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Original article

Clinical and functional outcome of assertive outreach for patients with schizophrenic disorder: Results of a quasi-experimental controlled trial

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ABSTRACT

Background: The majority of studies support modern assertive health service models. However, the evidence is limited for parts of continental Europe, as well as for the pharmacological adherence outcome parameter.
Method: We conducted a quasi-experimental controlled trial including adult patients with a schizophreniform disorder and a maximum of 60 points on the Global Assessment of Functioning Scale (GAF). Interventions ($n = 176$) and controls (TAU, $n = 142$) were assessed every six-month within one year in 17 study practices in rural areas. Mental and functional state were rated using the Brief Psychiatric Rating Scale (BPRS) and the GAF. Functional limitations and pharmacological adherence were patient-rated using the WHO-Disability Assessment Schedule II (WHODAS–II) and the Medication Adherence Report Scale (MARS). We computed multilevel mixed models.
Results: The GAF and BPRS of both groups improved significantly, yet the increase in the intervention group was significantly higher. In contrast, patient-rated variables – WHODAS–II and MARS – neither showed a stable temporal improvement nor a difference between groups.
Conclusion: Our findings only partly support the investigated AO intervention, because of conflicting results between clinician- and patient-ratings. Accordingly, the benefits of AO need to be further evaluated.

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1. Introduction

Schizophrenia is among the leading disorders causing disability [39]. It is associated with relapse [33] and long-lasting negative effects on various life domains, such as impairments in psychological, social and occupational functioning [45], and somatic health [35], as well as with increased mortality compared to the general population [33]. Relapses and rehospitalisation are often related to poor adherence, which is estimated to occur in the majority of patients with schizophrenia within the course of their treatment [28]. These relapses are, in turn, suspected to cause illness progression and further psychosocial and biological harm [16]. Only 14–20% of the patients diagnosed with schizophrenia recover completely [33].

Against this background, it is evident that the requirements for an effective care exceed the mere treatment of the psychiatric symptoms. Instead, it is recommended that patients with severe mental illnesses like schizophrenia are treated within modern assertive community-based care systems. Depending on the concrete composition, these interventions are labelled Assertive Community Treatment, Intensive Case Management, Integrated Care, or Assertive Outreach (AO) [10,14]. Key components of all these interventions are flexible, team-based, assertive care delivery, small case-loads, regular home visits, crisis services, case management, psycho-education, and responsibility for health

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and social needs [49]. Assertive community-based models were developed in the 1970s in the US and subsequently implemented and evaluated in the US and the UK. Recently, nation-wide implementation processes have begun in The Netherlands and in Denmark [34,48], whereas for other parts of continental Europe only a few projects have been studied and reported on [7,18,22]. The latter holds true for Germany, where even though assertive community-based models are guideline recommended, care reality is dominated by a fragmented health care system consisting of independently working psychiatrists within the outpatient care [13]. To our knowledge, findings from only three German pilot projects for patients with schizophrenia in specific urban catchment areas have been published [24,25,40,41,44].

However, the need for modern assertive community-based models is supported by the majority of randomized-controlled trials and naturalistic studies with respect to objective (hospitalization, days hospitalized, independent living, contact to the health care system) and subjective outcome parameters [14,42]. Among the subjective parameters, functioning and psychopathology are among the most frequently studied. Regarding functioning, reviews and recent single studies favour assertive community-based models [6,14,18,25,42,48]. Despite the comparably large evidence base, the clinical meaning of the significant, yet relatively small changes is unclear [14]. Current evidence on psychopathology is also mainly in support of assertive models [3,6,15,18,25,42], yet conflicting results exist [1,48,46]. Finally, the last outcome parameter relevant in the present study, pharmacological adherence, was found to be a clinically important aspect, yet it is typically neglected in studies [14]. The few existing investigations show mixed results [4], some favouring assertive community-based models [25,42], whereas others do not [18,31]. Conflicting results were often explained by differences within design, setting, intervention, and control condition; namely treatment as usual within a specific region [9,23].

Given the limited available data, particularly on pharmacological adherence, as well as the regionally lacking evidence for rural parts of Germany, the present quasi-experimental trial aims to evaluate the effect of an already implemented AO model on the mentioned outcome parameters using patient- and clinician-ratings.

2. Materials and methods

2.1. Intervention and treatment as usual (TAU)

The investigated AO model is an approach to improve the outpatient care delivery in predominantly rural areas (Lower Saxony) by installing ambulatory psychiatric nursing services and standardising the collaboration between office-based psychiatrists and ambulatory psychiatric nurses. It is a real-life implemented AO intervention, which is adapted to the existing structures of the German health care system in rural areas. Within the context of an integrated care contract need-oriented case management, 24-h crisis service, home treatment and psycho-education is offered by psychiatric nurses, who meet regularly with the treating psychiatrist (i.e., the team leader within treatment conferences). At the beginning of the intervention, a treatment plan is developed for each patient. This plan is subsequently adapted as discussed within the treatment conferences. Another part of the intervention is a treatment guideline, which is binding to the service providers upon signing the integrated care contract. This guideline is used to assure fidelity. A management association (IVPNetworks GmbH), which contracted the statutory health insurance companies and the service providers, assisted with the implementation. The association also took care that service providers perform according to the treatment guideline.

The standard mental health care delivery in Germany (treatment as usual – TAU) is of high quality, but the system is fragmented. Health services, social care, and rehabilitation are financed through different funds. Outpatient medical care for severely mentally ill patients is mainly constituted of visits to office-based psychiatrists, who work as independent entrepreneurs. Team-based approaches within the community scarcely exist, and the cooperation of the office-based psychiatrists with other professions, as well as across sectors, is individually and regionally diverse. Possibilities of a prompt integration of additional resources to prevent or treat crises outside the hospital are limited [8]. In principle, case management functions could be performed by different professionals (e.g., social workers, outpatient clinics, or ambulatory nursing services), as it is legally established in Germany. Yet, these services are seldom standardised and only a minority of severely mentally ill patients receives case management in Germany [13].

2.2. Study design and population

Detailed descriptions of intervention and TAU, design, and instruments were published in the study protocol by Bramesfeld et al. [8]. We conducted a quasi-experimental controlled trial, where due to practical circumstances the implementation of the AO intervention backdated the beginning of the evaluation by a few months. The recruitment took place in the practices of participating psychiatrists from May 2011 to June 2012. Due to the earlier start of the real-life AO-implementation, a time difference of a few months between AO inclusion and study inclusion might have occurred with patients who were recruited in the very first months (1–2 months of recruitment: $n = 27$ AO patients, 1–3 months of recruitment: $n = 50$ AO patients). The allocation to intervention vs. control was determined by the health insurance affiliation of the patient. This quasi-experimental design was a pragmatic decision due to the fact that only two large health insurance companies held the integrated care contract required to receive AO. These two companies together insure about one third of the population of Lower Saxony. Insurants from various other health insurances formed the control group. We cannot completely rule out disparities between the insured populations, but a free choice of the insurance exists for more than 15 years and differences are likely to be decreasing. We included patients who were 18 years or older with a schizophreniform disorder (ICD 10 F2) and a maximum score of 60 on the Global Assessment of Functioning Scale (GAF). Prior to the inclusion into the study, all participants gave written informed consent. Information on the flow of participants is shown in Fig. 1. We could recruit 176 patients receiving AO and 142 patients receiving TAU in 17 participating study practices. Three assessments over the course of 1 year took place: baseline (t0), 6-month follow-up (t1) and 12-month follow-up (t2). The assessments consisted of various instruments completed by the treating psychiatrist and the patient, as well as a structured interview conducted by the practice assistant with the patient. Results regarding other relevant outcome parameters, such as in-patient days or cost-effectiveness will be reported elsewhere.

The trial was approved by the local ethics board and is registered as an International Standard Randomised Controlled Trial (ISRCTN34900108).

2.3. Clinician-rated instruments

The Brief Psychiatric Rating Scale (BPRS) [36] is a widely used instrument to measure current psychopathology (e.g., depression, anxiety, hallucinations, and suicidality), especially in patients with schizophrenia. It consists of 18 items and was completed by the treating psychiatrist following an appointment with the patient. Thereby, the presence and severity of different symptoms is judged

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