



DESIGN, IMPLEMENTATION, MONITORING, AND
EVALUATION OF CROSS-CULTURAL HIV-RELATED MENTAL
HEALTH AND PSYCHOSOCIAL ASSISTANCE PROGRAMS:
A USER'S MANUAL FOR RESEARCHERS AND PROGRAM
IMPLEMENTERS
(ADULT VERSION)

MODULE 6:
USING CONTROLLED TRIALS TO ASSESS
PROGRAM IMPACTS

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ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AMHR	Applied Mental Health Research
ART	Antiretroviral therapy
BA	Behavioral activation
CBI	Components based intervention
CBT	Cognitive Behavior Therapy
CD4	T-helper cell targeted by HIV
CDC	Centers for Disease Control
CPT	Cognitive Processing Therapy
CSADHS	Child sexual abuse
DHS	Demographic health survey
DIME	Design, implementation, monitoring and evaluation
DRC	Democratic Republic of Congo
EBT	Evidence Based Treatment
FG	Focus Group
FL	Free List
GBV	Gender Based Violence
HIN	Health information network
HIV	Human immunodeficiency virus
IDU	Injecting drug user
IPT	Interpersonal Therapy for Depression
IRB	Institutional Review Board
JHU	Johns Hopkins University
KAP	Knowledge, attitudes and practices
KI	Key Informant
LGBT	Lesbian, gay, bisexual, transgender
LMIC	Low and middle income countries
MEMS	Medication Event Monitoring System
MI	Motivational interviewing
MOH	Ministry of Health
MSM	Men who have sex with men
NGO	Non-governmental organizations
OVC	Orphans and vulnerable children
PE	Prolonged Exposure
PLWHA	People living with HIV/AIDS

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POFO	Positive Outcome for Orphans Study
PPS	Probability proportional to size
PRA	Participatory rural appraisal
PTSD	Post traumatic stress disorder
R2P	Research to Prevention
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
ROC	Receiver Operating Characteristic
SEARCH	Supporting Evaluation and Research to Combat HIV/AIDS
SES	Social economic status
SMS	Short Message Service
SOW	Scope of Work
SRP	Stress related response
STI	Sexually transmitted infections
SW	Sex worker
USAID	United States Agency for International Development
TFCBT	Trauma Focused Cognitive Behavior Therapy
VCT	Voluntary counseling and testing
VOT	Victims of Torture Program
WHO	World Health Organization

INTRODUCTION TO THE MANUAL

The Manual for Design, Implementation, Monitoring, and Evaluation of Cross-Cultural HIV-Related Mental Health and Psychosocial Assistance Programs: A User's Manual for Researchers and Program Implementers has been written to assist researchers and organizations developing and implementing programs in HIV 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) to develop or adapt appropriate interventions to address these problems; and 3) to 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 in sequence, to follow the life of a project, or as stand-alone units 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.



This symbol indicates that what follows is a critical requirement or constraint.

INTENDED USERS

This manual is primarily intended for researchers and groups responsible for mental health and psychosocial interventions for HIV-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 methods (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.



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.

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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.

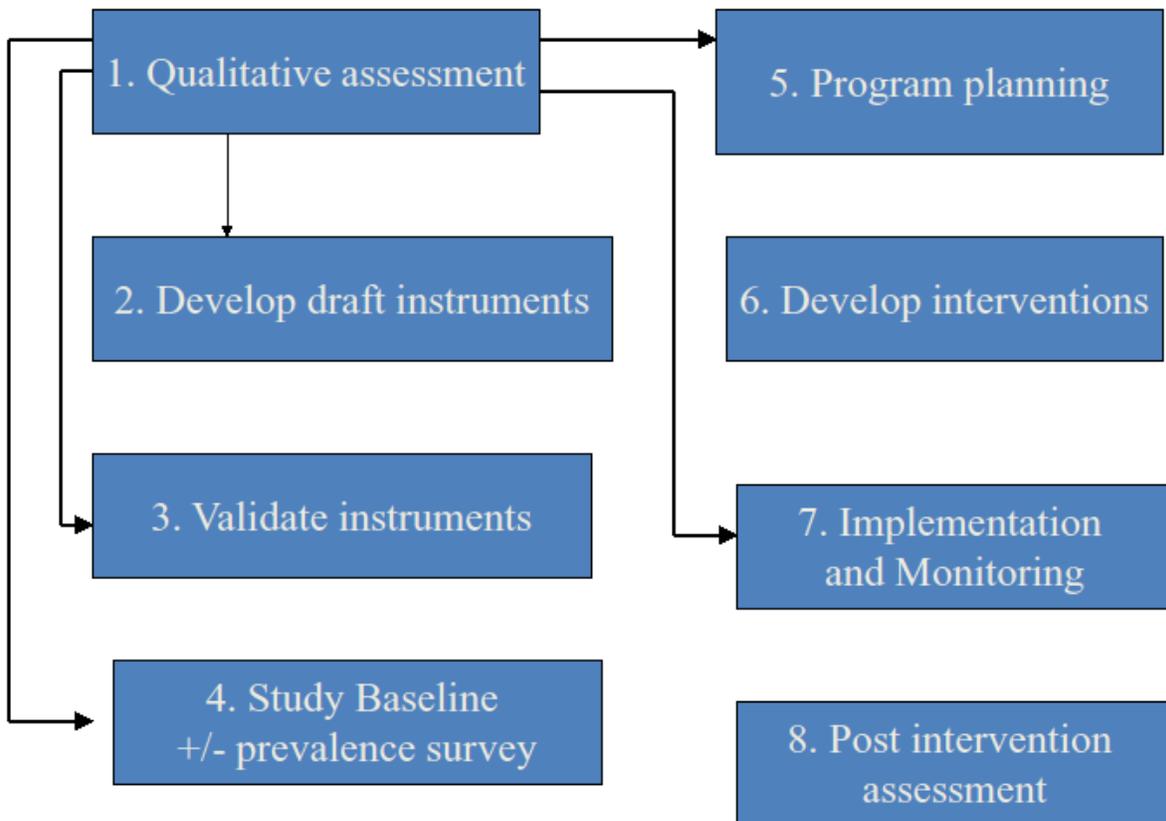
The authors would be pleased to discuss training and technical assistance with any interested organization or individual.

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.

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 the diagram indicates which of the subsequent steps (2-8) are informed by qualitative data. 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: (Module 1)

Variations in culture and environment affect how people understand the mental health and psychosocial problems related to HIV. 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 HIV-related mental health and psychosocial problems: (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 where 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 and also provide 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 as well as giving 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 HIV-related mental health and psychosocial problems: (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 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. Post 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:
USING CONTROLLED TRIALS
TO ASSESS PROGRAM IMPACTS**

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 receiving them. However, the current evidence base for psychosocial and mental health interventions in low middle income (LMIC) countries is poor, and most interventions are unproven for most populations. It is quite possible that the approach used for one culture may not be appropriate or acceptable for another, particularly for counseling-based interventions, so adaptation and testing is indicated upon introduction to a new population. While it cannot simply be assumed that the new intervention will be acceptable and effective based on results elsewhere, it is not always possible 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 beginning their programs, or as part of the implementation process.

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. Where they are done they typically consist only of comparing recipient assessments that were 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 their 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. This approach uses scientific research methods, yet is designed to be low cost, to complement program activities, and be largely conducted by the service organizations themselves with external technical input. Such studies are intended to achieve three important objectives:

1. To evaluate the extent to which programs are actually benefiting their recipients
2. To serve as a basis for ongoing improvement of those programs

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3. To advance the field by building evidence of the effectiveness of different approaches

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 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 interim, the social, economic, political or physical environment may have altered in ways that affect the project outcomes, making the intervention appear more or less effective than it actually is. Determining the impact of the intervention requires assessment 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 disasters. However, these are the situations in which controlled studies are most needed because of the high likelihood that 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, as need normally exceeds service capacity, waiting for a service tends to be the norm of any program. 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 1, 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

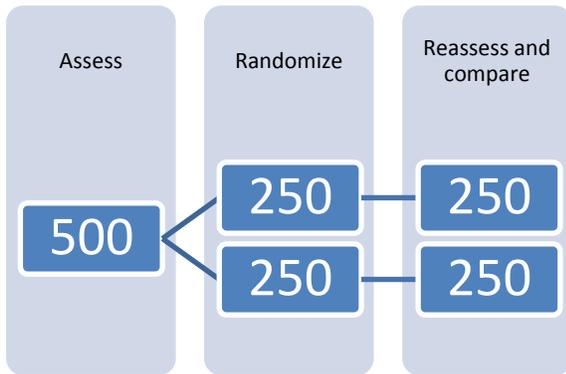
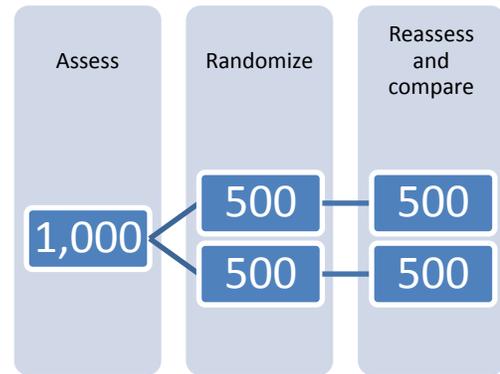


Figure 2a



A related concern is **identifying** a particular person in need of mental health services and **asking** them to wait. Some program staff consider it preferable 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 the program can offer assistance to the person while they wait for services.

In controlled trials the preferred way of deciding who will receive services first (the intervention group) is by random selection. For programs this usually depends on who turns up first at the service facility or through community outreach. 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 are concerns 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/clinic/etc, 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.

A.3.2. ASSESSMENTS PRE- AND POST-INTERVENTION

Quantitative assessments of the key programs 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 direct providers. Where this is not possible – when the provider must do the interview – she/he might conduct the pre-intervention interview but another provider who did not serve that particular participant should do the post-intervention interview. 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 are thought to likely 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 and/or areas needing improvement 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 are not fundamental to the intervention, but usually refer to improvements in access, feasibility, and acceptability among the population. Fundamental changes to the intervention itself would suggest that the intervention is inappropriate, leading to its cessation and substitution with something more promising.

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), though this is rarely done in practice. In the study context, monitoring is necessary for three reasons:

1. To determine whether it 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, the conclusion that it is ineffective would 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 (1) expected positive impacts, (2) expected negative impacts, (3) unexpected positive impacts, and (4) unexpected 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. Where possible, impact assessments should identify and assess as many of the program impacts as possible in order to get more comprehensive picture of a program's net benefit (or lack thereof), 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)

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, 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. 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.

Both interviewer and supervisor roles may be filled by people identified from the implementing organization, by outside hires, or a combination of both. 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. As organizations often lack sufficient staff to cover all positions, interviewers and supervisors are typically a mix of staff and outside hires.

B.1.1 INTERVIEWER QUALIFICATIONS

Unlike the instrument validity studies and prevalence studies, 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 will depend 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
- ✓ In good health and able to travel to wherever interviews are conducted (clinics, homes, etc.)
- ✓ Acceptable to the target population (in terms of personal reputation, where they are from, gender, age, ethnicity, etc.)

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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.

It is important to ensure that the selected interviewers will be acceptable to the population being interviewed. This is particularly important for HIV-affected persons who have been stigmatized by (and therefore 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. Consultation with community leaders and stakeholders is useful in thinking through who would be appropriate interviewers.

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 (in Module 5). The second set of activities refers to 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 dropouts. 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. Where the provider and interviewer roles are combined, the supervision of providers and interviewers is also provided by the same person.

Persons who will supervise 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 interviewers and research team (latter usually by phone)
- ✓ Acceptable to and respected by the interviewers

As described in other modules, supervisors provide the link between the research team and the interviewers. 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 on sessions when interviewers are unavailable or else require

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additional supervision. 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 but depending on the rate of interviews. Supervisors also meet weekly with the field study director.

B.1.3. FIELD STUDY DIRECTOR QUALIFICATIONS

One person is needed on-site to lead the study from beginning to end. This includes: the planning period; subject recruitment, assessment, randomization; the conduct of the intervention and tracking of controls; and the follow-up assessments. This position is ideally full-time. Field study directors should be persons who are:

- ✓ Preferably a 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 duration of the study itself (1-2 years, depending on the rate of recruitment and treatment).
- ✓ Speaks 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 2-3 days of didactic training, which includes standardized interviewing methods and procedures as well as specific orientation and practice with the instrument among themselves. They also learn how to determine whether the interviewee is eligible for the impact study and 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, etc.



If a person misses any of the classroom training — either the review of the questionnaire or the practice periods — she/he cannot continue as an interviewer or supervisor regardless of the cause. Without the training she/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 study/program
2. Screening into study and pre-intervention assessment
3. Allocation of participants to immediate intervention or wait-list 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. Implementation of 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; 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 subjects should not currently be a danger to themselves or others. Those that are must receive urgent monitoring and treatment with interventions already known to be effective, rather than being randomized to either a wait-list control or to an intervention whose effectiveness is currently unknown. Interventions that require significant cooperation from the subject (such as returning for multiple treatment visits) normally require that the subject is capable of such actions or has someone that can ensure that they return. In some cases, this may exclude severe mental illness such as uncontrolled psychoses or severe cognitive deficits. Participants should also live in the study area throughout the treatment period.

Eligibility criteria based on the study outcomes commonly vary for difference types of trials. These are expressed as the presence/absence of a problem or (more commonly) the severity of a problem. 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. To be considered eligible, a subject must meet a minimum severity *cutoff score* on one or more

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of these scales (depending on which scale(s) is the main study outcome). Calculation of the appropriate cutoff score is usually completed 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 identify most persons with significant problems (i.e., good specificity) but low enough not to exclude many of the same (i.e., 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 in question (See Module 2). The score that 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.



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)

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 (4) being able to understand and speak the local language (*Acholi Luo*) and (5) have 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 (as they need referral immediately and cannot be put into a control condition).

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 (32 points) below this average score.

As stated above, one of the exclusion criteria was having a high degree of suicidal thoughts. Based on this criterion, six adolescents exhibiting a high degree of suicidal ideation were excluded from the formal study. These six all happened to live in one camp, and so in consultation with mental health professionals involved with the study, all six were constituted into a single and separate intervention group. This high-risk group met throughout the study period and was assessed at follow-up, but their data are not included in the intervention impact analyses.

B.4 SCREENING INTO 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 study via local leaders or other influential persons, or through local

organizations or town hall meetings. Service providers frequently have such personal connections, including those created during previous steps in the DIME process. Publicity can encourage all persons to be screened, or it can target those who feel they may have the problems being assessed and treated. If there has been a prior prevalence study using the instrument, then those 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 inviting those validity study interviewees who met the study criteria to join the study without repeat 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.

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 amount of 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 that we have completed, these figures and the various variance estimates have suggested a sample size of 80-100 persons per arm. This means that we needed 80-100 clients to complete the intervention and pre-and post-intervention assessment and 80-100 wait-list controls to complete only the pre- and post-intervention assessments. To calculate the number of persons

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/

who need to be recruited into the study, we typically estimate that approximately one third will not complete treatment. This inflates the number of persons to be recruited into the study (i.e., found eligible and agree to participate) to 110-130. Numbers for controls can be less, as there is not the same concern about dropping out of treatment. However, controls may not be available for post-intervention assessment for reasons such as moving or deciding they do not want to be re-interviewed, health issues, death, etc. For controls, we usually recruit approximately 90-110. The example box on the following page describes how a sample was recruited in Uganda.

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 required sample size simultaneously. However, recruitment often proceeds slowly and there is not the capacity to treat the required numbers all at once. Additionally, 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 new clients as they are recruited until reaching their capacity. 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-list control arm begin to receive treatment once their designated wait period is completed. This rolling admission approach takes much longer to complete the study. Exactly how long it takes will depend on the number and capacity of the providers and the required sample size.

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

Allocation of participants to study arms should occur only after determining eligibility and securing their agreement 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 a Randomized Control Trial (RCT) of Treatments for Depression and trauma symptoms among Adult Torture Survivors in Northern Iraq (unpublished)

This was a study of the impact of an intervention being provided by 20 Community Mental Health Workers (CMHWs). We wanted to ensure that CMHWs 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 waiting list. 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, this 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-list control group (or vice versa).
2. For each CMHW, individually sealed envelopes containing a paper indicating the treatment assignment (immediate therapy or wait-list 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 put on the wait list.

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

example



Example of Stratified Random Selection 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 304 eligible youth who agreed to participate were stratified 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-List 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 with the numbers one, two and three appearing randomly throughout. As he read each number, he assigned the next name on the list to the corresponding study group. He continued in this manner until all children had been randomized.

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 assessment and screening into the study, consent procedures, refusals, adherence, dropouts, and repeat assessments.

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 that has important implications for impact assessment. This aspect of intervention monitoring and the monitoring of adherence to study design (#3) are described in the following pages.

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

Module 5 describes how the supervision system enables training to continue during implementation. In fact, most skills are developed during implementation/supervision and for this reason this approach to supervision is referred to as an ‘apprenticeship’ training model. Under this model, local supervisors are trained with the providers and subsequently meet with them weekly to review their cases. The supervisors also meet weekly by phone with the trainers (to date these trainers are U.S.-based and have conducted these calls from there). In this way both the supervisors and providers continue to receive training in their roles while maintaining treatment quality and fidelity through on-going engagement by the trainers.

This on-going interaction between the levels of client, provider, supervisor, and trainer/expert has important implications for the conduct of trials. Communication between the staff facilitates the detection of problems during implementation, and facilitates the cooperative solving of these problems. Continued communication during trial and errors of problem solving 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. However, when interventions are being introduced for the first time and simultaneously tested, 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 now will render the trial irrelevant (since future implementers will have to address them anyway).



Example of Implementation Problems Emerging During Multiple Randomized Control Trials (RCT) of Counseling Treatments for Trauma among Torture Survivors Living in Iraq

Examples of problems emerging at four levels (clients, providers, supervisors, and trainers), and consequent changes in the interventions:

- 1. Clients:** Between sessions, clients were required to complete self-assessment forms at home to record change in behaviors. Many could not do this because they were illiterate.
Change: Visual representations (drawings) were created of both the concept being assessed (in this case, activities) and the amount of change experienced. Clients indicated the pictures that best represented the type of activity and degree of behavior change.
- 2. Providers:** Families of clients were angry with the providers because they did not want the clients coming for treatment. They believed that non-drug counseling could not be effective, and that seeking treatment stigmatized the whole family.
Change: Early psycho-education sessions held with clients were expanded to include family members.
- 3. Supervisors:** Despite emphasis in the initial training, providers continued to have difficulty distinguishing between “thoughts” and “emotions” and explaining these differences to clients.
Change: Additional training materials were created by the trainers. Supervisors used these materials in additional training sessions for the providers.
- 4. Trainers:** Clients were taking too long to complete the 12 weekly hour-long sessions. Instead of the usual 2-3 months, some clients required up to 4-5 months to complete treatment because they found it difficult to travel to the clinic.
Change: Session length was expanded to 2 hours whenever possible, thereby reducing the number of clinic visits required.

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 (e.g., improvements to clinic accessibility.)
2. All changes occur at the same time for all participants/providers/supervisors.
3. Changes should not be fundamental but instead refer to how the intervention is provided or changes in the relative emphasis of different content areas. If fundamental

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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 includes 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, dropouts, and conduct of repeat assessments.

Monitoring overall recruitment progress

Appendix F includes part² of a tracking tool used in a study in Southern Iraq to monitor the status of recruitment on a weekly basis (Weekly Recruitment Form).

This tool has space to track the number of study participants recruited by each therapist (called a *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

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

requirements given time and budget constraints. If not, study managers can make adjustments in activities, personnel, or other resources in order to meet study deadlines.

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; consent of participants prior to enrollment; enrollment and randomization of participants; follow-up with participants who do not comply with research or intervention procedures; and monitoring of participants for signs of danger (e.g., suicide). Appendix G shows the client tracking form used in the Southern Iraq RCT. This form tracks events by study participant and is organized by CMHW. The form tracks dates of key events such as intake, consent, sessions, calls to control clients, exit interview, etc. There is space for comments about the study participant. The random allocation of the client to intervention or control is also indicated. This is unknown to the therapist prior to enrollment of the participant.

Appendix H 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 (all names in the original document, both clients and staff, have been replaced with 'xx'). Each row represents a study participant, beginning with her/his ID. The progress of each participant is recorded on a weekly basis throughout the various study stages by entering the date of each event when it occurs. For those in the intervention arm, most columns represent each of the intervention sessions; for controls, each column represents the date of a regular check-in to ensure their safety while they wait for treatment. The second-to-last column records the date of the post-intervention assessment, while the final "comments" column records any current issues with the client that affects her/his participation in the study, as well as any steps taken to address this. Comments here typically refer to problems in finding the participant and/or to the client's compliance. This column is also used to record the person who conducted the final assessment in case of problems with the assessment.

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), to ask them to return to the study, or (if they refuse) to conduct the repeat interview. When the final analysis was done for the Southern Iraq RCT, these interviews were used as part of the post-intervention assessments regardless of whether the participant completed the intervention or control period.

Monitoring each contact with participants

In the Southern Iraq RCT, the research design submitted for approval to the institutional ethics review board (IRB) included outside referral 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. We developed a system to monitor study participants for these issues on a regular basis. Therapists referred such participants to their supervisor (a psychiatrist) who would help make the determination about where to refer the client. Appendix E is a client monitoring form that CPT therapists used at the beginning of each therapy session to screen for these dangers, among other things. A similar form was developed for the other study arms. Intervention participants were assessed at each weekly session. Controls were assessed by telephone or met briefly at the therapist's clinic on a monthly basis.

Using Google Documents to monitor study procedures

In Southern Iraq, Google Documents was used as a workspace for the monitoring forms and processes described. First, study tracking forms were created as Google spreadsheet documents and were located online only in the project's Google Documents folder. Data entry and review of the tracking forms were 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 (intake forms, consent forms, client monitoring forms) were scanned into a *.pdf format and uploaded to the project's Google Documents folder. This helped prevent loss of key project documents during transport. This also allowed us to double-check that the events documented on the tracking sheets actually occurred. For example, if the consent of a participant is indicated on the tracking sheet, we can verify that the signed consent form actually exists by checking the Google Documents folder for the scanned document. Completing (and scanning) a unique Client Monitoring Form for each therapy session (for intervention participants) and phone contact (for control participants) facilitates the accurate tracking of key events and study protocols.

B.7 POST INTERVENTION QUALITATIVE ASSESSMENT

B.7.1 QUALITATIVE ASSESSMENT AMONG STUDY PARTICIPANTS

After the intervention is completed, a qualitative assessment is conducted among a sub-set of study participants in each of the study intervention arms 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 on these effects to the quantitative assessment instrument. 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.

Approximately 20 participants are needed per intervention for the qualitative assessment (therefore, 40 would be needed for studies with 2 intervention arms). They can be a convenience sample or purposively selected to represent the range of important variables (e.g., age group, gender, site, etc.). In the case of rolling admissions, the qualitative study should be conducted among the first 20 clients to finish each intervention. Since the interviews refer to effects of the intervention, controls are included.

Data collection consists of Free Listing interviews (see Module 1). Normally Free Lists (FLs) are done, although the number of FL and the primary question 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 the participant may not recognize as attributable to the intervention (but may be so). The second FL acts as a specific probe on the first FL. However, clients can give responses on the second FL 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 A for an example of a completed FL interview form.

FL forms are analyzed in the same way as described in Module 1. The left and right columns of 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).

B.7.2 QUALITATIVE ASSESSMENT AMONG PROGRAM STAFF

Program staff—those implementing the intervention(s)—may also be interviewed using methods such as FL, semi-structured interview and/or group methods such as focus groups. These interviews explore facilitators and barriers to program implementation. This is done not to expand the quantitative instrument and widen impact assessment (see section B.8 below),

but rather to learn ways to improve the program in the future.

Regardless of the method, interviews begin with an open-ended question about their experiences implementing the intervention. Program staff are then asked follow-on probe questions about which aspects of the program were particularly helpful and which were problematic or challenging. Positive and negative aspects of the program implementation (both expected and unexpected) are specifically probed for. Participants are typically also asked for their advice on future implementation. The box below is an example of the process and summary of the results from a trial in Uganda.



Example of Results of a Post-intervention Qualitative Study from a Randomized Control Trial (RCT) of Two Treatments for Depression among Adolescents living in Internally Displaced Person Camps 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 any unexpected effects of the interventions that were not assessed by the original study questionnaire. Ten interviewers from the pre-intervention qualitative study exploring adolescent problems received refresher training on qualitative interviewing methods and specific training on the questions used for this study. In order to explore a variety of study experiences, the intervention providers were asked to provide names of 5-7 youth per camp whom they thought had substantially improved over the course of the intervention period, as well as the names of 5-7 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 previous experience interviewing local youth.

Example box (continued)

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 lived. 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’s 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 that they felt hatred towards others. However, 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 providers (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 that there was more respect between them.

B.8 ADDITIONS TO ASSESSMENT INSTRUMENT BASED ON POST INTERVENTION QUALITATIVE ASSESSMENT

Frequent responses to the qualitative assessment of participants form the basis for questions that are added to the post-intervention quantitative survey instrument. Less frequent responses may also be selected if they refer to changes of particular 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 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 B.

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 study arms (intervention and controls). 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 refuse to participate.

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.

Why are all participants 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.



Example of Follow Up Assessment 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)

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

Thirty interviewers, 22 of whom had been involved in the screening assessment, conducted the post-intervention surveys. None of the follow-up interviewers were involved in implementing the interventions. All received training in general quantitative interviewing methods and specific training in the quantitative survey instrument prior to the interviews. 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 the 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, 10 had moved too far away to be contacted or were away for an extended holiday break, and 10 were unable to be identified and/or 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 scales 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 (Figure 3), 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.

Figure 3: Male Function Instrument

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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 function scale scores comparable, we must first calculate the mean score on those function questions that were answered, 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 "a moderate amount" for the remaining nine, then the mean score for the 18 items with responses would be 2.5 $(9 \times 3 + 9 \times 2 / 18)$ This mean value then

NOTE:

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

be substituted for the "not applicable" responses when calculating the function score.

Alternatively, using *averaging* of mean item responses 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.

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. Achieving similarity is the purpose of random assignment, but it does not guarantee that the groups will be comparable. Non-comparability may occur due to random effects or to a faulty random assignment process. Typically, comparisons are made of the demographic data for both arms (including gender proportion and 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 due to the intervention or to the fact that the two groups are themselves fundamentally different.



Example of Baseline Data Comparison 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)

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 is the opposite of the relative gender distributions reported for the total camp populations: 40% and 54% of the adolescents ages 14-17 are 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, etc.) must be controlled for in order to correctly infer the impact of the program intervention. Where interventions are provided in groups, 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 of Comparisons of Change Scores 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)

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. Analysis consists of descriptions of the distributions of the responses to each question as both percentages and mean change per item (see example in Appendix C).

B.11 PROVISION OF INTERVENTION TO WAIT CONTROL GROUP

In studies that use a rolling admission format, once wait-list control participants finish their wait period, they are then offered the intervention. This occurs despite the fact that 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.



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

Intervention B was found to be effective for the treatment of depression-like problems in an adolescent war-affected population in Northern Uganda. It was more effective at treating depression-like symptoms among girls, and only the intervention B girls 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 intervention 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-adolescents and 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.

In the case of single cohort studies, preliminary analysis will demonstrate whether the intervention is effective prior to offering it to the wait-list 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 with-hold the intervention, it is also unreasonable to expend program resources (and for participants to expend their own time and resources) on an intervention that is not helpful.

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 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 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 to ongoing 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 (e.g., gender, age group, study site), these differences can be explored further with the goal of improving the effectiveness 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 of Recommendations 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)

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) common in this war-affected population. Similarly, no specific adaptations of intervention A had been made to address the trauma issues. At a minimum, future training of B and A facilitators 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 treatment arose in the B intervention. Although no such urgent cases arose in A, there were a handful of young people about whom staff were concerned 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 to better prepare them to handle trauma-related material during group discussions and 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 duration of impact of intervention B, 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 at this time, to determine whether further improvement has occurred since the end of the interventions.

(continued on next page)

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 study design since the A groups differed greatly from the groups receiving intervention B, 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 quantitative findings suggest that there are potential broad-based psychosocial benefits of the A model. With the lessons learned from the present trial and the experience gained in 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 types of psychosocial problems. They might also take into account measurements on various levels (i.e., child, family, peer, and community). Additionally, instruments could be developed that are less targeted to 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.

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

APPENDIX A: 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. 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.

Changes due to the intervention

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

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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 B: 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 (e.g., 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, ability to give advice, quarreling with other children, and confidence. Questions also referred to reluctance to do positive activities (e.g., 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). Response choices were: 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 below:

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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, or 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

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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 C: 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. 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. 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. This indicates that participating in either one of the intervention groups resulted in worrying less on average than being assigned to the control group.

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*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
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		66	75	32	68		34	
Started a new friendship	51		40	49	55	45		62	

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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
	Controls	A	B		Controls	A	B
	Average Score	Average Score	Effect Size **		Average Score	Average Score	Effect Size **
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

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 problems in life generally, and improved physical health. Participants in the B intervention also indicated significant improvements on average 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.

* 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.

APPENDIX D: EXAMPLE OF RESOURCES REQUIRED FOR RCT

** Position titles and compartmentalization of tasks are flexible.

Project manager: (100% time)

- Assures supervision groups are occurring
- Follows-up on any problems (e.g., space, attendance)
- Ensures supervisors' access to Skype for supervision calls
- Arranges for recruitment and follow-up
- Holds weekly phone calls with technical advisors
- Oversees all staff related to project; weekly meetings with project staff
- Assures all assessment and monitoring forms are updated, copied when needed, and received by counselors and supervisors
- Reviews assessors' intakes for mistakes/corrections; assures procedure for randomization is followed
- Assigns counselors cases after assessed and consented
- Keeps running lists of cases and controls (numbered)
- Involved in any safety procedures and aware of any cases with safety issues; promptly alerts all relevant project staff

Recruiters: (number needs vary based on recruitment plan)

- Local staff that are sometimes used to help recruit children/caregivers. This entails going into the community to find kids that need help.

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

- Trained in research ethics and intake/assessment form
- Meets with child/caregivers to give screening measure/intake measure and consent to study; arranges follow-up meeting with counselor
- When counselor finishes treatment with a client, assessor meets again with the family to re-administer the assessment

Data entry: 1 full time, or multiple part time

- Trained in data entry; helps collect and organize papers/intake forms
- Enters scores/responses into computer (and/or scan forms to JHU)
- Exchanges weekly emails with JHU to send data and monitor data collection/input

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

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

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

- Sees children/caregivers for treatment
- 2 hours per week for supervision
- 3-4 hours per week for each client (actual client time, transport, prep and documentation after)
- Completes monitoring forms with clients each session (turned into supervisors)
- Completes “case notes” documenting what they did in session (turned into supervisors weekly)

Supervisors: (2 in this case)

- 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)
- 2-3 hours per week for Skype calls with trainers
- Carries at least one case (3-4 hours/week for case)
- Collects and organizes forms from counselors, assuring all forms completed and either entered or received by data entry staff
- Completes supervision form for each counselor’s case to report to trainers
- Monitors any safety issues with cases (may mean visits with the counselor to the clients home...etc.)

APPENDIX E: EXAMPLE CLIENT MONITORING FORM

	:Site المكان		:Date التاريخ
	: Client ID رقم هويه المريض		: Client Name اسم المريض
	: CMHW ID رقم هويه الموضف		: CMHW Name اسم موضف المجتمع للصحه النفس
	:Duration of Session طول الجلسه		: Session Number رقم الجلسه

مراجعه المشاكل- راجع ايه تغيرات حدثت بالمقارنه مع الاسبوع السابق (اختار اى مشكله تنطبق على المريض)

Problem Review - review for change from prior session (Check all that apply)

Very often (more than 5 times a week)	Often (3-5 times a week)	Sometimes (1-2 times a week)	Never or No	الأعراض Symptom
غالباً (اكثر من خمس مرات في الاسبوع)	مراراً (3-5 مرات في الاسبوع)	بعض الاوقات (1-2 مرات في الاسبوع)	لا أو أبداً	
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. تلووم نفسك بسبب اشياء 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. تنكر واسترجاع الذكريات أو افكار مؤلمة أو أحداث مرعبة Recurrent thoughts or memories of the hurtful or terrifying events
3	2	1	0	BT06. سرعه الاجفل Feeling jumpy, easily startled
3	2	1	0	BT11. تتجنب النشاطات أو الأشياء التي تنكرك 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 أوقاتاً بالتفكير حول سبب حدوث هذه الحوادث لك Spending time thinking about why these events happened to you

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What did you do in session with your client? (Check all that apply)

ماذا فعلت مع مريضك في هذه الجلسة؟ (اختر الخيارات المطابقه)

	Checked symptoms فحصت الاعراض	What homework did you review? ما هو الواجب البيتي الذي راجعته مع المريض؟
	Reviewed homework راجعت الواجب البيتي	
Provided education about: _____ قدمت التثقيف عن-----		Taught a skill: _____ علمت المهارة-----
	Trauma problems مشاكل الصدمه	Identify thoughts and feelings & using ABC sheets تشخيص الافكار و المشاعر باستخدام فورم الابدديه
	CPT and how it thinks about trauma و كيفيه تفكيره عن الصدمه الCPT	Identifying stuck points تشخيص النقاط العالقه
	CPT and how it will help كيف يساعد الCPT	Using the Thinking Questions form استخدام فورم اسئله التفكير
	Avoidance الاجتناب	Using the Changing and Feelings form استخدام فورم تغير الافكار و المشاعر
	Safety issues المشاكل المتعلقة بالسلامه	Listened for and talked about stuck points with client الاستماع الى و التحدث عن النقاط العالقه مع المريض
	Trust issues المشاكل المتعلقة بالثقه	Used gentle, open ended questions to help the client challenge stuck points استخدمت اسئله مفتوحه و رقيقه لمساعدته المريض على تحدى النقاط العالقه
	Power/control issues المشاكل المتعلقة بالقوه و السيطرة	Discussed the impact of trauma statement ناقشت تاثير سرد الصدمه
	Respect issues المشاكل المتعلقة بالاحترام	Discussed the trauma memory statement ناقشت سرد ذاكره الصدمه
	Caring issues المشاكل المتعلقة بالاهتمام	Assigned homework: الواجب البيتي
What homework did you assign? _____ ما هو الواجب البيتي الذي اعطيته للمريض؟		

Please refer to the CPT Checklist. Did you complete all items on the checklist for the session you did with your client? Yes No

الرجاء الرجوع الى جدول الCPT هل قمت باكمال جميع النقاط في الجدول لهذه الجلسة مع المريض؟

لا نعم

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If you did something differently from the checklist, why did you do so? (check all that apply)

هل قمت بشئ اخر غير الموجود فى الجدول؟ لماذا قمت بذلك؟ (اختار جميع الخيارات التى تنطبق)

	Client was late to session تأخر المريض عن الجلسه		Client didn't complete homework لم يكمل المريض الواجب البيتي
	I was late to session تأخرت عن الجلسه		Talked with client about avoidance تحدثت مع المريض عن الاجتناب
	I accidentally forgot to do a section لقد نسيت بالصدفه الجلسه		Talked with client about coming to sessions regularly تحدثت مع المريض عن المجئ الى الجلسه بصوره منتظمه
	Didn't have enough time لم يكن لدى الوقت الكافى		Other: اخرى
	Client had a crisis مر المريض بازمه		Other: اخرى
	Client had trouble doing homework واجه المريض مشاكل فى اداء الواجب		Other: اخرى

One stuck point this client has is: نقطه عالقه واحده لدى المريض

Any challenges or problems in therapy for this client (homework completion, attendance, participation in group, changes in symptoms, crises)?

هل هناك ايه تحديات و مشاكل فى العلاج لهذا المريض (اكمال الواجب البيتي، الحضور، المشاركه فى الفعاليات الجماعيه، التغير فى الاعراض، الازمات)

What questions do you have for supervision this week?

ما هى الاسئله التى لديك للاشراف فى هذا الاسبوع؟

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

هل هناك ايه افكار انتحاريه؟ لا نعم (اذا نعم، الرجاء وصف ادناه ما هي هذه الافكار، كيف قمت بالتقييم، و ماهي الخطه المستقبليه)

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

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

Please mark if client is taking any of these medications

الرجاء اختيار الادويه التي ياخذها المريض من القائمه ادناه

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

ادويه اخرى

ملاحظات اخرى: _____

Additional Comments:

APPENDIX F: EXAMPLE WEEKLY RECRUITING FORM

Download usable recruiting form in Excel format.

APPENDIX G: EXAMPLE CLIENT TRACKING FORM 1

Download usable tracking form in Excel format.

APPENDIX H: EXAMPLE CLIENT TRACKING FORM 2

CMHW name and location	Client ID	Intake dd/mm/yy	Consent dd/mm/yy	session1	session2	Exit interview	Comment
		3/9/2009	3/9/2009	9/9/2009	18/9/09	16/12/09	Exit interview done by xx
		6/9/2009	6/9/2009	10/10/2009	DROPOUT	8/12/2009	Exit interview done by xx
		6/9/2009	6/9/2009	phone			On (date) client came to the clinic with health problems
		7/9/2009	7/9/2009	14/9/09	25/9/09	16/12/09	Exit interview done by xx
		5/9/2009	5/9/2009	12/9/2009	18/9/09	8/12/2009	Exit interview done by xx
		12/9/2009	12/9/2009	14/9/09	25/9/09	16/12/09	Exit interview done by xx
		14/9/09	14/9/09	14/9/09	24/9/09	16/12/09	Exit interview done by xx
		14/9/09	14/9/09	phone			
		7/10/2009	7/10/2009	29/10/09	7/11/2009		Client is a cleaner at xx hospital has difficulty coming weekly to the session
		15/10/09	15/10/09	18/10/09	25/10/09		
		1/11/2009	1/11/2009	2/11/2009	DROPOUT		