Family Empowerment (FAME): A pilot implementation and evaluation of multi-family groups as a secondary prevention program for asylum seeker families.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46624

Source
ToetsingOnline

Brief title
FAME: a pilot implementation and evaluation

Condition

- Other condition
- Anxiety disorders and symptoms
- Family issues

Synonym
anxiety, depressive symptoms, Symptoms of anxiety

Health condition

somberheid en depressie

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum 45 (Oegstgeest)
Source(s) of monetary or material Support: Kinderpostzegels

Intervention

Keyword: Asylum seeker families, Family empowerment, Multi-family groups, Pilot implementation

Outcome measures

Primary outcome

The main study parameter is the pre-post FAME change in family functioning and parental symptoms of anxiety and depression.

Secondary outcome

Secondary study parameters include:

- Baseline differences on questionnaires measuring family functioning and parental symptoms of anxiety and depression, and an observational scale measuring emotional availability (between families living in family locations and those living in asylum centers).

- A qualitative evaluation of the program, using semi-structured interviews.

- A quantitative evaluation of each session, using rating scales.

- A quantitative list measuring program integrity, filled in by an assessor during the sessions.

Study description

Background summary

Families applying for asylum have often experienced multiple potentially traumatic events and face continuous stressors, such as a long and complex asylum procedure. Studies have indicated that experiencing traumatizing events can impact parenting behavior and child development (Van Ee, 2012). To target these at-risk families, the prevention program Family Empowerment (FAME) was developed (Mooren & Bala, 2016). This program aims to strengthen parenting skills and prevent further development of emotional problems.

Study objective

This study concerns a pilot implementation and evaluation of FAME.
- It aims to provide an initial indication of the efficacy of FAME in families in two living conditions: asylum centers and family locations. It is hypothesized that FAME has a positive impact on family functioning and prevents further development of parental symptoms of anxiety and depression.
- A second aim is to study baseline differences and similarities in parent-child relationship, parental symptoms and family functioning between families living in asylum centers and families living family locations.
- The study also assesses whether FAME can be carried out as intended in a naturalistic setting.
- Moreover, it will explore how the program is evaluated by participants and professionals who took part in the study.

Study design

The current study concerns a pilot implementation and evaluation, two-group pre-posttest, using a mixed-methods approach. Standardized questionnaires, semi-structured interviews, an observational scale and a list created for measuring program integrity will be used.

Intervention

All participants will take part in a secondary prevention multi-family program: FAME, lasting seven sessions with a duration of 2-3 hours.

Study burden and risks

Clinical experience with the program has indicated that there is no extra burden or risk involved for the participants. On the contrary: parents and children can benefit from the sessions. Moreover, families who have participated in the program evaluated the program positively (Mooren & Bala, 2016). Participation will be on a voluntary basis and information will be handled confidentially. The only added burden for participants is their time investment. Participants take part in seven sessions of FAME, lasting approximately 2-3 hours. Measurement include questionnaires, a semi-structured interview and observational scale. Families will be visited twice for

assessment (before- and after FAME). Participants fill in a short scale during every session of FAME.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

At least one caregiver is present (male or female)
At least one child aged 0-18
Living in an asylum center or family location

Exclusion criteria

Not being able to function in a group or to profit from participating:
- Severe psychiatric illness (such as psychosis)
- Severe mental challenges
- Severe behavioral problems
Although speaking a different language in the group is not an obstacle to taking part in this study, the limit to the number of interpreters present in one group is 3 interpreters.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-02-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-03-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20143
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63272.058.17
OMON	NL-OMON20143