Towards a better trauma treatment for older adults:
From comparative research to actual implementation.

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a. By this research a treatment protocol for NET will be quantitatively and qualitatively evaluated on its effects. b. With the research findings it is possible to identify subgroups within the research population and indicate who benefits most from...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON39655

Source
ToetsingOnline

Brief title
NET WITH OLDER ADULTS

Condition

- Anxiety disorders and symptoms

Synonym
Psychotrauma; Post Traumatic Stress Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum 45 (Oegstgeest)

Source(s) of monetary or material Support: Fonds Nuts Ohra en Centrum '45

Intervention

Keyword: Older adults, Psychotherapy, RTC, Trauma

Outcome measures

Primary outcome

Primary research variables:

Symptoms and severity of PTSD: Clinician Administered PTSD Scale (CAPS) +

Harvard Trauma Questionnaire (HTQ-16)

Secondary outcome

Symptoms and severity of depression: Beck Depression Inventory (BDI-II);

Quality of life: WHO Quality of Life Assessment (WHOQOL-Bref);

Self-efficacy: Self Efficacy Scale (SES);

Attribution of meaning: Meaning of War Scale (MoWS);

Anger and aggression: State-trait Anger Scale (STAS);

Syndromes of pathology: Brief Syndrome Inventory (BSI-53);

Qualitative results of short interview (attribution of meaning, treatment

process)

Study description

Background summary

In mental health services older adults with trauma-related psychopathology present a growing population. According to recent research (Van Zelst, 2006)

the prevalence rate of Post Traumatic Stress Disorder (PTSD) among the older population in the Netherlands varies from 1% (full criteria) to 13% (subthreshold PTSD). The disorder is often associated with comorbid disorders and high usage of medical services. Patients with PTSD are often not recognized, incorrectly diagnosed and inappropriately treated. One can speak of robust but hidden health problems. Trauma-related psychopathology has severe impact on the quality of life. Effective trauma-treatment for older adults may enhance their health and wellbeing and diminish medical consumption. With effective trauma-treatment for older adults it is possible to develop a specific outpatient treatment setting for older adults short-term, protocol-driven interventions. In this way it will in many cases be possible to shorten treatment time and prevent clinical admission. Diminishing medical consumption may reduce expenses for mental health services and enhance the quality of life of this population.

For traumafocused psychotherapy, exposure (real-life or imaginary) is proven an effective treatment procedure and the treatment of choice (Multidisciplinaire richtlijnen voor angststoornissen, 2003, van Minnen, 2008). For older patients however, classical exposure procedures can present a major burdening of their emotional capacities (Multidisciplinaire richtlijnen voor angststoornissen, Addendum ouderen, 2008). What is more, Cognitive Behavior Therapy (CBT) and Eye Movement Desensitisation and Reprocessing (EMDR) are appropriate for treating one or few traumatic memories. Older adults may suffer from multiple traumatization and may have the need to put their experiences into order within a context of meaning. Narrative Exposure Therapy or NET (Schauer, Neuner & Elbert, 2011) is a technique for exposure, for multiple and/or sequential traumatization and combines exposure with attribution of meaning. Therefore NET seems more suitable as a trauma-treatment for older adults than classical CBT or EMDR. NET is a form of exposure therapy, based on recent theories of cognitive and emotional processing, in which narrative (autobiografic) elements are integrated. This treatment intervention is developed for adults and children in a context of emercency aid in post-conflict areas. Is this intervention also effective for older patients in the context of Dutch mental health care? To answer that question NET will be evaluated on its effects in a randomized controlled trial (RCT) with older patients with trauma-related psychopathology at Foundation Centrum *45. The experimental intervention (NET) will be compared with Present Centered Therapy (Schnurr e.a., 2005) as a control condition for the non-specific therapeutic elements. The measurements do not only apply to symptoms, but also to quality of life and attribution of meaning. It is expected that NET will constitute an effective part of future ambulatory treatment services for older patients with trauma-related psychopathology.

References:

Multidisciplinaire richtlijnen GGZ (2003). Multidisciplinaire richtlijn angststoornissen. Stuurgroep Multidisciplinaire Richtlijnontwikkeling GGZ.

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Minnen, A. van (2008). Wie durft? PhD-thesis. St. Radboud Universiteit, Nijmegen.

Schauer, M., Neuner, F. & Elbert, T. (2005). Narrative Exposure Therapy. A Short-term Intervention for Traumatic Stress Disorders after War, Terror or Torture. 2nd revised and expanded edition. Göttingen: Hogrefe & Huber Publishers.

Schnurr, P.P., Friedman, M.J., Engel, C.C. Foa, E.B., Tracie Shea, M., Resick, P.M., James, K.E., Chow, B.K. (2005). Issues in te design of multisite trials of psychotherapy: VA Cooperative Study No. 494 as an example. Contemporary Clinical Trials 26 (2005) 626-636. Elsevier Inc.

Zelst, van W.H. (2006). Posttraumatic Stress Disorder in late life. Groningen, The Netherlands.

Study objective

a. By this research a treatment protocol for NET will be quantitatively and qualitatively evaluated on its effects.
b. With the research findings it is possible to identify subgroups within the research population and indicate who benefits most from the NET treatment protocol.
c. Based on this research adaptations in the existing protocol may be proposed to make a better fit of NET for older patients. If necessary the intervention will be adapted to specific sub-groups.
d. This research will enable us to develop an ambulatory setting for short-term trauma-treatments for older patients.
e. This research will enable us to develop a treatment manual in Dutch for NET and to offer training in working with NET.

Study design

The study will take place at Foundation Centrum '45, the national Dutch treatment centre for psychotrauma following war, persecution and violence and Sinai Centre, Jewish Mental Health institution. The participants are older adults (>55 years of age), for whom individual ambulatory traumafocused treatment has been indicated.
A sample size of N=80 (N=40 participants for the experimental condition and N=40 participants for the control condition) is estimated large enough for finding moderate effect sizes and comparing the results with the findings of other research on NET. For research ends a NET-protocol will be developed, based on the general treatment manual of NET (Schauer, Neuner & Elbert, 2011). Besides, a protocol for PCT (Bernardy et al., 2003) will be followed. The

participants are assigned at random to 11 sessions of one of both interventions (each N=40). Before the main study is started, the research procedure and both protocols will be tested on feasability in a pilot study. This study will have a quantitative and a qualitative character. In the qualitative part content analysis and form analysis (MAXQDA) will be used. The interviews will consist of eight standardized questions. In the quantitative part a repeated measures design with two groups will be used. The participants will be randomly assigned to one of two interventions: the experimental condition or the control-condition. For assigning the participants a computer-program will be used of single treatment allocation with randomly permuted blocks (www.randomization.com). Measures will be taken to safeguard blinding for the researchers during assessments. The two groups will be compared on different moments. For each participant there will be four measurements: the clinical interview at inclusion, measurements before and after treatment and one follow-up measurement at four months after completing the intervention.

Intervention

Narratieve Exposure Therapy (NET) is a form of exposure therapy, based on recent theories of cognitive en emotional processing, in which narrative (autobiografical) elements are integrated. NET (Schaer, Neuner & Elbbert, 2011) is een short-term individual intervention (four to fifteen sessions), in which patients with posttraumatic stress symptoms look back on their life trajectory together with their therapist. There is attention for positive and adverse events and experiences. Exposure takes place for the traumatic memories; in this process the therapist supports the patient in an active and directive way. Positive memories are honoured as well. This approach seems suitable to multiple traumatic memories and combines exposure with attribution of meaning. The resulting narrative is documented and can be used by the participant as a witness document of important life experiences. In Foundation Centrum *45 NET is performed on a regular basis with adults as individual traumafocused psychotherapy with good results.

The NET-treatment condition exists of 11 weekly sessions of 90 minutes duration. The Present Centered Therapy (Schnurr e.a., 2005) exists of 11 weekly sessions of 90 minutes duration. Both interventions start with one introductory sessions to establish a working alliance, to construct a shared explanatory model and to formulate treatment goals. The consent for videotaping the sessions will be discussed. The explanatory model of the patient is discussed and psychoeducation on PTSD en the treatment condition will be offered.

In the NET-treatment the NET-protocol will be followed. In the session following the introductory session an overview of the life trajectory will be made. In the following eight sessions exposure on the traumatic experiences will be offered. The last session is for looking back on the therapy, offering the document and saying goodbye. The next assessment will be announced. All

sessions will be videotaped, with written consent of the participant. The NET-sessions are performed by health-care psychologists, psychotherapists or clinical psychologists,all with the Dutch professional registration (BIG), with the assistance of the research assistant. A manual for the therapists will be developed. In the manual the therapist may find information about the research-process and guidelines about the content of treatment. All NET-therapists will be trained in the NET-method. This training will be offered by the NET-team that developed the method or by colleagues who are experienced NET-therapists. All NET-therapists will have fulfilled at least an elementary training. Control of protocol adherence will take place with the help of the videotapes and a reliability-scale for NET.

In the control-condition the PCT-protocol (Bernardy et al., 2003) will be followed. After the introductory session participants continue with nine sessions of Present Centered Therapy. The last session is for looking back on the therapy and saying goodbye. All sessions will be videotaped, with written consent of the participant. A manual for the therapists will be developed. In the manual the therapist may find information about the research-process and guidelines about the content of treatment. All PCT-therapists will be trained in the PCT-method. This training will be offered by therapists who are familiar with this method. The Present Centered Therapy adresses current interpersonal problems but avoids a trauma focus. Control of protocol adherence will take place with the help of the videotapes and a reliability-scale for PCT

References:

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Schnurr, P.P., Friedman, M.J., Engel, C.C., Foa, E.B., Tracy Shea, M., Resick, P.M., James, K.E., Chow, B.K. (2005). Issues in the design of multisite clinical trials of psychotherapy: VA Cooperative Study no. 494 as an example. Contemporary Clinical Trials 26. 626-636.

Study burden and risks

Risks are prevented by application of the criteria of exclusion. Furthermore, by taking informed decisions about the criteria of inclusion under medical-psychiatric supervision
and by performing the research treatments by qualified professionals with adequate training and supervision
and well-controlled treatment protocolls.

Burden:
At indication the question will be included if a patient fulfills the criteria of inclusion. Is this the case, he/she is asked to participate at the moment of the regular advisory session. The information is offered by the researcher or his assistant. The written information about the research will be offered for informed consent. This information will need 30 minutes at its most.

Patients who decide not to participate are offered a regualr and suitable treatment at Foundation Centrum '45. Patients may need deliberation time. Seven to ten days seems reasonable. Patients who decide, after written consent, to participate will fill out extra questionnaires. Patients will be assigned at random to one of two conditions: NET or PCT.

Each possible participant of the research will perform a clinical interview before the baseline measurement. In this clinical interview the criteria of exclusion are tested. This clinical interview will take 140 minutes. If necessary the patients will be supported by a research assistant.

Each treatment consists of eleven weekly sessions of 90 minutes duration. Before treatment (baseline), after the last session and four months after completing the intervention there will be a measurement. After the last measurement patients can discuss a possible follow-up treatment with their therapist. Who decides, for whatever reason, to finish participation in the research before completing the research-treatment, can continue his/her treatment in a different way.

So the burden for participants consists of information (30 minutes at most), the clinical interview (140 minutes), three measurements (each about 180 minutes) and a research intervention (eleven sessions of 90 minutes). If necessary assistance for the measurements will be offered, but in such a way that blinding of the researchers will be safeguarded.

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

Patients of Foundation Centrum '45 and Sinai Centre, older than 55 years of age, with a DSM-IV classification of (full or subthreshold) Post Traumatic Stress Disorder and a treatment indication of individual outpatient trauma focused Psychotherapy, without the need for assistance of interpreters

Exclusion criteria

Substance dependence
Remittance of substance dependence should be at least 3 months;
Psychotic disorder
Current manic or bipolar disorder
Severe depressive disorder (with suicidal or psychotic symptoms)
Cognitive impairments or cognitive disorder;

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-09-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL40757.058.13