

Assertive outreach for people with schizophrenia in Germany

Submission date 01/12/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/01/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/04/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The German mental health system often lacks the ability to provide integrated and intensified outpatient care for people with severe mental illness. Assertive Outreach (AO), an approach for an intensive, community-based health care delivery, could help to overcome some of the deficits. A model of AO treatment in which office-based psychiatrists collaborate with ambulatory nursing services to provide a complex model of intensive homecare is currently being used in rural areas of Lower Saxony, Germany. The aim of this study is to investigate the effectiveness and efficiency of this model for adult patients suffering from schizophrenia, a severe long-term mental health condition.

Who can participate?

Patients aged 18 or older with schizophrenia

What does the study involve?

Patients receiving AO are compared to patients who are not eligible for AO because this treatment model is not reimbursed by their health insurance (they receive treatment as usual). The observation period for each patient spans over 12 months with assessments every 3 months for healthcare use and every 6 months for all other parameters (psychopathology, level of functioning, patient satisfaction with care and healthcare costs).

What are the possible benefits and risks of participating?

It is hoped that patients receiving AO require fewer days of hospital treatment than patients receiving treatment as usual. The findings from the study will be of great help for the further development of mental healthcare in Germany.

Where is the study run from?

Leuphana University Lüneburg (Germany)

When is the study starting and how long is it expected to run for?

May 2011 to March 2012.

Who is funding the study?

The study is funded through European Funds for Regional Development and through the Federal State of Lower Saxony within the framework of the Innovation-Incubator at Leuphana University Lüneburg (Germany)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

DRKS00003351

Study information

Scientific Title

Comparing assertive outreach with standard care for people with schizophrenia in Germany: health care utilization, psychopathology and level of functioning after 12 months

Study objectives

Assertive outreach (AO) is superior to standard care for people with schizophrenia. Patients receiving assertive outreach use significantly fewer days of inpatient treatment than patients receiving standard care. In addition, AO leads to better clinical and functional outcomes, to greater patient satisfaction with care and lower health care costs compared to standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Commission & Medical Association in Lower Saxony (Ethikkommission bei der Ärztekammer Niedersachsen), 14/03/2011, ref: Bo/03/2011

Primary study design

Interventional

Study design

Multi-centred naturalistic quasi-randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

1. Assertive Outreach (with home care and case management provided by a mental health nurse, a 24-hour, seven days a week available crisis service, psychoeducation, an evidence informed treatment guideline and a strong collaboration between the psychiatrist and ambulatory nursing service)
2. Treatment as usual

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Number of days spent in inpatient psychiatric care measured with the German version of the Client Socio-demographic and Service Receipt Inventory (CSSRI, interview with the patient) at baseline (t0) and every three month within 1 year (t1-t4).

Key secondary outcome(s)

1. Psychosocial functioning, measured with the WHO-Disability Assessment Scale II (patient rating) and the Global Assessment of Functioning (physician rating) at baseline (t0) and after 6 month and 12 month (t2 and t4)
2. Psychopathology, measured with the Brief Psychiatric Rating Scale (physician rating) and a 2-item-version of the Alcohol Use and Drug Use Scale (patient rating) at t0, t2 and t4
3. Life satisfaction, measured with single item (11-point scale, patient rating) at t0, t2 and t4
4. Patient satisfaction with care, measured with the short version of the Patient Assessment of Chronic Care (patient rating) at t0, t2 and t4
5. Direct and indirect costs, measured with the CSSRI (interview) at t0-t4

Completion date

31/03/2013

Eligibility

Key inclusion criteria

Adult patients (18 years or older) with a clinical diagnosis of schizophrenia (F20) and moderate or severe impairments in the level of functioning rated by the physician using the global assessment of function scale (Global Assessment of Functioning (GAF) $\leq$ 60)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients with medium or severe cognitive impairments or organic mental disorder
2. Patients with insufficient language ability
3. Individuals who are unwilling or unable to give informed consent to the study participation
4. Patients who refuse Assertive Outreach

Date of first enrolment

03/05/2011

Date of final enrolment

31/03/2013

Locations**Countries of recruitment**

Germany

Study participating centre

Volgershall 1

Lueneburg

Germany

21339

Sponsor information**Organisation**

European Fund for Regional Development (Germany)

Funder(s)

Funder type

Government

Funder Name

European Funds for Regional Development (Germany)

Funder Name

Federal State of Lower Saxony (Germany)

Funder Name

Innovation-Incubator, Leuphana University Lueneburg (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2013		Yes	No