

Equator evaluation study: evaluation of the equator day care treatment for traumatised refugees

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Registration date 07/03/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR910

Study information

Scientific Title

Equator evaluation study: evaluation of the equator day care treatment for traumatised refugees

Study objectives

Suffering from mental health problems constitutes a major obstacle for successful integration into Dutch society for refugees. The majority of refugees report one or more psychiatric disorders, often related to previously experienced traumatic events. To those refugees whose problems are of such severe nature that mental health treatment is indicated, the Academic Medical Centre (AMC) offers the Equator day care treatment.

Equator day care treatment aims at the decrease of trauma related mental health problems. Moreover, the treatment aims at strengthening the patient's self-reliance, and offers techniques for the improvement of social (re)-integration. This study has the objective to evaluate Equator day care treatment and to define factors affecting treatment effectiveness. Consequently the study hopes to increase the body of knowledge with respect to the relationship between mental health and social integration.

The research questions of the study are:

1. What is the relationship between mental health and social integration?
- 2.a. What are the short and long term effects of the Equator day care treatment on the mental health of refugees?
- 2.b. What are the short and long term effects of refugees of the Equator day care treatment on the social integration?

The general hypothesis of the study is that the Equator day care treatment results in a significant improvement on indicators of mental health and social integration, compared to a control group consisting of respondents that did not receive Equator day care treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Commission of the Academic Medical Centre (University of Amsterdam) on the 22nd November 2006 (ref: 06.17.1651).

Study design

Non-randomised, controlled, parallel group clinical trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Refugees, mental health

Interventions

Equator day care treatment is a three days a week group intervention over a six month period. Per year, around 40 refugee patients attend the Equator day care treatment. Most patients are men (+/- 70%), as most refugees in The Netherlands are men. The backgrounds of these patients are Afghan, Irakese, Iranese, Sierra Leoneese, Rwandese, Burundese, Angolese, Somalian etc.

The treatment integrates a psychiatric and a community approach to mental illness. The psychiatric approach aims at stabilising the mental health status and regaining control over effect and behaviour. Medication is central in this approach. Individual counselling with a psychologist or psychiatrist has a supporting nature. If indicated a psychotherapeutic or trauma focused therapy is started. The community approach consists of a socio-therapeutic intervention. This intervention aims at increasing social functioning. The therapeutic environment helps in regaining a basic sense of security.

The control group will be sampled from the adult refugee population living in the Netherlands. The control group will be matched on sex, ethnicity and living area.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

T0: start of intervention

T1: end of intervention (T0 and six months)

T2: three-months follow-up

T3: six-months follow-up

Method: assisted self-administering using a structured questionnaire. Questionnaire is translated in the mother tongue of the respondent. Complete questionnaire:

1. Diagnostics:

a. Psychopathology (Mini International Neuropsychiatric Interview Plus [MINIPlus])

b. Post-Traumatic Stress Syndrome (PTSS) (Clinician-Administered PTSS Scale [CAPS])

2. Socio-demographics: traumatic events (Stressful Life Events [SLE]-Equator; questionnaire developed for this particular study)

3. Mental health:

a. Impact of events (Impact of Event Scale-Revised [IES-R])

b. Anxiety and depression symptoms (Hamilton Anxiety Depression Scale [HADS])

c. Disability and wellbeing (Medical Outcomes Study short-form general health survey 36 MOS-sf-36)

- d. Somatic complaints (Subjective Health Complaint [SHC])
- 4. Social integration:
 - a. Social capital (ASCAT)
 - b. Social support (Social Support List-Interactions [SSL-I])
 - c. Acculturation questionnaire (Language Assessment Scales [LAS])
 - d. Loneliness (questionnaire developed for this particular study)
 - e. Frequency and quality of interaction/communication (questionnaire developed for this particular study)
- 5. Patient satisfaction

Secondary outcome measures

No secondary outcome measures

Overall study start date

14/08/2006

Completion date

15/08/2009

Eligibility

Key inclusion criteria

Treatment group: Equator day care patients: adult refugees with severe trauma related mental health problems

Control group: refugees in population, matched on sex, age, ethnicity and living area

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

60

Total final enrolment

72

Key exclusion criteria

1. Disturbed reality testing
2. Mentally retarded
3. No residence permit
4. Simultaneously receiving comparable mental health treatment

Date of first enrolment

14/08/2006

Date of final enrolment

15/08/2009

Locations

Countries of recruitment

Netherlands

Study participating centre**Equator**

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (The Netherlands)

Sponsor details

Equator

Academic Medical Centre

University of Amsterdam

Department of Psychiatry

Meibergdreef 5

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Government

Funder Name

European Refugee Fund (Belgium)

Funder Name

Added as of 06/10/2008:

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands). The funding from ZonMw will start on 1st January 2009 and end on 1st July 2009.

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2012	03/07/2019	Yes	No