

Families in the frontline;An evaluation study of parenting interventions for veteran families

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45333

Source

ToetsingOnline

Brief title

Families in the frontline

Condition

- Other condition
- Psychiatric disorders NEC
- Family issues

Synonym

complex PTSD and severe affected family functioning

Health condition

ernstige traumagerelateerde geestelijke gezondheidsproblematiek

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Landelijk zorgsysteem Veteranen-PAO

Intervention

Keyword: Evaluation study, Family interventions, PTSD, Veterans

Outcome measures

Primary outcome

The main study parameter is the difference in family functioning (SCORE-15) and child functioning (SDQ) between the parenting treatment modality and treatment as usual.

Secondary outcome

Secondary study parameters are emotion regulation as measured by the Difficulties in Emotion Regulation Scale (DERS), veteran PTSD symptoms as measured by PTSD Checklist (PCL-5), parental reflective functioning as measured by (RFQ), perspective taking as measured by the Barnes-Holmes Protocol (BHP), and relationship adjustment as measured by The Experiences in Close Relationships questionnaire (ECR).

Study description

Background summary

The negative influence of PTSD and more specifically deployment-related PTSD on family relationships has been well documented. Despite this fact, there is a dearth of empirically supported parenting programs addressing family functioning and PTSD within veteran populations. In particular, Interventions that are tailored to the needs of veteran families are relatively new and

under-studied.

Study objective

The main objective is to investigate the effectiveness of parenting programs addressing family functioning and PTSD within the Dutch veteran population. A secondary objective is to unravel and identify the role of emotion regulation and mentalisation within these veteran families and therefore within these interventions.

Study design

In this intervention study we use a controlled trial in a parallel design to study the effectiveness of both ADAPT (N = 45) and MFT (N = 45) in comparison to treatment as usual (N = 90), and a controlled trial to study the effectiveness and change-mechanisms between ADAPT and MFT.

Intervention

After Deployment, Adaptive Parenting Tools (ADAPT) is a program targeting families of children aged 4-12 with at least one parent who has deployed. ADAPT targets the improvement of parenting skills and emotion regulation. The group-based program is delivered in 14 weekly multifamily sessions of 2 hours each. Multi-family therapy (MFT) is a program targeting families with children of all ages and aims to elicit behavioural changes in family members through the restructuring of interactional patterns in families. The mentalization based model primarily focuses on enhancing mentalizing strengths and secondarily on emotion regulation. MFT runs for 10 days spread out in blocks of 2-3 days over 4 months.

Study burden and risks

MFT and ADAPT are widely used and considered to be *good practice* Their effectiveness has been established in a variety of populations. Therefore it is not likely that this therapy will be counterproductive. Participants in the wait-list comparison are closely monitored. The administration of questionnaires into symptoms of PTSD and emotion regulation are brief and already part of ROM. The administration of additional questionnaires and interview are not upsetting and well supervised. The risk and burden are therefore minimal. Participants potentially can benefit from this study as it immediately increases the availability of a parenting intervention. In the long term the study adds to the evidence for parenting programs designed for veteran families and opens the possibility to develop a stepped-care model for family interventions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. veteran with symptoms of deployment-related PTSD (score >38 on PCL-5)
2. with a partner and children who experience difficulties caused by the deployment-related PTSD (score > 2,5 on SCORE) and an attribution of the veteran family to the deployment related PTSD.

Exclusion criteria

1. severe alcohol and/or substance dependence, 2. abuse of partner or children, 3. mental retardation, 4. acute psychotic disorder, 5. acute suicidality, 6. severe personality disorders that prevent participation within a group-treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

Ethics review

Not approved	
Date:	17-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL60660.041.17