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Keywords:	MENTAL HEALTH, Chechnya, functioning, anxiety and depression, individual counselling

Title

Outcomes of an individual counselling programme in Grozny, Chechnya: a randomized controlled study

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ABSTRACT

Objectives

To evaluate the effectiveness of individual counselling on functioning of clients of a mental health programme.

Design

Randomised controlled trial.

Setting

Mental health programme implemented by Medecins Sans Frontieres in Grozny, Republic of Chechnya.

Participants

168 eligible clients were randomly assigned to the intervention and waitlisted (2 months) arms between November 2014 and February 2015.

Intervention

Individual counselling sessions.

Main outcome measures

Change in functioning was measured using the Short Form 6 (SF6) and gender-specific locally adapted Chechen functioning instruments in the intervention group at the end of counselling and the waitlisted group after their waitlisted period. Unadjusted differences in gain scores (DGS) between intervention and waitlisted groups were calculated with effect size (Cohen's d) for both tools. Linear regression compared the mean DGS in both groups.

Results

The intervention group (n=78) improved compared with controls (n=80) on the four SF6 measures with moderate to large effect sizes: general health (DGS 12.14, d=0.52), body pain (DGS 10.26, d=0.35), social support (DGS 16.07, d=0.69), and emotional functioning (DGS 16.87, d=0.91). Similar improvement was seen using the Chechen tool score (female DGS -0.33, d=0.55; male DGS -0.40, d=0.99). Adjusted analysis showed significant improvement ($p<0.05$) in the intervention group for all SF6 measures and for the Chechen tool score in women but not men (p=0.07).

Conclusions

Individual counselling significantly improved participants' ability to function in the intervention group compared with the waitlisted group. Further research is needed to determine whether similar positive results can be shown in other settings.

Trial Registration

Clinical Trials NTR4689

Keywords

Mental health, Chechnya, functioning, anxiety, depression, individual counselling

Strengths and limitations of this study

- Randomised controlled trial conducted in a humanitarian setting in a scientifically rigorous way;
- Very low rate of loss to follow up in the intervention and control group throughout the study period;
- Intervention impact evaluated using different psychological measurement instruments;
- Participant recruitment occurred at hospitals thus the study population might not be fully representative of the general population in Grozny;
- Blinding of study counsellors could not be ensured in all cases;

INTRODUCTION

Mental health (MH) needs of people affected by emergencies are undisputed. Recognition of the need for scale-up of MH programming in lower income countries and humanitarian contexts was solidified by the World Health Organization (WHO) mhGAP 2010 Intervention Guide, updated in 2015 [1]. WHO recently issued Problem Management Plus (PM+) guidance to support implementation of individual psychological support for adults in communities affected by adversity [2]. The guidelines address the challenges encountered during humanitarian emergencies: inability to ensure long-term and sustained counselling sessions and absence of fully trained MH workers in affected areas.

A systematic review from 2011 described seven studies of non-specialised counselling interventions for adults in emergency settings; using a meta-analysis, they showed a beneficial effect of MH interventions on post-traumatic stress disorder (PTSD) [3]. Several randomised controlled trials (RCTs) in humanitarian settings have since been published [4]. However, the interventions vary in terms of approach, target groups, duration of intervention, and types of MH staff used. Outcomes are mostly measured in terms of daily functioning and the main psychosocial distress categories of depression, anxiety, and PTSD. Individual cognitive behavioural therapy (CBT) and cognitive processing therapy (CPT) have been shown to have positive outcomes on depression, anxiety, and PTSD in RCTs in Iraq and Iraqi Kurdistan in war traumatised adults and survivors of violence, torture, and militant attacks [5–7]. Several other RCTs have addressed other methods of psychosocial support including transdiagnostic approaches, Common Elements Treatment Approach (CETA), behavioural interventions, and psychosocial counselling in individual and group interventions in various countries [8–14].

The main psychological component of the MH programmes implemented by Médecins Sans Frontières - Operational Centre Amsterdam (MSF-OCA) is the provision of individual counselling [15]. The individual component of the MH intervention aims to enhance clients' functionality, reduce symptoms, and identify new coping strategies [15]. The programme does not address severe MH disorders such as severe depression, bipolar disorder, or psychosis. The counselling approach is based on principles derived from brief-trauma-focused therapy and CBT's techniques integrated into the cultural context [16]. A review of 18 MSF-OCA individual-focused non-specialised counselling programmes comprising 15,000 clients showed positive outcomes among those returning for follow-up [15]. However, no evaluation using a control group to determine the impact of individual counselling has been conducted.

A programme in Grozny, Republic of Chechnya was initiated to offer MH and psychosocial services to internally displaced people (IDP) on the border with Ingushetia in 2001. Many clients had trauma-related symptoms resulting from heavy shelling and massive explosions. In the following 2 years, violence continued in the region. The programme was focused on IDP dwellings and in 2003 expanded to include activities in Grozny City Hospital. By 2008-2009, the situation in Chechnya was improving but with ongoing violence and insecurity. The MH programme continued to provide psychosocial support to the population. The programme was closed in March 2017 and therefore the MH services offered in three hospitals in Grozny, one hospital in Shatoy district and one hospital in Vedeno district.

To document evidence of Médecins Sans Frontières (MSF) psychosocial counselling effectiveness and because the MH programme in Grozny had never been formally evaluated, we conducted an RCT using a stepped-wedge design. Our hypothesis was that the individual counselling would improve individuals' ability to function in daily life.

METHODS

Study location and design

The study was conducted in Grozny, capital of the Republic of Chechnya, and implemented in three Ministry of Health hospitals where MSF's MH programme functions. It was an RCT using a stepped-wedge design. Participants were randomly assigned to intervention or waitlisted control arms, based on order of arrival for counselling (Figure 1). The intervention group received individual counselling immediately after enrolment. The control group had their counselling deferred for 2 months. The 2-month waiting period was based on the average length of treatment for clients enrolled in the programme in Grozny before the study, and on a community consultation exercise. The intervention group completed measurements at enrolment/pre-intervention (T0), post-intervention (T1), and 3 and 6 months post-intervention (T2 and T3). The control group completed measurements at enrolment (baseline), pre-intervention (T0, before the start of counselling), following the end of counselling (T1), and 3 months later (T2).

Participants

All clients seeking care at the MSF-OCA MH programme in Grozny between November 2014 and February 2015 were considered for eligibility. Clients were self-referred or referred by staff and volunteers at the three hospitals. Clients were eligible for inclusion if they were aged 18 years or older, able to provide informed consent, and willing and able to return for follow-up. Clients were not eligible if they had cognitive, visual, or other impairments that would limit their ability to participate, were considered at acute risk of suicide, had a severe MH disorder requiring medications, or had been enrolled in MSF counselling services in the previous 6 months. Inclusion and exclusion criteria were established at presentation by a study interviewer/counsellor using a pre-established checklist.

All eligible clients were asked if they would consent to undergoing screening using the Hopkins Symptom Checklist-25. All those scoring 1.75 or greater on this questionnaire were asked to undergo the informed consent process to participate in the study. This included a detailed explanation of the study, the process of randomisation, the possibility of being waitlisted for 2 months, and the required follow-up periods. They received the same explanation in writing, after which they could ask further questions, and were then invited to sign the informed consent.

Interventions

During the study period, the study sites functioned with six full-time counsellors. Most counsellors had an academic background in psychology and had been working for MSF for more than 10 years. Of the eight counsellors working in the programme at the time of this study, five specialised in pedagogy and psychology, one specialised in clinical psychology, and two completed medical school.

The counselling approach was standardised through training modules delivered by trainers from the Netherlands Institute of Psychology. Follow-up supervision and quality control used the

MSF-OCA MH guideline [17], annual workshops for MH officers, oversight from headquarters-based MH advisors, and clinical supervision by international MH officers.

The counselling approach is based on principles derived from brief-trauma-focused therapy, with an 'individual development oriented' approach [17]. The first task of the counsellor is to make a personal and meaningful contact with the client [18]. After identifying the main complaint, the counsellor explores any specific precipitating events to gain a clear picture from the client's point of view about the history of the complaint. During subsequent sessions, the counsellor works with the client according to the goals set during the first consultation and an individualised treatment plan. No intervention other than individual counselling was offered.

Outcomes

The primary outcome was change in functioning, measured using the Short Form 6 (SF6, an adapted version of the SF36) and locally adapted gender-specific Chechen functioning instruments [19,20]. The SF6 uses six questions to assess self-perceived general health, bodily pain, social functioning, and role emotional functioning [21]. The raw scores are transformed to fit a 0-100 scale, with high scores representing better functioning [19]. We also developed and piloted two daily functioning scales for men and women in Chechnya, using an extensive qualitative study before the start of this study [20]. These gender-specific instruments used four-point Likert scales including a 'not applicable' score for activities considered to be part of daily life for people in Chechnya. The female instrument included 27 items and the male instrument 28. A reduction in score suggests improvement in functioning.

Secondary outcomes included changes in symptoms of anxiety and depression, coping strategies, and perceived social support as measured by the Hopkins Symptoms Checklist-25 (HSCL-25), the Coping Strategy Indicator (CSI), and the Social Provisions Scale (SPS), respectively [22–24]. We also aimed to measure whether any changes were sustained at 3 and 6 months post-intervention. The HSCL-25 evaluates anxiety- and depression-related symptoms and is rated like a Likert scale from 1 to 4 where 1 means that the client does not associate with the symptom and 4 means they associate with it "extremely". Three scores are calculated: an anxiety score , a depression score , and an overall score measuring psychological distress [22]. The scale was validated in the Russian language in Chechen refugees living in Austria [25]. Mean overall symptom scores of more than 1.75 for each subcategory have been found to predict clinical diagnosis of anxiety and affective disorders [26]. We used this cut-off as an indication of symptoms of mental distress in clients eligible for enrolment in the study. The CSI [23] includes three subscales of coping strategies: problem-solving, avoidance, and social-support seeking. A reduction in scores indicates an improvement in coping strategies. The 12-item SPS scale measures perceived social support [24,27], using a five-point Likert-type scale allowing for an unsure response. Participants rated their level of agreement from 1 (strongly disagree) to 5 (strongly agree) with statements regarding respect from others, offering support to others, common interests, feeling supported by others, and feeling close to others. An increase in score indicated an improved perception of social support.

Finally, the prevalence of PTSD in the study population before the intervention was estimated and the impact of the intervention on prevalence of PTSD was measured using the Harvard Trauma Questionnaire (HTQ-16) [28]. This scale evaluates the 16 commonly reported symptoms

of PTSD as described in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)[29]. It has been used as a screening tool for PTSD in numerous war-affected populations. We defined cases meeting PTSD symptom criteria according to a scoring algorithm proposed by the Harvard Refugee Trauma Group [28].

As Chechen is mostly an oral language, all instruments were translated into Russian and back translated into English to ensure consistency of language. The language used in each instrument was carefully double checked in the piloting process. This included identifying Chechen words to better explain the written Russian translations of each of the instruments.

Data collection

A case reporting form (CRF) was developed for each participant for each relevant visit. The visits were defined as baseline (at enrolment for both groups), T0 (at enrolment/baseline and just before the counselling intervention for the intervention group; after the waitlisted period before the intervention for the waitlisted group), T1 (after the intervention for both groups), T2 (3 months after the intervention for both groups), and T3 (6 months after the intervention for the intervention group). This CRF included all study instruments and allowed the study interviewer to collect information on important life events that occurred between visits. Study interviewers were trained for 2 weeks to ensure consistency in language and style of administering the instruments.

Routine data on the counselling intervention was collected separately according to the MSF-OCA MH programme specifications, using a unique patient ID number and no other identifying data. Linkage between the participant's number and their patient ID number could only be done by the study coordinator through a password-protected database.

Sample size

A sample size of 46 in both the control and intervention arms was calculated for an estimated effect size (estimated difference in means between intervention and control divided by common standard deviation) of 0.40, 80% power, and an alpha of 0.05. We conservatively assumed a 45% loss to follow-up in our total sample, and thus aimed to include 84 participants in each arm for a total sample size of 168.

Randomisation and masking

Randomisation to the intervention and control groups used a computer-generated sequence for each hospital. This sequence was only accessible to the study coordinator and study assistant in a password-protected file. The statistician generated the random allocation sequences before the study started, using the Proc Plan procedure in SAS version 9.4 (SAS Institute, Cary, NC).

After participants had provided informed consent and officially been enrolled, the study interviewers called the study coordinator for information on the allocated study arm of that participant. Participants were informed of their allocated study arm, and a follow-up visit for the counselling intervention or for the follow-up visit after the waitlist period was established. At the next visit (T1 for the intervention group and T0 for the waitlisted group); the study interviewer was switched to maintain blinding of the allocation arm. Participants were instructed to not reveal their allocation at this visit. Although the study team did their best to ensure blinding up to

T1 for the intervention group and T0 for the waitlisted group, maintaining this at all times was difficult, as normal conversation between interviewers and participants might have elicited this information. After the post-intervention visit, no further blinding was maintained.

Statistical methods

Descriptive analysis on demographic indicators (sex, age, marital status etc.) for both groups involved calculating means (and standard deviations) for continuous variables and proportions for categorical variables. Differences between the groups were determined using the t-test to compare means and chi-squared to test differences between proportions.

For each participant, we calculated individual scores for the SF6, HSCL-25, CSI, and SPS at each visit. For the intervention group, we calculated mean changes in individual gain scores between the baseline/T0 and T1 visits and the mean gain score for this period. For the waitlisted group, we calculated the individual gain scores between enrolment at baseline and T0 after their waitlisted period and the mean gain score for the whole group for the same period. We then compared the difference between the mean gain scores (DmGS) of the groups using regression models. A multivariable regression model was constructed to estimate the adjusted DmGS between the groups, incorporating the following covariates to adjust for potential confounding: hospital, age, sex, and education level, marital status, and employment status at enrolment. We also adjusted for the total number of counselling sessions for each participant.

We analysed the data in the intention-to-treat model to test the intervention effects, including all participants enrolled in the study even if they dropped out between the two time points. For participants lost to follow-up, we imputed the last known value from the previous visit. Cohen's *d* effect sizes were calculated for the unadjusted differences in gain scores comparing the groups. We defined an effect size of <0·15 as negligible, 0·15-0·40 as small, 0·41-0·75 as medium, and >0·75 as large [30]. The difference between the mean adjusted difference in gains scores for the two groups were compared using the F-statistic and corresponding p-values.

To determine whether the change in scores after the intervention was maintained in both groups, we combined all data for mean scores at T1 and T2 (3 months after finishing counselling). We also looked at maintenance of the score in the intervention group 6 months after counselling finished (T3). Regression models were used to measure the difference in the mean of the pooled scores between T1 and T2 (both groups combined) and between T2 and T3 (intervention group only).

For the HTQ-16 (PTSD), we calculated prevalence of PTSD in the two groups at all visits by identifying participants meeting DSM-IV criteria. We compared the change in prevalence in the intervention group between baseline/T0 and T1 with the change in prevalence in the waitlisted group between baseline and T0, using logistic regression estimated by generalized estimating equations to account for the repeated measures of PTSD. The model included an interaction term for group and time to account for the change in the PTSD status of participants in each group between the two time points, and adjusted for sex, hospital of recruitment, and age. Measures of association were calculated as odds ratios with 95% confidence intervals and p-values.

All analysis was done in STATA version 13.0 (Statacorp, College Station, Texas, USA) and SAS version 9.4 (Cary, NC, USA).

Ethical considerations

In February 2013, a community consultation was conducted in Grozny with six groups of participants including nurses, social workers, pharmacy staff, and patients in the hospital [31]. The outcomes were used to inform the final study design (notably reducing the waitlist period from 3 to 2 months). The study protocol was reviewed and approved by the MSF Ethical Review Board and the Ethical Review Board in Chechnya State University. The study protocol was also reviewed at CDC and determined to meet the criteria for non-engagement of CDC staff in human subjects' research.

Informed consent forms were translated into Russian and Chechen, back-translated into English, and piloted in the area of the study. We explained to clients that participation in the study was voluntary, that they could discontinue from the study at any time without explanation, and that they would receive the same standard of treatment whether or not they agreed to participate. Participants were reimbursed approximately 10 US Dollars to cover transport costs for each follow-up visit. At the end of the study, all participants were offered an appointment to review their own results.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis and interpretation and writing of this article. The corresponding author had full access to all the data in the study and is the final responsible.

RESULTS

Participant recruitment and follow-up

Between 17 November 2014 and 9 February 2015, we assessed 203 patients presenting for care at the MSF MH programme for eligibility. Thirty-five people not eligible (n=12) or declined to participate (n=23). We randomised 168 participants: 84 to each group.

One participant's MH condition deteriorated immediately following enrolment into the study (intervention group); the participant was referred for psychiatric care before starting the intervention and was no longer followed in the study. We lost another 19 participants to follow-up (11·30%): six (7·14%) in the intervention group (five during the intervention and one between 3 and 6 months post-intervention) and 13 (15·48%) in the waitlisted group (four during the waitlisted period, seven during the intervention, and two between the end of counselling and 3-month follow-up). The total proportion lost to follow-up did not differ between the groups (p=0·082) (Figure 1).

Baseline data

Demographic characteristics of the intervention and waitlisted group participants were similar; most were female, married, and employed, had completed high school, and were not hospitalised at the time of enrolment (Table 1). There was no evidence of differences in characteristics of the two groups (p≥0·26).

Table 1: Baseline characteristics of participants

Characteristic	Sub-category	Waitlisted arm		Intervention arm		T-test or χ2	p-value
		n	*%*	*n*	*%*		
Sample size		84	50	84	50		
		mean	*SD*	*mean*	*SD*		
Age		41·43	13·53	40·54	14·62	0·41	0·68
		n	*%*	*n*	*%*		
Sex	Male	24	28·57	21	25·00	0·27	0·60
	Female	60	71·43	63	75·00		
Marital status	Married	44	52·38	47	55·95	0·89	0·93
	Single	18	21·43	19	22·62		
	Widowed	8	9·52	8	9·52		
	Divorced	12	14·29	9	10·71		
	Separated	2	2·38	1	1·19		
Employment	Employed	32	38·10	31	36·90	2·23	0·82
	Housewife	8	9·52	12	14·29		
	Student	6	7·14	6	7·14		
	Unemployed	25	29·76	24	28·57		
	Retired	13	15·48	10	11·90		
	Other	0	0	1	1·19		
Education	Primary	2	2·38	0	0	2·22	0·27
	Secondary	58	69·05	53	63·10		
	Higher education	24	28·57	30	35·71		
	None	0	0	1	1·19		
Hospitalised	No	75	89·29	79	94·05	1·25	0·26
	Yes	9	10·71	5	5·95		

For the 78 intervention group participants who completed counselling, information from the programmatic data was available for 76 on the number of counselling sessions completed and the duration of those sessions [mean sessions: 3·8 (SD=0·7); duration: 29·7 days (SD=9·7)]. Seventy-one waitlisted participants for whom this information was available (of the 73 who completed counselling) had a higher mean number of counselling sessions [4·1 (SD=0·6); t-value=2·1, p=0·04], and mean duration of counselling [33·6 days (SD=12·0); (t-value=2·2; p=0·03]. The presenting complaint for counselling was similar between the groups (χ^2=5·5, p=0·6); most sought counselling for anxiety-related (n=54, 36·7%), mood-related (n=34, 23·1%), family-related (n=22, 15·0%), and behaviour-related complaints (n=20, 13·6%). The precipitating event leading to seeking counselling was also similar between groups (χ^2=10·3, p=0·2), with similar proportions seeking care due to psychological violence (n=43, 39·3%),

domestic discord or domestic violence (n=41, 27·9%), or non-violence-related events (n=41, 27·9%). During the intervention, the counselling focus was similar in the two groups (χ^2=1·62, p=0·8). In descending order of frequency, the focus was on practical problems (n=58, 39·5%), overwhelming feelings (n=32, 21·8%), trauma-related symptoms (n=29, 19·7%), inner problems (n=17, 11·6%), and lack of skills (n=11, 7·5%).

Numbers analysed

For the primary outcome and secondary outcomes looking at differences in mean gain scores between the groups from T0 and T1 for the intervention group and baseline and T0 for the waitlisted group, we included 84 participants in both groups with imputed data on scores from the last known follow-up visit. For the secondary outcomes around maintenance of scores after the intervention, we included 78 people in the intervention group and 71 from the waitlisted group.

Functioning

Using the SF6, the counselling intervention had moderate to large effect sizes in the intervention group compared with the waitlisted group (general health DmGS=12·14, effect size=0·52; bodily pain DmGS=10·26, effect size=0·35; social functioning DmGS=16·07, effect size=0·69; and role emotional DmGS=16·87, effect size=0·91) (Table 2). The Chechen functioning instruments showed a DmGS of -0·33 (effect size=0.54) for females and a DmGS of -0·40 (effect size=0·99) for males. In the adjusted analysis, the intervention group also showed improved functioning by SF6 and the Chechen female functioning scale (all p<0·05) (Table 3). For the male score, the adjusted analysis showed less strong evidence of an improvement in functioning in the intervention group compared with the waitlisted group (F=3·52, p=0·0691).

Table 2: Average treatment effects (n=168) for functioning: unadjusted scores

	Control group		Intervention group		Net effect		Effect size estimate*	p-value
	Mean score	(95%CI)	Mean score	(95%CI)	DmGS between scores for intervention and waitlist	(95%CI)	*d*	
SF6 General Health (score out of 100, increase=improvement)								
Pre-intervention	26·13	(22·31, 29·95)	23·39	(19·57, 27·22)				
Post-intervention	31·85	(26·67, 37·02)	41·25	(36·08, 46·42)				
Pre-post change	5·71	(0·72, 10·71)	17·86	(12·86, 22·85)	12·14	(5·08, 19·20)	0·52	0·0009
SF6 Body Pain (score out of 100, increase=improvement)								
Pre-intervention	39·9	(35·75, 44·06)	42·74	(38·58, 46·89)				
Post-intervention	47·05	(41·66, 52·44)	60·14	(54·75, 65·53)				
Pre-post change	7·14	(0·86, 13·43)	17·40	(11·12, 23·69)	10·26	(1·37, 19·15)	0·35	0·024
SF6 Social Functioning (score out of 100, increase=improvement)								
Pre-intervention	54·17	(49·97, 58·37)	52·38	(48·18, 56·58)				
Post-intervention	51·19	(47·06, 55·32)	65·48	(61·35, 69·61)				
Pre-post change	-2·98	(-7·99, 2·04)	13·10	(8·08, 18·11)	16·07	(8·98, 23·16)	0·69	<0·0001
SF6 Role Emotional (score out of 100, increase=improvement)								
Pre-intervention	56·15	(52·96, 59·34)	51·88	(48·7, 55·07)				
Post-intervention	56·35	(52·68, 60·01)	68·95	(65·28, 72·61)				
Pre-post change	0·20	(-3·79, 4·18)	17·06	(13·08, 21·08)	16·87	(11·23, 22·50)	0·91	<0·0001
Chechen Female Functioning (score 1-4, reduction=improvement)								
Pre-intervention	1·99	(1·83, 2·14)	2·04	(1·89, 2·19)				
Post-intervention	1·90	(1·76, 2·04)	1·63	(1·49, 1·77)				
Pre-post change	-0·09	(-0·24, 0·07)	-0·41	(-0·57, -0·26)	-0·33	(-0·54, -0·11)	0·54	0·004
Chechen Male Functioning (score 1-4, reduction=improvement)								
Pre-intervention	1·72	(1·53, 1·92)	1·71	(1·50, 1·91)				
Post-intervention	1·70	(1·54, 1·87)	1·28	(1·10, 1·46)				
Pre-post change	-0·02	(-0·19, 0·15)	-0·43	(-0·60, -0·25)	-0·40	(-0·65, -0·16)	0·99	0·0018

*measured using Cohen's d statistic

Table 3: Adjusted treatment effects for functioning (n=168)

	Adjusted DmGS between intervention and control	(95%CI)	F value	p-value
SF6 General Health	11·81	(4·90, 18·72)	11·41	0·0009
SF6 Body Pain	10·55	(1·91, 19·19)	5·82	0·017
SF6 Social Functioning	15·7	(8·53, 22·86)	18·71	<0·0001
SF6 Emotional Role	17·05	(11·45, 22·65)	36·19	<0·0001
Chechen Female Functioning	-0·36	(-0·57, -0·14)	10·79	0·0014
Chechen Male Functioning	-0·27	(-0·56, -0·02)	3·52	0·0691

Anxiety and depression

The unadjusted DmGS between the intervention and waitlisted groups using the HSCL-25 was -0·55 for anxiety symptoms, -0·50 for depression symptoms, and -0·52 for overall psychological distress (Table 4). The effect sizes calculated in the unadjusted analysis for all three measurements were large (all d>1·0 and p<0·0001). This positive impact of counselling in the intervention group compared with the waitlisted group was maintained in the adjusted analysis, with p<0·0001 for all three measurements (Table 5).

Table 4: Average treatment effects (n=168) for symptoms, coping, and perceived social support: unadjusted scores

	Control group		Intervention group		Net effect		Effect size estimate*	p-value
	Mean score	(95%CI)	Mean score	(95%CI)	**DmGS**	(95%CI)	*d*	
HSCL-25 Anxiety (score 1-4, reduction=improvement)								
Pre-intervention	2·49	(2·40, 2·58)	2·54	(2·45, 2·63)				
Post-intervention	2·21	(2·10, 2·33)	1·71	(1·6, 1·83)				
Pre-post change	-0·28	(-0·40, -0·17)	-0·83	(-0·94, -0·71)	-0·55	(-0·71, -0·39)	1·03	<0·0001
HSCL-25 Depression (score 1-4, reduction=improvement)								
Pre-intervention	2·43	(2·33, 2·52)	2·43	(2·34, 2·52)				
Post-intervention	2·23	(2·13, 2·34)	1·74	(1·63, 1·85)				
Pre-post change	-0·.19	(-0·30, -0·09)	-0·69	(-0·79, -0·58)	-0·50	(-0·65, -0·35)	1·01	<0·0001
HSCL-25 Total (score 1-4, reduction=improvement)								
Pre-intervention	2·45	(2·37, 2·54)	2·48	(2·39, 2·56)				
Post-intervention	2·22	(2·12, 2·33)	1·73	(1·63, 1·83)				
Pre-post change	-0·23	(-0·33, -0·13)	-0·74	(-0·85, -0·65)	-0·52	(-0·66, -0·37)	1·11	<0·0001
Coping Problem Solving (score 1-3, reduction=improvement)								
Pre-intervention	1·58	(1·50, 1·67)	1·54	(1·45, 1·62)				
Post-intervention	1·58	(1·50, 1·66)	1·64	(1·56, 1·72)				
Pre-post change	-0·01	(-0·10, 0·09)	0·10	(0·01, 0·19)	0·11	(-0·02, 0·24)	0·25	0·103
Coping Social Support (score 1-3, reduction=improvement)								
Pre-intervention	2·12	(2·01, 2·23)	2·08	(1·97, 2·19)				
Post-intervention	2·12	(2·01, 2·22)	2·06	(1·96, 2·16)				
Pre-post change	0	(-0·12, 0·12)	-0·02	(-0·14, 0·10)	-0·01	(-0·18, 0·16)	0·02	0·871
Coping Avoidance (score 1-3, reduction=improvement)								
Pre-intervention	2·13	(2·05, 2·21)	2·10	(2·01, 2·18)				
Post-intervention	2·11	(2·02, 2·20)	2·38	(2·30, 2·47)				
Pre-post change	-0·02	(-0·07, 0·11)	0·29	(-0·20, 0·38)	0·31	(0·18, 0·44)	0·72	<0·0001
Perceived Social support (score out of 60, increase=improvement)								
Pre-intervention	44·33	(43·34, 45·33)	44·23	(43·23, 45·22)				
Post-intervention	44·96	(44·05, 45·88)	46·75	(45·84, 47·67)				
Pre-post change	0·63	(-0·32, 1·58)	2·52	(1·58, 3·47)	1·89	(0·55, 3·23)	0·43	0·006

*measured using Cohen's d statistic

Table 5: Adjusted treatment effects for symptoms and coping, and social support (n=168)

	Adjusted DmGS between intervention and control	(95%CI)	F value	p-value
Symptoms				
HSCL 25 Anxiety	-0·56	(-0·72, -0·39)	46·06	<0·.0001
HSCL 25 Depression	-0·51	(-0·65, -0·36)	44·90	<0·0001
HSCL 25 Overall	-0·53	(-0·67, -0·38)	53·71	<0·0001
Coping and social support				
Problem solving	0·12	(0·02, 0·25)	3·05	0·0825
Social support	-0·02	(-0·19, 0·16)	0·03	0·8622
Avoidance	0·30	(0·17, 0·43)	20·16	<0·0001
Perceived social support	2·03	(0·68, 3·37)	8·83	0·0034

Coping and perceived social support

Using the CSI, the unadjusted DmGS related to problem solving and social support were very small with small effect sizes (problem solving DmGS=0·11, d=0·25, p=0·103; social support DmGS=-0·01, d=0·02, p=0·871) (Table 4). In the adjusted analysis, problem solving and social support showed no significant evidence of difference between the groups (p=0·08 and p=0·86, respectively (Table 5). The coping scale for avoidance showed a significant worsening, with a moderate effect size (DmGS=0·31, d=0·72, p<0·0001). In the adjusted analysis, the worsening in avoidance coping skills remained (F=20·16, p<0·001). Perceived social support improved in the intervention group compared with the waitlisted group, with a moderate effect size (DmGS=1·89, d=0·43, p=0·006), and this remained relevant in the adjusted analysis (F=8·83, p=0·0034) (Table 5).

Maintenance of scores after counselling

A continued improvement was observed using the scales for SF6 social functioning, SF6 role emotional, and the Chechen female and male functioning scales at T2 compared with T1 (all p<0·05). The effect was maintained at T3 with no further improvement for SF6 social functioning (p=0·60), SF6 role emotional (p=0·25), or the Chechen male functioning scale (p=0·17). Further significant improvement was observed at T3 compared with T2 in female participants from the intervention group (p=0·02). The effect of counselling was sustained (but not further improved) at T2 compared with T1 when measured on the SF6 general health (p=0·38) and body pain (p=0·10) scales. Similar trends were observed for these two scales at T3 compared with T2 (p=0·94 and p=0·95, respectively) (Table 6).

Table 6: Sustained improvement for functioning (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and control group combined]*			3 months to 6 months follow-up (T2 to T3), N=77 *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
SF6 General Health (score out of 100, increase=improvement)								
	T1	41·78	(37·77, 45·78)		T2	41·88	(36·30, 47·47)	
	T2	39·97	(36·05, 43·88)		T3	42·08	(36·67, 47·48)	
	Pre-post change	-1·81	(-5·88, 2·26)	0·38	Pre-post change	0·19	(-4·71, 5·10)	0·94
SF6 Body Pain (score out of 100, increase=improvement)								
	T1	60·72	(56·69, 64·76)		T2	66·96	(61·04, 72·88	
	T2	64·40	(60·43, 68·37)		T3	67·14	(61·26, 73·03)	
	Pre-post change	3·68	(-0·70, 8·06)	0·10	Pre-post change	0·18	(-5·32, 5·68)	0·95
SF6 Social Functioning (score out of 100, increase=improvement)								
	T1	65·27	(61·89, 68·65)		T2	71·10	(65·.89, 76·32)	
	T2	70·64	(67·25, 74·02)		T3	72·73	(67·93, 77·53)	
	Pre-post change	5·37	(1.47, 9.26)	0·007	Pre-post change	1·62	(-4·44, 7·68)	0·60
SF6 Role Emotional (score out of 100, increase=improvement)								
	T1	69·30	(66·55, 72·04)		T2	75·00	(70·88, 79·12)	
	T2	73·88	(70·92, 76·84)		T3	77·49	(73·60, 81·38)	
	Pre-post change	4·59	(1·36, 7·81)	0·006	Pre-post change	2·49	(-1·76, 6·74)	0·25
Chechen Female Functioning (N=111 and N=57) (score 1-4, reduction=improvement)								
	T1	1·53	(1·44, 1·63)		T2	1·42	(1·31, 1·53)	
	T2	1·42	(1·33, 1·51)		T3	1·28	(1·21, 1·36)	
	Pre-post change	-0·12	(-0·22, -0·01)	0·03	Pre-post change	-0·14	(-0·25, -0·02)	0·02
Chechen Male Functioning (n=38 and n=20) (score 1-4, reduction=improvement)								
	T1	1·38	(1·26, 1·50)		T2	1·19	(1·07, 1·32)	
	T2	1·24	(1·15, 1·33)		T3	1·12	(1·06, 1·19)	
	Pre-post change	-0·14	(-0·25, -0·03)	0·018	Pre-post change	-0·07	(-0·18, 0·03)	0·17

Symptoms of anxiety, depression, and psychological distress, measured by the HSCL-25, improved further at T2 compared with T1 (p=0·03, p=0·003, and p=0·005, respectively). This improvement continued in the intervention group at T3 compared with T2 (p=0·0009, p=0·001, and p=0·0005, respectively). Results for all aspects of the CSI showed either no change or a slight deterioration at T2 and T3. For perceived social support, a small improvement was observed at T2 (p=0·002) compared with T1, which was sustained but not further improved at T3 in the intervention group (Table 7).

Table 7: Change in scores for symptoms, coping, and social support at 3 and 6 months follow-up (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and control group combined]*				3 months to 6 months follow-up (T2 to T3), N=77 *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
HSCL-25 Anxiety (score 1-4, reduction=improvement)								
	T1	1·63	(1·56, 1·71)		T2	1·58	(1·47, 1·68)	
	T2	1·54	(1·47, 1·61)		T3	1·39	(1·30, 1·48)	
	Pre-post change	-0·09	(-0·18, -0·01)	0·03	Pre-post change	-0·19	(-0·29, -0·08)	0·0009
HSCL-25 Depression (score 1-4, reduction=improvement)								
	T1	1·69	(1·62, 1·76)		T2	1·60	(1·50, 1·69)	
	T2	1·57	(1·51, 1·64)		T3	1·44	(1·36, 1·51)	
	Pre-post change	-0·12	(-0·20, -0·04)	0·003	Pre-post change	-0·16	(-0·26, -0·06)	0·001
HSCL-25 Total (score 1-4, reduction=improvement)								
	T1	1·67	(1·60, 1·74)		T2	1·59	(1·50, 1·68)	
	T2	1·56	(1·50, 1·62)		T3	1·42	(1·34, 1·49)	
	Pre-post change	-0·11	(-0·19, -0·03)	0·005	Pre-post change	-0·17	(-0·27, -0·08)	0·0005
Coping Problem Solving (score 1-3, reduction=improvement)								
	T1	1·64	(1·58, 1·69)		T2	1·76	(1·65, 1·86)	
	T2	1·76	(1·69, 1·82)		T3	1·82	(1·71, 1·92)	
	Pre-post change	0·12	(0·05, 0·19)	<0·0001	Pre-post change	0·06	(-0·05, 0·16)	0·27
Coping Social Support (score 1-3, reduction=improvement)								
	T1	2·08	(2·01, 2·15)		T2	2·12	(2·00, 2·24)	
	T2	2·13	(2·05, 2·20)		T3	2·21	(2·10, 2·33)	
	Pre-post change	0·04	(-0·05, 1·14)	0·33	Pre-post change	0·09	(-0·04, 0·22)	0·18
Coping Avoidance (score 1-3, reduction=improvement)								
	T1	2·39	(2·33, 2·44)		T2	2·46	(2·38, 2·53)	
	T2	2·46	(2·41, 2·51)		T3	2·49	(2·41, 2·57)	
	Pre-post change	0·07	(0·01, 0·13)	0·02	Pre-post change	0·03	(-0·04, 0·11)	0·38
Perceived Social support (score out of 60, increase=improvement)								
	T1	46·74	(46·12, 47·36)		T2	47·88	(47·17, 48·60)	
	T2	47·75	(47·24, 48·26)		T3	48 ·12	(47·40, 48·84)	
	Pre-post change	1·01	(0·37, 1·66)	0·002	Pre-post change	0·23	(-0·60, 1·07)	0·58

PTSD

At baseline, 32 (N=84, 38·10%) participants in the intervention group and 39 (N=84, 46·43%) in the waitlisted group were classified as meeting DSM-IV criteria for PTSD using HTQ-16 ($\chi 2$=1·20, p=0·274). At T1, the prevalence in the intervention group had reduced (n=5/78, 6·41%). The prevalence of PTSD in the waitlisted group was 38.75% after the waitlisted period at T0 and had also reduced at T1 (n=8/73, 10·96%). The adjusted reduction in PTSD prevalence in the intervention group between baseline/T0 and T1 was significantly lower than that in the waitlisted group between baseline and T0 (odds ratio 0·11; 95% CI: 0·04-0·28, p<0·001) (Table 8).

Table 8: Unadjusted and adjusted odds ratios of comparison between change in PTSD prevalence of intervention group pre-intervention and post-intervention compared with waitlisted group

PTSD	Unadjusted			Adjusted		
	OR	**(95%CI)**	**p-value**	**OR**	**(95%CI)**	**p-value**
Control group						
Pre-intervention	1·00			1·00		
Post-intervention	0·73	(0·44, 1·20)	0·218	0·76	(0·46, 1·26)	0·280
Intervention group						
Pre-intervention	1·00			1·00		
Post-intervention	0·11	(0·04, 0·29)	<0·001	0·11	(0·04, 0·28)	<0·001
Intervention group vs. control group						
Post-intervention vs. pre-intervention	0·15	(0·05, 0·45)	0·001	0·14	(0·05, 0·43)	<0·001

DISCUSSION

The results confirm our hypothesis that individual counselling sessions improved the functioning of adults enrolled in the programme. Both instruments used to test functioning, including a scale that was specifically designed for use in Chechen adults, showed an improvement in the intervention group compared with the waitlisted group. The unadjusted and adjusted analyses for the functioning instruments showed very similar results, suggesting that the improvement in the intervention group compared with the waitlisted group was not importantly influenced by age, sex, marital and employment status, number of counselling sessions, and hospital of recruitment. The absence of statistical evidence for a true difference in the Chechen male functioning scale is likely due to the study being underpowered to detect differences among sub-groups.

The results are especially encouraging as different instruments to measure functioning recorded similar positive outcomes, strongly suggesting that the counselling is effective in improving this aspect of clients' lives. Such positive outcomes have also been shown in a retrospective review of programmatic data from 18 MSF projects with MH programmes in conflict and post-conflict settings [15]. As this study was a stepped-wedge RCT using validated outcome measures, we provide further evidence that the brief counselling intervention used among people affected by conflict can have a positive impact on their ability to function.

Different counselling strategies in other studies have also shown positive effects on functioning, PTSD, depression, and anxiety. Moderate to high improvements in the intervention group compared with the control group on these outcomes were measured using CETA in Burmese refugees in Thailand and in Iraqi Kurdistan [12,14]. In contrast, mixed results from group problem-solving counselling in terms of functioning were observed in war-affected adults in Aceh, Indonesia [32]. A recent RCT in adults with psychological distress in a conflict area in Pakistan identified a large improvement in functioning and symptoms of PTSD, depression, and anxiety following five weekly sessions of individual counselling delivered by trained lay workers using the WHO PM+ approach [10]. This study mirrors the intervention described in our study in that it limited the number of counselling sessions to five and did not rely on clinically trained MH professionals. It slightly differs from our approach in that the PM+ is a manualised intervention, whereas the MSF one is a semi-structured approach allowing for individual adaptation by the counsellor.

The coping scale did not show evidence for improvement with the intervention, and avoidance appeared to worsen. This suggests that the improvement functioning and symptoms was not achieved through improvement in the three coping skills measured by the CSI. Alternately, the CSI may not be well adapted to measure coping strategies in this population. The study by our colleagues in Aceh [32] also observed a small decline in the use of coping strategies among women in the intervention group.

The SPS scale showed a significant increase in perceived social support in the intervention group compared with the waitlisted group, which was sustained after completion of counselling. The MSF-OCA MH programme in Grozny includes encouragement to establish positive coping mechanisms (including social support). Social support has been shown to have a positive effect on mental and physical health [33] and is associated with lower posttraumatic stress scores [34]. It is also notable that social functioning improved with the intervention.

Longer-term efficacy of the individual counselling was demonstrated in that functioning and symptoms of depression and anxiety either maintained the improvement or continued to improve at 3 and 6 months after completion of counselling. Studies on Rwandan and Somali refugees in Uganda showed that NET counselling sustained the reduction in PTSD in all participants at 6 and 12 months' follow-up, although the dropout rates were high [35]. The functioning scales addressing general health and body pain were not sustained or further improved after completion of counselling. We do not know why this is the case but hypothesise that the counselling does not address other existing health problems. Neither coping mechanisms nor social support showed any further changes following the end of counselling.

The study has some limitations. Although few of the participants were hospitalised at enrolment, the MSF MH programme is located in hospital settings, which might have biased care-seeking behaviour. The study population therefore might not be entirely representative of those seeking help for MH concerns in Grozny. We worked hard to ensure that study interviewers remained blinded to the group allocation up to T1 of the intervention group, but this could not be ensured in all cases. We do not think that this potential bias would have changed our findings substantially, as all instruments had a fixed script for questions to be asked by interviewers and answers provided by participants, not allowing much space for interviewers to influence participants' answers. Grozny represents a specific and long-term unstable situation, so we cannot be certain that similar outcomes would be found in other acute emergencies. Finally, the counsellors delivering the intervention, while non-specialised, all had academic training and many years of experience delivering the intervention, which is not the case in many humanitarian settings. However, we have shown previously that although lay counsellors used more sessions than academically trained counsellors, the outcomes in clients were similar [15].

Despite its limitations, this study represents a scientifically rigorous evaluation of an individual counselling intervention in a humanitarian setting, in that it includes a randomised waitlisted group to avoid over-estimating improvements due to the effect of time alone. We were also able to show that the improvements due to the intervention were not only maintained but continued to improve at 3 and 6 months after completion of the intervention. This approach both improved functioning in daily life and reduced symptoms of mental distress including anxiety and depression, while decreasing the prevalence of PTSD in adults in Chechnya with similar effect sizes to other interventions. In parallel with the PM+ guidelines, we have shown that low-intensity MH interventions in humanitarian settings play an important role in improving functioning and reducing psychosocial distress. Further research is needed to determine whether similar results can be shown in acute conflict settings, and where less experienced/trained counsellors deliver the intervention.

RESGISTRATION

The study was registered with the Netherlands Trial Register (http://www.trialregister.nl/trialreg/index.asp) which is recognised by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICJME) under registration number NTR4689 (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4689). The protocol is available from http://fieldresearch.msf.org/msf/bitstream/10144/618741/1/1326_MSFH+MH+Chechnya+outcomes+evaluation+protocol_amendment+November+2016_clean_final.pdf.

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DISCLAIMER

The findings and conclusions in this report are those of the authors and do not represent the official position of the Centers for Disease Control and Prevention.

AUTHOR CONTRIBUTIONS

BLC, LS, CB, KI, PB and GP designed the study. CF, ZT, GP and AL acquired the data. CF, CB and AL analyzed the data. All authors contributed to the interpretation of data. AL, BLC and GP wrote the manuscript and all authors critically reviewed the manuscript.

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COMPETING INTEREST

The authors declare to have no competing interests.

DATA SHARING

All data and study materials are available on request from the corresponding author on reasonable request.

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Figure 1: CONSORT* Flowchart of participants
*Consolidated Standards of Reporting Trials (http://www.consort-statement.org/)

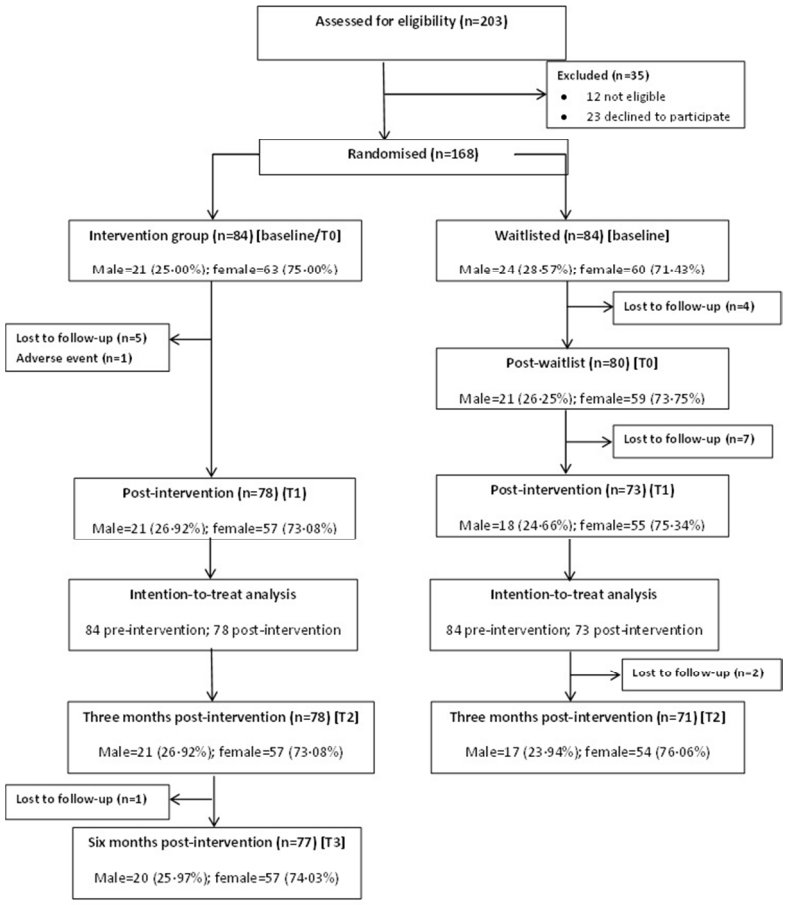

Figure 1: CONSORT* Flowchart of participants
*Consolidated Standards of Reporting Trials (http://www.consort-statement.org/)

197x304mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-24
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-24
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17-24
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	13
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Outcomes of an individual counselling programme in Grozny, Chechnya: a randomized controlled study

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Keywords:	MENTAL HEALTH, Chechnya, functioning, anxiety and depression, individual counselling

Title

Outcomes of an individual counselling programme in Grozny, Chechnya: a randomized controlled study

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ABSTRACT

Objectives

To evaluate the effectiveness of individual counselling on functioning of clients of a mental health intervention in a humanitarian setting.

Design

Randomised controlled trial.

Setting

Mental health programme implemented by Medecins Sans Frontieres in Grozny, Republic of Chechnya.

Participants

168 eligible clients were randomly assigned to the intervention and waitlisted (2 months) arms between November 2014 and February 2015.

Intervention

Individual counselling sessions.

Main outcome measures

Change in functioning was measured using the Short Form 6 (SF6) and gender-specific locally adapted Chechen functioning instruments in the intervention group at the end of counselling and the waitlisted group after their waitlisted period. Unadjusted differences in gain scores (DGS) between intervention and waitlisted groups were calculated with effect size (Cohen's d) for both tools. Linear regression compared the mean DGS in both groups.

Results

The intervention group (n=78) improved compared with controls (n=80) on the SF6 measures with moderate to large effect sizes: general health (DGS 12.14, d=0.52), body pain (DGS 10.26, d=0.35), social support (DGS 16.07, d=0.69), and emotional functioning (DGS 16.87, d=0.91). Similar improvement was seen using the Chechen tool score (female DGS -0.33, d=0.55; male DGS -0.40, d=0.99). Adjusted analysis showed significant improvement ($p<0.05$) in the intervention group for all SF6 measures and for the Chechen tool score in women but not men (p=0.07).

Conclusions

Individual counselling significantly improved participants' ability to function in the intervention group compared with the waitlisted group. Further research is needed to determine whether similar positive results can be shown in other settings and further exploring the impact in male clients population.

Trial Registration

Clinical Trials NTR4689

Keywords

Mental health, Chechnya, functioning, anxiety, depression, individual counselling

Strengths and limitations of this study

- Randomised controlled trial conducted in a humanitarian setting in a scientifically rigorous way;
- Very low rate of loss to follow up in the intervention and control group throughout the study period;
- Intervention impact evaluated using different psychological measurement instruments;
- Participant recruitment occurred at hospitals thus the study population might not be fully representative of the general population in Grozny;
- Blinding of study counsellors to the intervention and control group could not be ensured in all cases;

INTRODUCTION

Mental health (MH) needs of people affected by emergencies are undisputed. Recognition of the need for scale-up of MH programming in lower income countries and humanitarian contexts was solidified by the World Health Organization (WHO) mhGAP 2010 Intervention Guide, updated in 2015 [1]. WHO recently issued Problem Management Plus (PM+) guidance to support implementation of individual psychological support for adults in communities affected by adversity [2]. The guidelines recommend the implementation of brief mental health interventions during humanitarian emergencies as often these contexts limit the ability to implement longer term counselling strategies. Furthermore, the guidelines recognise that fully trained MH workers in emergency affected areas are often limited and thus mental health interventions often rely on non-specialised mental health staff.

MH interventions involving non-specialised counselling for adults conducted in emergency settings have shown to have a beneficial effect on post-traumatic stress disorder (PTSD) in meta-analysis conducted on seven studies in 2011 [3]. Several randomised controlled trials (RCTs) looking at different mental health interventions in humanitarian settings have since been published [4]. However, the interventions vary in their approach, target groups, duration of intervention, and types of MH staff used. Cognitive behavioural therapy (CBT) and cognitive processing therapy (CPT) have been shown to have positive outcomes on depression, anxiety, and PTSD in RCTs in Iraq and Iraqi Kurdistan in war traumatised adults and survivors of violence, torture, and militant attacks [5–7]. Several other RCTs have addressed other methods of psychosocial support including transdiagnostic approaches, Common Elements Treatment Approach (CETA), behavioural interventions, and psychosocial counselling in individual and group interventions in various countries [8–14].

The main mental health intervention implemented by Médecins Sans Frontières - Operational Centre Amsterdam (MSF-OCA) is the provision of individual counselling [15]. It aims to enhance clients' functionality, reduce symptoms of mental distress, and identify new coping strategies [15]. The intervention does not address severe MH disorders such as severe depression, bipolar disorder, or psychosis. The counselling approach is based on principles derived from brief-trauma-focused therapy and CBT's techniques integrated into the cultural context [16]. A review of 18 MSF-OCA individual-focused non-specialised counselling programmes comprising 15,000 clients showed positive outcomes among those returning for follow-up [15]. However, no evaluation using a control group to determine the impact of this form of individual counselling was conducted before this study.

Grozny, the capital of the Republic of Chechnya has been exposed to different waves of violence and humanitarian strife since 2001. Between 2001 and 2003, MSF provided MH services to internally displaced people (IDP) with trauma-related symptoms resulting from heavy shelling and massive explosions. Since 2008, the situation in Chechnya has improved, but there continued to be ongoing violence and insecurity. Between 2008 and 2017 MSF provided individual counselling and psychosocial services support to the population through three hospitals in Grozny, one hospital in Shatoy district and one hospital in Vedeno district.

The primary objective of our study was to estimate the effectiveness of the individual counselling intervention in Grozny on the daily functioning of clients enrolled using an

individual level stepped wedge RCT. Functioning was chosen as the main outcome of the study as this is the primary goal in the MSF individual counselling approach. Our hypothesis was that the individual counselling would improve individuals' ability to function in daily life.

METHODS

Study location and design

The study was conducted in Grozny, capital of the Republic of Chechnya, and implemented in three Ministry of Health hospitals where MSF's MH programme functions. The design was an RCT using a stepped-wedge design at the individual level [17] . Stepped wedge randomised trial designs involve sequential roll-out of an intervention to participants (individuals or clusters) over a number of time periods [17]. Study participants were randomly assigned to intervention or waitlisted control arms, based on order of arrival for counselling (Figure 1) and thus by the end of the random allocation all individuals enrolled in the study would have received the individual counselling intervention. The intervention group received individual counselling immediately after enrolment. The waitlisted group had their counselling deferred for 2 months. The 2-month waiting period was based on the average length of treatment for clients enrolled in the programme in Grozny before the study, and on a community consultation exercise implemented prior to the study [18]. The intervention group completed measurements at enrolment/pre-intervention (T0), post-intervention (T1), and 3 and 6 months post-intervention (T2 and T3). The control group completed measurements at enrolment (baseline/B), pre-intervention (T0), before the start of counselling), following the end of counselling (T1), and 3 months later (T2) (Figure 1). The waitlisted group was not followed up at 6 months post intervention due to practical considerations around the duration of the trial.

Participants

All clients seeking care at the MSF-OCA MH programme in Grozny between November 2014 and February 2015 were considered for eligibility. Clients were self-referred or referred by staff and volunteers at the three hospitals. Clients included outpatients but could also include those admitted to the hospitals in question. Clients were eligible for inclusion if they were aged 18 years or older, able to provide informed consent, and willing and able to return for follow-up. Clients were not eligible if they had cognitive, visual, or other impairments that would limit their ability to participate, were considered at acute risk of suicide, had a severe MH disorder requiring medications, or had been enrolled in MSF counselling services in the previous 6 months. Inclusion and exclusion criteria were established at presentation by a study interviewer/counsellor using a pre-established checklist.

All eligible clients were asked if they would consent to undergoing screening using the Hopkins Symptom Checklist-25. All those scoring 1.75 or greater on this questionnaire were asked to undergo the informed consent process to participate in the study. This included a detailed explanation of the study, the process of randomisation, the possibility of being waitlisted for 2 months, and the required follow-up periods. They received the same explanation in writing, after which they could ask further questions, and were then invited to sign the informed consent.

Interventions

The counselling approach was based on principles derived from brief-trauma-focused therapy, with an 'individual development oriented' approach [19]. The first task of the counsellor is to

make a personal and meaningful contact with the client [20]. After identifying the main complaint, the counsellor explores any specific precipitating events to gain a clear picture from the client's point of view about the history of the complaint. During subsequent sessions, the counsellor works with the client according to the goals set during the first consultation and an individualised treatment plan. No intervention other than individual counselling was offered. Sessions aimed to finish within 50 minutes, and the number of sessions held were dependent on the needs of the individual, thus there was no formal limit.

The counselling approach was standardised through training modules delivered by trainers from the Netherlands Institute of Psychology. Follow-up supervision and quality control used the MSF-OCA MH guideline [19], clinical supervision by international MH experts based in Grozny and oversight from headquarters-based MH advisors. The training for the counselling approach always included: theory of psychosocial counselling, the five categories of problems that are covered in sessions (lack of practical and social skills, practical problems, inner conflict, overwhelming feelings and trauma related symptoms), general problems that counsellors might encounter with the clients they see, knowledge/attitudes/skills of the counsellor, intervention options, counselling processes and reporting and referral procedures. Clinical supervision was done on-site by the international MH experts and through weekly discussions and case reviews. The MH advisor from headquarters would also undertake annual visits in which all aspects of supervision were also covered. The MH advisor would also have regular telephone/skype contact with the MH expert in Grozny to discuss arising questions, issues and progress.

During the study period, there were eight full time counsellors providing the individual counselling intervention. Most counsellors had an academic background in psychology and had been working for MSF for more than 10 years. Of the eight counsellors, five specialised in pedagogy and psychology, one specialised in clinical psychology, and two had completed medical school. Six of the eight full time counsellors were involved in counselling study participants as they were based at the three hospitals which were the study locations. The remaining two counsellors worked in other locations not included in the study.

Outcomes

The primary outcome was change in functioning, measured using the Short Form 6 (SF6, an adapted version of the SF36) and locally adapted gender-specific Chechen functioning instruments [21,22]. The SF6 selected six questions from the SF-36 to assess self-perceived general health, bodily pain, social functioning, and role emotional functioning. The SF6 has been used successfully in similar work conducted in war-affected adults in Afghanistan [23]. The raw scores from the SF6 are transformed to fit a 0-100 scale, with high scores representing better functioning [21]. We also developed and piloted two daily functioning scales for men and women in Chechnya, using an extensive qualitative study before the start of this study [22]. These gender-specific instruments used four-point Likert scales including a 'not applicable' score for activities considered to be part of daily life for people in Chechnya. The female instrument included 27 items and the male instrument 28. A reduction in score suggests improvement in functioning.

Secondary outcomes included changes in symptoms of anxiety and depression, coping strategies, and perceived social support as measured by the Hopkins Symptoms Checklist-25 (HSCL-25), the Coping Strategy Indicator (CSI), and the Social Provisions Scale (SPS), respectively [24–26]. We also aimed to measure whether any changes were sustained at 3 and 6 months post-intervention. The HSCL-25 evaluates anxiety- and depression-related symptoms and is rated like a Likert scale from 1 to 4 where 1 means that the client does not associate with the symptom and 4 means they associate with it "extremely". Three scores are calculated: an anxiety score , a depression score , and an overall score measuring psychological distress [24]. The scale was validated in the Russian language in Chechen refugees living in Austria [27]. Mean overall symptom scores of more than 1.75 for each subcategory have been found to predict clinical diagnosis of anxiety and affective disorders [28]. We used this cut-off as an indication of symptoms of mental distress in clients eligible for enrolment in the study. The CSI [25] includes three subscales of coping strategies: problem-solving, avoidance, and social-support seeking. A reduction in scores indicates an improvement in coping strategies. The 12-item SPS scale measures perceived social support [26,29], using a five-point Likert scale allowing for an unsure response. Participants rated their level of agreement from 1 (strongly disagree) to 5 (strongly agree) with statements regarding respect from others, offering support to others, common interests, feeling supported by others, and feeling close to others. An increase in score indicated an improved perception of social support.

Finally, the prevalence of PTSD in the study population before the intervention was estimated and the impact of the intervention on prevalence of PTSD was measured using the Harvard Trauma Questionnaire (HTQ-16) [30]. This instrument evaluates the 16 commonly reported symptoms of PTSD on a scale of 1-4, as described in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)[31]. It has been used as a screening tool for PTSD in numerous war-affected populations. This definition of PTSD requires a score of 3 or 4 on at least one of four re-experiencing symptoms, at least three of seven avoidance and numbing symptoms, and at least two of five arousal symptoms [30].

As Chechen is mostly an oral language but the majority of Chechens speak, read and write Russian, we chose to translate the instruments into Russian. All Russian translations were back translated into English to ensure consistency of language. The Russian terminology used in each instrument was carefully double checked in the piloting process of all instruments. Together with the study interviewers, we created verbal Chechen translations for specific Russian phrases or words which were not well understood by individuals that participated in the pilot of the instruments. As such, study interviewers used the same Chechen and Russian vocabulary for all administered instruments.

Data collection

A case reporting form (CRF) was created for each participant for each relevant visit. The visits were defined as baseline (B; at enrolment for both groups), T0 (just before the counselling intervention in both groups)), T1 (after the intervention for both groups), T2 (3 months after the intervention for both groups), and T3 (6 months after the intervention for the intervention group). This CRF included all study instruments and allowed the study interviewer to collect information on important life events that occurred between visits. Study interviewers were trained for 2 weeks to ensure consistency in language and style of administering the instruments.

Routine data on the counselling intervention was collected separately according to the MSF-OCA MH programme specifications, using a unique patient ID number and no other identifying data. Linkage between the participant's number and their patient ID number could only be done by the study coordinator through a password-protected database.

Sample size

A sample size of 46 in both the control and intervention arms was calculated for an estimated effect size (estimated difference in means between intervention and control divided by common standard deviation) of 0.40, 80% power, and an alpha of 0.05. We conservatively assumed a 45% loss to follow-up in our total sample, and thus aimed to include 84 participants in each arm for a total sample size of 168.

Randomisation and masking

Randomisation to the intervention and control groups used a computer-generated sequence for each hospital. This sequence was only accessible to the study coordinator and study assistant in a password-protected file. The statistician generated the random allocation sequences before the study started, using the Proc Plan procedure in SAS version 9.4 (SAS Institute, Cary, NC).

After participants had provided written informed consent and officially been enrolled, the study interviewers called the study coordinator for information on the allocated study arm of that participant. Participants were informed of their allocated study arm, and a follow-up visit for the counselling intervention or for the follow-up visit after the waitlist period was established. At the next visit (T1 for the intervention group and T0 for the waitlisted group); the study interviewer was switched to maintain blinding of the allocation arm. Participants were instructed to not reveal their allocation at this visit. Although the study team did their best to ensure blinding up to T1 for the intervention group and T0 for the waitlisted group, maintaining this at all times was difficult, as normal conversation between interviewers and participants might have elicited this information. After the post-intervention visit, no further blinding was maintained.

Statistical methods

Descriptive analysis on demographic indicators (sex, age, marital status etc.) for both groups involved calculating means (and standard deviations) for continuous variables and proportions for categorical variables. Differences between the groups were determined using the t-test to compare means and chi-squared to test differences between proportions.

For each participant, we calculated individual scores for the SF6, HSCL-25, CSI, and SPS at each visit. For the intervention group, we calculated mean changes in individual gain scores between the baseline/T0 and T1 visits and the mean gain score for this period. For the waitlisted group, we calculated the individual gain scores between enrolment at baseline and T0 after their waitlisted period and the mean gain score for the whole group for the same period. We then compared the difference between the mean gain scores (DmGS) of the groups using mixed regression models accounting for individual change. A multivariable regression model was constructed to estimate the adjusted DmGS between the groups, incorporating the following covariates to adjust for potential confounding: hospital, age, sex, and education level, marital

status, and employment status at enrolment. We also adjusted for the total number of counselling sessions for each participant.

We analysed the data in the intention-to-treat model to test the intervention effects, including all participants enrolled in the study even if they dropped out between the two time points. For participants lost to follow-up, we imputed the last known value from the previous visit. Cohen's *d* effect sizes were calculated for the unadjusted differences in gain scores between the groups. We defined an effect size of <0·15 as negligible, 0·15-0·40 as small, 0·41-0·75 as medium, and >0·75 as large [32]. The difference between the mean adjusted difference in gains scores for the two groups were compared using the F-statistic and corresponding p-values.

To determine whether the change in scores after the intervention was maintained in both groups, we combined all data for mean scores at T1 and T2 (3 months after finishing counselling). This analysis did not use the intention-to-treat model.We also looked at maintenance of the score in the intervention group 6 months after counselling finished (T3). Mixed regression models were used to measure the difference in the mean of the pooled scores between T1 and T2 (both groups combined) and between T2 and T3 (intervention group only).

For the HTQ-16 (PTSD), we calculated prevalence of PTSD in the two groups at all visits by identifying participants meeting DSM-IV criteria. We compared the change in prevalence in the intervention group between baseline/T0 and T1 with the change in prevalence in the waitlisted group between baseline and T0, using logistic regression estimated by generalized estimating equations to account for the repeated measures of PTSD. The model included an interaction term for group and time to account for the change in the PTSD status of participants in each group between the two time points, and adjusted for sex, hospital of recruitment, and age. Measures of association were calculated as odds ratios with 95% confidence intervals and p-values. This analysis was not using the intention-to-treat model.

All analysis was done in STATA version 13.0 (Statacorp, College Station, Texas, USA) and SAS version 9.4 (Cary, NC, USA).

Ethical considerations

In February 2013, a community consultation about this study was conducted in Grozny with six groups of participants including nurses, social workers, pharmacy staff, and patients in the hospital [18]. The outcomes were used to inform the final study design (notably reducing the waitlist period from 3 to 2 months). The study protocol was reviewed and approved by the MSF Ethical Review Board and the Ethical Review Board in Chechnya State University. The study protocol was also reviewed at CDC and determined to meet the criteria for non-engagement of CDC staff in human subjects' research.

Informed consent forms were translated into Russian and verbal Chechen, back-translated into English, and piloted in the area of the study. We explained to clients that participation in the study was voluntary, that they could discontinue from the study at any time without explanation, and that they would receive the same standard of treatment whether or not they agreed to participate. Participants were reimbursed approximately 10 US Dollars to cover transport costs for each study-related follow-up visit.

Patient and public involvement

Prior to the implementation of this RCT, two community based studies were carried out in Grozny in preparation for this study. The first was a community consultation that discussed the stepped-wedge design of the RCT and the acceptability around the waiting list group and the length of the waitlisted period [18]. As mentioned before, the waitlisted period for this RCT was reduced from the proposed three months to two months following this community consultation. The second study involved the design of culturally adapted instruments to measure mental distress in the current RCT [33]. We assumed that the communities involved in these two prior studies were the same as those from which the participants of the RCT arose. Also, at the end of the study, all participants were offered an appointment (and transport costs) to review their own results.

Role of the funding source

MSF funded all costs associated with the implementation of this study. MSF had no role in the study design, data collection, data analysis and interpretation and writing of this article. The corresponding author had full access to all the data in the study and is the final responsible.

RESULTS

Participant recruitment and follow-up

Between 17 November 2014 and 9 February 2015, we assessed 203 patients presenting for care at the MSF MH programme for eligibility. Thirty-five people not eligible (n=12) or declined to participate (n=23). Those that declined to participate in the study cited the following reasons: personal reasons (n=11, 47.8%), unwilling to wait for counselling (n=6, 26.1%), distance too far for counselling (n=3, 13.0%), no permission from family to attend counselling (n=1), lack of time to attend counselling (n=1) and for one individual this information was missing. We randomised 168 participants: 84 to each group.

One participant's MH condition deteriorated immediately following enrolment into the study (intervention group); the participant was referred for psychiatric care before starting the intervention and was no longer followed in the study. We lost another 19 participants to follow-up (11·30%): six (7·14%) in the intervention group (five during the intervention and one between 3 and 6 months post-intervention) and 13 (15·48%) in the waitlisted group (four during the waitlisted period, seven during the intervention, and two between the end of counselling and 3-month follow-up). The total proportion lost to follow-up did not differ between the groups (p=0·082) (Figure 1).

Baseline data

Demographic characteristics of the intervention and waitlisted group participants were similar; most were female, married, and employed, had completed high school, and were not hospitalised at the time of enrolment (Table 1). Out of the 14 hospitalised participants, it should be noted that they were all hospitalised for non-MH related reasons. There was no evidence of differences in characteristics of the two groups (p≥0·26).

Table 1: Baseline characteristics of participants

Characteristic	Sub-category	Waitlisted arm		Intervention arm		T-test or $\chi 2$	p-value
		n	*%*	*n*	*%*		
Sample size		84	50	84	50		
		mean	*SD*	*mean*	*SD*		
Age		41·43	13·53	40·54	14·62	0·41	0·68
		n	*%*	*n*	*%*		
Sex	Male	24	28·57	21	25·00	0·27	0·60
	Female	60	71·43	63	75·00		
Marital status	Married	44	52·38	47	55·95	0·89	0·93
	Single	18	21·43	19	22·62		
	Widowed	8	9·52	8	9·52		
	Divorced	12	14·29	9	10·71		
	Separated	2	2·38	1	1·19		
Employment	Employed	32	38·10	31	36·90	2·23	0·82
	Housewife	8	9·52	12	14·29		
	Student	6	7·14	6	7·14		
	Unemployed	25	29·76	24	28·57		
	Retired	13	15·48	10	11·90		
	Other	0	0	1	1·19		
Education	Primary	2	2·38	0	0	2·22	0·27
	Secondary	58	69·05	53	63·10		
	Higher education	24	28·57	30	35·71		
	None	0	0	1	1·19		
Hospitalised	No	75	89·29	79	94·05	1·25	0·26
	Yes	9	10·71	5	5·95		

For the 78 intervention group participants who completed counselling, information was available for 76 on the number of counselling sessions completed and the duration of those sessions [mean sessions: 3·8 (SD=0·7); duration: 29·7 days (SD=9·7)]. Seventy-one waitlisted participants for whom this information was available (of the 73 who completed counselling) had a higher mean number of counselling sessions [4·1 (SD=0·6); t-value=2·1, p=0·04], and mean duration of counselling [33·6 days (SD=12·0); (t-value=2·2; p=0·03]. The presenting complaint for counselling as assessed by the counsellor was similar between the groups (χ^2=5·5, p=0·6); most sought counselling for anxiety-related (n=54, 36·7%), mood-related (n=34, 23·1%), family-related (n=22, 15·0%), and behaviour-related complaints (n=20, 13·6%). The precipitating event leading to seeking counselling was also similar between groups (χ^2=10·3, p=0·2), with similar proportions seeking care due to psychological violence (n=43, 39·3%), domestic discord or

domestic violence (n=41, 27·9%), or non-violence-related events (n=41, 27·9%). During the intervention, the counselling focus was similar in the two groups (χ^2=1·62, p=0·8). The counselling focus was on practical problems (n=58, 39·5%), overwhelming feelings (n=32, 21·8%), trauma-related symptoms (n=29, 19·7%), inner problems (n=17, 11·6%), and lack of essential practical or social skills (n=11, 7·5%).

Numbers analysed

For the primary outcome and secondary outcomes looking at differences in mean gain scores between the groups from T0 and T1 for the intervention group and baseline and T0 for the waitlisted group, we included 84 participants in both groups with imputed data on scores from the last known follow-up visit. For PTSD analysis we compared the difference in PTSD prevalence in the intervention group between B/T0 (84 participants) and T1 (80 participants) to that in the waitlisted participants between B (84 participants) and T0 (80 participants). For the maintenance of scores after the intervention, we included 78 people in the intervention group and 71 from the waitlisted group.

Functioning

Using the SF6, the counselling intervention had moderate to large effect sizes in the intervention group compared with the waitlisted group (general health DmGS=12·14, effect size=0·52; bodily pain DmGS=10·26, effect size=0·35; social functioning DmGS=16·07, effect size=0·69; and role emotional DmGS=16·87, effect size=0·91) (Table 2). The Chechen functioning instruments showed a DmGS of -0·33 (effect size=0.54) for females and a DmGS of -0·40 (effect size=0·99) for males. In the adjusted analysis, the intervention group also showed improved functioning by SF6 and the Chechen female functioning scale (all p<0·05) (Table 3). For the male score, the adjusted analysis showed less strong evidence of an improvement in functioning in the intervention group compared with the waitlisted group (F=3·52, p=0·0691).

Table 2: Average treatment effects (n=168) for functioning: unadjusted scores

Waitlist group			Intervention group			Net effect		Effect size estimate*	p-value
Follow Up Time	Mean score	(95%CI)	Follow Up Time	Mean score	(95%CI)	DmGS between scores for intervention and waitlist	(95%CI)	*d*	
SF6 General Health (score out of 100, increase=improvement)									
B	26·13	(22·31, 29·95)	B/T0	23·39	(19·57, 27·22)				
T0	31·85	(26·67, 37·02)	T1	41·25	(36·08, 46·42)				
Change B-T0	5·71	(0·72, 10·71)	Change T0-T1	17·86	(12·86, 22·85)	12·14	(5·08, 19·20)	0·52	0·0009
SF6 Body Pain (score out of 100, increase=improvement)									
B	39·9	(35·75, 44·06)	B/T0	42·74	(38·58, 46·89)				
T0	47·05	(41·66, 52·44)	T1	60·14	(54·75, 65·53)				
Change B-T0	7·14	(0·86, 13·43)	Change T0-T1	17·40	(11·12, 23·69)	10·26	(1·37, 19·15)	0·35	0·024
SF6 Social Functioning (score out of 100, increase=improvement)									
B	54·17	(49·97, 58·37)	B/T0	52·38	(48·18, 56·58)				
T0	51·19	(47·06, 55·32)	T1	65·48	(61·35, 69·61)				
Change B-T0	-2·98	(-7·99, 2·04)	Change T0-T1	13·10	(8·08, 18·11)	16·07	(8·98, 23·16)	0·69	<0·0001
SF6 Role Emotional (score out of 100, increase=improvement)									
B	56·15	(52·96, 59·34)	B/T0	51·88	(48·7, 55·07)				
T0	56·35	(52·68, 60·01)	T1	68·95	(65·28, 72·61)				
Change B-T0	0·20	(-3·79, 4·18)	Change T0-T1	17·06	(13·08, 21·08)	16·87	(11·23, 22·50)	0·91	<0·0001
Chechen Female Functioning (score 1-4, reduction=improvement)									
B	1·99	(1·83, 2·14)	B/T0	2·04	(1·89, 2·19)				
T0	1·90	(1·76, 2·04)	T1	1·63	(1·49, 1·77)				
Change B-T0	-0·09	(-0·24, 0·07)	Change T0-T1	-0·41	(-0·57, -0·26)	-0·33	(-0·54, -0·11)	0·54	0·004
Chechen Male Functioning (score 1-4, reduction=improvement)									
B	1·72	(1·53, 1·92)	B/T0	1·71	(1·50, 1·91)				
T0	1·70	(1·54, 1·87)	T1	1·28	(1·10, 1·46)				
Change B-T0	-0·02	(-0·19, 0·15)	Change T0-T1	-0·43	(-0·60, -0·25)	-0·40	(-0·65, -0·16)	0·99	0·0018

*measured using Cohen's d statistic

Table 3: Adjusted treatment effects for functioning (n=168)

	Adjusted DmGS between intervention and waitlist groups	(95%CI)	F value	p-value
SF6 General Health	11·81	(4·90, 18·72)	11·41	0·0009
SF6 Body Pain	10·55	(1·91, 19·19)	5·82	0·017
SF6 Social Functioning	15·7	(8·53, 22·86)	18·71	<0·0001
SF6 Emotional Role	17·05	(11·45, 22·65)	36·19	<0·0001
Chechen Female Functioning	-0·36	(-0·57, -0·14)	10·79	0·0014
Chechen Male Functioning	-0·27	(-0·56, -0·02)	3·52	0·0691

Anxiety and depression

The unadjusted DmGS between the intervention and waitlisted groups using the HSCL-25 was -0·55 for anxiety symptoms, -0·50 for depression symptoms, and -0·52 for overall psychological distress (Table 4). The effect sizes calculated in the unadjusted analysis for all three measurements were large (all d>1·0 and p<0·0001). This positive impact of counselling in the intervention group compared with the waitlisted group was maintained in the adjusted analysis, with p<0·0001 for all three measurements (Table 5).

Table 4: Average treatment effects (n=168) for symptoms, coping, and perceived social support: unadjusted scores

Waitlist group			Intervention group			Net effect		Effect size estimate*	p-value
Follow Up Time	Mean score	(95%CI)	Follow Up Time	Mean score	(95%CI)	DmGS between scores for intervention and waitlist	(95%CI)	*d*	
HSCL-25 Anxiety (score 1-4, reduction=improvement)									
B	2·49	(2·40, 2·58)	B/T0	2·54	(2·45, 2·63)				
T0	2·21	(2·10, 2·33)	T1	1·71	(1·6, 1·83)				
Change B-T0	-0·28	(-0·40, -0·17)	Change T0-T1	-0·83	(-0·94, -0·71)	-0·55	(-0·71, -0·39)	1·03	<0·0001
HSCL-25 Depression (score 1-4, reduction=improvement)									
B	2·43	(2·33, 2·52)	B/T0	2·43	(2·34, 2·52)				
T0	2·23	(2·13, 2·34)	T1	1·74	(1·63, 1·85)				
Change B-T0	-0·.19	(-0·30, -0·09)	Change T0-T1	-0·69	(-0·79, -0·58)	-0·50	(-0·65, -0·35)	1·01	<0·0001
HSCL-25 Total (score 1-4, reduction=improvement)									
B	2·45	(2·37, 2·54)	B/T0	2·48	(2·39, 2·56)				
T0	2·22	(2·12, 2·33)	T1	1·73	(1·63, 1·83)				
Change B-T0	-0·23	(-0·33, -0·13)	Change T0-T1	-0·74	(-0·85, -0·65)	-0·52	(-0·66, -0·37)	1·11	<0·0001
Coping Problem Solving (score 1-3, reduction=improvement)									
B	1·58	(1·50, 1·67)	B/T0	1·54	(1·45, 1·62)				
T0	1·58	(1·50, 1·66)	T1	1·64	(1·56, 1·72)				
Change B-T0	-0·01	(-0·10, 0·09)	Change T0-T1	0·10	(0·01, 0·19)	0·11	(-0·02, 0·24)	0·25	0·103
Coping Social Support (score 1-3, reduction=improvement)									
B	2·12	(2·01, 2·23)	B/T0	2·08	(1·97, 2·19)				
T0	2·12	(2·01, 2·22)	T1	2·06	(1·96, 2·16)				
Change B-T0	0	(-0·12, 0·12)	Change T0-T1	-0·02	(-0·14, 0·10)	-0·01	(-0·18, 0·16)	0·02	0·871
Coping Avoidance (score 1-3, reduction=improvement)									
B	2·13	(2·05, 2·21)	B/T0	2·10	(2·01, 2·18)				
T0	2·11	(2·02, 2·20)	T1	2·38	(2·30, 2·47)				
Change B-T0	-0·02	(-0·07, 0·11)	Change T0-T1	0·29	(-0·20, 0·38)	0·31	(0·18, 0·44)	0·72	<0·0001
Perceived Social support (score out of 60, increase=improvement)									
B	44·33	(43·34, 45·33)	B/T0	44·23	(43·23, 45·22)				
T0	44·96	(44·05, 45·88)	T1	46·75	(45·84, 47·67)				
Change B-T0	0·63	(-0·32, 1·58)	Change T0-T1	2·52	(1·58, 3·47)	1·89	(0·55, 3·23)	0·43	0·006

*measured using Cohen's d statistic

Table 5: Adjusted treatment effects for symptoms and coping, and social support (n=168)

	Adjusted DmGS between intervention and waitlist groups	(95%CI)	F value	p-value
Symptoms				
HSCL 25 Anxiety	-0·56	(-0·72, -0·39)	46·06	<0·.0001
HSCL 25 Depression	-0·51	(-0·65, -0·36)	44·90	<0·0001
HSCL 25 Overall	-0·53	(-0·67, -0·38)	53·71	<0·0001
Coping and social support				
Problem solving	0·12	(0·02, 0·25)	3·05	0·0825
Social support	-0·02	(-0·19, 0·16)	0·03	0·8622
Avoidance	0·30	(0·17, 0·43)	20·16	<0·0001
Perceived social support	2·03	(0·68, 3·37)	8·83	0·0034

Coping and perceived social support

Using the CSI, the unadjusted DmGS related to problem solving and social support were very small with small effect sizes (problem solving DmGS=0·11, d=0·25, p=0·103; social support DmGS=-0·01, d=0·02, p=0·871) (Table 4). In the adjusted analysis, problem solving and social support showed no significant evidence of difference between the groups (p=0·08 and p=0·86, respectively (Table 5). The coping scale for avoidance showed a significant worsening, with a moderate effect size (DmGS=0·31, d=0·72, p<0·0001). In the adjusted analysis, the worsening in avoidance coping skills remained (F=20·16, p<0·001). Perceived social support improved in the intervention group compared with the waitlisted group, with a moderate effect size (DmGS=1·89, d=0·43, p=0·006), and this remained relevant in the adjusted analysis (F=8·83, p=0·0034) (Table 5).

Maintenance of scores after counselling

A continued improvement was observed using the scales for SF6 social functioning, SF6 role emotional, and the Chechen female and male functioning scales at T2 compared with T1 (all p<0·05). The effect was maintained at T3 with no further improvement for SF6 social functioning (p=0·60), SF6 role emotional (p=0·25), or the Chechen male functioning scale (p=0·17). Further significant improvement was observed at T3 compared with T2 in female participants from the intervention group (p=0·02). The effect of counselling was sustained (but not further improved) at T2 compared with T1 when measured on the SF6 general health (p=0·38) and body pain (p=0·10) scales. Similar trends were observed for these two scales at T3 compared with T2 (p=0·94 and p=0·95, respectively) (Table 6).

Table 6: Sustained improvement for functioning (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and waitlist group combined]*			**3 months to 6 months follow-up (T2 to T3), N=77** *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
SF6 General Health (score out of 100, increase=improvement)								
	T1	41·78	(37·77, 45·78)		T2	41·88	(36·30, 47·47)	
	T2	39·97	(36·05, 43·88)		T3	42·08	(36·67, 47·48)	
	Pre-post change	-1·81	(-5·88, 2·26)	0·38	Pre-post change	0·19	(-4·71, 5·10)	0·94
SF6 Body Pain (score out of 100, increase=improvement)								
	T1	60·72	(56·69, 64·76)		T2	66·96	(61·04, 72·88	
	T2	64·40	(60·43, 68·37)		T3	67·14	(61·26, 73·03)	
	Pre-post change	3·68	(-0·70, 8·06)	0·10	Pre-post change	0·18	(-5·32, 5·68)	0·95
SF6 Social Functioning (score out of 100, increase=improvement)								
	T1	65·27	(61·89, 68·65)		T2	71·10	(65·.89, 76·32)	
	T2	70·64	(67·25, 74·02)		T3	72·73	(67·93, 77·53)	
	Pre-post change	5·37	(1.47, 9.26)	0·007	Pre-post change	1·62	(-4·44, 7·68)	0·60
SF6 Role Emotional (score out of 100, increase=improvement)								
	T1	69·30	(66·55, 72·04)		T2	75·00	(70·88, 79·12)	
	T2	73·88	(70·92, 76·84)		T3	77·49	(73·60, 81·38)	
	Pre-post change	4·59	(1·36, 7·81)	0·006	Pre-post change	2·49	(-1·76, 6·74)	0·25
Chechen Female Functioning (N=111 and N=57) (score 1-4, reduction=improvement)								
	T1	1·53	(1·44, 1·63)		T2	1·42	(1·31, 1·53)	
	T2	1·42	(1·33, 1·51)		T3	1·28	(1·21, 1·36)	
	Pre-post change	-0·12	(-0·22, -0·01)	0·03	Pre-post change	-0·14	(-0·25, -0·02)	0·02
Chechen Male Functioning (n=38 and n=20) (score 1-4, reduction=improvement)								
	T1	1·38	(1·26, 1·50)		T2	1·19	(1·07, 1·32)	
	T2	1·24	(1·15, 1·33)		T3	1·12	(1·06, 1·19)	
	Pre-post change	-0·14	(-0·25, -0·03)	0·018	Pre-post change	-0·07	(-0·18, 0·03)	0·17

Symptoms of anxiety, depression, and psychological distress, measured by the HSCL-25, improved further at T2 compared with T1 (p=0·03, p=0·003, and p=0·005, respectively). This improvement continued in the intervention group at T3 compared with T2 (p=0·0009, p=0·001, and p=0·0005, respectively). Results for all aspects of the CSI showed either no change or a slight deterioration at T2 and T3. For perceived social support, a small improvement was observed at T2 (p=0·002) compared with T1, which was sustained but not further improved at T3 in the intervention group (Table 7).

Table 7: Change in scores for symptoms, coping, and social support at 3 and 6 months follow-up (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and waitlist group combined]*				3 months to 6 months follow-up (T2 to T3), N=77 *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
HSCL-25 Anxiety (score 1-4, reduction=improvement)								
	T1	1·63	(1·56, 1·71)		T2	1·58	(1·47, 1·68)	
	T2	1·54	(1·47, 1·61)		T3	1·39	(1·30, 1·48)	
	Pre-post change	-0·09	(-0·18, -0·01)	0·03	Pre-post change	-0·19	(-0·29, -0·08)	0·0009
HSCL-25 Depression (score 1-4, reduction=improvement)								
	T1	1·69	(1·62, 1·76)		T2	1·60	(1·50, 1·69)	
	T2	1·57	(1·51, 1·64)		T3	1·44	(1·36, 1·51)	
	Pre-post change	-0·12	(-0·20, -0·04)	0·003	Pre-post change	-0·16	(-0·26, -0·06)	0·001
HSCL-25 Total (score 1-4, reduction=improvement)								
	T1	1·67	(1·60, 1·74)		T2	1·59	(1·50, 1·68)	
	T2	1·56	(1·50, 1·62)		T3	1·42	(1·34, 1·49)	
	Pre-post change	-0·11	(-0·19, -0·03)	0·005	Pre-post change	-0·17	(-0·27, -0·08)	0·0005
Coping Problem Solving (score 1-3, reduction=improvement)								
	T1	1·64	(1·58, 1·69)		T2	1·76	(1·65, 1·86)	
	T2	1·76	(1·69, 1·82)		T3	1·82	(1·71, 1·92)	
	Pre-post change	0·12	(0·05, 0·19)	<0·0001	Pre-post change	0·06	(-0·05, 0·16)	0·27
Coping Social Support (score 1-3, reduction=improvement)								
	T1	2·08	(2·01, 2·15)		T2	2·12	(2·00, 2·24)	
	T2	2·13	(2·05, 2·20)		T3	2·21	(2·10, 2·33)	
	Pre-post change	0·04	(-0·05, 1·14)	0·33	Pre-post change	0·09	(-0·04, 0·22)	0·18
Coping Avoidance (score 1-3, reduction=improvement)								
	T1	2·39	(2·33, 2·44)		T2	2·46	(2·38, 2·53)	
	T2	2·46	(2·41, 2·51)		T3	2·49	(2·41, 2·57)	
	Pre-post change	0·07	(0·01, 0·13)	0·02	Pre-post change	0·03	(-0·04, 0·11)	0·38
Perceived Social support (score out of 60, increase=improvement)								
	T1	46·74	(46·12, 47·36)		T2	47·88	(47·17, 48·60)	
	T2	47·75	(47·24, 48·26)		T3	48 ·12	(47·40, 48·84)	
	Pre-post change	1·01	(0·37, 1·66)	0·002	Pre-post change	0·23	(-0·60, 1·07)	0·58

PTSD

At baseline, 32 (N=84, 38·10%) participants in the intervention group and 39 (N=84, 46·43%) in the waitlisted group were classified as meeting DSM-IV criteria for PTSD using HTQ-16 ($\chi 2$=1·20, p=0·274). At T1, the prevalence in the intervention group had reduced (n=5/78, 6·41%). The prevalence of PTSD in the waitlisted group was 38.75% after the waitlisted period at T0 and had also reduced at T1 (n=8/73, 10·96%). The adjusted reduction in PTSD prevalence in the intervention group between baseline/T0 and T1 was significantly lower than that in the waitlisted group between baseline and T0 (odds ratio 0·11; 95% CI: 0·04-0·28, p<0·001) (Table 8).

Table 8: Unadjusted and adjusted odds ratios of comparison between change in PTSD prevalence of intervention group pre-intervention and post-intervention compared with waitlisted group

PTSD		Unadjusted			Adjusted		
		OR	(95%CI)	p-value	OR	(95%CI)	p-value
Waitlist group							
	B (n=84)	1·00			1·00		
	T0 (n=80)	0·73	(0·44, 1·20)	0·218	0·76	(0·46, 1·26)	0·280
Intervention group							
	B/T0 (n=84)	1·00			1·00		
	T1 (n=78)	0·11	(0·04, 0·29)	<0·001	0·11	(0·04, 0·28)	<0·001
Intervention group vs. waitlist group							
T1 vs. B/T0		0·15	(0·05, 0·45)	0·001	0·14	(0·05, 0·43)	<0·001

DISCUSSION

We have shown that individual counselling in conflict affected adults in Chechnya improved their daily functioning. Both study instruments used to test functioning, including a scale that was specifically designed for use in Chechen adults, showed an improvement in the intervention group compared with the waitlisted group. The unadjusted and adjusted analyses for the functioning instruments showed very similar results, suggesting that the improvement in the intervention group compared with the waitlisted group was not importantly influenced by age, sex, marital and employment status, number of counselling sessions, and hospital of recruitment. The absence of statistical evidence for a true difference in the Chechen male functioning scale is likely due to the study being underpowered to detect differences among sub-groups.

The results are especially encouraging as different instruments to measure functioning recorded similar positive outcomes, strongly suggesting that the counselling is effective in improving this aspect of clients' lives. Such positive outcomes have also been shown in a retrospective review of programmatic data from 18 MSF projects with MH programmes in conflict and post-conflict settings [15]. As this study was a stepped-wedge RCT using validated outcome measures, we provide further evidence that the brief counselling intervention used among people affected by conflict can have a positive impact on their ability to function.

Different counselling strategies in other studies have also shown positive effects on functioning, PTSD, depression, and anxiety. Moderate to high improvements in the intervention group compared with the control group on these outcomes were measured using CETA in Burmese refugees in Thailand and in Iraqi Kurdistan [12,14]. In contrast, mixed results from group problem-solving counselling in terms of functioning were observed in war-affected adults in Aceh, Indonesia [34]. A recent RCT in adults with psychological distress in a conflict area in Pakistan identified a large improvement in functioning and symptoms of PTSD, depression, and anxiety following five weekly sessions of individual counselling delivered by trained lay workers using the WHO PM+ approach [10]. This study mirrors the intervention described in our study in that it limited the number of counselling sessions to five and did not rely on clinically trained MH professionals. It slightly differs from our approach in that the PM+ is a manualised intervention, whereas the MSF one is a semi-structured approach allowing for individual adaptation by the counsellor.

The coping scale did not show evidence for improvement with the intervention, and avoidance appeared to worsen. This suggests that the improvement functioning and symptoms was not achieved through improvement in the three coping skills measured by the CSI. Alternately, the CSI may not be well adapted to measure coping strategies in this population. The study by our colleagues in Aceh [34] also observed a small decline in the use of coping strategies among women in the intervention group.

The SPS scale showed a significant increase in perceived social support in the intervention group compared with the waitlisted group, which was sustained after completion of counselling. The MSF-OCA MH programme in Grozny includes encouragement to establish positive coping mechanisms (including social support). Social support has been shown to have a positive effect on mental and physical health [35] and is associated with lower posttraumatic stress scores [36]. It is also notable that social functioning improved with the intervention.

We were able to determine that there was longer-term efficacy of the individual counselling on functioning and symptoms of depression and anxiety in both the intervention and waitlisted groups. Scores on the instruments that tested these items either maintained the improvement or continued to improve at 3 and 6 months after completion of counselling. Studies on Rwandan and Somali refugees in Uganda showed that NET counselling sustained the reduction in PTSD in all participants at 6 and 12 months' follow-up, although the dropout rates were high [37]. Very few studies have measured the maintenance of these scores and thus the current study provides much needed evidence in this regard.

The expression of mental health difficulties as physical symptoms, called somatization, is common in many cultures [38]. In our study, the functioning scales addressing general health and body pain were not sustained or further improved after completion of counselling. Whether this is due to continuing physical complaints in the study population or because of ongoing psychosomatic complaints, we cannot say. However, we think the latter is more unlikely as the counselling intervention is also addressing medically unexplained physical symptoms, but did not change or address any physical illness. . Neither coping mechanisms nor social support showed any further changes following the end of counselling.

The study has some limitations. Although few of the participants were hospitalised at enrolment, the MSF MH programme is located in hospital settings, which might have biased care-seeking behaviour. The study population therefore might not be entirely representative of those seeking help for MH concerns in Grozny. We worked hard to ensure that study interviewers remained blinded to the group allocation up to T1 of the intervention group, but this could not be ensured in all cases. We do not think that this potential bias would have changed our findings substantially, as all instruments had a fixed script for questions to be asked by interviewers and answers provided by participants, not allowing much space for interviewers to influence participants' answers. Grozny represents a specific and long-term unstable situation, so we cannot be certain that similar outcomes would be found in other acute emergencies. The counsellors delivering the intervention, while non-specialised, all had academic training and many years of experience delivering the intervention, which is not the case in many humanitarian settings. However, we have shown previously that although lay counsellors used more sessions than academically trained counsellors, the outcomes in clients were similar [15]. Also, we conducted a sensitivity analysis which included the counsellor as a covariate in the multivariate regression models and the results did not change our interpretation of the study findings. This suggests that the positive outcomes measured were not linked to individual counsellors. Finally, we employed widely used instruments to measure mental health distress and functioning in this study and thus have equated numerical improvements in the scores of study participants with clinical improvements. This is supported by the knowledge that individual counselling in Grozny was only finalised when the client and counsellor agreed that the main complaint for attending counselling had been resolved (thus improved).

Despite its limitations, this study represents a scientifically rigorous evaluation of an individual counselling intervention in a humanitarian setting, in that it includes a randomised waitlisted group to avoid over-estimating improvements due to the effect of time alone. We were also able to show that the improvements due to the intervention were not only maintained but continued to

improve at 3 and 6 months after completion of the intervention. This approach both improved functioning in daily life and reduced symptoms of mental distress including anxiety and depression, while decreasing the prevalence of PTSD in adults in Chechnya with similar effect sizes to other interventions. In parallel with the PM+ guidelines, we have shown that low-intensity MH interventions in humanitarian settings play an important role in improving functioning and reducing psychosocial distress. Further research is needed to determine whether similar results can be shown in acute conflict settings, and where less experienced/trained counsellors deliver the intervention. Additionally, further exploration on the impact of individual counselling in men specifically would be important as they are frequently underrepresented in studies in this area.

REGISTRATION

The study was registered with the Netherlands Trial Register (http://www.trialregister.nl/trialreg/index.asp) which is recognised by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICJME) under registration number NTR4689 (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4689). The protocol is available from http://fieldresearch.msf.org/msf/bitstream/10144/618741/1/1326_MSFH+MH+Chechnya+outcomes+evaluation+protocol_amendment+November+2016_clean_final.pdf.

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DISCLAIMER

The findings and conclusions in this report are those of the authors and do not represent the official position of the Centers for Disease Control and Prevention.

AUTHOR CONTRIBUTIONS

BLC, LS, CB, KI, PB and GP designed the study. CF, ZT, GP and AL acquired the data. CF, CB and AL analyzed the data. All authors contributed to the interpretation of data. AL, BLC and GP wrote the manuscript and all authors critically reviewed the manuscript.

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COMPETING INTEREST

The authors declare to have no competing interests.

DATA SHARING

MSF has a a managed access system for data sharing. Data are available on request in accordance with MSF's data sharing policy. Requests for access to data should be made to data.sharing@msf.org.

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Figure 1: CONSORT* Flowchart of participants
*Consolidated Standards of Reporting Trials (http://www.consort-statement.org/)

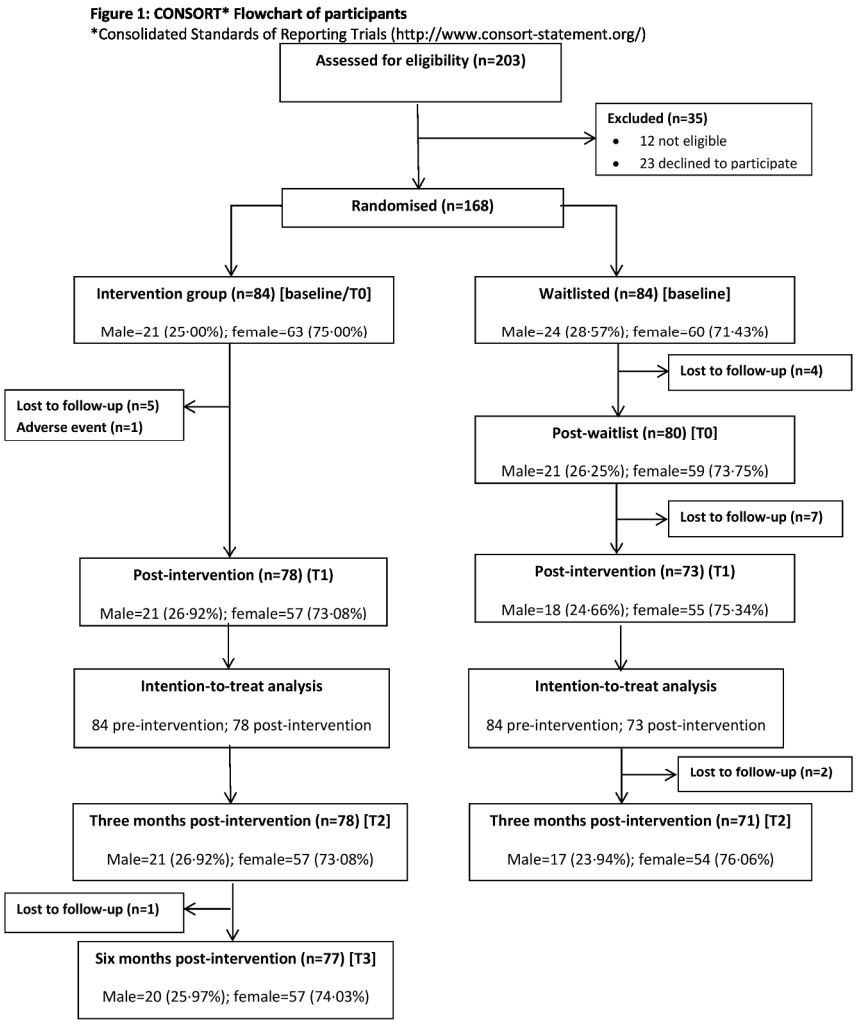

Figure 1: CONSORT* Flowchart of participants

215x279mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-24
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-24
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17-24
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	13
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Outcomes of an individual counselling programme in Grozny, Chechnya: a randomized controlled study

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Keywords:	MENTAL HEALTH, Chechnya, functioning, anxiety and depression, individual counselling

Title

Outcomes of an individual counselling programme in Grozny, Chechnya: a randomized controlled study

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ABSTRACT

Objectives

To evaluate the effectiveness of individual counselling on functioning of clients participating in a mental health intervention in a humanitarian setting.

Design

Randomised controlled trial.

Setting

Mental health programme implemented by Médecins Sans Frontières in Grozny, Republic of Chechnya.

Participants

168 eligible clients were randomly assigned to the intervention and waitlisted (2 months) arms between November 2014 and February 2015.

Intervention

Individual counselling sessions.

Main outcome measures

Change in functioning was measured using the Short Form 6 (SF6) and gender-specific locally adapted Chechen functioning instruments in the intervention group at the end of counselling and the waitlisted group after their waitlisted period. Unadjusted differences in gain scores (DGS) between intervention and waitlisted groups were calculated with effect size (Cohen's d) for both tools. Linear regression compared the mean DGS in both groups.

Results

The intervention group (n=78) improved compared with waitlisted controls (n=80) on the SF6 measures with moderate to large effect sizes: general health (DGS 12.14, d=0.52), body pain (DGS 10.26, d=0.35), social support (DGS 16.07, d=0.69), and emotional functioning (DGS 16.87, d=0.91). Similar improvement was seen using the Chechen functioning instrument score (female DGS -0.33, d=0.55; male DGS -0.40, d=0.99). Adjusted analysis showed significant improvement ($p<0.05$) in the intervention group for all SF6 measures and for the Chechen functioning instrument score in women but not men ($p=0.07$).

Conclusions

Individual counselling significantly improved participants' ability to function in the intervention group compared with the waitlisted group. Further research is needed to determine whether similar positive results can be shown in other settings and further exploring the impact in male clients' population.

Trial Registration

Clinical Trials NTR4689

Keywords

Mental health, Chechnya, functioning, anxiety, depression, individual counselling

Strengths and limitations of this study

- Randomised controlled trial conducted in a humanitarian setting in a scientifically rigorous way;
- Very low rate of loss to follow up in the intervention and waitlisted group throughout the study period;
- Intervention impact evaluated using different psychological measurement instruments;
- Participant recruitment occurred at hospitals thus the study population might not be fully representative of the general population in Grozny;
- Blinding of study counsellors to the intervention and waitlisted group could not be ensured in all cases;

INTRODUCTION

Mental health (MH) needs of people affected by emergencies are undisputed. Recognition of the need for scale-up of MH programming in lower income countries and humanitarian contexts was solidified by the World Health Organization (WHO) mhGAP 2010 Intervention Guide, updated in 2016 [1]. WHO recently issued Problem Management Plus (PM+) guidance to support implementation of individual psychological support for adults in communities affected by adversity [2]. The guidelines recommend the implementation of brief mental health interventions during humanitarian emergencies as often these contexts limit the ability to implement longer term counselling strategies. Furthermore, the guidelines recognise that fully trained MH workers in emergency affected areas are often limited and thus mental health interventions often rely on non-specialised mental health staff.

MH interventions involving non-specialised counselling for adults conducted in emergency settings have shown to have a beneficial effect on post-traumatic stress disorder (PTSD) in meta-analysis conducted on seven studies in 2011 [3]. Several randomised controlled trials (RCTs) looking at different mental health interventions in humanitarian settings have since been published [4]. However, the interventions vary in their approach, target groups, duration of intervention, and types of MH staff used. Cognitive behavioural therapy (CBT) and cognitive processing therapy (CPT) have been shown to have positive outcomes on depression, anxiety, and PTSD in RCTs in Iraq and Iraqi Kurdistan in war traumatised adults and survivors of violence, torture, and militant attacks [5–7]. Several other RCTs have addressed other methods of psychosocial support including transdiagnostic approaches, Common Elements Treatment Approach (CETA), behavioural interventions, and psychosocial counselling in individual and group interventions in various countries [8–14].

The main mental health intervention implemented by Médecins Sans Frontières - Operational Centre Amsterdam (MSF-OCA) is the provision of individual counselling [15]. It aims to enhance clients' functionality, reduce symptoms of mental distress, and identify new coping strategies [15]. The intervention does not address severe MH disorders such as severe depression, bipolar disorder, or psychosis. The counselling approach is based on principles derived from brief-trauma-focused therapy and CBT's techniques integrated into the cultural context [16]. A review of 18 MSF-OCA individual-focused non-specialised counselling programmes comprising 15,000 clients showed positive outcomes among those returning for follow-up [15]. However, no evaluation using a control group to determine the impact of this form of individual counselling was conducted before this study.

Grozny, the capital of the Republic of Chechnya has been exposed to different waves of violence and humanitarian strife since 2001. Between 2001 and 2003, MSF provided MH services to internally displaced people (IDP) with trauma-related symptoms resulting from heavy shelling and massive explosions. Since 2008, the situation in Chechnya has improved, but there continued to be ongoing violence and insecurity. Between 2008 and 2017 MSF provided individual counselling and psychosocial services support to the population through three hospitals in Grozny, one hospital in Shatoy district and one hospital in Vedeno district.

The primary objective of our study was to estimate the effectiveness of the individual counselling intervention in Grozny on the daily functioning of clients enrolled using an

individual level stepped wedge RCT. Functioning was chosen as the main outcome of the study as this is the primary goal in the MSF individual counselling approach. Our hypothesis was that the individual counselling would lead to improved functioning in daily life for intervention clients compared to waitlisted clients.

METHODS

Study location and design

The study was conducted in Grozny, capital of the Republic of Chechnya, and implemented in three Ministry of Health hospitals where MSF's MH programme functions. The design was an RCT using a stepped-wedge design at the individual level [17] . Stepped wedge randomised trial designs involve sequential roll-out of an intervention to participants (individuals or clusters) over a number of time periods [17]. Study participants were randomly assigned to intervention or waitlisted control arms, based on order of arrival for counselling (Figure 1) and thus by the end of the random allocation all individuals enrolled in the study would have received the individual counselling intervention. The intervention group received individual counselling immediately after enrolment. The waitlisted group had their counselling deferred for 2 months. The 2-month waiting period was based on the average length of treatment for clients enrolled in the programme in Grozny before the study, and on a community consultation exercise implemented prior to the study [18]. The intervention group completed measurements at enrolment/pre-intervention (B/T0), post-intervention (T1), and 3 and 6 months post-intervention (T2 and T3). The waitlisted group completed measurements at enrolment (baseline/B), pre-intervention immediately before the start of counselling (T0), following the end of counselling (T1), and 3 months later (T2) (Figure 1). The waitlisted group was not followed up at 6 months post intervention due to practical considerations around the duration of the trial.

Participants

All clients seeking care at the MSF-OCA MH programme in Grozny between November 2014 and February 2015 were considered for eligibility. Clients were self-referred or referred by staff and volunteers at the three hospitals. Clients included outpatients but could also include those admitted to the hospitals in question. Clients were eligible for inclusion if they were aged 18 years or older, able to provide informed consent, and willing and able to return for follow-up. Clients were not eligible if they had cognitive, visual, or other impairments that would limit their ability to participate, were considered at acute risk of suicide, had a severe MH disorder requiring medications, or had been enrolled in MSF counselling services in the previous 6 months. Inclusion and exclusion criteria were established at presentation by a study interviewer/counsellor using a pre-established checklist.

All eligible clients were asked if they would consent to undergoing screening using the Hopkins Symptom Checklist-25 (HSCL-25). All those scoring 1.75 or greater on this questionnaire were asked to undergo the informed consent process to participate in the study. This included a detailed explanation of the study, the process of randomisation, the possibility of being waitlisted for 2 months, and the required follow-up periods. They received the same explanation in writing, after which they could ask further questions, and were then invited to sign the informed consent.

Interventions

The counselling approach was based on principles derived from brief-trauma-focused therapy, with an 'individual development oriented' approach [19]. The first task of the counsellor is to make a personal and meaningful contact with the client [20]. After identifying the main complaint, the counsellor explores any specific precipitating events to gain a clear picture from the client's point of view about the history of the complaint. During subsequent sessions, the counsellor works with the client according to the goals set during the first consultation and an individualised treatment plan. No intervention other than individual counselling was offered. Sessions aimed to finish within 50 minutes, and the number of sessions held was dependent on the needs of the individual, thus there was no formal limit.

The counselling approach was standardised through training modules delivered by trainers from the Netherlands Institute of Psychology. Follow-up supervision and quality control used the MSF-OCA MH guideline [19], clinical supervision by international MH experts based in Grozny and oversight from headquarters-based MH advisors. The training for the counselling approach included: theory of psychosocial counselling, the five categories of problems that are covered in sessions (lack of practical and social skills, practical problems, inner conflict, overwhelming feelings and trauma related symptoms), general problems that counsellors might encounter with the clients they see, knowledge/attitudes/skills of the counsellor, intervention options, counselling processes and reporting and referral procedures. Clinical supervision was done on-site by the international MH experts and through weekly discussions and case reviews. The MH advisor from headquarters would also undertake annual visits in which all aspects of supervision were reviewed. The MH advisor would also have regular telephone/skype contact with the MH expert in Grozny to discuss arising questions, issues and progress.

During the study period, there were eight full time counsellors providing the individual counselling intervention. Most counsellors had an academic background in psychology and had been working for MSF for more than 10 years. Of the eight counsellors, five specialised in pedagogy and psychology, one specialised in clinical psychology, and two had completed medical school. Six of the eight full time counsellors were involved in counselling study participants as they were based at the three hospitals which were the study locations. The remaining two counsellors worked in other locations not included in the study.

Outcomes

The primary outcome was change in functioning, measured using the Short Form 6 (SF6, an adapted version of the SF36) and locally adapted gender-specific Chechen functioning instruments [21,22]. The SF6 selected six questions from the SF-36 to assess self-perceived general health, bodily pain, social functioning, and role emotional functioning. The SF6 has been used successfully in similar work conducted in war-affected adults in Afghanistan [23]. The raw scores of each of the four individual items from the SF6 are transformed to fit a 0-100 scale, with high scores representing better functioning [21]. We also developed and piloted two daily functioning scales for men and women in Chechnya, using an extensive qualitative study before the start of this study [22]. These gender-specific instruments a scale from 1 to 4,including a 'not applicable' score, to rate the participant's abilities to participate in activities considered to be part of daily life for people in Chechnya. The female instrument included 27 items and the male instrument 28 items. A reduction in score suggested improvement in functioning.

Secondary outcomes included changes in symptoms of anxiety and depression, coping strategies, and perceived social support as measured by the Hopkins Symptoms Checklist-25 (HSCL-25), the Coping Strategy Indicator (CSI), and the Social Provisions Scale (SPS), respectively [24–26]. We also aimed to measure whether any changes were sustained at 3 and 6 months post-intervention. The HSCL-25 evaluates anxiety- and depression-related symptoms and is rated on a scale from 1 to 4 where 1 means that the client does not associate with the symptom and 4 means they associate with it "extremely". Three scores are calculated: an anxiety score , a depression score , and an overall score measuring psychological distress [24]. The scale was validated in the Russian language in Chechen refugees living in Austria [27]. Mean overall symptom scores of more than 1.75 for each subcategory have been found to predict clinical diagnosis of anxiety and affective disorders [28]. We used this cut-off as an indication of symptoms of mental distress in clients eligible for enrolment in the study. The CSI [25] includes three subscales of coping strategies: problem-solving, avoidance, and social-support seeking. A reduction in scores indicates an improvement in coping strategies. The 12-item SPS scale measures perceived social support [26,29], using a five-point Likert scale allowing for an unsure response. Participants rated their level of agreement from 1 (strongly disagree) to 5 (strongly agree) with statements regarding respect from others, offering support to others, common interests, feeling supported by others, and feeling close to others. An increase in score indicated an improved perception of social support.

Finally, the proportion of study participants with PTSD before and after the intervention was measured using the Harvard Trauma Questionnaire (HTQ-16) [30]. This instrument evaluates the 16 commonly reported symptoms of PTSD on a scale of 1-4, as described in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)[31]. It has been used as a screening tool for PTSD in numerous war-affected populations and has been validated in Chechen refugees in Austria [32]. This definition of PTSD requires a score of 3 or 4 on at least one of four re-experiencing symptoms, at least three of seven avoidance and numbing symptoms, and at least two of five arousal symptoms [30]. Thus, any person that met the aforementioned criteria, was considered to be screened positive PTSD. The prevalence of PTSD in the intervention and waitlisted group was calculated by dividing the number of PTSD-screened positive participants by the total number of participants in their study group.

As Chechen is mostly an oral language but the majority of Chechens speak, read and write Russian, we chose to translate the instruments into Russian. All Russian translations were back translated into English to ensure consistency of language. The Russian terminology used in each instrument was carefully double checked in the piloting process of all instruments. Together with the study interviewers, we created verbal Chechen translations for specific Russian phrases or words which were not well understood by individuals that participated in the pilot of the instruments. As such, study interviewers used the closest term that conveyed the same meaning in Chechen and Russian language for all administered instruments.

Data collection

A case reporting form (CRF) was created for each participant for each relevant visit. The visits were defined as baseline (B; at enrolment for both groups), T0 (just before the counselling intervention in both groups), T1 (after the intervention for both groups), T2 (3 months after the intervention for both groups), and T3 (6 months after the intervention for the intervention group).

This CRF included all study instruments and allowed the study interviewer to collect information on important life events that occurred between visits. Study interviewers were trained for 2 weeks to ensure consistency in language and style of administering the instruments.

Routine data on the counselling intervention was collected separately according to the MSF-OCA MH programme specifications, using a unique patient ID number and no other identifying data. Linkage between the participant's number and their patient ID number could only be done by the study coordinator through a password-protected database.

Sample size

A sample size of 46 in both the waitlisted and intervention arms was calculated for an estimated effect size (estimated difference in means between intervention and waitlisted divided by common standard deviation) of 0.40, 80% power, and an alpha of 0.05. We conservatively assumed a 45% loss to follow-up in our total sample, and thus aimed to include 84 participants in each arm for a total sample size of 168.

Randomisation and masking

Randomisation to the intervention and waitlisted groups used a computer-generated sequence for each hospital. This sequence was only accessible to the study coordinator and study assistant in a password-protected file. The statistician generated the random allocation sequences before the study started, using the Proc Plan procedure in SAS version 9.4 (SAS Institute, Cary, NC).

After participants had provided written informed consent and officially been enrolled, the study interviewers called the study coordinator for information on the allocated study arm of that participant. Participants were informed of their allocated study arm, and a follow-up visit for the counselling intervention or for the follow-up visit after the waitlist period was established. At the next visit (T1 for the intervention group and T0 for the waitlisted group); the study interviewer was switched to maintain blinding of the allocation arm. Participants were instructed to not reveal their allocation at this visit. Although the study team did their best to ensure blinding up to T1 for the intervention group and T0 for the waitlisted group, maintaining this at all times was difficult, as normal conversation between interviewers and participants might have elicited this information. After the post-intervention visit, no further blinding was maintained.

Statistical methods

Descriptive analysis on demographic indicators (sex, age, marital status etc.) for both groups involved calculating means (and standard deviations) for continuous variables and proportions for categorical variables. Differences between the groups were determined using the t-test to compare means and chi-squared to test differences between proportions.

For each participant, we calculated individual scores for the SF6, HSCL-25, CSI, and SPS at each visit. For the intervention group, we calculated mean changes in individual gain scores between the B/T0 and T1 visits and the mean gain score for this period. For the waitlisted group, we calculated the individual gain scores between enrolment at baseline and T0 after their waitlisted period and the mean gain score for the whole group for the same period. We then compared the difference between the mean gain scores (DmGS) of the groups using mixed regression models accounting for individual change. A multivariable regression model was

constructed to estimate the adjusted DmGS between the groups, incorporating the following covariates to adjust for potential confounding: hospital, age, sex, and education level, marital status, and employment status at enrolment. We also adjusted for the total number of counselling sessions for each participant.

We analysed the data in the intention-to-treat model to test the intervention effects, including all participants enrolled in the study even if they dropped out between the two time points. For participants lost to follow-up, we imputed the last known value from the previous visit. Cohen's *d* effect sizes were calculated for the unadjusted differences in gain scores between the groups. We defined an effect size of <0·15 as negligible, 0·15-0·40 as small, 0·41-0·75 as medium, and >0·75 as large [33]. The difference between the mean adjusted difference in gains scores for the two groups were compared using the F-statistic and corresponding p-values (equations of the analysis are available in the Supplementary Information).

To determine whether the change in scores after the intervention was maintained in both groups, we combined all data for mean scores at T1 and T2 (3 months after finishing counselling). This analysis did not use the intention-to-treat model. We also looked at maintenance of the score in the intervention group 6 months after counselling finished (T3). Mixed regression models were used to measure the difference in the mean of the pooled scores between T1 and T2 (both groups combined) and between T2 and T3 (intervention group only). The analysis was only performed on those participants for whom we had outcome measures at these time points.

For the HTQ-16 (PTSD), we calculated prevalence of PTSD in the two groups at all visits by identifying participants meeting DSM-IV criteria. We compared the change in prevalence in the intervention group between B/T0 and T1 with the change in prevalence in the waitlisted group between B and T0, using logistic regression estimated by generalized estimating equations to account for the repeated measures of PTSD. The model included an interaction term for group and time to account for the change in the PTSD status of participants in each group between the two time points, and adjusted for sex, hospital of recruitment, and age. Measures of association were calculated as odds ratios with 95% confidence intervals and p-values. This analysis was not using the intention-to-treat model.

All analysis was done in STATA version 13.0 (Statacorp, College Station, Texas, USA) and SAS version 9.4 (Cary, NC, USA).

Ethical considerations

In February 2013, a community consultation about this study was conducted in Grozny with six groups of participants including nurses, social workers, pharmacy staff, and patients in the hospital [18]. The outcomes were used to inform the final study design (notably reducing the waitlist period from 3 to 2 months). The study protocol was reviewed and approved by the MSF Ethical Review Board and the Ethical Review Board in Chechnya State University. The study protocol was also reviewed at CDC and determined to meet the criteria for non-engagement of CDC staff in human subjects' research.

Informed consent forms were translated into Russian and verbal Chechen, back-translated into English, and piloted in the area of the study. We explained to clients that participation in the

study was voluntary, that they could discontinue from the study at any time without explanation, and that they would receive the same standard of treatment whether or not they agreed to participate. Participants were reimbursed approximately 10 US Dollars to cover transport costs for each study-related follow-up visit.

Patient and public involvement

Prior to the implementation of this RCT, two community based studies were carried out in Grozny in preparation for this study. The first was a community consultation that discussed the stepped-wedge design of the RCT and the acceptability around the waitlist group and the length of the waitlisted period [18]. As mentioned before, the waitlisted period for this RCT was reduced from the proposed three months to two months following this community consultation. The second study involved the design of culturally adapted instruments to measure mental distress in the current RCT [34]. We assumed that the communities involved in these two prior studies were the same as those from which the participants of the RCT arose. Also, at the end of the study, all participants were offered an appointment (and transport costs) to review their own results.

RESULTS

Participant recruitment and follow-up

Between 17 November 2014 and 9 February 2015, we assessed 203 patients presenting for care at the MSF MH programme for eligibility. Thirty-five people were not eligible (n=12) or declined to participate (n=23). Those that declined to participate in the study cited the following reasons: personal reasons (n=11, 47.8%), unwilling to wait for counselling (n=6, 26.1%), distance too far for counselling (n=3, 13.0%), no permission from family to attend counselling (n=1), lack of time to attend counselling (n=1) and for one individual this information was missing. We randomised 168 participants: 84 to each group.

One participant's MH condition deteriorated immediately following enrolment into the study (intervention group); the participant was referred for psychiatric care before starting the intervention and was no longer followed in the study. We lost another 19 participants to follow-up (11·30%): six (7·14%) in the intervention group (five during the intervention and one between 3 and 6 months post-intervention) and 13 (15·48%) in the waitlisted group (four during the waitlisted period, seven during the intervention, and two between the end of counselling and 3-month follow-up). The total proportion lost to follow-up did not differ between the groups (p=0·082) (Figure 1).

Baseline data

Demographic characteristics of the intervention and waitlisted group participants were similar; most were female, married, and employed, had completed high school, and were not hospitalised at the time of enrolment (Table 1). Out of the 14 hospitalised participants, it should be noted that they were all hospitalised for non-MH related reasons. There was no evidence of differences in characteristics of the two groups (p≥0·26).

Table 1: Baseline characteristics of participants

Characteristic	Sub-category	Waitlisted arm		Intervention arm		T-test or $\chi 2$	p-value
		n	*%*	*n*	*%*		
Sample size		84	50	84	50		
		mean	*SD*	*mean*	*SD*		
Age		41·43	13·53	40·54	14·62	0·41	0·68
		n	*%*	*n*	*%*		
Sex	Male	24	28·57	21	25·00	0·27	0·60
	Female	60	71·43	63	75·00		
Marital status	Married	44	52·38	47	55·95	0·89	0·93
	Single	18	21·43	19	22·62		
	Widowed	8	9·52	8	9·52		
	Divorced	12	14·29	9	10·71		
	Separated	2	2·38	1	1·19		
Employment	Employed	32	38·10	31	36·90	2·23	0·82
	Housewife	8	9·52	12	14·29		
	Student	6	7·14	6	7·14		
	Unemployed	25	29·76	24	28·57		
	Retired	13	15·48	10	11·90		
	Other	0	0	1	1·19		
Education	Primary	2	2·38	0	0	2·22	0·27
	Secondary	58	69·05	53	63·10		
	Higher education	24	28·57	30	35·71		
	None	0	0	1	1·19		
Hospitalised	No	75	89·29	79	94·05	1·25	0·26
	Yes	9	10·71	5	5·95		

For the 78 intervention group participants who completed counselling, information was available for 76 on the number of counselling sessions completed and the duration of those sessions [mean sessions: 3·8 (SD=0·7); duration: 29·7 days (SD=9·7)]. Seventy-one waitlisted participants for whom this information was available (of the 73 who completed counselling) had a higher mean number of counselling sessions [4·1 (SD=0·6); t-value=2·1, p=0·04], and mean duration of counselling [33·6 days (SD=12·0); t-value=2·2; p=0·03]. The presenting complaint for counselling as assessed by the counsellor was similar between the groups (χ^2=5·5, p=0·6); most sought counselling for anxiety-related (n=54, 36·7%), mood-related (n=34, 23·1%), family-related (n=22, 15·0%), and behaviour-related complaints (n=20, 13·6%). The precipitating event leading to seeking counselling was also similar between groups (χ^2=10·3, p=0·2), with similar proportions seeking care due to psychological violence (n=43, 39·3%), domestic discord or domestic violence (n=41, 27·9%), or non-violence-related events (n=41, 27·9%). During the

intervention, the counselling focus was similar in the two groups (χ^2=1·62, p=0·8). The counselling focus was on practical problems (n=58, 39·5%), overwhelming feelings (n=32, 21·8%), trauma-related symptoms (n=29, 19·7%), inner problems (n=17, 11·6%), and lack of essential practical or social skills (n=11, 7·5%). [Note: please note that this data is collected in our routine MH programme data. For further details on how this information is collected, please contact the corresponding author].

Numbers analysed

For the primary outcome and secondary outcomes looking at differences in mean gain scores between the groups from T0 and T1 for the intervention group and baseline and T0 for the waitlisted group, we included 84 participants in both groups with imputed data on scores from the last known follow-up visit. For PTSD analysis we compared the difference in PTSD prevalence in the intervention group between B/T0 (84 participants) and T1 (80 participants) to that in the waitlisted participants between B (84 participants) and T0 (80 participants). For the maintenance of scores after the intervention, we included 78 people in the intervention group and 71 from the waitlisted group.

Functioning

Using the SF6, the counselling intervention had moderate to large effect sizes in the intervention group compared with the waitlisted group (general health DmGS=12·14, effect size=0·52; bodily pain DmGS=10·26, effect size=0·35; social functioning DmGS=16·07, effect size=0·69; and role emotional DmGS=16·87, effect size=0·91) (Table 2). The Chechen functioning instruments showed a DmGS of -0·33 (effect size=0.54) for females and a DmGS of -0·40 (effect size=0·99) for males. In the adjusted analysis, the intervention group also showed improved functioning by SF6 and the Chechen female functioning scale (all p<0·05) (Table 3). For the male score, the adjusted analysis showed less strong evidence of an improvement in functioning in the intervention group compared with the waitlisted group (F=3·52, p=0·0691).

Table 2: Average treatment effects (n=168) for functioning: unadjusted scores

Waitlist group			Intervention group			Net effect		Effect size estimate*	p-value
Follow Up Time	Mean score	(95%CI)	Follow Up Time	Mean score	(95%CI)	DmGS between scores for intervention and waitlist	(95%CI)	*d*	
SF6 General Health (score out of 100, increase=improvement)									
B	26·13	(22·31, 29·95)	B/T0	23·39	(19·57, 27·22)				
T0	31·85	(26·67, 37·02)	T1	41·25	(36·08, 46·42)				
Change B-T0	5·71	(0·72, 10·71)	Change T0-T1	17·86	(12·86, 22·85)	12·14	(5·08, 19·20)	0·52	0·0009
SF6 Body Pain (score out of 100, increase=improvement)									
B	39·9	(35·75, 44·06)	B/T0	42·74	(38·58, 46·89)				
T0	47·05	(41·66, 52·44)	T1	60·14	(54·75, 65·53)				
Change B-T0	7·14	(0·86, 13·43)	Change T0-T1	17·40	(11·12, 23·69)	10·26	(1·37, 19·15)	0·35	0·024
SF6 Social Functioning (score out of 100, increase=improvement)									
B	54·17	(49·97, 58·37)	B/T0	52·38	(48·18, 56·58)				
T0	51·19	(47·06, 55·32)	T1	65·48	(61·35, 69·61)				
Change B-T0	-2·98	(-7·99, 2·04)	Change T0-T1	13·10	(8·08, 18·11)	16·07	(8·98, 23·16)	0·69	<0·0001
SF6 Role Emotional (score out of 100, increase=improvement)									
B	56·15	(52·96, 59·34)	B/T0	51·88	(48·7, 55·07)				
T0	56·35	(52·68, 60·01)	T1	68·95	(65·28, 72·61)				
Change B-T0	0·20	(-3·79, 4·18)	Change T0-T1	17·06	(13·08, 21·08)	16·87	(11·23, 22·50)	0·91	<0·0001
Chechen Female Functioning (score 1-4, reduction=improvement)									
B	1·99	(1·83, 2·14)	B/T0	2·04	(1·89, 2·19)				
T0	1·90	(1·76, 2·04)	T1	1·63	(1·49, 1·77)				
Change B-T0	-0·09	(-0·24, 0·07)	Change T0-T1	-0·41	(-0·57, -0·26)	-0·33	(-0·54, -0·11)	0·54	0·004
Chechen Male Functioning (score 1-4, reduction=improvement)									
B	1·72	(1·53, 1·92)	B/T0	1·71	(1·50, 1·91)				
T0	1·70	(1·54, 1·87)	T1	1·28	(1·10, 1·46)				
Change B-T0	-0·02	(-0·19, 0·15)	Change T0-T1	-0·43	(-0·60, -0·25)	-0·40	(-0·65, -0·16)	0·99	0·0018

*measured using Cohen's d statistic

Table 3: Adjusted treatment effects for functioning (n=168)

	Adjusted DmGS between intervention and waitlist groups	(95%CI)	F value	p-value
SF6 General Health	11·81	(4·90, 18·72)	11·41	0·0009
SF6 Body Pain	10·55	(1·91, 19·19)	5·82	0·017
SF6 Social Functioning	15·7	(8·53, 22·86)	18·71	<0·0001
SF6 Emotional Role	17·05	(11·45, 22·65)	36·19	<0·0001
Chechen Female Functioning	-0·36	(-0·57, -0·14)	10·79	0·0014
Chechen Male Functioning	-0·27	(-0·56, -0·02)	3·52	0·0691

Anxiety and depression

The unadjusted DmGS between the intervention and waitlisted groups using the HSCL-25 was -0·55 for anxiety symptoms, -0·50 for depression symptoms, and -0·52 for overall psychological distress (Table 4). The effect sizes calculated in the unadjusted analysis for all three measurements were large (all d>1·0 and p<0·0001). This positive impact of counselling in the intervention group compared with the waitlisted group was maintained in the adjusted analysis, with p<0·0001 for all three measurements (Table 5).

Table 4: Average treatment effects (n=168) for symptoms, coping, and perceived social support: unadjusted scores

Waitlist group			Intervention group			Net effect		Effect size estimate*	p-value
Follow Up Time	Mean score	(95%CI)	Follow Up Time	Mean score	(95%CI)	DmGS between scores for intervention and waitlist	(95%CI)	*d*	
HSCL-25 Anxiety (score 1-4, reduction=improvement)									
B	2·49	(2·40, 2·58)	B/T0	2·54	(2·45, 2·63)				
T0	2·21	(2·10, 2·33)	T1	1·71	(1·6, 1·83)				
Change B-T0	-0·28	(-0·40, -0·17)	Change T0-T1	-0·83	(-0·94, -0·71)	-0·55	(-0·71, -0·39)	1·03	<0·0001
HSCL-25 Depression (score 1-4, reduction=improvement)									
B	2·43	(2·33, 2·52)	B/T0	2·43	(2·34, 2·52)				
T0	2·23	(2·13, 2·34)	T1	1·74	(1·63, 1·85)				
Change B-T0	-0·.19	(-0·30, -0·09)	Change T0-T1	-0·69	(-0·79, -0·58)	-0·50	(-0·65, -0·35)	1·01	<0·0001
HSCL-25 Total (score 1-4, reduction=improvement)									
B	2·45	(2·37, 2·54)	B/T0	2·48	(2·39, 2·56)				
T0	2·22	(2·12, 2·33)	T1	1·73	(1·63, 1·83)				
Change B-T0	-0·23	(-0·33, -0·13)	Change T0-T1	-0·74	(-0·85, -0·65)	-0·52	(-0·66, -0·37)	1·11	<0·0001
Coping Problem Solving (score 1-3, reduction=improvement)									
B	1·58	(1·50, 1·67)	B/T0	1·54	(1·45, 1·62)				
T0	1·58	(1·50, 1·66)	T1	1·64	(1·56, 1·72)				
Change B-T0	-0·01	(-0·10, 0·09)	Change T0-T1	0·10	(0·01, 0·19)	0·11	(-0·02, 0·24)	0·25	0·103
Coping Social Support (score 1-3, reduction=improvement)									
B	2·12	(2·01, 2·23)	B/T0	2·08	(1·97, 2·19)				
T0	2·12	(2·01, 2·22)	T1	2·06	(1·96, 2·16)				
Change B-T0	0	(-0·12, 0·12)	Change T0-T1	-0·02	(-0·14, 0·10)	-0·01	(-0·18, 0·16)	0·02	0·871
Coping Avoidance (score 1-3, reduction=improvement)									
B	2·13	(2·05, 2·21)	B/T0	2·10	(2·01, 2·18)				
T0	2·11	(2·02, 2·20)	T1	2·38	(2·30, 2·47)				
Change B-T0	-0·02	(-0·07, 0·11)	Change T0-T1	0·29	(-0·20, 0·38)	0·31	(0·18, 0·44)	0·72	<0·0001
Perceived Social support (score out of 60, increase=improvement)									
B	44·33	(43·34, 45·33)	B/T0	44·23	(43·23, 45·22)				
T0	44·96	(44·05, 45·88)	T1	46·75	(45·84, 47·67)				
Change B-T0	0·63	(-0·32, 1·58)	Change T0-T1	2·52	(1·58, 3·47)	1·89	(0·55, 3·23)	0·43	0·006

*measured using Cohen's d statistic

Table 5: Adjusted treatment effects for symptoms and coping, and social support (n=168)

	Adjusted DmGS between intervention and waitlist groups	(95%CI)	F value	p-value
Symptoms				
HSCL 25 Anxiety	-0·56	(-0·72, -0·39)	46·06	<0·.0001
HSCL 25 Depression	-0·51	(-0·65, -0·36)	44·90	<0·0001
HSCL 25 Overall	-0·53	(-0·67, -0·38)	53·71	<0·0001
Coping and social support				
Problem solving	0·12	(0·02, 0·25)	3·05	0·0825
Social support	-0·02	(-0·19, 0·16)	0·03	0·8622
Avoidance	0·30	(0·17, 0·43)	20·16	<0·0001
Perceived social support	2·03	(0·68, 3·37)	8·83	0·0034

Coping and perceived social support

Using the CSI, the unadjusted DmGS related to problem solving and social support were very small with small effect sizes (problem solving DmGS=0·11, d=0·25, p=0·103; social support DmGS=-0·01, d=0·02, p=0·871) (Table 4). In the adjusted analysis, problem solving and social support showed no significant evidence of difference between the groups (p=0·08 and p=0·86, respectively) (Table 5). The coping scale for avoidance showed a significant worsening, with a moderate effect size (DmGS=0·31, d=0·72, p<0·0001). In the adjusted analysis, the worsening in avoidance coping skills remained (F=20·16, p<0·001). Perceived social support improved in the intervention group compared with the waitlisted group, with a moderate effect size (DmGS=1·89, d=0·43, p=0·006), and this remained relevant in the adjusted analysis (F=8·83, p=0·0034) (Table 5).

Maintenance of scores after counselling

A continued improvement was observed using the scales for SF6 social functioning, SF6 role emotional, and the Chechen female and male functioning scales at T2 compared with T1 (all p<0·05). The effect was maintained at T3 with no further improvement for SF6 social functioning (p=0·60), SF6 role emotional (p=0·25), or the Chechen male functioning scale (p=0·17). Further significant improvement was observed at T3 compared with T2 in female participants from the intervention group (p=0·02). The effect of counselling was sustained (but not further improved) at T2 compared with T1 when measured on the SF6 general health (p=0·38) and body pain (p=0·10) scales. Similar trends were observed for these two scales at T3 compared with T2 (p=0·94 and p=0·95, respectively) (Table 6).

Table 6: Sustained improvement for functioning (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and waitlist groups combined]*			3 months to 6 months follow-up (T2 to T3), N=77 *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
SF6 General Health (score out of 100, increase=improvement)								
	T1	41·78	(37·77, 45·78)		T2	41·88	(36·30, 47·47)	
	T2	39·97	(36·05, 43·88)		T3	42·08	(36·67, 47·48)	
	Pre-post change	-1·81	(-5·88, 2·26)	0·38	Pre-post change	0·19	(-4·71, 5·10)	0·94
SF6 Body Pain (score out of 100, increase=improvement)								
	T1	60·72	(56·69, 64·76)		T2	66·96	(61·04, 72·88	
	T2	64·40	(60·43, 68·37)		T3	67·14	(61·26, 73·03)	
	Pre-post change	3·68	(-0·70, 8·06)	0·10	Pre-post change	0·18	(-5·32, 5·68)	0·95
SF6 Social Functioning (score out of 100, increase=improvement)								
	T1	65·27	(61·89, 68·65)		T2	71·10	(65·.89, 76·32)	
	T2	70·64	(67·25, 74·02)		T3	72·73	(67·93, 77·53)	
	Pre-post change	5·37	(1.47, 9.26)	0·007	Pre-post change	1·62	(-4·44, 7·68)	0·60
SF6 Role Emotional (score out of 100, increase=improvement)								
	T1	69·30	(66·55, 72·04)		T2	75·00	(70·88, 79·12)	
	T2	73·88	(70·92, 76·84)		T3	77·49	(73·60, 81·38)	
	Pre-post change	4·59	(1·36, 7·81)	0·006	Pre-post change	2·49	(-1·76, 6·74)	0·25
Chechen Female Functioning (N=111 and N=57) (score 1-4, reduction=improvement)								
	T1	1·53	(1·44, 1·63)		T2	1·42	(1·31, 1·53)	
	T2	1·42	(1·33, 1·51)		T3	1·28	(1·21, 1·36)	
	Pre-post change	-0·12	(-0·22, -0·01)	0·03	Pre-post change	-0·14	(-0·25, -0·02)	0·02
Chechen Male Functioning (n=38 and n=20) (score 1-4, reduction=improvement)								
	T1	1·38	(1·26, 1·50)		T2	1·19	(1·07, 1·32)	
	T2	1·24	(1·15, 1·33)		T3	1·12	(1·06, 1·19)	
	Pre-post change	-0·14	(-0·25, -0·03)	0·018	Pre-post change	-0·07	(-0·18, 0·03)	0·17

Symptoms of anxiety, depression, and psychological distress, measured by the HSCL-25, improved further at T2 compared with T1 (p=0·03, p=0·003, and p=0·005, respectively). This improvement continued in the intervention group at T3 compared with T2 (p=0·0009, p=0·001, and p=0·0005, respectively). Results for all aspects of the CSI showed either no change or a slight deterioration at T2 and T3. For perceived social support, a small improvement was observed at T2 (p=0·002) compared with T1, which was sustained but not further improved at T3 in the intervention group (Table 7).

Table 7: Change in scores for symptoms, coping, and social support at 3 and 6 months follow-up (unadjusted scores)

	Post-intervention to 3 months follow-up (T1 to T2), N=149 *[Intervention and waitlist groups combined]*				3 months to 6 months follow-up (T2 to T3), N=77 *[Intervention group only]*			
	Follow-up visit	Mean score	(95%CI)	p-value	Follow-up visit	Mean score	(95%CI)	p-value
HSCL-25 Anxiety (score 1-4, reduction=improvement)								
	T1	1·63	(1·56, 1·71)		T2	1·58	(1·47, 1·68)	
	T2	1·54	(1·47, 1·61)		T3	1·39	(1·30, 1·48)	
	Pre-post change	-0·09	(-0·18, -0·01)	0·03	Pre-post change	-0·19	(-0·29, -0·08)	0·0009
HSCL-25 Depression (score 1-4, reduction=improvement)								
	T1	1·69	(1·62, 1·76)		T2	1·60	(1·50, 1·69)	
	T2	1·57	(1·51, 1·64)		T3	1·44	(1·36, 1·51)	
	Pre-post change	-0·12	(-0·20, -0·04)	0·003	Pre-post change	-0·16	(-0·26, -0·06)	0·001
HSCL-25 Total (score 1-4, reduction=improvement)								
	T1	1·67	(1·60, 1·74)		T2	1·59	(1·50, 1·68)	
	T2	1·56	(1·50, 1·62)		T3	1·42	(1·34, 1·49)	
	Pre-post change	-0·11	(-0·19, -0·03)	0·005	Pre-post change	-0·17	(-0·27, -0·08)	0·0005
Coping Problem Solving (score 1-3, reduction=improvement)								
	T1	1·64	(1·58, 1·69)		T2	1·76	(1·65, 1·86)	
	T2	1·76	(1·69, 1·82)		T3	1·82	(1·71, 1·92)	
	Pre-post change	0·12	(0·05, 0·19)	<0·0001	Pre-post change	0·06	(-0·05, 0·16)	0·27
Coping Social Support (score 1-3, reduction=improvement)								
	T1	2·08	(2·01, 2·15)		T2	2·12	(2·00, 2·24)	
	T2	2·13	(2·05, 2·20)		T3	2·21	(2·10, 2·33)	
	Pre-post change	0·04	(-0·05, 1·14)	0·33	Pre-post change	0·09	(-0·04, 0·22)	0·18
Coping Avoidance (score 1-3, reduction=improvement)								
	T1	2·39	(2·33, 2·44)		T2	2·46	(2·38, 2·53)	
	T2	2·46	(2·41, 2·51)		T3	2·49	(2·41, 2·57)	
	Pre-post change	0·07	(0·01, 0·13)	0·02	Pre-post change	0·03	(-0·04, 0·11)	0·38
Perceived Social support (score out of 60, increase=improvement)								
	T1	46·74	(46·12, 47·36)		T2	47·88	(47·17, 48·60)	
	T2	47·75	(47·24, 48·26)		T3	48 ·12	(47·40, 48·84)	
	Pre-post change	1·01	(0·37, 1·66)	0·002	Pre-post change	0·23	(-0·60, 1·07)	0·58

PTSD

At baseline, 32 (N=84, 38·10%) participants in the intervention group and 39 (N=84, 46·43%) in the waitlisted group were classified as meeting DSM-IV criteria for PTSD using HTQ-16 ($\chi 2$=1·20, p=0·274). At T1, the prevalence in the intervention group had reduced (n=5/78, 6·41%). The prevalence of PTSD in the waitlisted group was 38.75% after the waitlisted period at T0 and had also reduced at T1 (n=8/73, 10·96%). The adjusted reduction in PTSD prevalence in the intervention group between baseline/T0 and T1 was significantly lower than that in the waitlisted group between baseline and T0 (odds ratio 0·11; 95% CI: 0·04-0·28, p<0·001) (Table 8).

Table 8: Unadjusted and adjusted odds ratios of comparison between change in PTSD prevalence of intervention group pre-intervention and post-intervention compared with waitlisted group

PTSD		Unadjusted			Adjusted		
		OR	(95%CI)	p-value	OR	(95%CI)	p-value
Waitlist group							
	B (n=84)	1·00			1·00		
	T0 (n=80)	0·73	(0·44, 1·20)	0·218	0·76	(0·46, 1·26)	0·280
Intervention group							
	B/T0 (n=84)	1·00			1·00		
	T1 (n=78)	0·11	(0·04, 0·29)	<0·001	0·11	(0·04, 0·28)	<0·001
Intervention group vs. waitlist group							
T1 vs. B/T0		0·15	(0·05, 0·45)	0·001	0·14	(0·05, 0·43)	<0·001

DISCUSSION

We have shown that individual counselling in conflict affected adults in Chechnya improved their daily functioning. Both study instruments used to test functioning, including one that was specifically designed for use in Chechen adults, showed an improvement in the intervention group compared with the waitlisted group. The unadjusted and adjusted analyses for the functioning instruments showed very similar results, suggesting that the improvement in the intervention group compared with the waitlisted group was not importantly influenced by age, sex, marital and employment status, number of counselling sessions, or hospital of recruitment. The absence of statistical evidence for a true difference in the Chechen male functioning scale is likely due to the study being underpowered to detect differences among sub-groups.

The results are especially encouraging as different instruments to measure functioning recorded similar positive outcomes, strongly suggesting that the counselling is effective in improving this aspect of clients' lives. Such positive outcomes have also been shown in a retrospective review of programmatic data from 18 MSF projects with MH programmes in conflict and post-conflict settings [15]. As this study was a stepped-wedge RCT using validated outcome measures, we provide further evidence that the brief counselling intervention used among people affected by conflict can have a positive impact on their ability to function.

Different counselling strategies in other studies have also shown positive effects on functioning, PTSD, depression, and anxiety. Moderate to high improvements in the intervention group compared with the waitlisted group on these outcomes were measured using CETA in Burmese refugees in Thailand and in Iraqi Kurdistan [12,14]. In contrast, mixed results from group problem-solving counselling in terms of functioning were observed in war-affected adults in Aceh, Indonesia [35]. A recent RCT in adults with psychological distress in a conflict area in Pakistan identified a large improvement in functioning and symptoms of PTSD, depression, and anxiety following five weekly sessions of individual counselling delivered by trained lay workers using the WHO PM+ approach [10]. This study mirrors the intervention described in our study in that it limited the number of counselling sessions to five and did not rely on clinically trained MH professionals. It slightly differs from our approach in that the PM+ is a manualised intervention, whereas the MSF one is a semi-structured approach allowing for individual adaptation by the counsellor.

The coping scale did not show evidence for improvement with the intervention, and avoidance appeared to worsen. This suggests that the improvement in functioning and symptoms was not achieved through improvement in the three coping skills measured by the CSI. Alternately, the CSI may not be well adapted to measure coping strategies in this population. The study by our colleagues in Aceh [35] also observed a small decline in the use of coping strategies among women in the intervention group.

The SPS scale showed a significant increase in perceived social support in the intervention group compared with the waitlisted group, which was sustained after completion of counselling. The MSF-OCA MH programme in Grozny includes encouragement to establish positive coping mechanisms (including social support). Social support has been shown to have a positive effect on mental and physical health [36] and is associated with lower posttraumatic stress scores [37]. It is also notable that social functioning improved with the intervention.

We were able to determine that there was longer-term efficacy of the individual counselling on functioning and symptoms of depression and anxiety in both the intervention and waitlisted groups. Scores on the instruments that tested these items either maintained the improvement or continued to improve at 3 and 6 months after completion of counselling. Studies on Rwandan and Somali refugees in Uganda showed that Narrative Exposure Therapy (NET) counselling sustained the reduction in PTSD in all participants at 6 and 12 months' follow-up, although the dropout rates were high [38]. Very few studies have measured the maintenance of these scores and thus the current study provides much needed evidence in this regard.

The expression of mental health difficulties as physical symptoms, called somatization, is common in many cultures [39]. In our study, the functioning scales addressing general health and body pain were not sustained or further improved after completion of counselling. Whether this is due to continuing physical complaints in the study population or because of ongoing psychosomatic complaints, we cannot say. However, we believe the latter is unlikely as the counselling intervention is addressing medically unexplained physical symptoms, but did not change or address any physical illness. Neither coping mechanisms nor social support showed any further changes following the end of counselling.

The study has some limitations. Although few of the participants were hospitalised at enrolment, the MSF MH programme is located in hospital settings, which might have biased care-seeking behaviour. The study population therefore might not be entirely representative of those seeking help for MH concerns in Grozny. We worked hard to ensure that study interviewers remained blinded to the group allocation up to T1 of the intervention group, but this could not be ensured in all cases. We do not think that this potential bias would have changed our findings substantially, as all instruments had a fixed script for questions to be asked by interviewers and answers provided by participants, not allowing much space for interviewers to influence participants' answers. Grozny represents a specific and long-term unstable situation, so we cannot be certain that similar outcomes would be found in other acute emergencies. The counsellors delivering the intervention, while non-specialised, all had academic training and many years of experience delivering the intervention, which is not the case in many humanitarian settings. However, we have shown previously that although lay counsellors used more sessions than academically trained counsellors, the outcomes in clients were similar [15]. Also, we conducted a sensitivity analysis which included the counsellor as a covariate in the multivariate regression models and the results did not change the interpretation of the study findings. This suggests that the positive outcomes measured were not linked to individual counsellors. Finally, we employed widely used instruments to measure mental health distress and functioning in this study and thus have equated numerical improvements in the scores of study participants with clinical improvements. This is supported by the knowledge that individual counselling in Grozny was only finalised when the client and counsellor agreed that the main complaint for attending counselling had been resolved (thus improved).

Despite its limitations, this study represents a scientifically rigorous evaluation of an individual counselling intervention in a humanitarian setting, in that it includes a randomised waitlisted group to avoid over-estimating improvements due to the effect of time alone. We were also able to show that the improvements due to the intervention were not only maintained but continued to

improve at 3 and 6 months after completion of the intervention. This approach both improved functioning in daily life and reduced symptoms of mental distress including anxiety and depression, while decreasing the prevalence of PTSD in adults in Chechnya with similar effect sizes to other interventions. In parallel with the PM+ guidelines, we have shown that low-intensity MH interventions in humanitarian settings play an important role in improving functioning and reducing psychosocial distress. Further research is needed to determine whether similar results can be shown in acute conflict settings, and where less experienced/trained counsellors deliver the intervention. Additionally, further exploration on the impact of individual counselling in men specifically would be important as they are frequently underrepresented in studies in this area.

REGISTRATION

The study was registered with the Netherlands Trial Register (http://www.trialregister.nl/trialreg/index.asp) which is recognised by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICJME) under registration number NTR4689 (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4689). The protocol is available from http://fieldresearch.msf.org/msf/bitstream/10144/618741/1/1326_MSFH+MH+Chechnya+outcomes+evaluation+protocol_amendment+November+2016_clean_final.pdf.

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DISCLAIMER

The findings and conclusions in this report are those of the authors and do not represent the official position of the Centers for Disease Control and Prevention.

AUTHOR CONTRIBUTIONS

BLC, LS, CB, KI, PB and GP designed the study. CF, ZT, GP and AL acquired the data. CF, CB and AL analysed the data. All authors contributed to the interpretation of data. AL, BLC and GP wrote the manuscript and all authors critically reviewed the manuscript.

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COMPETING INTEREST

The authors declare to have no competing interests.

DATA SHARING

MSF has a managed access system for data sharing. Data are available on request in accordance with MSF's data sharing policy. Requests for access to data should be made to data.sharing@msf.org.

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Figure 1: CONSORT* Flowchart of participants
*Consolidated Standards of Reporting Trials (http://www.consort-statement.org/)

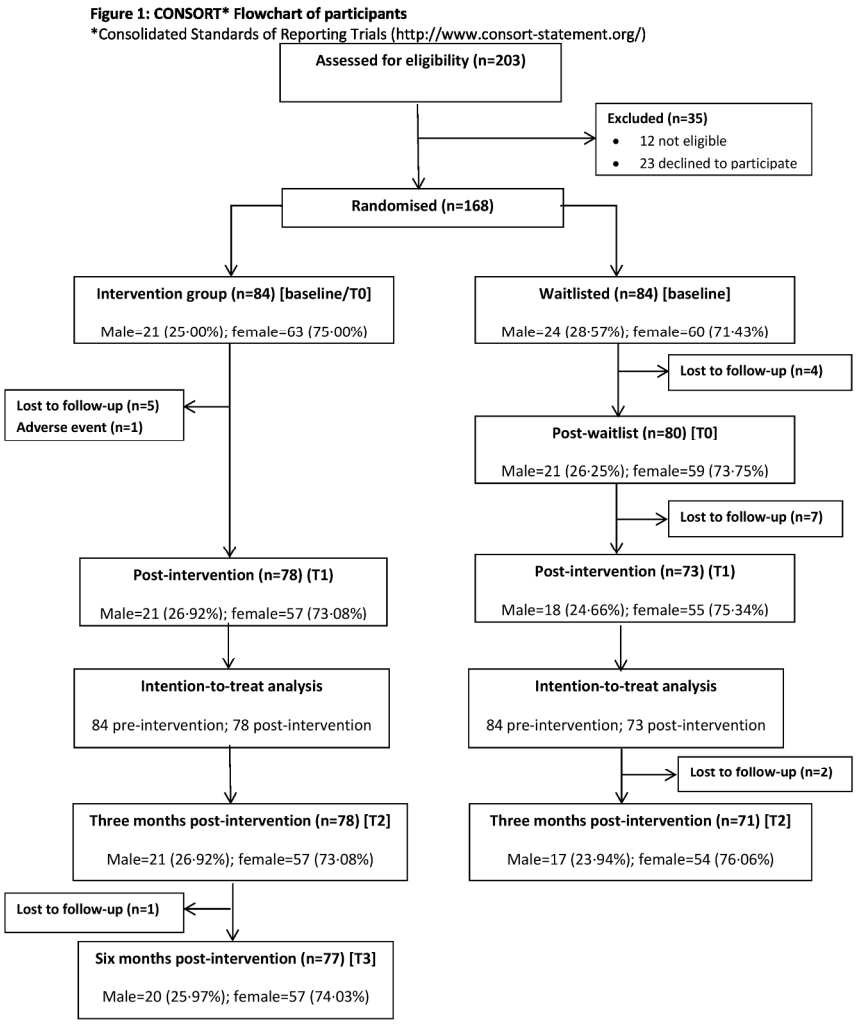

Figure 1: CONSORT* Flowchart of participants

215x279mm (300 x 300 DPI)

Gain Score Linear Regression baseline/T0 and T1

$$(Y_{it} - Y_{it-1}) = \beta_0 + B_{i1}Group + B_{i2}Hospital + B_{i3}Age + B_{i4}Sex + B_{i5}Education + B_{i5}Marital + B_{i6}Employment$$

Where:

$Y_{it} = score\ of\ subject\ i\ at\ time\ t$
$\beta_0 = intercept$
$\beta_{ij} = standardized\ regression\ coefficient\ of\ independent\ variable\ j\ for\ subject\ i$

Gain Score Linear Regression Follow-up

$$(Y_{it} - Y_{it-1}) = \beta_0 + B_{i1}Hospital + B_{i2}Age + B_{i3}Sex + B_{i4}Education + B_{i5}Marital + B_{i6}Employment$$

Where:

$Y_{it} = score\ of\ subject\ i\ at\ time\ t$
$\beta_0 = intercept$
$\beta_{ij} = standardized\ regression\ coefficient\ of\ independent\ variable\ j\ for\ subject\ i$

GEE Repeated Measures Logistic Regression Model

$$\ln\left(\frac{\pi_{it}}{1-\pi_{it}}\right) = \beta_0 + B_{i1}Group + B_{i2}Time + B_{i3}\,(Group\ x\ Time) + B_{i4}Hospital + B_{i5}Age + B_{i6}Sex$$

Where:
$\pi_{it} = conditional\ probability\ that\ subject\ i\ at\ time\ t\ has\ PTSD$
$\beta_0 = intercept$
$\beta_{itj} = standardized\ regression\ coefficient\ of\ independent\ variable\ j\ for\ subject\ i$

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-24
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-24
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17-24
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	13
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.