

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Hein de Haan

Contact details

Keulenstraat 3
Deventer
Netherlands
7418 ET

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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).

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

15/11/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

Keulenstraat 3

Deventer

Netherlands

7418 ET

Sponsor type

Hospital/treatment centre

Website

<http://tactus.nl>

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**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration