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Assertive outreach for people with schizophrenia in Germany

Submission date
01/12/2011

Recruitment status
No longer recruiting

Registration date
27/01/2012

Overall study status
Completed

Last Edited
12/04/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 Lueneburg (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 Lueneburg (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multi-centred naturalistic quasi-randomised controlled trial

Primary study design
Interventional

Secondary study design
Quasi-randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
03/05/2011

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) ≤ 60)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
536

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)

Sponsor details
Friedrichswall 1
Hannover
Germany
30159

Sponsor type
Government

Website
http://www.efre.niedersachsen.de

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

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

Study outputs

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