

## Trial Description

### Title

**Prevention of aggressive behavior occurring in psychotic disorders by complex intervention in outpatient setting**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The study focusses on patients with psychotic disorders with compulsory admission because of aggressive behavior against others. After the compulsory hospital stay patients get an outpatient treatment of six month consisting of a complex intervention. The interventions consist of several nonpharmacological treatments all adopted for the special needs of these patients with aggression. Treatment occurs individualized in a group and in a personal setting. The aim is to avoid further compulsory admissions. The project addresses patients with psychotic disorders and hospitalization by law because of dangerous behavior against others. A special treatment option of psychotherapy and sociotherapie etc. is offered for them in a group and single setting and of six month duration. The treatment modules are focussed on the special needs of this group, and are applied individualized.**

**The rate of rehospitalization of the treatment group is compared with rate of rehospitalization of a matched comparison group (artificial control group) out of routine data, who did not get any special treatment but treatment as usual.**

### Brief Summary in Scientific Language

**The aim is to optimize the treatment of patients with diagnoses of schizophrenia or bipolar disorders and dangerous / aggressive behavior after a compulsory treatment. Patients with illness related dangerous behavior or aggression as defined by German law have a higher risk to become forensic patients in future. The intervention focusses on the risk of a forensic development and combines treatment options from the forensic aftercare and guideline treatment of general psychiatry.**

## Organizational Data

- DRKS-ID: **DRKS00003738**
- Date of Registration in DRKS: **2012/05/03**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **3781 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F20.0 - Paranoid schizophrenia**
- ICD10: **F31.0 - Bipolar affective disorder, current episode hypomanic**
- ICD10: **F31.1 - Bipolar affective disorder, current episode manic without psychotic symptoms**
- ICD10: **F31.2 - Bipolar affective disorder, current episode manic with psychotic symptoms**
- ICD10: **F31.6 - Bipolar affective disorder, current episode mixed**
- ICD10: **F31.8 - Other bipolar affective disorders**
- ICD10: **F25 - Schizoaffective disorders**

## Interventions/Observational Groups

- Arm 1: **individualized complex interventions outpatient setting, 6 month**
- Arm 2: **treatment as usual outpatient treatment 6 months**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
-

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Allocation: **Non-randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: [---]\*

Control: **Other**

- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Aim: avoidance of compulsory admissions; catamnesis 6 month, Outcome rate of further compulsory admissions during 6 month after treatment phase**

### Secondary Outcome

**improvements in psychopathology and social functioning, measured by standardized scales (PANSS, GAF) at the timepoints before intervention, after intervention and 6 months after end of intervention.**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- University Medical Center **Klinik und Poliklinik f. Psychiatrie u. Psychotherapie der HHU, Düsseldorf**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/24**
- Target Sample Size: **79**
- 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

**former compulsory admissions concerning the local law and illness related aggressive or dangerous behavior against others; diagnosis of schizophrenia, schizoaffective or bipolar disorder, age between 18 and 65, written informed consent, actual voluntary treatment**

### Exclusion criteria

**difficulties in German language**

### Addresses

#### ■ Primary Sponsor

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#### ■ Contact for Scientific Queries

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Ms. Dr. Dipl. Psych. Nicole Frommann**

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### Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Ministerium für Gesundheit, Emanzipation Pflege und Alter des Landes**

**Nordrhein-Westfalen**

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**40213 Düsseldorf**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

### Trial Publications, Results and other documents

\* 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.