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Screening and personality-aspects in post-traumatic stress disorder (PTSD) - substance use disorder patients

Submission date	Recruitment status	[ ] Prospectively registered
01/12/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/02/2009	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL24822.044.08

Study information

Scientific Title
A study on the psychometric qualities of post-traumatic stress disorder (PTSD) screeners and the role of personality (measured by the NEO Five-Factor Inventory [NEO-FFI]) in patients with the comorbid diagnosis of PTSD and substance use disorder (SUD)

Study objectives
1. What are the sensitivity and specificity of the Self Inventory List (Zelf inventarisatie lijst [ZIL]) and the post-traumatic stress disorder (PTSD) section of the Mini-International Neuropsychiatric Interview Plus (MINI-PLUS) as a screening instrument for PTSD in substance use disorder (SUD) patients?
2. What are the personality profiles for patients with the comorbid diagnosis of PTSD-SUD?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Testing Committee (METC) of Medisch Spectrum Twente, approved in November 2008 (ref: NL 24822.044.08).

Primary study design
Observational

Study design
Observational cross-sectional study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Post-traumatic stress disorder, substance use disorder

Interventions
This observational cross-sectional study examines whether patients in four addiction centres meet criteria for PTSD as well as criteria for SUD. Participants will be asked to complete the following assessments in two days:

Day 1:
1. Clinical Interview for PTSD (Klinische Interview voor PTSS [KIP])
2. ZIL
3. M.I.N.I. Plus (PTSD section)

Day 2:
4. Depression Anxiety Stress Scales (DASS)
5. Composite International Diagnostic Interview (CIDI) - Substance Abuse Module (CIDI-SAM)
6. Traumatic Experiences Questionnaire (Vragenlijst Belastende Ervaringen [VBE])
7. European Addiction Severity Index (EuropASI)
8. NEO Five-Factor Inventory (NEO-FFI)
9. Twenty-Item Toronto Alexithymia Scale (TAS-20)
10. Bermont-Vorst Alexithymia Questionnaire (BVAQ)
11. Pictorial Representation of Illness Measure (PRISM)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Sensitivity and specificity of ZIL and MINI plus (PTSD section), with KIP as gold standard
2. Difference between the NEO FFI profiles of the group PTSD-SUD and the group SUD-PTSD

Key secondary outcome(s)
1. History of several kinds of trauma, severity and time-course are carefully traced by VBE. Comparison will be made between groups that differ in the order of onset of the comorbid disorders, with regard to various outcomes of VBE (nature of trauma, duration, severity, age at onset).
2. Psychometric qualities of DASS in detecting PTSD in relation to other instruments (KIP, ZIL, M.I. N.I.-plus)
3. Alexithymia, assessed by TAS-20 and BVAQ

Completion date
15/06/2009

Eligibility

Key inclusion criteria
1. Patients who are at least 18 years old, both males and females
2. Patients of addiction treatment centres who are inpatient for at least 4 weeks
3. Patients who meet the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (with text revision) (DSM-IV-TR) criteria for Substance Use Disorder

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Inadequate level of the Dutch language
2. Severe cognitive impairment or damage
3. Severe (self) destructive behaviour

If a practitioner declares the patient is incapable of participation, the patient will be excluded.

Date of first enrolment
15/11/2008

Date of final enrolment

15/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Keulenstraat 3
Deventer
Netherlands
7418 ET

Sponsor information

Organisation
Tactus Addiction Care Centre (Tactus Verslavingszorg) (Netherlands)

ROR
https://ror.org/00v0vvh64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This study is funded by the following four addiction centres:

Funder Name
Tactus Addiction Care Centre (Tactus Verslavingszorg) (Netherlands)

Funder Name
IrisZorg (Netherlands)

Funder Name

GGZ Noord en Midden Limburg (Netherlands)

Funder Name
Novadic Kentron (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration