

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Evaluation of an integrated care program for schizophrenia**

### Trial Acronym

**[---]\***

### URL of the trial

**<http://www.evaluation-schizophrenie.de/>**

### Brief Summary in Lay Language

**Schizophrenia is one of the most costly psychiatric disorders, compared with the direct and indirect costs of common somatic diseases, and therefore a major challenge to health care system. Inpatient care has been identified as primary driver of direct treatment costs (Wobrock et al. 2006).**

**A regional German social health insurance fund (AOK Lower Saxony) started a tender procedure calling for proposals to manage integrated care for their members in Lower Saxony suffering from schizophrenia.**

**A management company, an independent affiliate of the pharmaceutical company Janssen-Cilag, won the EU-wide bidding and was instructed to implement their integrated care program for AOK patients suffering from schizophrenia in this federal state of Germany. This transfers the responsibility and budget to ensure the quality of care. In addition, the management company jointly organized with the AOK Federal Association and the AOK Lower Saxony the scientific evaluation. In Lower Saxony, therefore, specialized psychiatric nurses, office-based psychiatrists, community mental health services, hospitals and other outpatient and inpatient supply services work together in an interdisciplinary and cross-sectoral approach. An independent evaluation of this treatment approach of integrated schizophrenia care is performed jointly by the Universities of Duisburg-Essen, Göttingen and Bremen.**

**In this study schizophrenia patients receiving the integrated care, the intervention group (IG), are compared to patients under routine care conditions treated by the same physician (first control group, CG 1). A second control group (CG 2) of patients treated by office-based psychiatrists not participating in the integrated care program will be recruited and their data compared to the two other groups. This is a prospective cohort study with internal and external control group as an observational study. Cost-effectiveness and cost-utility analyzes are performed at the same time. The aim of this study (scientific evaluation of the AOK Lower Saxony integrated care program) is a comparison of schizophrenic patients participating in the integrated care program and those receiving usual care.**

### Brief Summary in Scientific Language

**Schizophrenia is one of the most costly psychiatric disorders, compared with the direct and indirect costs of common somatic diseases, and therefore a major challenge to health care system. Inpatient care has been identified as primary driver of direct treatment costs (Wobrock et al. 2006).**

**A regional German social health insurance fund (AOK Lower Saxony) started a tender procedure calling for proposals to manage integrated care for their members in Lower Saxony suffering from schizophrenia.**

**A management company, an independent affiliate of the pharmaceutical company Janssen-Cilag, won the EU-wide bidding and was instructed to implement their integrated care program for AOK patients suffering from schizophrenia in this federal state of Germany. This transfers the responsibility and budget to ensure the quality of care. In addition, the management company jointly organized with the AOK Federal Association and the AOK Lower Saxony the scientific evaluation. In Lower Saxony, therefore, specialized psychiatric nurses, office-based psychiatrists, community mental health services, hospitals and other outpatient and inpatient supply services work together in an interdisciplinary and cross-sectoral approach. An independent evaluation of this treatment approach of integrated schizophrenia care is performed jointly by the Universities of Duisburg-Essen, Göttingen and Bremen.**

**In this study schizophrenia patients receiving the integrated care, the intervention group (IG), are compared to patients under routine care conditions treated by the same physician (first control group, CG 1). A second control group (CG 2) of patients treated by office-based psychiatrists not participating in the integrated care program will be recruited and their data compared to the two other groups. This is a prospective cohort study with internal and external control group as an observational study. Cost-effectiveness and cost-utility analyzes are performed at the same time. The aim of this study (scientific evaluation of the AOK Lower Saxony integrated care program) is a comparison of schizophrenic patients participating in the integrated care program and those receiving usual care.**

## Organizational Data

- DRKS-ID: **DRKS00003711**
- Date of Registration in DRKS: **2012/07/31**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **20/05/11** , **Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F20 - Schizophrenia**

## Interventions/Observational Groups

- Arm 1: **All new patients of physicians participating in the evaluation which are enrolled in the integrated care will be included in the IG of the evaluation if they signed the informed consent form.**
- Arm 2: **Psychiatric specialists participating in the integrated care are asked to include those patients not interested in integrated care to be recorded for the CG 1.**
- Arm 3: **Psychiatric specialists not participating in the integrated care will be asked to take part in the evaluation. The patients receiving the standard therapy with physicians not participating in the integrated care will serve as the CG 2.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**days of psychiatric inpatient treatment after twelve month**

### Secondary Outcome

- **number of occupant days or days of hospitalisation** •

**psychiatricinpatientreadmission**



- **therapy monitoring for patients with long-term medication**
- **treatment of comorbidity of psychosis and addiction**
- **cooperation with the general practitioner (GP)**
- **involvement of family members in the therapeutic process**
- **involvement of self-help groups in the treatment concept**
- **comprehension of aspects of professional reintegration in the treatment concept**
- **comprehension of psychoeducational programmes in the treatment concept**
- **24h-contact-person for crisis situation**
- **professional assessment of quality circle and treatment conference of the integrated care**
- **professional assessment of using relational therapists in the integrated care**
- **quality of life**
- **patient satisfaction**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- **Doctor's Practice Land Niedersachsen**

## Recruitment

- **Planned/Actual: Actual**
- **(Anticipated or Actual) Date of First Enrollment: 2012/06/18**
- **Target Sample Size: 480**
- **Monocenter/Multicenter trial: Multicenter trial**
- **National/International: National**

## Inclusion Criteria

- **Gender: Both, male and female**
- **Minimum Age: 18 Years**
- **Maximum Age: no maximum age**

## Additional Inclusion Criteria

- **currently treated patients suffering from schizophrenia (GM-ICD 10 F20)**
- **age  $\geq$  18 years in 2009**
- **insured by AOK since 1-1-2009**
- **written informed consent**
- **hospitalized due to schizophrenia (GM-ICD 10 F20) as primary or secondary**

**diagnosis at least between 1-1-2005 and 31-12-2009 and/or being in continuous outpatient treatment due to schizophrenia since at least 2009**

### Exclusion criteria

- **insufficient knowledge of the German language**
- **intellectually and linguistically unable to answer the questionnaires or participation in an interventional study**
- **hospitalized for more than 4 weeks as a result of a major somatic condition during the last 12 months.**

### Addresses

#### ■ Primary Sponsor

**Lehrstuhl für Medizinmanagement  
Universität Duisburg-Essen  
Mr. Prof. Jürgen Wasem  
Schützenbahn 70  
45127 Essen  
Germany**

Telephone: **02011834072**

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

#### ■ Contact for Scientific Queries

**Lehrstuhl für Medizinmanagement  
Universität Duisburg-Essen  
Ms. Dr. Sarah Mostardt  
Schützenbahn 70  
45127 Essen  
Germany**

Telephone: **02011833180**

Fax: [---]\*

E-mail: **sarah.mostardt at medman.uni-due.de**

URL: [---]\*

#### ■ Contact for Public Queries

**Lehrstuhl für Medizinmanagement  
Universität Duisburg-Essen  
Ms. Linda Kerkemeyer  
Schützenbahn 70  
45127 Essen  
Germany**

Telephone: **02011834027**

### Contact for Public Queries

**Lehrstuhl für Medizinmanagement  
Universität Duisburg-Essen  
Ms. Linda Kerkemeyer  
Schützenbahn 70  
45127 Essen  
Germany**

Telephone: **02011834027**

Fax: [---]\*

E-mail: **linda.kerkemeyer at medman.uni-due.de**

URL: [---]\*

### 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.)**

**AOK Bundesverband  
10178 Berlin  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**I3G  
Johnson & Johnson Platz 1  
41470 Neuss  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**AOK Niedersachsen  
Hildesheimer Str. 273  
30519 Hannover  
Germany**

Telephone: [---]\*

DRKS-ID: **DRKS00003711**

Date of Registration in DRKS: **2012/07/31**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

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

**AOK Niedersachsen  
Hildesheimer Str. 273  
30519 Hannover  
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.