

NET with older adults.

NOVO: NET Onderzoek Voor ouderen.

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The treatment-effects of Narrative Exposure Rationale: In mental health services older adults represent a growing, but under-investigated population. However, trauma-related psychopathology for older adults represent robust, but often hidden...

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

Samenvatting

ID

NL-OMON26535

Bron

Nationaal Trial Register

Verkorte titel

In Dutch: NOVO

Aandoening

Post Traumatic Stress Disorder (PTSD) with older adults (> 55 years of age).
Posttraumatische stressstoornis (PTSS) bij ouderen (55+).

Ondersteuning

Primaire sponsor: Foundation Centrum '45
Rijnzichtweg 35, 2342 AX Oegstgeest
and

Nienoord 5, 1112 XE Diemen

Overige ondersteuning: Fonds Nuts Ohra
Postbus 229
1000 AE Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Clinician Administered PTSD Scale (CAPS);
2. Harvard Trauma Questionnaire (HTQ-16).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In mental health services older adults represent a growing, but under-investigated population. However, trauma-related psychopathology for older adults represent robust, but often hidden problems. In general, few psychotherapies are specially designed for older adults. This accounts all the more for traumatized older adults. Recently an exposure intervention with narrative elements is developed: Narrative Exposure Therapy or NET. In this research project NET will be evaluated to answer the question if NET is a feasible and effective trauma treatment for older adults.

Central question:

Has NET with older adults with PTSD an additional effect on 1. PTSD-symptoms and 2. comorbid depressive symptoms, quality of life and attribution of meaning, compared with an intervention which is focused on the present (Present Centered Therapy or PCT).

Objective:

With this study NET will be evaluated in its effects on older adults. The purpose is to show that NET is an effective evidence based individual intervention for older adults with trauma-related psychopathology. Based on this study a treatment protocol and specific out-patient trauma-services for elderly patients will be developed.

Study design:

The study will be a randomized controlled intervention study (RCT / Randomized Controlled Trial), repeated measures design, mixed methods.

Study population:

80 older adults from 55 years of age, with a diagnosis of PTSD, according to the DSM-IV classification (full criteria or sub threshold PTSD), patients of foundation Centrum '45. To be included as a subject, for him/her an individual outpatient trauma-focused psychotherapy has to be indicated and there is no need of assistance by an interpreter.

Intervention:

11 weekly session of 90 minutes consisting of NET. The control-group receives 11 weekly sessions of PCT : Present Centered Therapy (Schnurr e.a., 2005).

Main study parameters/endpoints:

The observed changes in PTSD-symptoms, measures with CAPS and HTQ-16. Secondary outcomes: the observes changes in comorbid depressive symptoms (BDI-II), quality of life (WHOQOL-bref and SES), attribution of meaning (MoW), general mental health (BSI-53), anger/agression (STAS), explanatory model and process-evaluation (short interview).

The participants will be enrolled in the Netherlands.

Doel van het onderzoek

The treatment-effects of Narrative Exposure

Rationale: In mental health services older adults represent a growing, but under-investigated population. However, trauma-related psychopathology for older adults represent robust, but often hidden problems. In general, few psychotherapies are specially designed for older adults. This accounts all the more for traumatized older adults. Recently an exposure intervention with narrative elements is developed: Narrative Exposure Therapy or NET. In this research project NET will be evaluated to answer the question if NET is a feasible and effective trauma treatment for older adults.

Hypothesis: Treatment-effects of Narrative Exposure Therapy with older adults are higher in comparison to the treatment-effects of Present Centered Therapy on symptoms of PTSD, on comorbid depressive symptoms, Quality of Life and Attribution of Meaning.

Onderzoeksopzet

1. Pretest;
2. Posttest;

3. Follow-up (4 months after completing the intervention);
4. Instruments: Mentioned under primary and secondary outcomes.

Onderzoeksproduct en/of interventie

1. Narrative Exposure Therapy (NET);
2. Present Centered Therapy (PCT).

11 weekly session of 90 minutes consisting of NET. The control-group receives 11 weekly sessions of PCT : Present Centered Therapy (Schnurr e.a., 2005).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Older Adults from 55 years of age onwards, who fulfill the classification of PTSD (DSM-IV), full criteria of one less Avoidance criterium (CAPS). Diverse trauma-contexts, mostly complex

trauma.

For patients an individual traumafocused psychotherapy is indicated and patients speak sufficiently Dutch not to need an interpreter.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Dependence of abuse of drugs (MINI-Plus, appropriate section);
2. Minimal remittance should be 3 months;
3. Psychotic disorder (MINI-plus, appropriate section);
4. Manic or bipolair disorder (MINI-plus, appropriate section);
5. Serious depressive disorder with suicidal thoughts of psychotic symptoms (MINI-plus appropriate section);
6. Cognitive impairment or cognitive disorder (MMSE <20).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	03-04-2013
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 07-05-2013

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	NL3820
NTR-old	NTR3987
Ander register	Fonds Nuts Ohra / CCMO / CME LUMC : 1201-053 / NL 40757.058.13, P13.009 / OND1352440;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A