20 caregivers (11 for A and 9 for B) were interviewed in this way.

Among the intervention A child respondents, the most frequently reported benefits of the program included the following: learning new ways of playing; meeting new people and making new friends; being more obedient and respectful to caretakers and teachers, including listening to them more; and having more unity with other children and staying together with them more than they used to. Many of the children spoke about how, before the intervention, they did not like to be with other children or they felt hatred towards others, but after the program they felt love towards others and did not stay alone anymore. For those who spoke about school-related issues, they mentioned that they now went to school regularly, listened to their teachers, and enjoyed their studies. The intervention A caregivers (interviewed separately) corroborated the child respondents' comments and added that the children were more obedient, would do housework without being told, and interacted better with other family members (including a reduction in quarreling) and with neighbors. In addition, both caregivers and children indicated that the caregivers trusted their children more and there was more respect between them.

Among the intervention B child respondents, the most frequently reported benefits included the following: reducing their worries; bringing them together with others and creating unity among their peers; helping them figure out ways to earn money or start income generating activities; reducing their thoughts of suicide; and being more obedient and respectful to others. Intervention B caregivers voiced the same changes as the participants and added that the children were more obedient, seemed happier, and did more housework without being told. They also spoke about their children's ability to give good advice to other children and to other family members.

Overall, the qualitative reports from the participants in both interventions indicated similar positive changes in how the children behaved and how they interacted with others, with the exception that more B than A youth indicated that they had learned about ideas for income generating activities. We interviewed both adolescents who had been identified by the group facilitators as 'having improved' and those who were identified as 'having not improved' and found no differences in the types of responses given; all of the adolescents and caregivers indicated that they thought the programs were helpful and should continue.

B.7.2. ADDITIONS TO ASSESSMENT INSTRUMENT BASED ON POST INTERVENTION QUALITATIVE ASSESSMENT

Frequent responses to the qualitative assessment form the basis for questions that are added to the post-intervention quantitative survey instrument. Depending on the nature of the program, less frequent responses may also be selected if they are changes related to the study outcomes or research questions of interest. For example, an infrequent response referring to

improved income may be included if the overall program is seeking to improve the local economic situation.

Questions are worded to ask whether the participant has experienced the change since the intervention began or within a similar time period, either as a yes/no question or quantified in the form of a Likert type scale (based on magnitude or frequency). Analysis explores whether there are differences in the responses between intervention and control groups to determine whether the change is really due to the intervention.

An example of how post-intervention qualitative data is used to generate additional questions is provided in Appendix L.

A similar example of the need to add additional questions to the assessment based on post-intervention qualitative data is provided in Appendix M.

B.8.3. QUALITATIVE ASSESSMENT AMONG PROGRAM STAFF

Providers implementing the intervention(s) may also be interviewed using individual interviewing methods such as free listing and semi-structured interviews, or group methods such as focus groups (FGs). These interviews explore facilitators and barriers to program implementation. This is done not to expand the quantitative instrument and widen impact assessment, but to learn ways to improve program implementation in the future.

Regardless of the method, interviews begin with an open-ended question about the project staff's experiences implementing the intervention. Providers are then asked follow up with probing questions about aspects of the program that were particularly helpful and those that were problematic or challenging. Positive and negative aspects of the program implementation (both expected and unexpected) are specifically probed for. Participants are also asked for their advice on future implementation.

The box below gives an example of the process and summary of the results from a trial in Zambia.

Example: Qualitative Assessment Among RCT Program Staff in Zambia

All counselors were contacted and asked to participate voluntarily. As all counselors spoke English, their interviews were conducted in English. The interviewers worked in pairs, with one being the lead interviewer and the other being the primary recorder. After each interview, the interviewers compared and consolidated their notes.

Participants were asked a series of six open-ended questions about their experience with TF-CBT. The six questions were:

1) Tell me about your experience with TF-CBT (the intervention).
2) Tell me about the challenges of the TF-CBT program.
3) What did you like about the program?
4) What did you dislike about the program?
5) Describe any changes in the clients/family/child/self (depending on who is the respondent) since starting the treatment?
6) Tell me about any recommendations for the program.

Interviewers used open-ended probes such as "tell me more about that," or "explain/describe that" to elicit additional information about responses.

Specific counselor responses across all questions fell into the broad categories of: a) Likes; b) Dislikes; c) Perceived changes in children and families; d) Cultural adaptations; e) Training and supervision; and f) Suggestions for improvement. The most frequently mentioned included terms (four or more counselors stated similar responses) are presented in Table 1 below, with brief summaries.

Table 1: Most frequently mentioned terms by Program Staff in Zambia Qualitative Assessment

Cover Term	Included term summary	Number reporting
TF-CBT is a good program	The skills counselors learn from TF-CBT are useful in their own life	9
	Structure of the program was useful to the counselor; easy to follow.	7
	The benefits of the program extend beyond patients – to the parents and counselors themselves	7
	TF-CBT builds the relationship between caregiver and child	6
	Involving the caregiver as the support system for the child is an important strength of the model	6
	TF-CBT is empowering	5
	TF-CBT is flexible - you can adapt it to the client	5
	Benefits for the clinicians to be involved in this	5

Cover Term	Included term summary	Number reporting
	The program is practical – both the exercises and the skills taught	4
	People appreciate the program	4
	Helps children get over/come to terms with thoughts and feelings	4
	Good program for sexual abuse	4
Challenges	Poor attendance at and/or commitment to therapy sessions	15
	TF-CBT duration is too long	9
	Challenges for first-time counselors	6
	Community misconceptions and/or lack of awareness of TF-CBT	5
	Challenging to explain TF-CBT in the local languages	4
	Difficult to talk about sex in our culture	4
Perceived changes in children and families	The child is more open (to talk about problems/trauma with the caregiver and others)	17
	Overall positive change/growth (attitudes, more trust, sleeps better, learns about feelings and thoughts, goes to school, good hygiene, self-esteem, self-confidence, less angry, more relaxed)	14
	Improved child/caregiver relationship.	11
	Increased support from caregivers	7
	Development of positive/helpful thoughts	7
	Caregiver learns parenting skills	5
	Child socializes more/better	5
	TF-CBT causes change and growth in the child and caregiver	5
	Clients make their own decisions	4
Cultural Adaptations	There is a need to adjust the activities from the TF-CBT manual to fit the local context	10
	Important to address issues/difficulties regarding use of local languages	9
	It is taboo to talk about sex	8
	Parenting skills were challenging for parents	6
	TF-CBT is working well in Zambia culture	4
	There are differences in parent/child relationship here	4
Training & Supervision	The practice and supervision groups were helpful and motivating	15
	Training was good – organized, comprehensive, experiential, fun, etc.	9
	Training should be longer	4
Suggestions for Improvement	Create a physical, permanent center for therapy	9
	Adjust the training in TF-CBT (lengthen, update with materials)	7
	Create awareness of sexual abuse and this treatment in the community	6
	Reduce length of TF-CBT treatment for clients	6
	Improve patient referral system	5
	Improve patient attendance	4
	Provide more funding	4
	Scale up program	4
	Need for programs like this in Zambia	4

Note: Additional Qualitative Data Collection

Similar qualitative feedback can also be obtained from other members of the research team (i.e. those who are not providers but who are involved in the day-to-day activities of the study, such as the field project director, local project coordinator, external interviewer, project translator, and others who are involved in the study's work in the field). These data are best collected by individuals completely unrelated to the study so that interviewees feel comfortable speaking freely and providing feedback.

B.9. POST INTERVENTION INTERVIEW USING EXPANDED INSTRUMENT

A post-intervention assessment among study participants is conducted to compare changes (pre- and post-intervention) between the intervention and control groups.

Rigorous efforts are made to assess as many study participants as possible, regardless of their level of participation and whether or not they dropped out of the study. Therefore, even persons from the intervention arm(s) who never attended treatment are followed up with and re-interviewed. The only persons not re-interviewed are those who cannot be found or who refuse.

Note: Why all participants are re-interviewed, regardless of level of participation

This is done for 2 reasons: 1) to avoid the possibility that those who are lost from the intervention arm(s) are different from others in the intervention or controls arms, therefore biasing the study results; and 2) so that results of the study reflect the effects of the intervention on all those who are eligible, and not just those who cooperate fully.

Where possible, persons conducting the interviews should be blind to the study arm that the interviewees are in. At minimum, they should not be the persons who provided the intervention to the interviewees, so as to reduce the desire of the interviewees to please the interviewer.

Example: Follow Up Assessment in the RCT in Northern Uganda (Bolton et al., 2007a)

Within two weeks of the completion of both interventions, almost all the study participants and controls were re-interviewed for the quantitative post-intervention survey, using the expanded version of the original screening instrument.

Thirty interviewers, 22 of whom had been involved in the screening assessment, conducted the post-intervention surveys. None of the follow-up interviewers had been involved in implementing the interventions. Prior to the interviews, all received training in general quantitative interviewing methods and specific training in the quantitative survey instrument. Care was taken to ensure that the interviewers were not told which study arm the interviewees belonged to, in order to reduce the likelihood of interviewers biasing the results.

Multiple efforts were made to find and assess all 304 youth and their caregivers. Most were in the camps and were able to be interviewed at or near to their homes. Some of the youth had moved to town and/or other nearby camps and were found at those sites. In addition, some of the youth had left the area for the school holiday period, and so an additional five youth interviews were conducted the following month. A total of 283 (93%) of the original 304 youth were found and re-assessed (94 for intervention A; 98 for intervention B and 91 controls). Of the 21 youth who were not interviewed, one had died, ten had moved too far away to be contacted or were away for an extended holiday break, and ten could not be found.

B.10. DATA ANALYSIS.

B.10.1. SCALE SCORING

Grouping of questions in the instrument into scales reflecting syndromes and function is discussed in Module 2. Symptom and function scale scores are calculated either by summation of responses on all individual items in the scale or by averaging the score for all items in the scale. Summation consists of adding the numeric scores assigned to each response on all the questions in a given scale. For example, in the function instrument below, a response of ‘very little’ on every question would result in a function scale score of 20 (score of 1 on 20 questions) while a score of 2 on every question would give a scale score of 40.

Male Functionality	***Amount of difficulty doing the task/activity***					
Tasks/activities	*None*	*Very little*	*Moderate amount*	*A lot*	*Cannot do*	*Not applicable*
AM01 Providing for the family	***0***	***1***	***2***	***3***	***4***	***99***
AM02 Looking after family behaviors	***0***	***1***	***2***	***3***	***4***	***99***
AM03 Labor	***0***	***1***	***2***	***3***	***4***	***99***
AM04 Giving advice to family members	***0***	***1***	***2***	***3***	***4***	***99***
AM05 Giving advice to other community members	***0***	***1***	***2***	***3***	***4***	***99***
AM06 Exchanging ideas with others	***0***	***1***	***2***	***3***	***4***	***99***
AM07 Harmonious relations with wife and family	***0***	***1***	***2***	***3***	***4***	***99***
AM08 Bringing up children correctly	***0***	***1***	***2***	***3***	***4***	***99***
AM09. Doing things to improve the community	***0***	***1***	***2***	***3***	***4***	***99***
AM10. Sympathizing with others	***0***	***1***	***2***	***3***	***4***	***99***
AM11 Visiting and socializing with others in community	***0***	***1***	***2***	***3***	***4***	***99***
AM12 Asking for or getting help when you need it	***0***	***1***	***2***	***3***	***4***	***99***
AM13 Making decisions	***0***	***1***	***2***	***3***	***4***	***99***
AM14 Taking part in family activities or events	***0***	***1***	***2***	***3***	***4***	***99***
AM15 Taking part in community activities/events	***0***	***1***	***2***	***3***	***4***	***99***
AM16. Learning new skills or knowledge	***0***	***1***	***2***	***3***	***4***	***99***
AM17. Concentrating on your tasks or responsibilities	***0***	***1***	***2***	***3***	***4***	***99***
AM18. Interacting with people you do not know	***0***	***1***	***2***	***3***	***4***	***99***
AM19. Attending mosque or religious gathering	***0***	***1***	***2***	***3***	***4***	***99***
AM20. Assisting others	***0***	***1***	***2***	***3***	***4***	***99***

We typically use summation for the symptom scales because it is simple. Since interviewees are required to respond to each question in the symptom scales, the results are comparable between participants.

Summation can also be used for function scale scores (as in the above example) where participants respond to all the function questions. However, participants are not required to answer every function question. Where the task activity is not relevant to them they can instead choose 'not applicable,' which is not scored. In order to make summation scores comparable for function scales, we must first calculate the mean score on those function questions that were answered, and then substitute this mean value for the missing responses. For example, if a respondent chose 'not applicable' for two items, 'a lot' for nine items and 'moderate amount' for the remaining nine, then the mean score for the 18 items with responses would be 2.5. (9X3+9X2/18) 2.5 would then be substituted for the 'not applicable' responses when calculating the function score.

Alternatively, using the mean item response as the scale score avoids this problem. In the above example, the function scale score would simply be reported as 2.5. This removes the need to substitute individual item scores with scale averages.

Either approach is acceptable as long as calculations are performed in the same way for all assessments and missing data are minimal. Special consideration must be taken when there are significant amounts of missing data, including investigation into the missing data mechanism. Advanced methods, such as multiple imputation for missing data, should be considered and discussed with persons experienced in such methods.

Note: Items added to the post-intervention instrument as a result of the post-intervention qualitative study are not formulated into scales. Instead, these items are normally considered to be a separate issue and therefore analyzed separately (see below).

B.10.2. COMPARISON OF BASELINE DATA

Baseline data for the intervention arms and control arms are compared to determine whether the groups were similar prior to the intervention. Random assignment is intended to produce similar groups, but does not guarantee this will be achieved. Non-comparability may occur due simply to random effects, or because the random assignment process was faulty. Typically, comparisons are made of the demographic data for both arms (including gender proportions, mean age and level of education) and mean scores on the symptom and function scales.

Populations are generally considered comparable (and random assignment done correctly) if **most** of these variables are similar across the groups (one or two measures may show significant differences between the groups simply due to random variation). Large differences for many variables would suggest that randomization has not been done correctly. When this occurs it makes it difficult to infer whether any differences between the study arms found in the post-intervention assessment are really due to the intervention or to the fact that the two groups are themselves fundamentally different.

Example: Baseline Data Comparison from the RCT in Northern Uganda (Bolton et al., 2007a)

Baseline Study Population Characteristics (N=304)

Characteristic	*Camp 1 (n=167)*	*Camp 2 (n=137)*	*Intervention B (n=103)*	*Intervention A (n=99)*	*Controls (n=102)*
Number of girls, N (%)	*79 (47%)*	*94 (69%)*	*58 (56%)*	*56 (57%)*	*59 (58%)*
Age in yrs mean (SD)	*15.0 (1.1)*	*14.9 (1.0)*	*14.9 (1.1)*	*14.7 (0.9)*	*15.2 (1.2)*
Number currently enrolled in school, N (%)	*117 (70%)*	*90 (66%)*	*68 (66%)*	*68 (69%)*	*71 (70%)*
Education in yrs, mean (SD)	*5.0 (1.4)*	*5.2 (1.5)*	*5.0 (1.5)*	*5.1 (1.4)*	*5.2 (1.3)*
Number with history of abduction, N (%)	*65 (39%)*	*62 (45%)*	*41 (40%)*	*46 (46%)*	*40 (39%)*
Years in camp, mean (SD)	*6.3 (3.2)*	*4.0 (2.9)*	*5.0 (2.9)*	*5.6 (3.5)*	*5.1 (3.2)*
*Depression score, mean (SD)**	*44.2 (11.1)*	*43.1 (10.4)*	*43.4 (10.2)*	*43.8 (11.3)*	*44.0 (10.8)*
*Function score for girls, mean (SD)***	*11.7 (6.7)*	*11.2 (6.9)*	*12.2 (6.8)*	*11.4 (6.7)*	*10.7 (6.9)*
*Function score for boys, mean (SD)***	*7.5 (4.0)*	*7.1 (4.1)*	*6.8 (3.8)*	*7.1 (4.1)*	*8.2 (4.2)*

** Depression scale score is made up of 35 symptoms from the APAI scale (37 symptoms of two tam, kumu and par minus the two school-related items).*

*** Function scale score for girls is made up of 9 tasks and activities; function scale score for boys is made up of 5 tasks and activities.*

Both interventions were conducted in both camps. The table compares the characteristics of the samples between camps and between study arms. The samples in each camp were similar in terms of

most of the major characteristics we assessed: age; percent enrolled in school; average years of education; and history of abduction. The only differences were that the youth in camp 1 reported living in the camp an average of 2.3 more years than those in camp 2 and the sample in camp 2 included proportionally more girls than in camp 1 (69% vs. 47%). This was the opposite of the relative gender distributions reported for the total camp populations: 40% and 54% of the adolescents age 14-17 were girls in camps 2 and 1 respectively, according to camp lists. A comparison of baseline characteristics across all three groups (both interventions and the controls) found that the groups were similar in terms of these major characteristics, though the control group was slightly older than the other groups. These findings suggest that the random assignment into the three study conditions successfully produced similar groups except with regard to gender.

B.10.3. COMPARISON OF AMOUNT OF CHANGE (FROM PRE- TO POST-INTERVENTION) BETWEEN STUDY ARMS

For each participant the score on each scale (symptom scales and function scales) at baseline is subtracted from that at repeat assessment to provide a 'change score'. Mean change scores for the intervention group(s) are then compared to those of the control group. Analyses are done to determine the statistical significance of differences in the change scores between the groups.

Various analytical methods can be used, depending on the situation. Correct conduct of the analyses requires the assistance of persons familiar with methods such as multivariate regression and the use of random-effects models. The potential impact of any differences in important background characteristics (e.g., age, gender, exposure to trauma) must be controlled for in order to correctly infer the impact of the program intervention. Where interventions are provided in group rather than individual formats, analyses also need to control for within-group similarities when calculating statistical significance.

Because of the need for persons experienced in both the choice and use of statistical methods, we do not include further discussion of analysis here or reference to publications. For further guidance on analysis for specific studies the reader can also contact the authors.

Example: Comparisons of Change Scores from the RCT in Northern Uganda (Bolton et al., 2007a)

Comparisons of pre- and post-intervention levels of depression and functional impairment were made to determine the amount of change. For each participant we subtracted the post-intervention scores from the scores attained during the original screening interviews (i.e., baseline). We then used regression analysis to assess the impact of the intervention while also controlling for demographic variables (e.g. age, camp, gender, school enrollment, history of abduction) and group effects. Adjustment for group effects was done using a random effects model. This was necessary since both interventions were provided in groups but analysis was done at the level of the individual participant.

B.10.4. ANALYSIS OF ADDITIONAL QUESTIONS ADDED TO THE STUDY INSTRUMENT

Analysis of additional questions added to the post-intervention instrument (Section B.7) is much simpler, since each question is considered separately and there is no baseline value to compare against. For each question, analysis consists of descriptions of the response distributions as percentages and mean change per item (see example in Appendix N).

B.11. PROVISION OF INTERVENTION TO WAIT CONTROL GROUP

In studies that use a rolling admission format, once wait control participants finish their wait period they are then offered the intervention, even though the study is still ongoing and the impact of the intervention is not yet demonstrated. In studies where multiple interventions are being tested, the choice of intervention depends on which one is available to the participant at the point of service.

In the case of single cohort studies, preliminary analysis will demonstrate whether the intervention is effective prior to offering it to the wait controls. (What constitutes effectiveness varies. As noted previously, we arbitrarily set the cutoff for effectiveness as a 20% improvement among the intervention group compared with controls). If the intervention is found not to be effective then it is not offered. This provision – that the intervention will be provided only if found to be effective – is included in the consent form at the beginning of the study. While it may seem unfair to withhold the intervention, it is also unreasonable to expend program resources and have participants expend their own time and resources on an intervention that is not helpful.

Example of Findings and Conclusions Drawn from the Findings of the RCT in Northern Uganda (Bolton et al., 2007a)

Intervention B was found to effective for the treatment of depression-like problems in this adolescent, war-affected population. It was more effective among girls, and only the intervention B girls also demonstrated improved function.

This conclusion is based on the highly significant improvement observed in the overall severity of locally-described depression and anxiety symptoms among those who received intervention B compared with the controls. These findings suggest that B is a promising basis for depression-focused interventions in this population, given that this was the first experience of the local facilitators in providing it. We might expect even greater impact with more facilitator experience and in more stable circumstances with fewer concurrent stressors. Note that, at this time, this conclusion can be applied with confidence only to the population studied. The extent to which the results apply to non-Acholi, to non-adolescents, and to populations exposed to different stressors is yet to be determined.

Prior to the commencement of the study our service partners agreed that whichever intervention(s) were found to be effective would then be provided to others in need in the camps, beginning with the controls. In light of the findings, we provided intervention B to members of the control group by many of the same facilitators who led the B groups for the study. This was the first phase of a new program for the camps based on intervention B.

B.12. IMPLEMENT ONGOING SCREENING, INTERVENTION, MONITORING, AND POST INTERVENTION ASSESSMENT (USING EXPANDED INSTRUMENT) AS AN ONGOING SERVICE PROGRAM USING LESSONS LEARNED IN THE STUDY

In addition to providing the effective intervention(s) to the control group, organizations should consider providing the effective intervention(s) to others in the population who meet eligibility criteria. Provision of the intervention should continue to be accompanied by the monitoring and evaluation activities (e.g., impact assessment, qualitative and quantitative) used in the study.

Lessons learned during the study should be documented, shared, and applied in follow-up activities with the goal of continuous improvement of program efforts. For example, specific issues that burden the population—issues that were learned about during the study—might be addressed by further adaptation of the interventions. Or, if the benefits of the intervention differed among types of participants (gender, age group, site), these can be explored further with the goal of improving the benefits of the interventions.

In addition, programs should consider carrying out follow up assessments with persons receiving the intervention to see if the benefits of the intervention are maintained over time.

Example: Recommendations from the RCT in Northern Uganda (Bolton et al., 2007a)

Adapt interventions to better address specific issues faced by the population.

Despite the efficacy of Intervention B demonstrated by this trial, the treatment was not specifically adapted to address issues of trauma (war-related violence exposure, loss and displacement) that were common in this war-affected population. Similarly, no specific adaptations of intervention A had been made to address the trauma issues. At a minimum, the training of B and A facilitators in the future should involve more preparation for identifying and/or addressing trauma-related issues in treatment. Despite the untested nature of B and A among highly traumatized populations, very few adverse events occurred. One case of a highly traumatized young person needing a more intensive level of services arose in the B intervention. Although no such urgent cases arose in A, staff were concerned about a handful of young people due to violent behaviors and themes that arose in intervention A activities. Exit interviews with B and A staff indicated that future training could be enriched by preparing facilitators to handle trauma-related material in group discussions and how to identify children whose experiences of prior trauma might make group participation difficult.

Conduct a follow up of study participants to examine whether there are long-term intervention effects

Since the study did not measure the duration of intervention B's impact this should be studied if possible. There could also be effects of the intervention that were not immediately apparent post-intervention. To examine this, the assessment of all study participants should be repeated 6 months or more after the interventions ended. It would also be useful to reassess functioning to determine if further improvement has occurred since the end of the interventions.

Continue to explore and test intervention effects by gender

Because treatment efficacy differences were observed between boys and girls participating in intervention B, there remains a need to explore whether other intervention models may be more effective among adolescent males than intervention B. In future iterations of both the B and A interventions for children and adolescents, efforts at evaluation should take explicit steps to organize and analyze the findings of treatment effects by gender. It may prove to be the case that "talking" therapies such as B are more appropriate for girls in this culture and context whereas more activity-based or skills-oriented therapies may have greater efficacy in boys when conducted in smaller groups with a focus on individual treatment planning and goals. Because girls in such resource poor settings can often face significant discrimination and have fewer opportunities, being able to participate in any intervention can naturally be a very positive experience for them. The division of B groups by gender and the matching of the facilitator gender to that of participants may also have contributed to greater treatment outcomes in girls. Such effects were not able to be teased apart in the present design since

the A groups differed greatly from the B intervention not only in the nature of the intervention offered, but also in terms of size and groups with participants and facilitators of both genders.

Continue to adjust and evaluate the A intervention model

Both the qualitative data and some of the quantitative findings point to broad-based potential psychosocial benefits of the A model. With the lessons learned from the present trial and the growing experience of WCH with adapting and delivering this model, future adaptations of A should continue to be developed and tested using methods similar to those of the present trial. As suggested by this trial, future investigations of A could explore its efficacy as a general psychosocial intervention as opposed to a treatment for locally-described symptoms of depression-like problems. Such future evaluations might examine the efficacy of A in different age groups and different types of psychosocial problems. They might also take into account measurements on different levels including the child, family, peer and community level. Also, instruments could be developed that are less focused on psychopathology and more suitable for evaluating psychosocial well-being. They might also explore outcomes more aligned with the stated goals of interventions, including strengthening children's psychosocial development.

REFERENCES

Bolton, P., Bass, J., Betancourt, T., Speelman, L., Onyango, G., Clougherty, K.F., Neugebauer, R., Murray, L., Verdeli, H.(2007a) Interventions for depression symptoms among adolescent survivors of war and displacement in northern Uganda: a randomized controlled trial. *Jama* 298, 519-527.

Bolton, P., Bass, J., Murray, L., Lee, K., Weiss, W., McDonnell, S.M.(2007b) Expanding the scope of humanitarian program evaluation. *Prehosp Disaster Med* 22, 390-395.

Consort Statement Website at http://www.consort-statement.org/. This website provides excellent general and specific advice on the conduct of trials.

APPENDIX A: SAFETY MONITORING FORM - THAILAND STUDY

စိတ်ကျန်းမာရေးဆန်းစစ်မှု၏ လုံခြုံမှုကိုပြန်လည်တုံ့ပြန်ခြင်းအတွင်

MHAP Safety Response Form

ပြီးသွားသည့်ဆန်းစစ်မေးမြန်းမှုတိုင်းအတွက် အောင်တစ်ခုခြင်းစီ ဆန်းစစ်မှုဖိုင်ထဲရှိ အခြားအောင်မွားနှင့်အတူ ပြန်အပ်ပါ။

Fill out one form for every Screening Interview Completed. Turn in with your Assessment packet.

Date of Interview: အင်တာဗျူးရက်စွဲ		**Counselor ID Number:** ကောင်စလာ နံပါတ်		**Recruitment ID Number:** ခြေကြားဒေပမည့် သူနံပါတ်		**Score on 3.10:** မေးခွန်း (၃.၁၀)၏အခြေ	

များသောအားဖြင့်တွေးတယ် (သို့) အချိတိုင်းနီးပါးတွေးတယ်ဟုဖြေပါက လုံခြုံမှုမေးခွန်း(၄)ခုကိုမေးပြီး ၎င်းအဆင့်များအတိုင်းပြု လုပ်ပါ။ If "most of the time" (2) or "almost all of the time" (3) then ask the 4 Safety Response questions, follow procedures.

လုံခြုံမှုမေးခွန်း (၄) ခု **4 Safety Response questions**	*အဖြေများကို မှတ်ပါ။* **Mark Response**	
	Yes	**No**
"သင့်ကိုယ်သင် သတ်သေဖို့ အကြောင်း စဉ်းစားဖူးလား" "Do you think about killing yourself"		
"သင့်ကိုယ်သင် သတ်သေမယ် အစီစဉ်ရှိလား။" "Do you have a plan to kill yourself"		
"ဒီအစီအစဉ်ကိုလုပ်ဖို့ နည်းလမ်းရှိပါသလား။ "Do you have a way to carry out this plan?"		
သင့်ကိုယ်သင် သတ်သေဖို့ ကြိုးစားဖူးပါသလား။ "Have you ever tried killing yourself?"		

နောက်ဆုံးမေးခွန်း(၂)ခုထဲမှ တစ်ခုခုကို 'ဟုတ်ကဲ့' ဟုဖြေပါက အခန်းထဲတွင် ကလိုင်းယန့်နှင့်အတူ ရှိနေသောအချိန်တွင် သင်၏ခု ပါဝိုင်စာကို ဖုန်းခေါ်ပါ။ မေးခွန်းအားလုံးမှာမှ တစ်ခုခုကို 'ဟုတ်ကဲ့' ဟုဖြေပါက တွေ့ဆုံမှုအပြီးတွင် ခုပါဝိုင်စာကို ချက်ချင်းဖုန်း ခေါ်ပါ။

If a client responds "yes" to either of the last 2 questions, call your supervisor immediately with the client still in the room with you. If a client responds "yes" to any of these questions, the counselor should call their supervisor immediately at the end of meeting.

လုပ်ဆောင်ပေးမှု ***Actions Taken***	**Mark here if done** *ပြီးလျှင် မှတ်ပါ။*	**Notes** *မှတ်ချက်များ*
ခုပါဝိုင်စာကိုခေါ်သည်။ - (အချိန်ကိုဖော်ပြပါ) Supervisor called – specify time of call		
ခုပါဝိုင်စာကောက်လာသည်။ (အချိန်ကိုဖော်ပြပါ) Supervisor arrived – specify time of arrival		
ကလိုင်းယန့်ထံမှ လုံခြုံမှုကတိတောင်းပါ။ Have the client give their safety word		
စောင့်ကြည့်လေ့လာမှုအစီအစဉ်တစ်ခုလုပ်ပါ။ Set up a safety watch		
ဌာနတစ်ခုခုသို့ ချက်ချင်းလွှဲအပ်သည်။ (အချိန်ကိုဖော်ပြပါ) Immediate referral to facility – specify time/place		

အဖြေများ၏အခြားအသေးစိတ်အချက်အလက်များကို (လိုအပ်လျှင် နောက်ကျောစာမျက်နှာများကိုအသုံးပြု၍) ရေးမှတ်ပါ။

Provide more detailed notes of the response (use back if needed)

အဖြေများကိုပြန်လည်သုံးသပ်ခြင်း **Review of Response**	*လက်မှတ်* **Signature**	*ရက်စွဲ* **Date**	*မှတ်ချက်များ* **Notes**
ကိတ်၏ပြန်လည်သုံးသပ်မှု (Cate)			
ဒေါက်တာတင်ဇော်၏ ပြန်လည်သုံးသပ်မှု (Dr. Htin Zaw)			

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	CLIENT / CMHW INFORMATION					PSYCHIATRIC MEDICATION (Y/N)				DATES OF KEY STUDY EVENTS: RECORD DATES ONLY (dd/mm/yy)										
2						Already on when starting therapy?	Started during therapy?	Stopped during therapy?		Intake Events (dd/mm/yy)			Referral to Psychiatrist		Date of Events for		Date of Events for CPT Intervention Patients (dd/mm/yy)/Score from Client Monitoring Form			
3																	Session_1			
4	CMHW_Number	CHMW_Name	Client_Number	Assignment						Intake_1	Consent		Referral_1		Call_1		Date	Score	Exit_Interview	Drop
5	101		101.01	intervention																
6	101		101.02	intervention																
7	101		101.03	control																
8	101		101.04	control																
9	102		102.01	intervention																
10	102		102.02	intervention																
11	102		102.03	control																
12	102		102.04	control																
13	103		103.01	control																
14	103		103.02	intervention																
15	103		103.03	control																
16	103		103.04	control																
17																				

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	CLIENT / CMHW INFORMATION					PSYCHIATRIC MEDICATION (Y/N)				DATES OF KEY STUDY EVENTS: RECORD DATES ONLY (dd/mm/yy)							Date of Events for CPT Intervention Patients (dd/mm/yy)/Score from Client Monitoring Form			
2						Already on when starting therapy?	Started during therapy?	Stopped during therapy?		Intake Events (dd/mm/yy)			Referral to Psychiatrist		Date of Events for		Session_1		Exit_Interview	Drop
3																	Date	Score		
4	CMHW_Number	CHMW_Name	Client_Number	Assignment						Intake_1	Consent		Referral_1		Call_1					
5	101		101.01	intervention		N				1/3/11	Y						5/3/11	21	10/5/11	
6	101		101.02	intervention		N				3/3/11	Y						7/3/11	19	12/5/11	
7	101		101.03	control		N				5/3/11	Y				5/4/11				15/5/11	
8	101		101.04	control		N				7/3/11	Y									5/4/11
9	102		102.01	intervention		N				2/3/11							6/3/11	12	11/5/11	
10	102		102.02	intervention		N	Y	N		4/3/11	Y						8/3/11	31	15/5/11	
11	102		102.03	control		N				6/3/11	Y		6/4/11		6/4/11				16/5/11	
12	102		102.04	control		N				8/3/11	Y				8/4/11				18/5/11	
13	103		103.01	control		N				4/3/11	Y				5/4/11				15/5/11	
14	103		103.02	intervention		Y		N		6/3/11	Y						9/3/11	21	16/5/11	
15	103		103.03	control		N				8/3/11	Y				8/4/11				18/5/11	
16	103		103.04	control		N				10/3/11	Y				10/4/11				20/5/11	
17																				

CMHW_ Number	CHMW_Name	Recruitment IDNumber	Client_Number	Assignment	Baseline Assessment	Traumatic Events	Depression				Trauma Symptoms					Safety Referral (dd/mm/yy)		Date of calls for Controls (dd/mm/yy)			
					(dd/mm/yy)	Meets criteria	Meets criteria	A	B	C	Meets Criteria	A	B	C	D	Referral_1	Referral_2	Month_1	Month_2	Month_3	Month_4
S-11		107	S-11-001	Control	27/8/2011	Yes	Yes	Yes	Yes	5	Yes	Yes	Yes	Yes	Yes			Attempted 1/9/11			
S-11		103	S-11-002	Treatment	27/8/2011	Yes	Yes	Yes	Yes	4	Yes	Yes	Yes	Yes	Yes						
S-11		755	S-11-003	Treatment	10/7/2012	Yes	Yes	Yes	Yes	4	Yes	Yes	No	Yes	No						
S-12		226	S-12-001	Treatment	30/12/11	Yes	Yes	Yes	No	5	Yes	Yes	Yes	Yes	No						
S-12		537	S-12-002	Treatment	20/04/12	Yes	Yes	Yes	Yes	4	Yes	No	Yes	Yes	No						
S-12		546	S-12-003	Treatment	24/04/2012	Yes	Yes	Yes	Yes	3	No	No	No	No	No						
S-15		222	S-15-001	Treatment	30/11/11	Yes	Yes	Yes	Yes	5	Yes	Yes	Yes	Yes	No						
S-15		225	S-15-002	Treatment	20/01/12	Yes	Yes	Yes	Yes	7	Yes	Yes	Yes	Yes	Yes						
S-15		250	S-15-003	Treatment	9/2/2012	Yes	Yes	Yes	Yes	8	Yes	Yes	Yes	Yes	Yes						

Session_1			Status	If Control ... request CBI?	Follow up Assessment (dd/mm/year)	Other services / support during CBI or wait period	Monitoring Forms turned in?	If post-wait control, and CBI requested, weekly forms turned in?	If post-wait control, and CBI requested, Assessment turned in?	COMMENTS
Date	Component	Score								
			WITHDRAW	N/A	Unavailable	Unknown	Yes	N/A	N/A	WITHDRAW: health condition - currently seeking medical care in Bangkok.
3/9/2011	EP, PE	9	COMPLETE	N/A	10/12/2011	None	Yes	N/A	N/A	DONE: FU 2/11/11.
										Est FU 18/9/12
10/1/2012	EP, PE	20	COMPLETE	N/A	1/4/2012	None	Yes	N/A	N/A	DONE: Rose did interview. Est. FU 09/03/12
1/5/2012	EP, PE	22								Est. FU 9/7/12
1/5/2012	EP, PE	20								Est. FU 5/7/12
15/12/11	EP,PE	12	COMPLETE	N/A	17/03/12	None	Yes	N/A	N/A	DONE. Est. FU 08/02/12. Rose completed follow up interview
24/01/12	EP,PE	16	COMPLETE	N/A	3/5/2012	None	Yes	N/A	N/A	DONE: Rose did interview. Est. FU 30/03/12
17/02/12	EP, PE	25	COMPLETE	N/A	3/5/2012	None	Yes	N/A	N/A	DONE: Rose did interview. Est. FU 19/04/12

Client Monitoring Form - CBI

	:Site المكان		:Date تاريخ
	: Client ID الرقم الخاص بالمريض		: Client Name اسم المريض
	: CMHW ID الرقم الخاص بالموظف		: CMHW Name اسم الموظف المجتمع للصحة النفسية
	:Duration of Session طول الجلسة		: Session Number رقم الجلسة

Problem Review - review for change from prior session (Check all that apply) مراجعة المشاكل المراجع اليه- التغييرات حدثت بالمقارنة مع الاسبوع
تنطبق على المريض (اختار اي مشكلة السابق)

Very often (more than 5 times a week)	Often (3-5 times a week)	Sometimes (1-2 times a week)	Never or No	Symptom
3	2	1	0	BD04. العصبية Nervousness
3	2	1	0	BD10. الشعور بالقلق، عدم القدرة على الجلوس بهدوء Feeling restless, can't sit still
3	2	1	0	BD11. الشعور بالخمول وقلة الطاقة والحيوية، بطء الحركة Feeling low in energy, slowed down
3	2	1	0	BT19 تلوم نفسك بسبب أشياء Blaming yourself for things
3	2	1	0	BT8. اضطراب النوم Trouble sleeping
3	2	1	0	BD18. الشعور بالكآبة Feeling depressed
3	2	1	0	BD22. القلق الزائد عن الحد على اشياء Worrying too much about things
3	2	1	0	BT01. تتذكر وباستمرار الذكريات أو افكار مؤلمة أو أحداث مزعجة Recurrent thoughts or memories of the hurtful or terrifying events
3	2	1	0	BT06. الاجفال بسرعة Feeling jumpy, easily startled
3	2	1	0	BT11. تتجنب النشاطات أو الأشياء التي تتذكرك بالحوادث المؤلمة أو التي سببت صدمة مثل الشرطة Avoiding activities or things that remind you of the traumatic or hurtful events such as the police
3	2	1	0	BT18. صعوبة في إنجاز عملك أو واجباتك اليومية Difficulty performing your work or daily tasks
3	2	1	0	BT23. تقضي أوقاتا بالتفكير حول سبب حدوث هذه الحوادث لك Spending time thinking about why these events happened to you

Gender الجنس		Main Syxs الاعراض الرئيسية		Behavior Act Need Score (/9) الى التنشيط الحاجة السلوكية	
Trauma Type نوع الصدمة		Total Score مجموع الدرجات		Functioning Items (general) (وحدات الوظائف العامة)	
Client Age سن المريض		Relax Need Score (/12) الى الحاجة الاسترخاء (12/)		Live Exposure Score (/3) التعرض الحي (3/درجة)	
Clinical Observations: الملاحظات السريرية					

# Sessions: عدد الجلسات	___ 12 Sessions ----- 12 جلسة	___ 8 sessions ----- 8 جلسات
Flow التسلسل	___ Standard ----- التسلسل العادي	___ + Relaxation ---------+ الاسترخاء ___ + Behavioral Activation ---------+ التنشيط السلوكي ___ + Live Exposure ----------+ التعرض الحي

Check Components covered in this session
المكونات التي استخدمت في هذه الجلسة

	Encouraging Participation تشجيع المشاركة		Cognitive Processing الادراكيه العيكل العاده
	Safety السلامة		Relaxation الاسترخاء
	Psychoeducation التثقيف النفسي		Live Exposure التعرض الحي
	Cognitive Coping الادراكيه التكيف		Behavioral Activation التنشيط السلوكي
	Gradual Exposure التعرض التدريجي		

For each component covered, explain what you did الشرح ماذا فعلت في الجلسة لكل مكون استخدمته

Main Component المكون الاساسي	
Other Component وحدات اخرى مكملة	
Other Component مكونات اخرى	
Other Component مكونات اخرى	

اشياء اخرى ناقشتها مع المريض في هذا الاسبوع اذكر ايه
List any other things you discussed with the client this week:

الجلسة التحديات واجهتها في هذه اذكر ايه

Describe any challenges you had in this session

صف الواجب البيتي للمريض

Describe client's homework

What ماذا	
When متى	
For how Long المدة الزمنية	
Reminder التذكيرات	
Feelings: Rate before and after المشاعر: قبل و بعد الواجب	___ I reminded the client to list and rate feelings ذكرت المريض بان يذكر و يقيس المشاعر ------

Any suicidal ideation? NO YES (if yes, explain below what they report, how you assessed, and what the plan forward is)

الافكار، كيف قمت | ما هي هذه رجاء وصف ادناه؟ لا نعم)اذا نعم، الا افكار انتحارية هل هناك اية
(المستقبل بالتقييم، و ما هي الخطه

____

____

Any homicidal ideation? NO YES (if yes, explain below what they report, how you assessed, and what the plan forward is)

الافكار، كيف | ما هي هذه نعم، الرجاء وصف ادناه؟ لا نعم)اذا افكار لقتل الاخرين هل هناك اية
(المستقبل قمت بالتقييم، و ما هي الخطه

____

____

Please mark if client is taking any of these medications:

: ادناه التي ياخذها المريض من القائمه الرجاء اختيار الادويه

Diazepam (Valium)		Fluoxitine (prozac)	
Chlodiazipoxide (librium)		Setraline (Zoloft)	
Lorazipam (ativan)		Paroxitine	
Imipramine (tofranil		Largactil (chlorpromazine)	
Amitryptyaline (tryptizol)		Stelazine (trifluperazine)	
Maprotiline (ludiomil)		Olanzipin (olan)	

____

اخر ادويه
Other meds: _______________

ملاحضات اخرى:

Additional Comments:

Thai-Burma Intervention Study: Client Monitoring Form

ဇယားမှတ် Date		နေရာ/အဖွဲ့အစည်း Site/Organization	
ဂလိုင်းယန့်ပါတ် Client ID		ဂကောင်စလာနံပါတ် Counselor ID	
ကျား/မ Gender		တွေ့ဆုံမှုနံပါတ် Session Number	
အသက် Age		တွေ့ဆုံမှုကြာချိန် Duration of Session	

အနားယူမှုလိုအပ်ခြင်းအမှတ် (/၂၃) Relaxation Need Score (/23)		အပြုအမူပြုပြင်ပြောင်းလဲခြင်းလိုအပ်မှု ရမှတ် (/၉) Behavior Activation Need Score (/9)		လုပ်ငန်းဆောင်ရွက်မှု Functioning Items မ Female Total possible 92 ကျား Male Total possible 64	
လက်တွေ့အတွေ့အကြုံရမှတ် (/၃) Gradual Exposure Live Score (/3)		အရက်နှင့်မူးယစ်ဆေးဝါးသုံးစွဲမှုကိုကုသခြင်းအနှစ်ချုပ်(/၄၀) Brief Intervention for Substance Use (SBI) (/40)			
စိတ်ဒဏ်ရာအမျိုးအစား Trauma Type					
အဓိကလက္ခဏာများ Main Symptoms					
ကုသမှုဆိုင်ရာတွေ့ရှိချက်များ Clinical Observations					

တွေ့ဆုံမှုအကြိမ်ရေ # Sessions:	___ ၈ ကြိမ် 8 Sessions	_____ ၁၀ ကြိမ် 10 Sessions
ကုသပုံ (ကုသမှုစီဆင်နုံ) Flow	___ Standard စံနှုန်း	___ + Relaxation အနားယူမှု/သက်တောင့်သက်သာဖြစ်စေမှု ___ + Behavioral Activation အပြုအမူပြုပြင်မြှောင်းလဲခြင်း ___ + Live Exposure လက်တွေ့အတွေ့အကြုံတိုးမှု ___ + Brief Intervention for Substance Use (SBI) အရက်နှင့်မူးယစ်ဆေးဝါးသုံးစွဲမှုကိုကုသခြင်းအနှစ်ချုပ်

သင်သည် ယခုလက်ရှိတွင် စိတ်ပိုင်းဆိုင်ရာရောဂါတစ်ခုခုအတွက် ဆေးဝါးသုံးစွဲနေသလား။
မဟုတ်ဘူး. No
သုံးတယ် Yes (သုံးဖူးသော အောက်တွင် ဆေးဝါး၏အမည်ကိုရေးမှတ်ထားပါ) (If yes, write name of medicine below)

Alcohol use questions	0	1	2	3	4
1. (အရက်ပါသောအရည်) အရက်ဘယ်နှစ်သောက်သောက်ပါသလား။ How often do you have a drink containing alcohol?	တစ်ကြိမ်မှမရှိပါ Never	တစ်လ (၁)ကြိမ် (သို့) ၄င်း အောက် နည်းသည် Monthly or less	တစ်လမှာ (၂-၄)ကြိမ် 2-4 times a month	တစ်ပတ်မှာ (၂-၃)ကြိမ် 2-3 times a week	တစ်ပတ်မှာ (၄)ကြိမ် နှင့် အထက် 4 or more times a week
2. တစ်ခါသောက်လျှင် ခြောက်ခွက် (သို့) ၄င်းထက်ပိုသောက်တာ ဘယ်နှစ်ကြိမ်ရှိပါသလဲ။ How often do you have 6 or more drinks on one occasion?	တစ်ကြိမ်မှမရှိပါ Never	တစ်လ (၁)ကြိမ် အောက် နည်း သည် Less than monthly	တစ်လ (၁)ကြိမ် Monthly	တစ်ပတ် (၁)ကြိမ် Weekly	နေ့တိုင်း (သို့) နေ့တိုင်းနီးပါး Daily or almost daily

ဤအပတ်တွင် အရက်နှင့်မူးယစ်ဆေးဝါးသုံးစွဲမှုမေးခွန်းများ၏စုစုပေါင်းအမှတ် _____
Total score this week for Alcohol use questions

အရက်အဓိများကိုပြည်လည်ဆန်းစစ်မှု - ယခင်တွေ့ဆုံမှု အပြောင်းအလဲများကို ပြည်လည်ဆန်းစစ်မှု
Problem Review - review for change from prior session (Check all that apply)

ယခင်အပတ်ကတည်းက သင်တွင် (_____) လကွက်ကာ မရှိပါ၊ အနည်းရှိပါသလား၊ အချို့အချိန်တွင်ရှိပါသလား၊ အများအားဖြင့်ရှိပါသလား၊ အချိန်တိုင်းနီးပါးရှိ ပါသလား။
In the last week, have you been feeling _____ none of the time, a little of the time, some of the time, most of the time, or almost all of the time?

	မရှိပါ None of the time	အနည်းငယ်ရှိ A little of the time	အချို့အချိန်တွင်ရှိ Some of the time	အများအားဖြင့်ရှိ Most of the time	အချိန်တိုင်းနီးပါး Almost all the tim
	0	1	2	3	4
5.4. စိုးရိမ်ကြောက်ရွံ့ခြင်း (သို့)စိတ်ထဲတွင် တုန်လှုပ်ခြင်း။ Nervousness or shakiness inside	0	1	2	3	4
5.9. ငြိမ်ငြိမ်နေ၍မရခြင်း၊ ဇာတ်မငြိမ်ဖြစ်ခြင်း။ Feeling restless, fidget all the time	0	1	2	3	4
3.3. ဝမ်းနည်းမှုခံစားရခြင်း၊ပျော်ရွှင်ခြင်း Feeling sad; unhappy	0	1	2	3	4
3.7. အင်အားချည့်နဲ့ခြင်း၊ အင်အားတဖြည်းဖြည်းကျဆင်းလာသကဲ့သို့ ခံစားရခြင်း Feeling low in energy, slowed down	0	1	2	3	4
3.9. အိပ်ပျော်ရန်ခက်ခဲခြင်း၊ အိပ်ပျော်ပြီးပြန်နိုးလျှင် လည်း ဆက်လက်အိပ်ပျော်ရန် ခက်ခြင်း။ ဤပြဿနာ Difficulty falling asleep, staying asleep; can't sleep well	0	1	2	3	4
3.12.အကြောင်းအရာများအတွက် စိတ်ပူပန်မှုများခြင်း။ "စိုးရိမ်ပူပန်ခြင်း" Worrying too much about things; worried	0	1	2	3	4
3.13 မိမိကိုယ်ကို အပြစ်တင်ခြင်း။ Blaming self for things	0	1	2	3	4
4.1. စိတ်နှလုံးကိုထိခိုက်စေသော (သို့) ဆိုးရွားသောအဖြစ်အ ပျက်များကို မကြာခဏာတွေးမိခြင်း သို့မဟုတ် အမှတ်ရနေ ခြင်း Recurrent thoughts or memories of the most hurtful or terrifying events	0	1	2	3	4
4.5. စိတ်မခုန်မြဲမြံယုယရာ (သို့) စိတ်ထိခိုက်စရာအဖြစ်အပျက် ဆိုးများကို ပြန်လည်သတိရစေသော လုပ်ရပ်များကို ရှောင်ရှားခြင်း။ စိတ်ထိခိုက်မှုဖြစ်စေသောအရာများကိုရှောင်ရှားခြင်း Avoiding activities that remind you of the traumatic or hurtful event or avoiding the things that cause bad feelings	0	1	2	3	4
4.12.ကြောက်လန့်တုန်လှုပ်ခြင်း၊ အလွယ်တကူကြောက်ရွံ့ခြင်း Feeling jumpy, easily startled	0	1	2	3	4
4.18. နေ့စဉ်လုပ်ငန်းတာဝန်များကို ပါဝင်ထမ်းဆောင်ရာ၌ အကေ အခဲရှိခြင်း Difficulty performing work or daily tasks;	0	1	2	3	4
4.23. ထိုအဖြစ်အပျက်များဘာကြောင့်ဖြစ်ပျက်ပါသလဲဟူသော အတွေးများတွေးရင်းအချိန်ကုန်ခြင်း Spending time thinking about why these events happened to you	0	1	2	3	4

ဤအပတ်တွင် အဂက်အခဲများကိုပြန်လည်ဆန်းစစ်မှုမေးခွန်းများ၏ရရှိသောပေါင်းအမှတ်များ _____
Total score this week for Problem Review questions

ကောင်စလာအတွက် လမ်းညွှန်- ယခု သင်၏အပိုင်းကိုပြီးအောင်လုပ်ပါ၊ ထို့နောက် ကျန်အပိုင်းများအားလုံးကို လုပ်ပါ။
Directions for Counselor: Now complete your session then finish the rest of this form

2

ဤအပိုင်းတွင်ဖော်ပြထားသောကုထုံးများကို စစ်ဆေးပါ။ Check Components covered in this session

ပူးပေါင်းပါဝင်မှုကိုအားပေးခြင်း Encouraging Participation		အတွေးနည်းလမ်းဖြင့်စဉ်းစားခြင်း Cognitive Processing	
လုံခြုံမှု Safety		သက်တောင့်သက်သာဖြစ်စေခြင်း Relaxation	
ပညာပေးခြင်း Psychoeducation		လက်တွေ့ကော်ထုတ်မှု Live Exposure	
အတွေး၊ ခံစားမှုနှင့် အပြုအမူတို့ဆက်စပ်မှုကို နားလည်ခြင်း Cognitive Coping		အပြုအမူပြုပြင်မြှောင်းလဲခြင်း Behavioral Activation	
တဖြည်းဖြည်းခေါ်ထုတ်မှု Gradual Exposure		အရက်နှင့်မူးယစ်ဆေးပါးသုံးစွဲမှုကိုကုသခြင်းအနှစ်ချုပ် Brief Intervention for Substance Use	

ဖော်ပြထားသောကုထုံးတစ်ခုစီအတွက် မည်သည့်အရာအများပြုလုပ်ခဲ့သည်ကို ရှင်းပြပါ။ For each component covered, explain what you did

အဓိကကုထုံး Main Component _____	
အခြားကုထုံး Other Component	
အခြားကုထုံး Other Component	
အခြားကုထုံး Other Component	

ဤအပတ်တွင် သင်က ကလိုင်းယန့်နှင့်ဆွေးနွေးခဲ့သော အခြားအရာများကို စာရင်းပြုစုပါ။ List any other things you discussed with the client this week:

ဤအပိုင်းတွင် သင်ကြုံတွေ့ခဲ့ရသောအခက်အခဲများ(ဝိန်ဓေါ်မှုများ)ကို ဖော်ပြပါ။ Describe any challenges you had in this session:

ကလိုင်းယန့်၏အိမ်စာအကြောင်းကို ဖော်ပြပါ။ Describe client's homework

ဘာလဲ What	
ဘယ်အချိန် When	
ဘယ်လောက်ကြာ For how Long	
သတိပေးစာရွက် Reminder	
.....ကျနေခဲ့၊ ကျမက ကလိုင်းယန့်အား ခံစားမှုကိုတိုင်းတာရန် သတိပေးခဲ့ပါသည်။ ___ I reminded the client to list and rate feelings	ပြီးဆုံးပြီးနောက် ခံစားမှု Feelings after

1. ကိုယ့်ကိုယ်ကို သတ်ဖြစ်ချင်လာတွေးတာတစ်ခုခုဖေါ်ပြသလား။ Any suicidal ideation? **မဖေါ်ဘူး** NO / **ဖေါ်တယ်/** YES (ဖေါ်လျှင် ကလိုင်းယန့် ပြောပြခဲ့သည့်အရာ၊ သင်ဆန်းစစ်ခဲ့ပုံနှင့် ဖရှ ဆက်အစီအစဉ်တို့ကို အောက်တွင် ရှင်းပြပါ။/ if yes, explain what they report, how you assessed, and what the plan forward is)

_____

2. အခြားသူတစ်ဦးဦးကို အနာတရဖြစ်စေမည့်လာတွေးတာတစ်ခုခုဖေါ်ပြသလား။ Any homicidal ideation? **မဖေါ်ဘူး** NO / **ဖေါ်တယ်/** YES (ဖေါ်လျှင် ကလိုင်းယန့် ပြောပြခဲ့သည့်အရာ၊ သင်ဆန်းစစ်ခဲ့ပုံနှင့် ဖရှ ဆက်အစီအစဉ်တို့ကို အောက်တွင် ရှင်းပြပါ။/ if yes, explain below what they report, how you assessed, and what the plan forward is)

အခြားအကြံပြုချက်များ
Additional Comments

APPENDIX G: EXAMPLE OF A CONTROL CLIENT MONITORING FORM – THAILAND STUDY

MHAP Monthly Questions for all Wait-Control Clients

စေ့တစ်းအရျတိ်အလတိ်များရတိ်စွဲ (ရတိ်၊ ထ၊ နှစ်) Today's Date: (dd/mm/yyyy)	
တွေ့ဆုံ မေးမြန်းထူနှံပါတိ် Interviewer ID	
ကလိုင်းဃနှံပါတ် Client ID	
ကျား/မ Gender	
အသက် Age	

ယခင်အပတ်ကတည်းက သင်တွင် (_____) လကွကာ မရှိပါ၊ အနည်းရှိပါသလား၊ အချို့အချိန်တွင်ရှိပါသလား၊ အများအားဖြင့်ရှိပါသလား၊ အချိန်တိုင်းနီးပါးရှိ ပါသလား။
In the last week, have you been feeling _____ none of the time, a little of the time, some of the time, most of the time, or almost all of the time?

	မရှိပါ None of the time	အနည်းငယ်ရှိ A little of the time	အချို့အချိန်တွင်ရှိ Some of the time	အများအားဖြင့်ရှိ Most of the time	အချိန်တိုင်းနီးပါးရှိ Almost all the time
5.4. စိုးရိမ်ကြောက်ရွံ့ခြင်း (သို့)စိတ်ထဲတွင် တုန်လှုပ်ခြင်း။ Nervousness or shakiness inside	0	1	2	3	4
5.9. ငြိမ်ငြိမ်နေ၍မရခြင်း၊ ဂဏှာမငြိမ်ဖြစ်ခြင်း Feeling restless, fidget all the time	0	1	2	3	4
3.3. ဝမ်းနည်းမှုခံစားရခြင်း။ ပျော်ရွှင်ခြင်း Feeling sad; unhappy	0	1	2	3	4
3.7. အင်အားချည့်နဲ့ခြင်း၊ အင်အားတဖြည်းဖြည်းကျဆင်းလာသကဲ့သို့ ခံစားရခြင်း Feeling low in energy, slowed down	0	1	2	3	4
3.9. အိပ်ပျော်ရန်ခက်ခဲခြင်း၊ အိပ်ပျော်ပြီးပြန်နိုးလျှင် လည်း ဆက်လက်အိပ်ပျော်ရန် ခက်ခြင်း၊ ဣန္ဒြိယမပျော်ခြင်း Difficulty falling asleep, staying asleep; can't sleep well	0	1	2	3	4
3.12.အကြောင်းအရာများအတွက် စိတ်ပူပန်မှုများခြင်း၊ "စိုးရိမ်ပူပန်ခြင်း" Worrying too much about things; worried	0	1	2	3	4
3.13 မိမိကိုယ်ကို အပြစ်တင်ခြင်း။ Blaming self for things	0	1	2	3	4
4.1. စိတ်နှလုံးကိုထိခိုက်စေသော (သို့) ဆိုးရွားသောအဖြစ်အပျက်များကို မကြာခဏတွေးမိခြင်း သို့မဟုတ် အမှတ်ရနေ ခြင်း Recurrent thoughts or memories of the most hurtful or terrifying events	0	1	2	3	4
4.5. စိတ်ဓနမ်းမြွေဖယ်ရာ (သို့) စိတ်ထိခိုက်စရာအဖြစ်အပျက်ဆိုးများကို ပြန်လည်သတိရစေသော လုပ်ရပ်များကို ရှောင်ရှားခြင်း၊ စိတ်ထိခိုက်မှုဖြစ်စေသောအရာများကိုရှောင်ရှားခြင်း Avoiding activities that remind you of the traumatic or hurtful event or avoiding the things that cause bad feelings	0	1	2	3	4
4.12.ကြောက်လန့်တုန်လှုပ်ခြင်း၊ အလွယ်တကူကြောက်ရွံ့ခြင်း Feeling jumpy, easily startled	0	1	2	3	4
4.18. နေ့စဉ်လုပ်ငန်းတာဝန်များကို ပါဝင်ထမ်းဆောင်ရာ၌ အခက် အခဲရှိခြင်း Difficulty performing work or daily tasks;	0	1	2	3	4
4.23. ထိုအဖြစ်အပျက်များဘာကြောင့်ဖြစ်ပျက်ပါသလဲဟူသော အတွေးများတွေးရင်းအချိန်ကုန်ခြင်း Spending time thinking about why these events happened to you	0	1	2	3	4

ဤအပတ်တွင် အခက်အခဲများကိုပြန်လည်ဆန်းစစ်မှုမေးခွန်းများ၏ရရှိသောဝေါင်းအမှတ်များ _____
Total score this week for Problem Review questions

MHAP Monthly Questions for all Wait-Control Clients

1. Since the last check in have you received help for any of the above problems? Yes/no

1a. If yes, please describe. (Record response).

2. Since the last check in have you taken medicines for any of these problems? Yes/no

2a. If yes, which medicine(s). (Record response).

လုံခြုံမှုမေးခွန်း (၄) ခု **4 Safety Response questions**	အဖြေများကို မှတ်ပါ။ **Mark Response**	
	Yes	**No**
"သင့်ကိုယ်သင် သတ်သေဖို့ အကြောင်း စဉ်းစားဖူးလား" "Do you think about killing yourself"		
"သင့်ကိုယ်သင် သတ်သေမယ့် အစီစဉ်ရှိလား။" "Do you have a plan to kill yourself"		
"ဒီအစီအစဉ်ကိုလုပ်ဖို့ နည်းလမ်းရှိပါသလား။ "Do you have a way to carry out this plan?"		
သင့်ကိုယ်သင် သတ်သေဖို့ ကြိုးစားဖူးပါသလား။ "Have you ever tried killing yourself?"		

နောက်ဆုံးမေးခွန်း(၂)ခုထဲမှ တစ်ခုကို 'ဟုတ်ကဲ့' ဟုဖြေပါက အခန်းထဲတွင် ကလိုင်းယန်နှင့်အတူ ရှိနေသောအချိန်တွင် သင်၏ဖူ ပါဝိုင်စာကို ဖုန်းခေါ်ပါ။ မေးခွန်းအားလုံးမှာမှ တစ်ခုခုကို 'ဟုတ်ကဲ့' ဟုဖြေပါက တွေ့ဆုံမှုအပြီးတွင် ဖူပါဝိုင်စာကို ချက်ချင်းဖုန်း ခေါ်ပါ။

If a client responds "yes" to either of the last 2 questions, call your supervisor immediately with the client still in the room with you. If a client responds "yes" to any of these questions, the counselor should call their supervisor immediately at the end of meeting.

လုပ်ဆောင်ပေးမှု ***Actions Taken***	**Mark here if done** ပြီးလျှင် မှတ်ပါ။	**Notes** မှတ်ချက်များ
ဖူပါဝိုင်စာကိုခေါ်သည်။ - *(အချိန်ကိုတော်ပြပါ)* Supervisor called – specify time of call		
ဖူပါဝိုင်စာကောက်လာသည်။ *(အချိန်ကိုတော်ပြပါ)* Supervisor arrived – specify time of arrival		
ကလိုင်းယန်ထံမှ လုံခြုံမှုကာတိတောင်းပါ။ Have the client give their safety word		
စောင့်ကြည့်လေ့လာမှုအစီအစဉ်တစ်ခုလုပ်ပါ။ Set up a safety watch		
ဌာနတစ်ခုခုသို့ ချက်ချင်းလွှဲအပ်သည်။ *(အချိန်ကိုတော်ပြပါ)* Immediate referral to facility – specify time/place		

အဖြေများ၏အခြားအသေးစိတ်အချက်အလက်များကို (လိုအပ်လျှင် နောက်ကျောစာမျက်နှာများကိုအသုံးပြု၍) ရေးမှတ်ပါ။
Provide more detailed notes of the response (use back if needed)

အဖြေများကိုပြန်လည်သုံးသပ်ခြင်း **Review of Response**	*လက်မှတ်* **Signature**	*ရက်စွဲ* **Date**	*မှတ်ချက်များ* **Notes**
ကိုတ်၏ပြန်လည်သုံးသပ်မှု (Cate)			
ဒေါက်တာတင်ထေ၏ ပြန်လည်သုံးသပ်မှု (Dr. Htin Zaw)			

APPENDIX H: SAFETY PLAN – THAILAND STUDY

1. Counselor identifies that a client is in need of help using the 4 Safety Steps outlined in training and follows the action points for the 4 Safety Steps.

2. Counselor calls his/her Clinical Supervisor if needed according to the 4 Safety Steps. Together, they follow the 4 Safety Step action points.

3. When needed, the Clinical Supervisor calls the MHAP Response Team. *The MHAP Response Team consists of the following people. The following list is in order of how each person should be called. If the Counselor cannot reach the Clinical Supervisor, he/she should call the Project Physician. If the Counselor cannot contact the Project Physician, he/she should call the Local Project Coordinator.*

   a. Counselor
   b. Clinical Supervisor
   c. Project Physician
   d. Local Project Coordinator
   e. Organization Supervisor

The MHAP Response Team should follow the Action Options listed below.

Local Project Coordinator calls Project Site Director. Project Site Director will make sure that the event and response are documented for the project using an incident report form.

Project Site Director will inform the Research Team by email and will update the team in the field.

4. Options

a. Project Physician can manage the case
b. MTC can manage the case. Either client already at MTC or client is referred to MTC. If referred to MTC, Counselor 32 should be called to assist the MHAP Response Team
c. Severe cases can be referred to Mae Sot Hospital directly
d. SAW can be contacted to see if a female client can stay at the shelter if needed

Note: Clients who have attempted suicide or who have been raped should be taken directly to Mae Sot Hospital if not already at MTC. If at MTC, the response team will make a decision about referral from there.

APPENDIX I: EXAMPLE OF A MASTER RECRUITMENT LIST – THAILAND STUDY

Number	Organization	Sex	Age	Name	Contact	Location	Assigned to:	Status
1	MTC	F	79		c/o Counselor 22	Central Market Area	22	Enrolled
2	AAPP	M	36		0824093899	Buffalo Farm	16	Refused screening
3	MTC	M	38		0827943800	Htung Htaung neighborhood	24	Didn't meet criteria
4	SAW	M	83		c/o Counselor 18	Mae Pa	18	Refused CBI
5	SAW	F	28		0824093800	Mae Tao	32	
6	AAPP	F	35		0719693800	Baan Tung	36	Enrolled

APPENDIX J: EXAMPLE OF WAIT CONTROL CALL AND FOLLOW UP INTERVIEW TRACKING LISTS – THAILAND STUDY

Wait Control Call Information

No.	Recruitment ID	Study ID	Sex	Age	Name	Contact Information	Notes	Counselor	Date follow up finished	Remarks
1	82	A-22-001	M	31		839623548	UNHCR area	22	5/11/11	Withdraw : Refused Follow up interview
2	111	S-14-001	F	41		843798455	Market area	14	6/11/2011	Done. CBI to be provided
3	107	S-32-001	F	39		821743633	Corn warehouse past UNHCR	32	6/11/2011	Withdraw : Refused Follow up interview
4	109	S-12-001	F	40		c/o Counselor 12	near General Hospital	12	8/11/2011	Done. CBI to be provided
5	79	A-26-004	F	51		896392457	Pho Phra	26	1/12/2011	Done. CBI to be provided
6	68	A-19-003	F	61		839623548	Near UNHCR	19	1/12/2011	Done. Refused CBI.

Follow up interviews

No.	Study ID	Gender	Age	Name	Contact Information	Location	Counselor	Clinical Supervisor	Date when Interview can be conducted	Enrollment Assignment (delete this column before giving to interviewer)	Remarks
1	A-26-001	M	34			UNHCR area	26	11	29/10/2011	C	Refused. Follow up interview
2	A-26-002	F	46			Htung Haung	26	11	30/10/2011	T	Done: FU done 24/12/11
3	S-21-002	F	40				19	12	30/10/11	T	LOST. 30/10/11 FS completed. FU unavailable (Burma). Feb 1, still trying to find phone number.
4	M-30-001	F	24			Mae Tao area	32	12	3/11/2011	T	Done: 28/11/11 FS completed. FU done 11/12/11
5	S-11-001	F	39				12	12	5/11/2011	C	Withdraw : health reasons.
6	S-11-002	M	70				12	12	5/11/2011	T	Done: 2/11/11 FS completed. FU done 10/12/11

APPENDIX K: EXAMPLE OF A POST INTERVENTION FREE LIST INTERVIEW

Example of a Post Intervention Free List Interview from a Randomized Control Trial (RCT) of Treatments for Depression and Trauma symptoms among Adult Torture Survivors in Northern Iraq (unpublished)

Client ID: AAAA

Interviewer name: BBBB

Date: DD.MM.YYYY

Changes since beginning the intervention

Startle: I don't startle anymore. The startling has gone and became less than before.

Anger: I am not angry as before. I used to become angry for the slightest of reasons. When I was getting an anger attack, I used to break everything in front of me; including the TV. I used to tear my cloths when I was getting those attacks. Now, when I am getting angry, I make a lot of calculations for everything. I have a lot of thoughts before I start breaking something. For example, I tell myself that if I break the TV, how can I pay for another one or why should disenfranchise my kids from watching TV. When I become angry and want to hit my children as I used to do previously, I tell myself why should I hit him or her? I may actually hurt them or break some part of their body for example their hands or legs. Now I also tell myself I should talk with my children and my wife before hitting them. I tell myself that I hit them a lot previously, did that was of any benefit? Why shouldn't I try other ways of disciplining my kids?

Sleep: I started to sleep like other people. I used to not know what sleep is.

Fear: I am not afraid anymore. I used to look right and left when I was going to the street. I was afraid that someone may be following me. I was thinking that someone who may be following me is trying to kill me. Now, I walk in the street freely without turning right or left and I don't think anymore that someone is following me or trying to kill me.

Relations with others: When I was going out of the home, I was thinking that people are laughing at me. Even with my children, when I was talking to them, I was thinking that they were making fun of what I was saying. Now, I trust myself more and talk with people and my children more comfortably and in way that I trust myself similar to all other men. I used to be isolated and introverted and don't like to communicate with others. But now I don't like to be alone and like to be with my friends and my family all the time. I started also to take care of my appearance because some people pay a lot of attention to the appearance.

Self trust: I started to respect myself after I was hating myself.

Family: I started to think about my family and think about what they need from food and drinks. I started to have conversations with my family and daughters and listen to them after I used to be living in an isolation and don't like to talk with anybody.

Job: I try very hard to find a job in order to improve my situation and family's situation as well. In fact I found a job after I was unemployed and I was thinking that there is no benefit from me. I am now happy because I have the ability to spend on my family and buy them cloths and food. I become very sad when I remember the past, when my family and children were having a hard time to get food and I used to cry a lot and tell myself that I was not thinking about them.

Religion: I started to get closer to God. I pray, fast and go to the holy shrines. It is true that I am doing that in order to get closer to God, but the most important part is that I started thinking about my family. I used to be a not wanted person previously in the society and by my family and brothers because I am a communist. They think in our society that a communist is a non-believer. Not all of the people think that way, but only the extremists who are a lot in our area. So when I was saying hello to my relatives, brothers and friends (those who were extremists and not those who are liberal seculars), they were telling me to shut up because I was an infidel. That affected my children. For example when my son proposed the hand of a girl, the family of the girl told me that I am a communist and infidel and that they will not let my son marry their daughter. I started to think about my children and say why they should be unwanted in this society. So I started to pray and fast and go to the holy shrines. My friends and family started to telling me that they noticed that change and they started to get closer to me and they began to visit me and respect me and my children and they were telling my children that your father has changed and that he became a believer. My brother even proposed my daughter for his son.

My wife: My relationship with my wife started to become better over the last four months. I didn't abuse her physically over those four months even once, given that I was hitting her daily for the most stupid reasons. I used to think that she was spending money when she was giving money away for charity. But now, and in accordance with the traditions, I don't think that that is a mistake. I started to agree with most of the traditions and customs and religious rituals that she does like any other member in the society that we live in. my wife noticed that change and she also noticed the change in my treatment to her. She started to get closer to me and now I feel that she is close and faithful to me.

Cultural activities: I started to appear in the society and have some cultural activities. I used to do those kinds of activities before but no one was listening to me. For example, I used to give lectures and the topic of the lecture was about issues that people had a hard time accepting to listen to. Now, I choose topics that people like to hear about. T therefore people started to attend my lectures and listen more.

Myself: I was viewing myself as a dictator. I wasn't thinking except of myself. I was abusing, shouting and insulting like a mad dog, I am now a forgiving, loving and nice father. At least this is the way that my children are describing me now.

<u>Changes due to the intervention</u>

Symptoms: Many of the symptoms that I have been suffering from had disappeared. For example I don't have startling, anger and sleep disturbances anymore.

Family: I started to have a family that care about me and I care about them, after I was living in a lonely and isolated world of myself. I started to think about the way that my family lives and I don't go to bed unless I visit them while they are sleeping and kiss them.

My wife: I feel that I married again with my wife. I try to make her happy and respect her believes and rituals and religious customs, like going to the religious shrines by walking long distances and giving away for charity. Myself: I became a person who has a personality and a job. I used to be a disabled person who was isolated and has no personality or status. I started also to realize the difference between right and wrong and between the good and bad.

Going out: I started to go out of my home without being afraid or hesitant. I used to be looking right and left and was afraid from the closest people to me.

Thinking: My thinking has changed. Not all of the Islamic people extremists; there are Islamic people who are tolerant, secular, and cultured and there are Islamic people who are extremist and intolerant and hypocrites. My thought also has changed with regard to the party that I am a member of. I used to think that the member of the communist party is infidel. But now I think that there are a lot of positive things about being a member of the communist party, a lot of people who are members are good, honest, democratic, progressive and respectful people.

Relations: I learnt how to behave with each personally according to his or her believes and thoughts. I used to be very extremist and holding believes that were not accepted by the society that I am living in. I started to accommodate myself according to the values and traditions that are common in my society. I started to believe in democracy at the level of the home and family and society. I don't have enemies like before. Even when I am in dispute with someone, I tell myself what should I fight for with him, he may be wrong, so instead of fighting I can try to make him understand his mistake. I started to become a known person in the society who is respected, after I was an unwanted and isolated person. I also started to respect the opinions of others and don't make fun of them. I remember that I made fun of the therapist with myself when he invited me to these sessions. I attended the first session to make fun of the therapist. But after the third session my thinking changed and felt inside that this is the right way that it can help me out of the way I was living.

Talking: I started to talk and sit with others and have conversations. I used to stay calm and without saying anything for days because of the isolation that I was living in.

APPENDIX L: USE OF QUALITATIVE DATA TO GENERATE ADDITIONAL IMPACT ASSESSMENT QUESTIONS

Example from a Randomized Control Trial (RCT) of Treatments for Depression among Adolescents living in Internally Displaced Person (IDP) Camps in Northern Uganda (Bolton et al., 2007a)

Analysis of the post-intervention qualitative assessment data with adolescent participants was used to generate additional questions for the quantitative post-intervention assessment. Additional questions were developed on specific problems mentioned by multiple informants, but not already included in the questionnaire. These questions referred to worries (education, health, people in the family), quarreling with family, financial situation, school attendance, concentration in school, confidence in future, ability to solve problems in life, relationships with other members in the family, ability to care for personal appearance, ability to solve problems paying school fees, and ability to solve health problems. Other additional questions referred to caretakers' respect for the informant, caretakers trust, feeling like you're important, enjoying being together with other children, feeling of unity with others, feeling like you can talk freely with others, and on ability to give advice, quarreling with other children and confidence. Questions also referred to reluctance to do positive activities (seeking health care, starting an income generating activity, getting an HIV/AIDS test, making new friends).

Questions asked how each problem had changed in the previous 6 months (the period of the intervention): gotten a lot worse, a little worse, stayed the same, a little better, and a lot better. Questions about specific activities (such as starting an income generating project) were asked using a yes/no/don't know format.

Part of the section on additional questions is shown on the following page:

Part E – Follow-Up Questions

For each of the following problems, please say whether the problem 'got a lot worse, got a little worse, stayed the same, got a little better, got a lot better, was never a problem/issue OVER THE LAST 6 MONTHS. (For each issue, say whether it has become a lot worse, a little worse, stayed the same, become a little better, a lot better, was never a problem/issue OVER THE LAST 6 MONTHS.')

Problems	Lot worse	Little worse	Stayed same	Little better	Lot better	Never an issue
E03 Worries about your education	1	2	3	4	5	0
E04 Worries about your health	1	2	3	4	5	0
E05 Worries about people in your family	1	2	3	4	5	0
E06 Worries about rebel attacks	1	2	3	4	5	0
E07 Quarrels with family members	1	2	3	4	5	0
E08 Your means of getting money	1	2	3	4	5	0
E09 Attendance in class	1	2	3	4	5	0
E10 Ability to concentrate in class	1	2	3	4	5	0
E11 Ability to give advice to others	1	2	3	4	5	0
E12 Physical health	1	2	3	4	5	0
E13 Confidence for the future	1	2	3	4	5	0
E14 Ability to solve problems paying school fees	1	2	3	4	5	0
E15 Ability to solve health problems	1	2	3	4	5	0
E16 Ability to solve problems in your life	1	2	3	4	5	0
E17 Relationship with other members of the family	1	2	3	4	5	0
E18 Ability to take care of personal appearance	1	2	3	4	5	0
E19 Quarreling with other children	1	2	3	4	5	0
E20 Your confidence	1	2	3	4	5	0

For each of the following activities, please state if you have done it IN THE LAST 6 MONTHS. **(For each activity, say 'yes, no, or I don't know.')**

Activities	Yes	No	Don't Know
E21 If you were sick, did you seek medical treatment for it	0	1	2
E22 Got an HIV/AIDS test	0	1	2
E23 Started a small business or income generating project	0	1	2
E24 Started up a new friendship	0	1	2

APPENDIX M: USE OF QUALITATIVE DATA TO INVESTIGATE THE NEED FOR ADDITIONAL IMPACT ASSESSMENT QUESTIONS

Example from a Thailand-Burma Border Randomized Control Trial (RCT) for Survivors of Torture and Systematic Violence (unpublished)

Purpose

This free-list activity was conducted with individuals enrolled in the Mental Health Assessment Project's randomized control trial, who completed the components based intervention (CBI) treatment. The aim was to collect and analyze feedback from clients to assess whether or not additional questions should be added to the existing assessment form.

Methods

Counselors asked the free-list questions of their clients at the end of their CBI sessions and recorded the information in Burmese. The responses were then translated to English by the project translator and analyzed by the JHU research team. In total, 11 clients were approached and provided answers to the free-list questions.

Respondents were asked to list changes and explanations for the following two questions:

1. What are all of the changes that you or your family have experienced since you began the program? (that is, since you began receiving CBI from the MHAP Project)
2. What are all of the changes that you or your family have experienced because of the program? (that is, because of the CBI from the MHAP Project)

Results

A review of the data collected from the free-list interviews showed that there were only two potential items to add to the current assessment form ("making fewer mistakes" and "using what they have learned to help others"). The remaining data reflect information already captured in the current assessment form. Below are examples of the summary tables of the free-list responses:

Question 1: Changes that you or your family have experienced **since** you began the program?		
Client ID Number	***Change***	***Explanation***
S-11-002	Feeling better and have a better relationship with family members	Understand that feelings and behaviors can be changed if the thought is changed. When the negative thoughts are changed then the client feels better and can live comfortably.

M-30-001	Feeling better and more comfortable. Relationships in the family and with other people have improved so dealing with people is smoother now. Now the client can think with more positive thoughts and whenever negative thoughts come to mind the client can change that thought and, as a result, the feelings and behaviors improve.	Client realized that negative thoughts cause unhappiness and feelings of difficulty. Now this client knows she needs to think in a positive way to change the negative thoughts.

Question 2: Changes that you or your family have experienced **because** of the program?		
Client ID Number	***Change***	***Explanation***
S-11-002	She has a positive view of her life now. She feels better instead of feeling disappointed or fed-up. She can understand her family members more so she has a better relationship with them and they have a happier family life.	Before CBI she didn't have a good understanding of her family members and she was afraid to deal with the family members. After receiving CBI she has become very optimistic and she can change her negative thoughts. Feel more comfortable. Become happier in life.
A-26-002	Feeling less disappointed. Gained a better relationship with neighbors. Client is able to remove negative thoughts. Client can solve his problems in general because he is able to change his thoughts now. The client is able to share his knowledge with the neighbors. Client now feels like he has more energy.	Before, the client was so disappointed that he would go crazy. Now after receiving CBI the client has changed. The client understands the condition of his neighbors more now. Client can think in a more positive way. Before, there was no one for the client to talk with to receive encouragement, but now after meeting the counselor he is feeling more calm and lighter.

Conclusions

The research team decided that these additional items—"making fewer mistakes" and "using what they have learned to help others"—being somewhat vague and only two in number, did not warrant amending the assessment form to include. The findings from this free-list activity showed that the current assessment form is sufficiently capturing the important and relevant outcomes as well as the actual changes occurring for the clients over the course of the CBI intervention.

APPENDIX N: EXAMPLE OF ANALYSIS OF ADDITIONAL IMPACT QUESTIONS

Example from a Randomized Control Trial (RCT) of Treatments for Depression among Adolescents living in Internally Displaced Person (IDP) Camps in Northern Uganda (Bolton et al., 2007a)

The items in the tables below refer to questions that were added to the post-intervention instrument as a result of the post-intervention qualitative study. In that study, these items were reported as having changed in the course of participation in the intervention groups (either A or B). For each question (other than the specific activity questions), the respondent was asked to indicate how much they had changed in the previous 6 months. Their response choices were: got a lot worse, got a little worse, stayed the same, got a little better and got a lot better. Table 1 presents the percentages of adolescent participants who indicated that things had gotten better (combination of the 'a little' and 'a lot' options), things had stayed the same, and things had gotten worse (combination of the 'a little' and 'a lot' options) for each of the questions. Note that the data may not sum to 100% for each question because some of the respondents indicated that a given question was not relevant (e.g. the school related questions if they did not go to school) or if they thought the issue was never a problem in the first place.

Table 2 presents the mean scores for each question and the amount of change compared with the controls. The possible range of scores is –2 (got a lot worse) to +2 (got a lot better). A negative average score indicates that on average, the respondents indicated getting worse over the previous 6 months. The impact of each intervention is calculated in the form of an effect size compared with the control group. For example, while on average all three groups indicated that their worries about their education got worse, the effect sizes were positive and statistically significant for both intervention groups, indicating that participating in either one of the intervention groups resulted in worrying less on average than being assigned to the control group.

Table 1. Child reports of type of change over the previous 6 months*

	Controls (n=91)			**Intervention A (n=82)**			**Intervention B (n=89)**		
	Better	**Same**	**Worse**	**Better**	**Same**	**Worse**	**Better**	**Same**	**Worse**
Worries:									
About education	26	13	56	34	15	44	45	8	43
About health	30	10	59	40	9	48	52	9	36
About family	26	19	55	33	16	50	52	13	33
About rebel attacks	6	7	87	9	9	80	11	8	79
Relationships:									
Quarrels with family	32	12	35	35	9	38	37	11	28

	Controls (n=91)			Intervention A (n=82)			Intervention B (n=89)		
	Better	**Same**	**Worse**	**Better**	**Same**	**Worse**	**Better**	**Same**	**Worse**
Quarrels with others	38	16	30	38	13	34	49	13	20
Relationship with family	56	16	23	68	9	21	71	12	12
School:									
Attendance in class	46	12	22	45	9	30	60	10	12
Concentration in class	48	8	25	50	6	24	55	7	20
Solving problems paying school fees	15	10	74	16	9	68	18	15	63
Abilities:									
To get money	8	9	84	11	11	78	25	4	69
Giving advice to others	64	9	25	66	10	17	63	13	18
Solving health problems	11	13	73	22	7	71	26	10	63
Solving life problems	16	13	69	32	15	54	30	17	52
Caring for personal appearance	70	9	18	63	12	20	79	8	10
Confidence:									
Confidence for the future	48	12	38	46	13	35	66	9	24
Confidence generally	49	13	32	48	18	32	64	18	17
Feelings:									
Caretakers respect for you	66	9	25	67	11	22	76	15	9
Caretakers trust for you	68	14	18	65	16	20	82	7	11
Feeling you are important	59	18	23	63	12	24	67	15	18
Unity with other children	64	22	14	70	11	20	80	13	6
Talking freely with others	62	14	24	70	11	20	75	13	11
Enjoying staying with other children	67	15	18	68	9	23	80	15	6
Health:									
Your physical health	32	16	46	49	11	37	61	12	22
Activities:	**Yes**	**No**		**Yes**	**No**		**Yes**	**No**	
Started a small business	25			75	32		68	34	
Started a new friendship	51			49	55		45	62	

Table 2. Mean change for each item*

	Controls	Intervention A			Intervention B		
	Average Score	Average Score	Effect Size**	p-value	Average Score	Effect Size**	p-value
Worries:							
About education	-0.70	-0.20	0.50	.04	-0.08	0.62	.01
About health	-0.51	-0.09	0.42	.06	0.34	0.85	<.01
About family	-0.57	-0.28	0.29	.18	0.33	0.90	<.01
About rebel attacks	-1.60	-1.34	0.26	.11	-1.28	0.32	.05
Relationships:							
Quarrels with family	-0.07	-0.01	0.06	.82	0.29	0.36	.13
Quarreling with children	0.21	0.18	-0.03	.91	0.62	0.41	.06
Relationship with family	0.48	0.75	0.27	.16	1.21	0.73	<.01
School:							
Attendance in class	0.41	0.38	-0.03	.89	1.03	0.62	<.01
Concentration in class	0.45	0.56	0.11	.63	0.75	0.30	.19
Solving problems paying school fees	-1.49	-1.03	0.46	.01	-0.98	0.51	<.01
Abilities:							
Getting money	-1.52	-1.29	0.23	.18	-0.95	0.57	<.01
Giving advice to others	0.55	0.73	0.18	.32	0.88	0.33	.08
Solving health problems	-1.15	-0.88	0.27	.17	-0.67	0.48	.02
Solving problems in life	-1.00	-0.41	0.59	<.01	-0.40	0.60	<.01
Caring for personal appearance	0.84	0.85	0.01	.99	1.24	0.40	.02
Confidence:							
Confidence for the future	0.11	0.14	0.03	.89	0.74	0.63	<.01
Confidence generally	0.27	0.28	0.01	.97	0.88	0.61	<.01
Feelings:							
Caretakers respect for you	0.66	0.79	0.13	.51	1.20	0.54	<.01
Caretakers trust for you	0.76	0.74	0.02	.94	1.33	0.57	<.01
Feeling you are important	0.48	0.55	0.07	.74	0.82	0.34	.08
Unity with other children	0.78	0.87	0.09	.65	1.25	0.47	<.01
Talking freely with others	0.55	0.82	0.27	.18	1.08	0.53	<.01
Enjoying staying together with other children	0.80	0.80	0.00	.99	1.25	0.45	<.01
Health:							
Your physical health	-0.31	0.18	0.49	.02	0.68	0.99	<.01

* This table presents the average scores for each group and the p-value for the comparison of the change in each intervention group vs. controls.

** The effect size is expressed as the difference in the change experienced by the intervention participants (A or B) compared with the difference experienced by the controls: Average change of A/B – Average change of controls. The p-value indicates the statistical significance of this difference.

Both interventions showed improvement on most items compared with controls. Participating in the B intervention conferred the most impact. Effect sizes suggest that either intervention was superior to controls in terms of improvements on worries about their education, solving problems paying school fees, solving problem in life generally, and improved physical health. Participants in the B intervention also on average indicated significant improvements compared with controls in their worries about their health and their family, their relationships within their family, their school attendance, their ability to get money and care for their personal appearance, their confidence, and in most of the questions associated with how they felt about their relationships with caregivers and others.

APPENDIX O: EXAMPLE OF RESOURCES REQUIRED FOR RCT

** Position titles and compartmentalization of tasks are flexible.

Project manager: (100% time)

- Assure supervision groups are occurring
- Follow up on any problems (e.g., space, attendance)
- Supervisors access to Skype for supervision calls
- Arrange for recruitment; follow this up
- Attend weekly phone calls with technical advisors
- Oversee all staff related to project; conduct weekly meetings with project staff
- Assure all assessment and monitoring forms are updated, copied when needed, and received by counselors and supervisors
- Review intake forms for mistakes/corrections. Assure procedure for randomization is followed
- Assign counselors cases after assessed and consented
- Keep running lists of cases and controls (numbered)
- Be involved in any safety procedures, aware of any cases with safety issues; promptly alert all relevant project staff

Recruiters: (number needs vary based on recruitment plan)

- Help recruit children/caregivers (e.g., go into community to find kids that need our help)

Assessors: 2-4 (depending on study design and time dedicated to project)

- Complete training in research ethics and intake/assessment form
- Meet with child/caregivers to give screening measure/intake measure and consent to study; arrange follow-up meeting with counselor
- Meet with child/caregivers again after a counselor finishes treatment with a client to re-administer assessment

Data entry: 1 full time, or multiple part time

- Complete training in data entry
- Help collect papers/intakes and organize them
- Enter scores/responses into computer (and/or scan forms to JHU if capacity)
- Exchange weekly emails with JHU to send data and monitor data collection/input

Community workers (# depends on design; likely at least 2)

- Follow up with controls; call once a month to check on
- Follow up with families who refuse to participate or drop out to understand why
- Complete post-study qualitative interviews to assess acceptability, pros/cons, etc.; get local feedback

Counselors (11 in this case; anywhere from 2 days dedicated to FT)

- See children/caregivers for treatment
- Set aside 2 hours per week for supervision
- Set aside 3-4 hours per week for each client (actual client time, transport, prep and documentation after)
- Complete of monitoring forms with clients each session; submitted to supervisors
- Completion of "case notes" documenting what they did in session; submitted to supervisor weekly

Supervisors: (2 in this case)

- Set aside 2-4 hours per week for supervision with counselors (group meeting usually 2 hours, sometimes 3; often have to call/meet with certain counselors for follow-up)
- Set aside 2-3 hours per week for Skype calls with trainers
- Carry at least one case (3-4 hours/week for case)
- Collect and organize forms from counselors; assure all forms are completed and entered (or received by data entry staff)
- Complete supervision form for each counselor's case to report to trainers
- Follow up closely for any safety issues with cases (may mean visits with the counselor to the client's home, etc.)