

**REVISION TO ERB**

**Addition concerning instruments to be used (27 March, 2014)**

**Protocol**

**Outcome Evaluation Study of MSF Mental Health Programs**

**in Grozny, Chechnya Republic**

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## List of Abbreviations

<b>CDC</b>	Centers for Disease Control and Prevention
<b>CSI</b>	Coping Strategy Indicator
<b>HTQ-2</b>	Harvard Trauma Questionnaire – Part 2
<b>HSCL-25</b>	Hopkins Symptom Checklist 25
<b>IDP</b>	Internally Displaced Population
<b>MSF</b>	Médecins Sans Frontières
<b>MH</b>	Mental Health
<b>MHO</b>	Mental Health Officer
<b>MH/PSS</b>	Mental Health Psychosocial Services
<b>MoH</b>	Ministry of Health
<b>PTSD</b>	Post-traumatic stress disorder
<b>MHO</b>	Mental Health Officer
<b>SF-36</b>	Short Form (36) Health Survey
<b>WHO</b>	World Health Organization

## Study Summary

**Title:** Outcome Evaluation Study of MSF Mental Health Programs in Grozny, Chechnya Republic

### Study Hypotheses

The counselling intervention will significantly improve the functioning of adult clients to the MSF mental health program in Chechnya who have been affected by years of war and ongoing violence.

### Study Design

The study will be a randomized controlled trial of the MSF individual counselling intervention using a stepped wedge design. Follow up will be for a period of 8 months from enrolment.

### Inclusion criteria

Participants who present for care to the MSF mental health program will be included if they meet the following inclusion criteria:

- age 18 years or older
- capable of providing informed consent for inclusion in the study
- No cognitive, visual or other impairments that would limit ability to participate in the study
- Score on HSCL-25 screening instrument greater than threshold
- Willing/able to return to counselling centre for follow up

### Exclusion criteria

Participants will be excluded from the study if they meet the following criteria:

- judged at intake interview to be at acute risk of suicide
- presence of a major psychiatric disorder requiring medication (e.g. psychosis, severe depression, or bipolar disease)
- have been enrolled in MSF's counselling services within the last 6 months

### Intervention:

The individual counselling intervention will be provided as per standard MSF protocols. The counsellor will determine with the client what the main problem is they are seeking to address with the counselling. This will be used to determine a counselling focus using pre-determined categories as described. The intervention will continue until the counsellor judges, together with

the client, that the presenting problem has resolved or improved to the point that counselling is no longer needed.

**Sample Size:**

The required sample size is 46 per arm. Planning for an expected drop out and loss to follow up rate of 45%, we will aim to enrol 168 subjects, 84 in each arm.

**Primary Outcome Measure**

- Change in functioning as measured by the adapted HSCL with the addition of locally adapted functioning questions

**Secondary Outcome Measures**

- Change in symptoms as measured on the HSCL-25
- Change in coping strategies as measured by the Coping Strategy Indicator
- Change in perceived social support as measured by the Social Provisions Scale
- Change in status at 3 and 6 months post intervention compared with the immediate post-intervention scores
- Prevalence of PTSD in the study population as measured by the Harvard Trauma Questionnaire part 2 (HTQ-2)
- Impact of the intervention on PTSD amongst those identified on entry as meeting the symptom criteria for PTSD on the HTQ-2
- Client rated symptoms and functionality scores as compared to gold standard
- Counsellor's perception of problem status compared to functioning instruments

## **Background**

Chechnya underwent two conflicts that left much of the health infrastructure destroyed. Substantial progress has been made in re-building the infrastructure destroyed in the wars, and in improving security. However the ongoing low level insurgency continues resulting in a number of ongoing incidents of violence and a general atmosphere of insecurity. The impact of these events on the population is significant particularly in terms of the psychological impact. The experience of the Médecins Sans Frontières (MSF) mental health programme reveals that high levels of traumatisation exist among at least parts of the population. The MSF programme focuses on those with acute traumatic reactions to sporadic violence and is based on direct referrals from emergency rooms as well as self referrals. The program also sees a number of cases who have chronic mental health problems as a result of the conflict as well.

### **Mental Health in MSF**

MSF has been providing mental health programming for over 20 years as part of its medical humanitarian programs in contexts affected by conflict and violence in countries around the world. Typical MSF mental health programmes consist of individual, group, and community activities which are integrated into basic health care activities. The counselling approach is based on principles derived from brief trauma focused therapy and is fully described in the MSF-OCA Mental Health guideline. The objectives of individual counselling are to reduce suffering and improve functioning. Counselling is provided by locally recruited counsellors who are supervised by a professional mental health officer. Where possible, counsellors have an academic background in psychology or social work. In areas where academically-trained counsellors are not available, programmes use lay counsellors, trained by MSF. Standardisation of the counselling intervention is achieved through standard training modules use of the MSF-Holland mental health guidelines, annual workshops for mental health officers, oversight from headquarters-based mental health advisors, and on-site clinical supervision from mental health officers. Treatment of major mental health disorders is beyond the scope of the counselling programmes but in some projects, physicians in the primary care services are able to provide psychiatric medications or refer patients to psychiatrists. Medications are not prescribed by the mental health counsellors.

A registration system exists whereby client information is recorded in a standardized fashion throughout the course of treatment. Data is entered into an electronic database without

personal identifiers and using a client number. The counsellor is the only one able to link the name to the client number. This database allows both monitoring and follow up of individual clients but also serves as a tool to monitor and improve programs across MSF-OCA. It was introduced into MSF programs in 2007.

In 2012, a total of 55,013 individual counselling sessions were provided in 19 projects.

### **Description of MSF Program in Grozny**

In 2001 many Chechen IDPs settled between the borders of Chechnya & Ingushetia as a result of the 2nd Chechnya war. Mental health and psychosocial services (MH/PSS) started to be offered in this area among this target population with an office in Nazran, Ingushetia. Many clients suffered acute psychological trauma as a result of heavy shelling and massive explosions. In the following 2 years violence continued in the region. Spontaneous settlements flourished in Ingushetia and temporary accommodations (TACs) in Chechnya. MH/PSS services were focused in these IDP dwellings. In 2003 Grozny MH activities started and included Grozny City Hospital #9 aside from the TACs.

A survey conducted in Chechnya in February 2004 (de Jong et al., 2007) highlighted that most people (94%) were confronted with violence in the past. Many respondents had witnessed the killing of people (22.7%) and nearly half of people interviewed witnessed arrests (53.1%) and maltreatment (56.2%). Approximately one third of those interviewed had directly experienced war-related violence. A substantial number of people interviewed (66.8%) – rarely felt safe. The violence was ongoing, with respondents reporting violence in the month before the survey (12.5%). Results of the general health questionnaire (GHQ 28) showed that nearly all internally displaced persons interviewed were suffering from health complaints such as somatic complaints, anxiety/insomnia, depressive feelings or social dysfunction.

By 2006 MH assessments revealed signs of distress in both republics despite the fact that acute emergency in Chechnya stopped. Main challenges during this period were 1) accessing vulnerable groups in relation to previous war-trauma; and, 2) focusing on group therapeutic activities by counsellors (while social activities are dealt with by volunteers). By 2008-2009 the situation in Chechnya was characterized as improving but violence was still continuing. Thus, the necessity of keeping access of Chechens to psychosocial support was still necessary for working out a prolonged multiple traumas over a long period of time despite the increasingly visible improvements in the republic. The program continued its active reactivity to the increasing tension experienced. Resources were shifted and adapted to locations with higher and acute needs. This was done on the basis of knowledge where the most recent incidents are taking place



through incident reports. Likewise, feedback from counsellors and clients was considered. This flexible process led to MSF reaching the most vulnerable victims of the persisting violence in Chechnya.

### **Components of MSF Psychosocial and Mental Health Program in Grozny**

The MSF mental health program in Grozny consists of the following components.

- Individual counselling
- Psycho education
- Group counselling
- Training of medics on how to identify and refer patients with mental health problems

### **Target population**

Grozny clients are those who continuously suffer from chronic stress (feelings of fear & hopelessness) and multiple traumas after many years of intensive armed confrontation. The service is integrated in the system of Ministry of Health (MoH) health care.

### **Individual Counselling**

The mainstay of the program is individual counselling by a mix of lay and academically trained counsellors from the community. The counselling approach is based on principles derived from brief trauma focused therapy as outlined in the MSF MH guidelines (de Jong, 2011). The objective of counselling is symptom reduction and improved functioning rather than treatment of specific psychiatric disorders.

### **Selection and Training of Counsellors**

Counsellors are recruited from the local population and are selected on the basis of their academic degree, literacy and empathetic qualities. Training is provided through an initial 2 week course which is based on principles of the widely available training guideline of van der Veer (2001). Subsequent training is done through clinical supervision by the Mental Health Officer (MHO), along with regular in-service trainings. The headquarters' based Mental Health Advisor supports and oversees the program through regular contact and coaching with the MHO, review of monthly narrative reports, and analysis of programmatic data. S/he visits to provide strategic programmatic advice and directly supervise the quality of the program.

## **Psychiatric disorders**

Individuals requiring psychiatric care or judged to be acutely suicidal are referred to the psychiatrists working at the Neuropsychiatry dispensary (MoH).

## **Program statistics 2012**

804 individual were admitted to counselling in the 3 hospital sites in Grozny in 2012. 98% of these were discharged by the counsellor at the end of treatment. 18% required only a single session. The average length of counselling amongst those receiving two or more sessions, was 32.1 days, with a median of 29 days. 66% of individuals seeking counselling were aged 20-44. Only 4% were less than 20 years old. The average change in complaint rating and functioning for all the program sites was 4.4 and 4.5 respectively.

## **Study Rationale**

The mental health of populations affected by conflict and violence is quickly becoming one of the core public health issues in complex emergencies. Mental health assessments and surveys conducted in refugee and post-war settings have shown high prevalence of mental health problems associated with the effects of armed conflict (Mollica et al., 2004). There is now widespread acceptance that mental health services are part of the minimum package of care in disasters (The Sphere Handbook, 2011). Guidelines exist to guide implementation; the most well known is the IASC Guidelines on Mental Health and Psychosocial Interventions in Emergencies (IASC, 2007). However, despite the progress that has been made in creating consensus regarding standards of care, the scientific basis for mental health and psychosocial interventions in humanitarian settings is still weak. Until now, very few randomized controlled trials or outcome evaluations of mental health interventions in complex emergencies have been conducted (Bolton et al., 2003; Tol et al., 2008; Scholte et al., 2011; Bass et al., 2013). Results of these evaluations have been mixed. A systematic review published in the Lancet, concludes that the most commonly used mental health and psychosocial interventions in humanitarian emergencies have little evidence to back them up (Tol et al., 2011). In the category of interventions, non-specialised focused care for adults that MSF plans to study (see annexe 1), only three of the six studies meeting inclusion criteria for the systematic review involved individual counselling. None of them included a similar intervention model to the one that MSF employs One of these involved a multi-disciplinary model of care that included counselling, physiotherapy, and medical care for torture victims in Nepal (Tol et al., 2009). The other was testimony therapy in

Mozambique which consisted of a single session (Igrega et al., 2004). The final study is unpublished, but consisted of counselling for women compared to medical treatment.

MSF Holland implements mental health and psychosocial programs in a variety of emergency settings around the world. The package of interventions is standardized as previously described, and based on well known principles of intervention that have been successfully used in Western settings. Nevertheless, the impact and effectiveness of the MSF style mental health program has not been measured through an outcome evaluation. Because MSF and other organizations use this type of mental health program in emergency settings around the world, it is important to know the effectiveness of this approach, and to ensure it does not cause harm.

## **Study Hypotheses**

The counselling intervention will significantly improve the functioning of adult clients to the MSF mental health program in Chechnya who have been affected by years of war and ongoing violence.

## **Study Objectives**

### *Primary Objective:*

- To evaluate the impact of MSF's individual counselling approach on the functioning of clients in Chechnya.

### *Secondary Objective:*

- To evaluate the impact of MSF's individual counselling approach on the symptoms of clients in Chechnya
- To evaluate the intervention's impact on coping skills and use of social supports
- To determine if the effect of the counselling intervention is sustained over a 6 month period
- To measure the change in prevalence of PTSD symptoms
- To measure the change in PTSD symptoms due to the intervention in those meeting the criteria for PTSD on entry
- To validate the monitoring tools used by MSF to measure outcome of counselling in routine programs

## **Study Design**

### **General design**

The study will be a randomized controlled trial of the MSF individual counselling intervention using a stepped wedge design. The control group will consist of a waitlist control, whereby the individuals randomized to this arm of the trial will have their counselling intervention deferred for 2 months. Two months is chosen as that is the median time to complete the treatment intervention. The stepped wedge design is chosen due to its ability to control for time effects (Brown & Lilford, 2006).

Follow up will be for a period of 8 months from enrolment for both groups during which each group will have the study instruments administered four times.

### **Outcome measures**

The overall effectiveness of the program will be systematically evaluated using pre- and post-test instruments to provide data on the effectiveness of improving functioning, among clients in the counselling intervention program. The control group will be administered these same instruments to ensure that any observed changes are due to the intervention and not due to changes over time.

#### **Primary Outcome Measure**

- Change in functioning as measured by the adapted SF-36 (Ware & Sherbourne, 1992; Ware et al., 1997) with the addition of locally adapted functioning questions

#### **Secondary Outcome Measures**

- Change in symptoms as measured on the HSCL-25
- Change in coping strategies as measured by the Coping Strategy Indicator (Amirkhan, 1994)
- Change in perceived social support as measured by the Social Provisions Scale (Cutrona, 1989)
- Change in status at 3 and 6 months post intervention compared with the immediate post-intervention scores
- Prevalence of PTSD in the study population as measured by the Harvard Trauma Questionnaire part 2 (HTQ-2) (Mollica et al., 1993)

- Impact of the intervention on PTSD amongst those identified on entry as meeting the symptom criteria for PTSD on the HTQ-2
- Client rated symptoms and functionality scores as compared to gold standard
- Counsellor's perception of problem status compared to functioning instruments (SF-36 locally developed instrument for functioning )

## **Questionnaire**

The questionnaire will contain instruments designed to assess the desired outcomes of this evaluation. A combination of standardized instruments which will be validated for the Chechen context and culture specific questions will be used. A qualitative assessment using focus groups and key informants will be conducted to inform the quantitative assessment instrument. The entire questionnaire will be pilot tested before use.

The instruments used will be translated into the local languages (Russian and Chechen), and back translated into English by different translators to check for accuracy of the translation.

### ***Hopkins Symptom Checklist (HSCL-25)***

The Hopkins Symptom Checklist (HSCL) was developed in the 1950s by Parloff, Kelman and Frank at Johns Hopkins University (Parloff et al. 1954) as a screening instrument. The HSCL-25 comprises of a symptom inventory with 10 items related to anxiety and 15 items related for depression symptoms. The scale is rated like a Likert scale from 1-4 where 1 means that the client does not associate to the symptom represented and the 4 means they associate with it "extremely". Two scores are calculated from the HSCL-25: a total score and a depression score which takes into account an average of the 15 depression items (Derogatis, 1974). The scale has been successfully used in different countries, language and cultural settings and has already been validated in the Russian language in a population of Chechnyan refugees living in Austria (Renner et al., 2011). Mean cumulative symptom scores of more than 1.75 for each subcategory have been found to be valid in predicting clinical diagnosis of anxiety and affective disorders (Mollica, 1987) and has been used successfully across different cultures ( Lopes Cardozo, 2004; Silove 2007; Vinck, 2010).

### ***Functioning***

Symptoms of psychological distress or mental illness may interfere with a person's functioning in various ways. Not every person who is suffering from psychological distress or mental illness has

impairment in functioning. There are a number of standardized functioning scales, none of which have been specifically adapted for the Chechen context. Ideally, the functioning instrument we want to use here would measure daily and social functioning in relation to psychological/emotional problems. The functioning instrument that comes closest to this goal is the SF-36, which has been adapted for developed countries but the CDC also used in countries such as Afghanistan and Kosovo (Lopes Cardozo et al., 2004; Lopes Cardozo et al., 2000).

For Chechnya we propose to select six questions from the SF-36 that assess self perceived general health, bodily pain, social functioning, and role-emotional functioning (Ware & Sherbourne, 1992). We will field test, and adapt these questions for the context in Chechnya. We will score the selected SF-36 questions as recommended in the user's manual; each raw score will be transformed to fit a 0-to-100 scale by using a standard formula, with the higher scores on this scale representing better functioning (Ware et al., 1997).

In addition, we will also include a new function assessment instrument developed through qualitative methods as described in the DIME Manual (Johns Hopkins University, 2011). These questions are intended to evaluate the individual's overall level of functioning, which are suitable for the local context in Chechnya (Bolton et al., 2000). The function instrument will be created using composite lists of important tasks and activities obtained from a free listing exercise and the data from focus groups on functioning. For each category of self, family, and community we will choose the most frequently mentioned tasks that also meet the following four criteria:

- 1) Inability to do the task will clearly affect others
- 2) The task is not actually the same as another task on the list
- 3) The task is clearly done by a large majority of the target population
- 4) The task is done frequently, such as daily or at least monthly.

The most frequently mentioned tasks in each category that meet the above criteria are then inserted into the function assessment template to form the local function assessment scale.

### ***Harvard Trauma Questionnaire (HTQ)***

We propose using part 2 of the Harvard Trauma Questionnaire (HTQ) which includes symptom of posttraumatic stress disorder (PTSD) as described in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* and includes all of the commonly reported symptoms associated with trauma listed above. The HTQ has been used as a screening tool for PTSD in numerous war-affected populations (i.e. in Cambodia, Bosnia, Kosovo, Afghanistan, Sri Lanka and Thailand). We defined cases meeting PTSD symptom criteria according to a scoring algorithm proposed by the Harvard Refugee Trauma Group, on the basis of *DSM-IV* diagnostic

criteria. This definition of PTSD requires a score of 3 or 4 on at least 1 of 4 re-experiencing symptoms, at least 3 of 7 avoidance and numbing symptoms, and at least 2 of 5 arousal symptoms. Recall period for symptom questions is the previous 4 weeks (Mollica et al., 1993).

### ***Coping***

As a proxy measure of resiliency participants will be asked to report on how they cope with problems and troubles in their lives. The instrument was adapted from the *Coping Strategy Indicator* (CSI) (Amirkhan, 1994), which includes three subscales of coping strategies: Problem-Solving, Avoiding, or Social-Support Seeking. The three items with the highest factor loadings on these subscales were used in this assessment. Average item scores for each of the three original CSI subscales will be utilized in analyses (Amirkhan, 1994).

### ***Social Support***

Social support is an important predictor of mental health and resiliency. Perceived social support will be assessed using the 12-item *Social Provisions Scale* (Cutrona, 1989; Cutrona & Russell, 1987). This measure assesses agreement in areas such as shared interests, respect, guidance and advice, and support of others. For this study, a five point Likert-type scale will be used allowing for an (3) *unsure* response. The negatively phrased items will be reverse scored, and a personal mean score of all answered items will be used for inferential analyses.

### ***MSF Scales***

MSF is currently using 10 point self-rating scales with “smiley” faces. The best score is the highest (10) and the worst is the lowest (1). Clients are asked by their counsellor to score the severity of their main complaint as well as the severity in which this complaint reduces their daily functioning. Baseline measurements are taken at the beginning of the intake, and at the start of each session. At the end of each follow up visit, the counsellor also scores the status of the presenting problem (worse, no change, improved, resolved).

Clients assigned to either arm will score the MSF client rated scale at each visit during the counselling intervention. In addition, the counsellor will provide a score at each follow up visit during the period of intervention. Both the client rated scoring and the counsellor rated scoring is the standard procedure for all clients in the MSF counselling programs.

### **Study Site**

The study will take place in the MSF project located in Grozny, Chechnya. There are 3 sites where clients will be recruited, all of which are hospitals located in Grozny. The 3 study sites are as follows:

Hospital number nine: is the most important hospital in Grozny, majority of the referrals from the villages and Grozny arriving here. There is an emergency department in this hospital. It is situated in central part of Grozny.

Hospital number seven: this hospital is focused in neurological department (children and adults), there is polyclinic (OPD) next to this hospital. It is situated in the edge of the city

Regional Hospital: patients arrive from all the districts of the Republic especially from the villages but the difference from Hospital number nine is that hospital number nine focused more on emergency aid and regional hospital is general diseases.

All mental health care is provided free of charge.

## Study Population

Patients are referred for care by medical staff and recruited from the hospital through psycho-education activities at the Emergency Room, wards and OPD. In addition, outpatients present through self-referral.

## Sample Size

Using the formula on p 31 of Diggle's textbook "Analysis of Longitudinal Data", which uses the average difference between the control and intervention groups, 46 persons per group will yield sufficient power (.80) to detect a medium effect size of .40 between the intervention and control groups at  $\alpha = 0.05$ .<sup>1</sup> We aim to enrol 168 subjects, 84 in each arm. Assuming an expected

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$$m = [2(z_{\alpha} + z_{\beta})^2 \{1 + (n - 1)\rho\}] / (n\Delta^2)$$

m = number in each group (e.g., intervention and non-intervention)

n = number of repeated measurements (equals 2 in this scenario)

$z_{\alpha}$  = Z score for alpha set at 0.05

$z_{\beta}$  = Power, set at 0.80

$\rho$  = correlation among repeated observations, estimated at 0.2

$\Delta = d / \sigma$  where d is the smallest meaningful difference and  $\sigma$  is the standard deviation,  $\sigma = 2.2$ ,  $d \sim 1$  the change in the mean scores of psychological distress between the intervention and control, set at 0.40



dropout and loss to follow up rate of 45%, this will yield approximately 48 persons per group for analysis.

## **Study Subject Selection and Withdrawal**

The study will recruit all adults presenting as new clients to MSF counselling services located in the study sites.

### **Inclusion criteria**

Participants who present for care to the MSF mental health program will be included if they meet the following inclusion criteria:

- age 18 years or older
- capable of providing informed consent for inclusion in the study
- no cognitive, visual or other impairments that would limit ability to participate in the study
- score on HSCL25 higher than establish cut-off
- able/willing to return to counselling centre for regular follow up

### **Exclusion criteria**

Participants will be excluded from the study if they meet the following criteria:

- judged at intake interview to be at acute risk of suicide
- presence of a major psychiatric disorder requiring medication (e.g. psychosis, severe depression, or bipolar disease)
- have been enrolled in MSF's counselling services within the last 6 months

### **Withdrawal of study participants**

Study participants who decide at any point to withdraw consent for involvement in the study will be removed from the analyses. This voluntary decision will not affect their access to care.

Clients from either intervention group who require referral to a physician for psychiatric medication will be excluded from the study.

Clients in the waitlist control group who at any time in the intervention, exhibit acute suicidal ideation or develop a major psychiatric illness that requires medication will be excluded from the study in order to allow them immediate access to treatment.

### **Data collection on study participants withdrawing from the study**

Attempts will be made to record the reason why study participants withdraw their consent to participate in the study.

### **Participant selection and enrolment**

All adult clients presenting to the MSF counselling centres for individual counselling will be screened for eligibility by a MSF intake counsellor. As part of the screening interview, the intake counsellor will ask the following question to all clients: “Has the thought of ending your life been on your mind?” If the answer is affirmative, the counsellor will explore if this suicidal ideation is just a fleeting thought or a more severe and persistent thinking about suicide. Screening will also take place for major psychiatric disorders. A person who is actively suicidal or in need of psychotropic medications will be referred to a physician and not to the counselling program as is standard practice in the current MSF mental health program. Finally clients will be screened to ensure their expectations of counselling match the reality of what MSF can provide. For example if the client expects the program to be providing drugs or group therapy, rather than individual counselling they will not be included. This latter practice is also done routinely in all regular MSF programs.

Regardless of eligibility, the intake counsellor will provide clients with referral services where appropriate and provide psychological first aid.

Study recruitment will be in the form of rolling admissions, to continue until the sample size is reached for both the intervention and control arms.

### **Consent procedure**

A two phase consent process will be employed. Clients passing the initial screening for eligibility for counselling will be asked if they verbally consent to undergo formal screening with the HSCL-25 instrument. Those meeting the inclusion criteria after this screening will be asked by the intake counsellor if they consent to be part of the study and to be randomized. Those consenting will be randomly allocated to either receive the intervention immediately or to wait for 2 months (the usual duration of treatment for counselling-type interventions) and to then receive

treatment (i.e., to be wait list controls). Those not meeting the severity criteria for eligibility will be referred to either routine counselling or an alternative as deemed appropriate by the intake counsellor.

Informed consent forms will be translated into local languages, Russian and Chechen, back-translated and piloted for comprehension in the area of the study site.

It will be explained to the client that participation is voluntary and that clients will receive the same standard of treatment whether or not they agree to participate in the study. It will be further explained that clients can discontinue participation from the study at any time without explanation and without any negative impact on their future care and treatment.

### **Randomisation procedures**

Randomisation will be performed after completion of the second phase of consent using random number allocation by the MSF study coordinator. This is to avoid that selection bias would occur if the counsellors themselves would decide which clients should be assigned to the wait list control or immediate intervention group. The randomization list used by the study coordinator will be computer generated by a statistician.

### **Intervention**

The counselling intervention will be provided as per standard protocols. The counsellor will determine with the client what the main problem is they are seeking to address with the counselling. This will be used to determine a counselling focus using pre-determined categories as described by van der Veer (2001). The intervention will continue until the counsellor judges, together with the client, that the presenting problem has resolved or improved to the point that counselling is no longer needed. If at any point, the counsellor judges the client to have need of psychiatric medication, or to be acutely suicidal, the client will be referred to the physician immediately.

### **Waitlist Control group**

The control group will not start the counselling intervention until 2 months after enrolment. During the 2 month waiting period, they will be visited at home by a member of the study team to ensure there is no acute deterioration (e.g. psychiatric disorder, acute suicidal ideation) that requires immediate intervention.

### **Baseline data collection**

Baseline data will be collected on each participant as described in annexe 2. It will include: age, gender, marital status, religion, ethnicity, education level, profession, and employment status.

### **Timeline**

The baseline screening will take place on enrolment for both arms. The intervention arm will receive the post test within one week of completion of the counselling intervention. This will normally be within 2 months of enrolment. Subsequent testing will take place at 3 and 6 months after the post-test.

The wait list control group will be re-tested at 2 months from enrolment. They will then undergo the counselling intervention, and receive a post test within 1 week of discharge from counselling. A follow up test will be performed at 3 months after the post test.

The study duration for each participant will be for approximately 8 months depending on the length of the counselling intervention. To achieve the sample size required, enrolment is expected to take 4 months.

### **Administering of the questionnaire**

The study questionnaires will be administered by a member of the study team who is blinded to the allocation of the participant. Similarly the counsellor will not be informed of the intervention arm of the participant. However it will be impossible in such a setting to ensure that both the counsellor and the study counsellor administering the questionnaires is completely blinded in practice as the client may refer to their participation in the study. Results from the instruments will not be shared with either the counsellor or the client during the study. After the study is completed, clients will be offered the chance to review their results with the study counsellor or their own counsellor.

### **Data analysis**

#### **Statistical methods**

Analyses of the evaluation data will be performed by CDC staff in close collaboration with MSF. Data will be entered into Excel spreadsheets. Analyses will be performed using SPSS, SAS or

similar statistical software. Changes in pre-test (time 0) measurements of individual study participants will be compared to post test (2 months), and follow-up (3 and 6 months post-intervention) measurements. The study is powered to be able to measure a change of 1 point with an assumed standard deviation of 2.2. We will use Chi-square statistics and Univariate Analysis of Variance to assess group differences across categorical and continuous variables. The questionnaire contains instruments measuring outcomes of psychological distress, functioning, and coping and support measures. Changes in the individual scoring of the instruments will be compared to individual test scores at baseline. The third measurement at 9 months will allow following the changes longitudinally. It is important to know if any changes due to the counselling intervention will still hold several months after the intervention takes place or if they will dissipate over time. The study hypothesis that the MSF counselling program will improve functioning will be confirmed if the participants will show a statistically significant improvement compared to the measurements of the control group at pre-intervention (2 months post study enrolment).

#### **Data Handling and Record Keeping**

Each participant will be assigned a unique study identification number, used to identify the study participant in all procedures. Study numbers will be assigned sequentially as subjects enter the study. Once a number has been assigned, that number will not be used again (e.g. if a subject discontinues or a number is allocated incorrectly).

In addition, counsellors will complete the MSF registration system for all clients undergoing the counselling. Data will be entered using a unique identifier into the electronic database. The counsellor and MHO will be the only ones with access to the names of the clients which will be kept separately.

The study coordinator will have access to the study identification number and the client number in the database, in order to be able to link the two sets of data. The codes will be safeguarded at MSF facilities during the course of the study. The codes will never be available to the CDC staff. CDC staff will not have direct contact with human subjects and will only provide technical expertise for the evaluation of the protocol and analysis of the data. CDC staff will not have access to any identifiable data.

## **Roles of the research team and funding**

### **CDC**

CDC staff led by Barbara Lopes-Cardozo as the principal investigator, will provide technical expertise with the design of the evaluation protocol, the analysis of the data, and participate in writing reports and publication based on the results of the evaluation.

### **MSF**

MSF staff will assist in the design of the study protocol, over see the study execution and contribute to the analysis of results, and writing of reports and publications. MSF will also fund the study, hire the field research coordinator, provide the study site and ensure all the necessary ethical approvals are obtained.

### **Johns Hopkins University**

Johns Hopkins staff will provide technical assistance with the design of the study, and assist with the local validation of the standardised instruments used in the study, and development of culturally valid and appropriate instruments.

### **Chechen State University**

Prof Kyuri Idrisov, Head of the Psychiatry Department at the Chechen State University will review and approve study design, obtain local ethics approval, provide technical assistance and oversight during validation of the instruments and throughout execution of the study.

### **Field research coordinator**

MSF will appoint a study research coordinator in Grozny who will be responsible for the implementation and data management of the outcome study. The study coordinator will receive extensive training from CDC staff on outcome evaluation methods, human subject's issues, and data management skills. The research coordinator will handle all day-to day activities and maintain contact with referring physicians, MSF headquarters, and CDC investigators. Regular communication systems, email, phone etc will be set up.

## **Human Participants Issues**

### **Benefits for participants**

Potential direct benefits for participating clients would be a decrease in trauma-related symptoms and improved functioning. This benefit, if present, would accrue to both the intervention arm and the wait list control, as both groups receive the intervention. However as the intervention has not been proven to be effective, it is possible that there is no beneficial effect of the intervention and a slight possibility that it could increase trauma-related psychological problems in some clients. Another risk involves possible psychological discomfort that may arise as a result of answering the questions during the application of the study instruments. Those risks and discomforts to participants are believed to be minimal (Griffin, et al., 2003).

Participation in the study will involve extra time to undergo the study questionnaire, and require additional follow up. This is judged to be approximately 4 hours in total and 3 additional visits. When travel costs are incurred, a monetary compensation will be provided as well as a small amount to compensate for the time spent. The follow up visits while potentially burdensome, will offer the benefit to the client of referral if there is severe deterioration noted.

The possible harms to those on the wait list control will be mitigated by screening out those felt to be severely affected (e.g acutely suicidal or psychiatric disorder requiring medication), and through monthly follow up to ensure no acute deterioration that would necessitate immediate referral to care, and therefore exclusion from the study. Interventions which have a proven effectiveness such as referral to a physician for medical treatment, referral to community supports and psychological first aid, will be provided by the intake counsellor as per standard care. It is only the counselling intervention, which has not been evaluated, that will be deferred for the wait list group.

Results of the questionnaire will not be shared with the client or the counsellor while the study is ongoing. This is to avoid biasing the results. However where the study questionnaire signals a concern that the client is either acutely suicidal or suffering from a psychiatric disorder requiring medication, the study coordinator will notify the counsellor and thereby withdrawing the client from the study. At the end of the study period, all participants will be offered an appointment to review their own results with the study team. Psychological support will be offered as needed.

### **Community involvement and benefit**

Consultations were had with community members, clients, and health care workers prior to starting the study to understand their perspective and feedback on the proposed research. There was overall support for the concept of MSF trying to better understand the mental health counselling program and gather more information on it. The major concern was the waiting time. Some individuals felt it would be fine as long as it was well explained and travel costs compensated or if people were paid an incentive. Others did not like the idea at all, and did not feel that compensating travel costs would make it okay to defer treatment. A common concern was that some people would go see another provider if there were randomised to the wait list rather than waiting, or might not come back. A number mentioned that if they went to the counsellor, they wanted to talk or get help immediately and not wait. The latter seemed to more strongly felt by those consulted who were inpatients in the hospital, as they said they were in the hospital and expected to see the health care workers they needed without waiting.

This feedback has helped us understand that good education will be very important to help people understand what is trying to be achieved. Psychological first aid will be provided at the first contact in order to help address what people expressed as a desire for immediate intervention when they first go to the counsellor. The risk of high drop out rates will be considered in the sample size. Finally, the interviews prompted us to review again the length of time on the waiting list, and this has been reduced to two months which is also consistent with the current length of treatment.

### **Ethical review**

The study protocol of this intervention study will be reviewed and approved by the MSF ethical review board. The protocol will also be reviewed by a local Ethical review Board in Chechnya. The CDC staff will provide technical expertise with the design of the evaluation protocol, perform the analysis of the data, and participate in writing reports and publication based on the results of the evaluation. Because CDC staff will not have access to any unique identifiers, and will not have any contact with human participants, a “non-engagement determination” and/or deferral to MSF’s IRB will be sought.



## **Dissemination Plan**

A written summary report of the evaluation will be provided to all participating agencies. Results from the evaluation may be presented at national and international meetings and will be published in international peer-reviewed journals.

Results of the study will also be shared with the local communities in Grozny and with the Ministry of Health. The dissemination to the community will take place through a written summary in lay language of the research results to be distributed through MSF community workers and at the study sites. In addition, the results will be shared verbally in meetings with community members at each study site. The results will also be shared with the Ministry of Health professional staff at a professional education session that allows for a full exploration of the results.

## **Evaluation Investigators**

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- Giovanni Pintaldi

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- Curtis Blanton, PhD (statistician)

Johns Hopkins University

- Paul Bolton, MBBS, MPH (consultant)
- Judith K. Bass, PhD, MPH (consultant)

Grozny co-investigator

Prof Kyuri Idrisov, Head of the Psychiatry Department at the Chechen State University.

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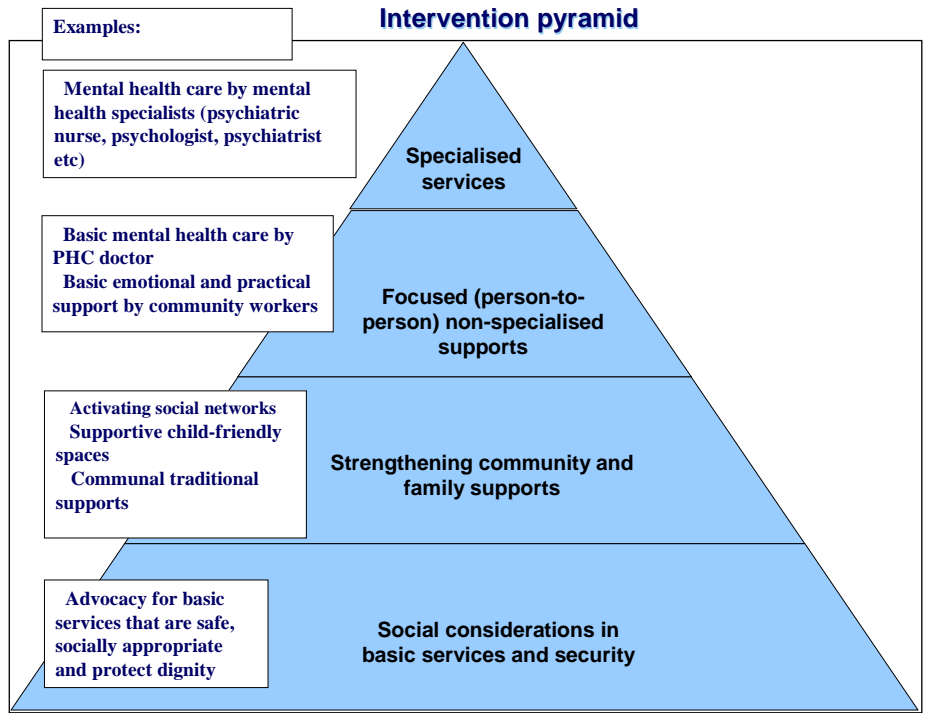
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# Annexe 1: Intervention pyramid for mental health and psychosocial support in emergencies



Reference: IASC Guidelines, 2007

## Annexe 2 Questionnaire

### Questionnaire

Instrument	# items
Demographics/economic functioning (to be adapted locally)	8
Culture-specific symptoms (to be developed locally)	2-3
Hopkins Symptom Checklist for Anxiety and Depression (HSCL-25)	25
Posttraumatic symptoms/HTQ	16
Coping	10
Social support	12
Functioning / questions from SF-36	6
Functioning questions, (to be developed locally)	6-10
MSF scale (complaint and functioning rating)	2

### Demographics

D1. Sex	1. Male 2. female
D2. Age	--
D3. Age Group	1. 18-34 2. 35-54 3. 55-64 4. ≥65

D4. Marital Status	<ol style="list-style-type: none"> <li>1. Married</li> <li>2. Single</li> <li>3. Widowed</li> <li>4. Divorced</li> <li>5. Separated</li> </ol>
D5. Education	<ol style="list-style-type: none"> <li>1. None</li> <li>2. Primary</li> <li>3. High school</li> <li>4. More than high school</li> </ol>
D6. Religion	<ol style="list-style-type: none"> <li>1. Muslim</li> <li>2.</li> <li>3.</li> <li>4. Christian</li> <li>5. None</li> <li>6. Other</li> </ol>
D7. Ethnicity	<ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> <li>4.</li> <li>5.</li> <li>6. Other</li> </ol>
D8. ARE YOU CURRENTLY WORKING TO EARN A LIVING?	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>
D8A. IF NO (NOT WORKING), WHY NOT?	<ol style="list-style-type: none"> <li>1. I have been physically ill</li> <li>2. I am disabled</li> <li>3. I am too old/retired</li> <li>4. I did not want to work</li> </ol>



	5. I had emotional problems 6. I am a student 7. I do housework and/or take care of children 8. I am too young 9. I was on vacation 10. No work exists 11. I don't know how to find a job 12. Other (specify.....)

Note: Demographics questions will be adapted according to the local context after information obtained from key informants.

**Hopkins Symptom Checklist (HSCL25)**

1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		

14.		
15.		
16.		
17.		
18.		
19.		
20.		

**Instructions:**

Listed below are symptoms or problems that people sometimes have. Please read each one carefully and describe how much the symptoms bothered you or distressed you in the past 4 weeks.

Place a check in the appropriate column.

<b>Part 1</b>	<b>Anxiety Symptoms</b>	<b>Not at all</b>	<b>A little</b>	<b>Quite a bit</b>	<b>Extremely</b>
1	Suddenly scared for no reason				
2	Feeling fearful				
3	Faintness, dizziness or weakness				
4	Nervousness or shakiness inside				
5	Heart pounding or racing				
6	Trembling				
7	Feeling tense or Keyed up				
8	Headache				
9	Spell of terror or panic				
10	Feeling restless or can't sit still				
<b>Part 2</b>	<b>Depression symptoms</b>	<b>Not at all</b>	<b>A little</b>	<b>Quite a bit</b>	<b>Extremely</b>
11	Feeling low in energy, slowed down				

12	Blaming yourself for things				
13	Crying easily				
14	Loss of sexual interest or pleasure				
15	Poor appetite				
16	Difficulty falling asleep, staying asleep				
17	Feeling hopeless about future				
18	Feeling sad				
19	Feeling lonely				
20	Thought of ending your life				
21	Feeling of being trapped or caught				
22	Worry too much about things				
23	Feeling no interest in things				
24	Feeling everything is an effort				
25	Feeling of worthlessness				

**1- For the responses to each item, assign the following numbers:**

1 = Not at all

2 = A little

3 = Quite a bit

4 = Extremely

**2- Add up item scores and divide by the total number of the answered items**

**Note:** < 1.75 is now considered a scientifically valid cut-off point.

**Harvard Trauma Questionnaire /PTSD Symptoms**

*Instructions: Please check one box per question. The following are symptoms that people have after experiencing hurtful or terrifying events in their lives. Please decide how much the symptoms bothered you in the past 4 weeks.*

	Not at all	A little	Quite a bit	Extremely
<b>PTSD1.</b> Recurrent thoughts or memories of the most hurtful or terrifying events.				
<b>PTSD 2.</b> Feeling as though the hurtful or terrifying event is happening again.				
<b>PTSD 3.</b> Recurrent nightmares				
<b>PTSD 4.</b> Feeling detached or withdrawn from people				
<b>PTSD 5.</b> Unable to feel emotions				
<b>PTSD 6.</b> Feeling jumpy, easily startled				
<b>PTSD 7.</b> Difficulty concentrating				
<b>PTSD 8.</b> Trouble sleeping				
<b>PTSD 9.</b> Feeling on guard.				
<b>PTSD 10.</b> Feeling irritable or having outburst of anger				

<b>PTSD 11.</b> Avoiding activities that remind you of the traumatic or hurtful event.				
<b>PTSD 12.</b> Inability to remember parts of the most traumatic or hurtful events				
<b>PTSD 13.</b> Less interest in daily activities				
<b>PTSD 14.</b> Feeling as if you don't have a future				
<b>PTSD 15.</b> Avoiding thoughts or feelings associated with the traumatic or hurtful events				
<b>PTSD 16.</b> Sudden emotional or physical reaction when reminded of the most hurtful or traumatic events				

## Coping

### Coping with Stress

We are interested in how people cope with the problems and troubles in their lives.

Listed below are several possible ways of coping. We would like you to indicate to what extent you, yourself, used each of these coping methods. Try to think of one problem you have encountered. This should be a problem that was important to you, and has caused you to worry (anything from the loss of a loved one to a traffic citation, but one that was important to you).

With this problem in mind, indicate how you coped by circling the appropriate number for each coping behaviour listed below. Answer each and every question even though some may sound similar.

Did you remember to write down your problem? If not, please do so before going on.

Keeping that stressful event in mind, indicate to what extent you...

COP 1. Went to a friend to help you feel better about the problem?	1. A Lot	2. A little	3. Not at all
COP 2. Formed a plan of action in your mind?	1. A Lot	2. A little	3. Not at all

COP 3. Thought about what needed to be done to straighten things out?	1. A Lot	2. A little	3. Not at all
COP 4. Avoided being with people in general?	1. A Lot	2. A little	3. Not at all
COP 5. Wished that people would just leave you alone?	1. A Lot	2. A little	3. Not at all
COP 6. Tried to solve the problem?	1. A Lot	2. A little	3. Not at all
COP 7. Confided your fears and worries to a friend or relative?	1. A Lot	2. A little	3. Not at all
COP 8. Sought reassurance from those you know best?	1. A Lot	2. A little	3. Not at all
COP 9. Watched television more than usual?	1. A Lot	2. A little	3. Not at all
COP 10. Used prayer or other religious practice?	1. A Lot	2. A little	3. Not at all

DRAFT

**Social Support**

We would like to learn about your perceptions of support, related to their everyday life. For the next items, “people” refers to any and all persons whom you know. Please mark the circle next to the response that is true for you at this moment.

SS 1. There are people I can depend on to help me if I really need it.	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree
SS 2. There is <u>no one</u> I can turn to for guidance in times of stress.	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree
SS 3. There are people who enjoy the same social activities I do.	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree
SS 4. I feel personally responsible for the well-being of another person. (i.e., to support another person).	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree
SS 5. I do <u>not</u> think other people respect my skills and abilities.	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree
SS 6. If something went wrong, <u>no one</u> would come to my assistance.	1. Strongly Disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly Agree

<p>SS 7. I have close relationships that provide me with a sense of emotional security and well-being (i.e., happiness, health, welfare).</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>
<p>SS 8. I have relationships where my competence and skill are recognized.</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>
<p>SS 9. There is <u>no one</u> who shares my interests and concerns.</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>
<p>SS 10. There is <u>no one</u> who really relies on me for her/his well-being.</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>
<p>SS 11. There is a trustworthy person I could turn to for advice if I were having problems.</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>
<p>SS 12. I lack emotional closeness with another person.</p>	<ol style="list-style-type: none"> <li>1. Strongly Disagree</li> <li>2. Disagree</li> <li>3. Unsure</li> <li>4. Agree</li> <li>5. Strongly Agree</li> </ol>



<b>Functioning</b> <span style="float: right;"><i>(Circle one number)</i></span>	
<p>SF1. In general would you say your health is?</p> <p><i>(Circle one number)</i></p>	<ol style="list-style-type: none"> <li>1. Excellent?</li> <li>2. Very good?</li> <li>3. Good?</li> <li>4. Fair?</li> <li>5. Poor?</li> </ol>
<p>SF2. How much bodily pain have you had during the past 4 weeks?</p> <p><i>(Circle one number)</i></p>	<ol style="list-style-type: none"> <li>1. None?</li> <li>2. Very mild?</li> <li>3. Mild?</li> <li>4. Moderate?</li> <li>5. Severe?</li> <li>6. Very severe?</li> </ol>
<p>SF3. During the past month, how much of the time, has your physical health or emotional problems interfered with your normal social activities (like visiting with friends or relatives)?</p> <p><i>(Circle one number)</i></p>	<ol style="list-style-type: none"> <li>1. All of the time?</li> <li>2. Most of the time?</li> <li>3. Some of the time?</li> <li>4. A little of the time?</li> <li>5. None of the time?</li> </ol>
<p>SF4. During the past month, how much of the time, have you had to cut down the amount of time you spent on work or regular daily activities as a result of any emotional problems, such as feeling depressed or anxious?</p> <p><i>(Circle one number)</i></p>	<ol style="list-style-type: none"> <li>1 All of the time?</li> <li>2 Most of the time?</li> <li>3 Some of the time?</li> <li>4 A little of the time?</li> <li>5 None of the time?</li> </ol>
<p>SF5. During the past four weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?</p> <p><i>(Circle one number)</i></p>	<ol style="list-style-type: none"> <li>1 All of the time?</li> <li>2 Most of the time?</li> <li>3 Some of the time?</li> <li>4 A little of the time?</li> <li>5 None of the time?</li> </ol>

SF6. During the past four weeks, how much of the time did you do your work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious?

(Circle one number)

- 1 All of the time?
- 2 Most of the time?
- 3 Some of the time?
- 4 A little of the time?
- 5 None of the time?

DRAFT

## **Annexe 3 Consent Form**

**(Flesch-Kincaid grade level: 8.8)**

### **Consent Form**

**Title:** Outcome evaluation study of MSF psychosocial program in Chechnya

**Sponsoring Organizations:**

MSF Holland

**Introduction and Purpose:**

We are inviting you to participate in an outcome evaluation study of the effectiveness of the MSF psychosocial program in Chechnya. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be part of the study. It is entirely your choice. The decision to join or not join the study will not cause you to lose any treatment options.

The data collected in this evaluation will be used to determine the effectiveness of the treatment program.

Full participation will require about one (1) hour of your time each, at four different time periods in addition to the counselling sessions you will receive. We will randomly assign you to an immediate intervention group or a group that will be waitlisted to receive the intervention 2 months later.

**Procedures:**

If you chose to be part of the study, you will be assigned to either immediate counselling or to a waiting group. The waiting group will wait for 2 months, and then start the counselling. You will not know before you agree to the study, what group you will be assigned to be in. The choice of the group you will be done by chance (like flipping a coin).

If you choose to be in the study we will ask you to fill out a questionnaire at 4 separate times over approximately the next 8 months. This questionnaire will:

- ask questions about psychological symptoms
- ask questions how you are functioning

### **Follow up**

By agreeing to be in the study, you agree that if you do not come for your scheduled follow up, one of the study team will contact you to remind you. This could take place by telephone or by visiting you at home. In addition, if you are in the waitlist group, then one of the study team will contact you once a month before you start the counselling to make sure everything is okay with you.

### **Risks and Discomforts:**

We do not expect this evaluation to cause any harm to you. There is a possibility that some of the questions will cause uncomfortable emotional feelings. You don't have to answer any questions you don't want to. If you do experience discomfort, and you would like to speak with someone about it, we will provide appropriate referrals.

### **Benefits**

Taking part in this outcome evaluation may not benefit you personally, but the evaluation coordinators may learn new things that will help improve the MSF mental health program. We will provide recommendations to MSF staff based on the evaluation results.

### **Withdrawal/Choosing Not to Participate**

You can choose to be in this study or not. If you decide not to be in the study, nothing will happen to you. If you participate in the study, you do not have to answer any questions you do not want to. You can also choose not to do some parts of the study and withdraw your consent to participate at any time. If you are in the waitlist group, and decide you do not want to wait any longer for counselling, you can also withdraw from the study and start counselling immediately.

### **Compensation**

You will not be offered payment for being in this study except to cover any travel costs and time.

### **Confidentiality**

A study number rather than your name will be used on the questionnaires. We will keep any information or data that we collect about you confidential and in a secured location. Only the coordinator and the investigators of the evaluation study will have access to the information. In addition information from your counselling chart will be entered into an electronic database using a number code. This is routinely done for all clients in MSF counselling programs. None of the

results will ever be identified by name. Your name and other facts that might point to you will not appear when we present this study or publish its results.

**Costs:**

There are no anticipated costs to you for participating in this study.

**Questions**

Please contact the MSF field investigator ..... at.....if you have any questions, concerns or complaints about this evaluation or your part in it.

**Consent**

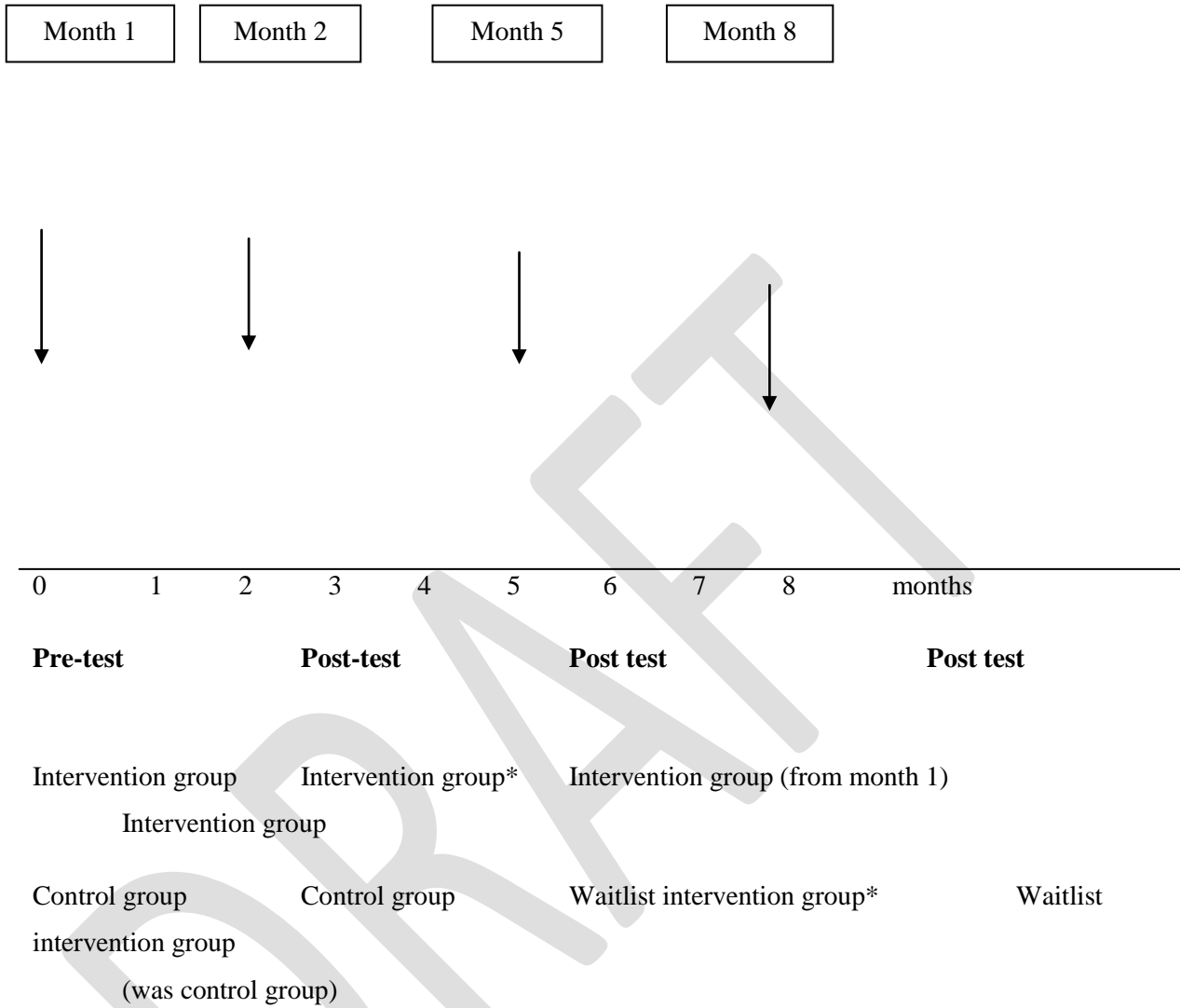
I have read this form. I have had a chance to ask questions about this evaluation and my questions have been answered. I have been given a copy of this form to keep.

I agree to take part in the study      Yes                      No

Date:

**Please mark both copies, keep one and return one to the study coordinator**

## Annexe 4 Timeline Evaluation



**\*Timing will vary depending on when discharged from treatment**