Trial Description

Title

Integrated Care (IC) with or without Assertive Community Treatment (ACT): a 12-month open randomized single blind trial in patients with early psychosis with 6-month post intervention follow-up (ACCESS study)

Trial Acronym

ACCESS

URL of the trial

http://www.psychose.de

Brief Summary in Lay Language

Psychotic disorders are a severe burden for patients, relatives and the health system. New findings suggest that integrated care (IC) in the early course of illness (= early psychosis [EP]) is related to a better outcome. However, within the first 12-months after beginning treatment, 20% to 50% of patients interrupt treatment despite of need (= service disengagement [SD]). SD is directly related to poor long-term outcome, triggered by a high relapse rate with subsequent treatment resistance. A new effective intervention to prevent SD and to improve outcome is Assertive Community Treatment (ACT). ACT is a team treatment approach designed to provide community-based psychiatric treatment for persons with severe mental illnesses (SMI). Although it has proven to be a robust treatment model, little is known about the effects of ACT in EP. In Germany, ACT is still only implemented and studied in the University Psychosis Centre in Hamburg where it is available as a treament option by various health insurances (e.g., DAK, HEK, IKK, GEK). It has been awarded "as one of the most innovative medical treatment models in Germany". During the current trial, 122 EP patients will receive either IC with or without ACT for a period of 12 months. Patients will be randomly assigned to these two treatment groups. Researchers who will judge the treatment effects will be unaware of the group the individual patient has been assigned to. After the end of the treatment period, there will be additional evaluations for up to 6 months. Treatment will take place within two specialized early detection and interventions centers in Germany (Hamburg and Cologne). Success of an intervention is primarily measured by the time until patients discontinue treatment despite ongoing need. Further measures include improvements of symptoms, functioning, quality of life, medication adherence, patients' and relatives' satisfaction with care, cost-effectiveness, and stability of possible ACT-related improvements over 6-month without ACT. The study could serve as a reference for integrating ACT into routine treatment in Germany.

Brief Summary in Scientific Language

Psychotic disorders including schizophrenia, bipolar I disorder, or severe depression with psychosis are 3 of 10 illnesses causing the main contribution to the global burden of disease. New findings suggest that integrated care (IC) in the early course of illness (= early psychosis [EP]) is related to a better outcome. However, within the first 12-month after treatment initiation, 20% to 50% of

patients interrupt treatment despite of need (= service disengagement [SD]). SD is directly related to poor long-term outcome, triggered by a high relapse rate with subsequent treatment resistance. A new effective intervention to prevent SD and to improve outcome is Assertive Community Treatment (ACT). ACT is a team treatment approach designed to provide community-based psychiatric treatment for persons with severe mental illnesses (SMI). ACT has proven to be a robust model for people with SMI. However, it was neither studied specifically in psychotic disorders nor in EP, only once as part of IC, and never as continuous intervention with a psychotherapeutic approach. In Germany, ACT is still only implemented and studied in the University Psychosis Centre in Hamburg where it is disbursed by various health insurances (e.g., DAK, HEK, IKK, GEK) and awarded "as one of the most innovative medical treatment models in Germany". The trial "IC with or without ACT in patients with EP" is a 12-month randomized single blind trial with 6-month post-trail follow-up. Within two specialized early detection and interventions centers in Germany (Hamburg and Cologne), 122 EP patients will be randomly assigned to receive 12-month IC with or without ACT with a 6-month post-trial intervention of only IC. Primary outcome is the time to SD; secondary outcomes comprise improvements of symptoms, functioning, quality of life, medication adherence, patients' and relatives' satisfaction with care, cost-effectiveness, and stability of possible ACT-related improvements over 6-month without ACT. The study could serve as a reference trial for the widespread implementation of ACT in Germany.

Organizational Data

- DRKS-ID: **DRKS00000126**
- Date of Registration in DRKS: **2009/10/12**
- 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.: **PV3237 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-6516**
- Sponsor-ID: **ACCESS**

Health condition or Problem studied

- Free text: **Schizophrenia (DSM-IV-TR 295.xx)**
- Free text: **Schizophreniform disorder (DSM-IV-TR 295.40)**
- Free text: **Schizoaffective disorder (DSM-IV-TR 295.70)**
- Free text: **Delusional disorder (DSM-IV-TR 297.1)**
- Free text: **Psychotic disorder not otherwise specified (DSM-IV-TR 298.9)**
- Free text: **Bipolar I disorder (DSM-IV-TR 296.44; 296.54; 296.64)**

- Free text: **Major depression, single or recurrent episode, severe with psychotic symptoms (DSM-IV-TR 296.24; 296.34)**
- ICD10: **F20 - Schizophrenia**
- ICD10: **F21 - Schizotypal disorder**
- ICD10: **F25 - Schizoaffective disorders**
- ICD10: **F22.0 - Delusional disorder**
- ICD10: **F28 - Other nonorganic psychotic disorders**
- ICD10: **F29 - Unspecified nonorganic psychosis**
- ICD10: **F31.5 - Bipolar affective disorder, current episode severe depression with psychotic symptoms**
- ICD10: **F33.3 - Recurrent depressive disorder, current episode severe with psychotic symptoms**

Interventions/Observational Groups

- Arm 1: **Integrated Care with Assertive Community Treatment for a period of 12 months**
- Arm 2: **Integrated Care without Assertive Community Treatment for a period of 12 months**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Time to Service Disengagement: The primary outcome of the study will be the time to service disengagement within the 12-month intervention period. According to Schimmelmann et al. (2006) service disengagement (SD) is defined as present, if a study participant actively refused any contact with the treatment facility or is not traceable (after at least >= 5 attempts). Routinely, the ACT team will made extensive efforts to reengage patients by repeated telephone calls, letters to the participants and their families, and home visits throughout the entire intervention period. The date of last face-to-face contact between case managers in both

treatment arms (ACT or IC) and a particular disengaged participant will be regarded as the date of disengagement.
The primary statistical analysis will consist of a stratified log-rank test with time to service disengagement as the primary outcome variable with a type-I error of 0.05 two-sided, the strata being the two centers that participate. The sample size calculation was based on the assumption of a disengagement rate of 25% in the control group vs. 10% in the intervention group according to previous studies. For a fixed sample size design, this would require 2x61 patients to reach a power of 80% if one assumed a recruitment period of two years and a follow-up time of 18 months.

Secondary Outcome

Improvements of symptoms, functioning, quality of life, medication adherence, patients' and relatives' satisfaction with care, cost-effectiveness, and stability of possible ACT-related improvements over 6-month without ACT
For the comparison of dimensional secondary outcome measures across the observation period, i.e. symptoms, functioning, quality of life, medication adherence, service engagement, and satisfaction with care, a series of Mixed Models Repeated Measures (MMRM) analyses will be specified (Mallinckrodt et al. 2001, 2004). This likelihood-based repeated measures approach, which is similar to a repeated measure ANOVA, has proven to be superior to e.g. last observation carried forward ANOVA in simulation scenarios patterned after acute phase neuropsychiatric clinical trials (Mallinckrodt et al. 2001, 2004) and is actively employed in schizophrenia research (Kennedy et al. 2003). Health economics will be analyzed according to the method of Knapp et al. (2008) using Quality-Adjusted Life Years (QALYs).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/01/01**
- Target Sample Size: **122**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **18 Years**
- Maximum Age: **35 Years**

Additional Inclusion Criteria

Male or female, age 18 to 35, with sufficient command of German language. Meet definition for early psychosis: a. Either first or second admission (within 2 years of first admission) to in-patient or day patient unit for treatment of psychosis; b. DSM-IV TR criteria for Schizophrenia (295.xx), Schizophreniform disorder (295.40), Schizoaffective disorder (295.70), Delusional disorder (297.1), Psychotic disorder not otherwise specified (298.9), Bipolar I disorder (including 296.44, 296.54 and 296.64), and Major depression, single or recurrent episode, severe with psychotic symptoms (296.24 and 296.34); c. Positive psychotic symptoms for 4 weeks or more; d. Score of 4 or more (moderate to severe) on the PANSS (Kay et al. 1989) target item either for delusions (P1) or hallucinations (P3). Outpatients or inpatients; Able and willing to meet or perform study requirements and consent

Exclusion criteria

Diagnosis of following psychotic disorders according to DSM-IV TR: a. Alcohol or substance-induced psychosis (i.e. 291.3, 291.5, 292.xx: -.11 or -.12), b. Psychotic disorder due to a general medical condition (i.e. 293.0, 290.12, 290.20, 290.42, 293.89), c. Brief Psychotic Episode (298.8). Mental retardation (intellectual quotient < 70). Pregnancy.

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.)**

Finanzierung ist beantragt

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*