### Trial Description

#### Title

Symptom management in complex post-traumatic stress disorder, view and experience of patients and their relatives: A mixed methods approach

#### Brief Summary in Lay Language

The purpose is to describe specific patient characteristics, levels of symptom burden and perspectives of adult inpatients with a complex posttraumatic stress disorder and their relatives in relation to their experiences, needs, facilitators of and barriers to symptom management.

#### Brief Summary in Scientific Language

The purpose of this mixed methods study with a sequential exploratory design, is to describe specific patient characteristics, levels of symptom burden and perspectives of adult inpatients with a complex posttraumatic stress disorder and their relatives in relation to their experiences, needs, facilitators of and barriers to symptom management.

### Organizational Data

- DRKS-ID: **DRKS00012268**
- Date of Registration in DRKS: **2017/04/21**
- Date of Registration in Partner Registry or other Primary Registry: [--]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
  - (leading) Ethics Committee Nr.: **BASEC-NR 2015-00096**, Kantonal Ethikkommission Zürich, Stampfenbachstrasse 121, 8000 Zürich, Schweiz

### Secondary IDs

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**PLEASE NOTE: This trial has been registered retrospectively.**
Health condition or Problem studied

- ICD10: F43.1 - Post-traumatic stress disorder

Interventions/Observational Groups

- Arm 1: The data basis for the quantitative part comprises data which are already collected during the regular inpatient treatment by the practitioner (psychologist or psychiatrist) and fed into a hospital-internal database. Time of measurement is the during entry period for inpatient treatment. Collected are the socio demographic data through of a clinical questionnaire, symptomdata using the symptom inventory Inventory®, Becks-Depression-Inventory®, health questionnaire SF-12® and the Impact of Events Scale - Revised. Patients who meet the criteria are during the inpatient treatment additionally diagnosed using the ICD-11 trauma questionnaire. Patients and relatives will be interviewed through a semi-structured interview on symptom management and their experience in everyday life.

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Other
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Supportive care
- Assignment: Single (group)
- Phase: [---]*
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

The socio demographic data through of a clinical questionnaire, symptomdata using the symptom inventory Inventory®, Becks-Depression-Inventory®, health questionnaire SF-12®, the Impact of Events Scale - Revised and through the ICD-11 trauma questionnaire.

Secondary Outcome

The symptom management in the everyday life, the experience of the patients, as well as the experience of a corresponding relative are going to be collected.
through semi-structured interviews.

Countries of recruitment

- CH Switzerland

Locations of Recruitment

- Medical Center integrierte Psychiatrie Winterthur, Winterthur

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2017/01/01
- Target Sample Size: 100
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: 65 Years

Additional Inclusion Criteria

- Age between 18 - 65 years
- Diagnosis of a cPTSD
- Outpatient processing is not possible
- good good spoken knowledge of German
- Participation by relatives
- First inpatient treatment

Exclusion criteria

- acute or latent unrecognizable suicidality
- a main diagnosis other than cPTSD
- endangerment of self and others

Addresses

- Primary Sponsor
Primary Sponsor

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Fax: [---]*
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Contact for Scientific Queries

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Telephone: 0041798196834
Fax: [---]*
E-mail: manuel.stadtmann at uni-wh.de
URL: http://www.uni-wh.de/

Sources of Monetary or Material Support

Institutional budget, no external funding (budget of sponsor/PI)

Integrierte Psychiatrie Winterthur
Wieshofstrasse 104
8400 Winterthur
Switzerland

Telephone: [---]*
Fax: [---]*
Institutional budget, no external funding (budget of sponsor/PI)

Integrierte Psychiatrie Winterthur
Wieshofstrasse 104
8400 Winterthur
Switzerland

Telephone: [---]*
Fax: [---]*
E-mail: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2017/12/31

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) Ethikvotum
- Trial results Symptom management in complex post-traumatic stress disorder (ICD-11), view and experience of patients and their relatives: a mixed methods approach (Research Proposal)
- Trial results Proposed ICD-11 complex posttraumatic stress disorder, characteristics and symptoms of adults in an inpatient psychiatric setting: A descriptive study

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.