Evaluating the outcome of mental health interventions in Chechnya

Gepubliceerd: 15-07-2014 Laatst bijgewerkt: 18-08-2022

The individual counselling intervention will significantly

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27124

Bron
Nationaal Trial Register

Verkorte titel
MH Study Chechnya

Aandoening

mental health

Ondersteuning

Primaire sponsor: Médecins Sans Frontières, Operational Center Amsterdam
Chechnya State University (Psychiatric Department)
Johns Hopkins University
Centers for Disease Control and Prevention
Overige ondersteuning: Médecins Sans Frontières, Operational Center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

locally adapted functioning questions.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

The individual counselling intervention will significantly

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	136
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-07-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten