Trial Description

Title

IVPOWER - effectiveness and efficiency of contracts in integrative care from patients suffering serious mental illnesses in real surroundings with particular attention to improvement of empowerment and quality of life

Trial Acronym

IVPOWER

URL of the trial

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Brief Summary in Lay Language

Currently, different models for improvement of psychiatric care are tested. The focus of these projects is the improvement of quality of life and of the ability for independent living (empowerment) of patients suffering serious mental illnesses. This study is meant to evaluate different concepts of psychiatric care. The results of this study will contribute to better understanding of need for ambulatory and stationary psychiatric care and will contribute to development of current care concepts. The study takes place in five regions in Germany (Berlin, Dresden, Kiel, Munich, Solingen). In the context of this study patients and their relatives will be interrogated four times within two years (every 6 months). The questionnaires include information to health state, quality of life and empowerment of patients. Moreover, data to the utilization of medical and psychotherapeutic offers will be collected.

Brief Summary in Scientific Language

Focus of this project is the transregional analysis of effectiveness and cost-effectiveness of contracts for integrated care programs according to NWpG compared to treatment as usual in real surroundings in the following regions: Berlin, Dresden, Kiel, Munich and Solingen.
The main outcome criteria are the improvement of empowerment as well as improvement of patients' subjective quality of life.
Moreover, the consequences of NWpG contracts for integrated care programs on burden and quality of life of relatives and persons of reference will be evaluated.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00005111**
- Date of Registration in DRKS: **2013/07/26**
- 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.: **129/13 , Ethik-Kommission der Universität Ulm**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20-F29 - Schizophrenia, schizotypal and delusional disorders**
- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40-F48 - Neurotic, stress-related and somatoform disorders**
- ICD10: **F60-F69 - Disorders of adult personality and behaviour**

Interventions/Observational Groups

- Arm 1: **The integrated care-group consists of 250 patients (50 patients per region) with schizophrenic (F2 ICD-10), affective (F3 ICD-10) disorders or other serious mental illnesses, who enroll in the IV programme according to NWpG model within 6 months after start of study. The recruitment for the integrated care-group takes place during general registration to a program of integrated care according to the NWpG model.**
  In the context of this study patients will be interrogated four times, every 6 months. The questionnaires include information to health state, quality of life and empowerment of patients. Moreover, data to the utilization of medical and psychotherapeutic offers will be collected.
- Arm 2: **The control group consists of 250 patients (50 patients per region) with schizophrenic (F2 ICD-10), affective (F3 ICD-10) disorders or other serious mental illnesses, who meet the criteria for enrollment in the integrated care program according to the NWpG model, but who haven’t enrolled so far and who are not willing to enroll in an integrated care program during course of the study. The recruitment for the control group happens with aid of service providers for integrated care and of cooperating psychiatric health institutions.**
  In the context of this study patients will be interrogated four times, every 6 months. The questionnaires include information to health state, quality of life and empowerment of patients. Moreover, data to the utilization of medical and psychotherapeutic offers will be collected.
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Arm 3: **Relatives and close persons of reference of in arm 1 included patients (integrated care, target: 125 persons).**
In the context of this study relatives of patients will be interrogated four times, every 6 months. The questionnaires include information to the relationship to the patient, the relative's quality of life and his satisfaction as regards treatment and care.

- Arm 4: **Relatives and close persons of reference of in arm 2 included patients (treated as usual, target: 125 persons).**
In the context of this study relatives of patients will be interrogated four times, every 6 months. The questionnaires include information to the relationship to the patient, the relative's quality of life and his satisfaction as regards treatment and care.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Health care system**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

EPAS: change in empowerment total score over 18 months; measuring points: 0 month / 6 months / 12 months / 18 months

Secondary Outcome

Interrogation of patients: measuring points: 0 month / 6 months / 12 months / 18 months
Reduction in psychosocial and clinical impairment using HoNos
Improvement of subjective quality of life using WHO-QoL
Reduction of unmet needs for psychiatric and psychosocial services using CAN-EU
Increase in satisfaction with psychiatric treatment using ZuF8
Reduction of utilization of stationary and simultaneous increase in utilization of ambulatory medical and psychosocial services using CSSRI
Reduction of direct and indirect healthcare costs using CSSRI
Reduction of costs of recovering a “healthy” year of life (QALY) using EQ-5D ///
Interrogation of relatives and persons of reference: measuring points: 0 month / 6 months / 12 months / 18 months
Perception of burden related to support of patient suffering serious mental illness using IEQ

Subjective quality of life using WHO-QoL-BREF
Satisfaction with psychiatric treatment using ZuF8

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Psychiatrische Versorgungseinrichtungen, Berlin**
- other **Psychiatrische Versorgungseinrichtungen, Dresden**
- other **Psychiatrische Versorgungseinrichtungen, Schleswig-Holstein (Kiel, ...)**
- other **Psychiatrische Versorgungseinrichtungen, München**
- other **Psychiatrische Versorgungseinrichtungen, Rheinland (Solingen, ...)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/08/23**
- Target Sample Size: **750**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

The integrated care group consists of 250 patients (50 patients per region) with schizophrenic (F2 ICD-10), affective (F3 ICD-10) disorders or other serious mental illnesses, who enroll in a program for integrated care according to the NWpG model within 6 months after start of study. /// The control group consists of 250 patients (50 patients per region) with schizophrenic (F2 ICD-10), affective (F3 ICD-10) disorders or other serious mental illnesses, who meet the criteria for enrollment in the program for integrated care according to the NWpG model but who haven’t enrolled so far and who are not willing to enroll in an integrated care program according to the NWpG during course of the study. /// Relatives and close persons of reference of in study included patients, who are willing to take part at study.

Exclusion criteria

primary diagnosis of ICD-10 groups F0 – F1;
existence of a care level

Addresses

- **Primary Sponsor**

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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.)**

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  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/02/04**

Trial Publications, Results and other documents

- Paper **Stierlin, Annabel Sandra; Herder, Katrin; Helmbrecht, Marina Julia; Prinz, Stefanie; Walendzik, Julia; Holzmann, Marco et al. (2014b): Effectiveness and efficiency of integrated mental health care programmes in Germany: study protocol of an observational controlled trial. In: BMC Psychiatry 14, S. 163. DOI: 10.1186/1471-244X-14-163.**
- Paper **Stierlin, Annabel Sandra; Becker, Thomas; Schützwohl, Matthias; Kilian, Reinhold (2014): Integrierte Versorgung in der Psychiatrie - ein Versorgungskonzept auf dem Prüfstand. In: Manfred Wolfersdorf und Gerd Laux (Hg.): Forschungskongress der Fachkliniken der bayerischen Bezirke. Kloster Irrsee 2013. neue Ausg. Regensburg: Roderer, S, S. 154–170.**

** 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.*