Evaluating the outcome of mental health interventions in Chechnya

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27124

Source
NTR

Brief title
MH Study Chechnya

Health condition

mental health

Sponsors and support

Primary sponsor: Médecins Sans Frontières, Operational Center Amsterdam
Chechnya State University (Psychiatric Department)
Johns Hopkins University
Centers for Disease Control and Prevention
Source(s) of monetary or material Support: Médecins Sans Frontières, Operational Center Amsterdam

Intervention

Outcome measures

Primary outcome

Change in functioning as measured by the adapted Short Form (SF-36) with the additional of

locally adapted functioning questions.

Secondary outcome

- Change in symptoms as measured on the HSCL-25

- Change in coping strategies as measured by the Coping Strategy Indicator

- Change in perceived social support as measured by the Social Provisions

Study description

Background summary

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

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

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

• age 18 years or older

• capable of providing informed consent for inclusion in the study

• No cognitive, visual or other impairments that would limit ability to participate in the study

• Score on HSCL-25 screening instrument greater than threshold

• Willing/able to return to counselling centre for follow up

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

• judged at intake interview to be at acute risk of suicide

• presence of a major psychiatric disorder requiring medication (e.g. psychosis, severe depression, or bipolar disease)

• have been enrolled in MSF's counselling services within the last 6 months

Intervention: The individual counselling intervention will be provided as per standard MSF protocols. The counsellor will determine with the client what the main problem is they are seeking to address with the counselling. This will be used to determine a counselling focus using pre-determined categories as described. The intervention will continue until the counsellor judges, together with the client, that the presenting problem has resolved or improved to the point that counselling is no longer needed.

Sample Size: The required sample size is 46 per arm. Planning for an expected drop out and loss to follow up rate of 30%, we will aim to enrol 136 subjects, 68 in each arm.

Primary Outcome Measure:

Change in functioning as measured by the adapted SF-36 with the addition of locally adapted functioning questions

Secondary Outcome Measures

• Change in symptoms as measured on the HSCL-25

• Change in coping strategies as measured by the Coping Strategy Indicator

• Change in perceived social support as measured by the Social Provisions Scale

• Change in status at 3 and 6 months post intervention compared with the immediate post-intervention scores

• Incidence of PTSD in the study population as measured by the Harvard Trauma Questionnaire part 2 (HTQ-2)

• Impact of the intervention on PTSD amongst those identified on entry as meeting the symptom criteria for PTSD on the HTQ-2

• Client rated symptoms and functionality scores as compared to gold standard

• Counsellor’s perception of problem status compared to functioning instruments

Study objective

The individual counselling intervention will significantly

Study design

- Change in status at 3 and 6 months post-intervention compared with the immediate post-intervention scores

Intervention

Individual counseling will be provided as per standard Medecins Sans Frontieres protocols. The counsellor will determine with the client what the main problem is they are seeking to address with the counselling. This will be used to determine a counselling focus using pre-determined categories as decribed. The intervention will continue until the counsellor judges, together with the client, that the presenting problem has resolved or improved to the point that counselling is no longer needed.

Contacts

Public
Epidemiology Advisor
Médecins Sans Frontières (MSF)
MSF-Operational Center Amsterdam
Annick Lenglet
Amsterdam
The Netherlands
Scientific
Epidemiology Advisor
Médecins Sans Frontières (MSF)
MSF-Operational Center Amsterdam
Annick Lenglet
Amsterdam
The Netherlands

Eligibility criteria

Inclusion criteria

- age 18 years or older

- capable of providing informed consent for inclusion in the study

- no cognitive, visual or other impairments that would limit ability to participate in the study

-score on Hopkins Symptom Checklist (HSCL-25) screening instrument greater than threshold

- willing/able to return to counselling centre for follow-up

Exclusion criteria

- judged at intake interview to be at acute risk of suicide

- presence of a major psychiatric disorder requiring medication (e.g. psychosis, severe depression or bi-polar disease)

- have been enrolled in Medecins Sans Frontieres' counselling services within the last 6 months

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	136

Type:	Actual

Ethics review

Positive opinion Date:	15-07-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4546
NTR-old	NTR4689
Other	: MSFOCA-010-10

Study results