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#### The real-life effectiveness of psychosocial therapies on social autonomy in schizophrenia patients: Results from a nationwide cohort study in France



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#### ABSTRACT

The objectives of the present study were to describe the prescribing patterns for psychosocial therapies in routine clinical practice and to assess the impact of psychoeducation on symptoms and social autonomy of patients with schizophrenia. We used data from the nationwide French ESPASS observational cohort study including 5967 patients with schizophrenia, which provided data on exposure to psychosocial therapies from 4961 (83%) participants. Patients who initiated psychosocial therapy within the first 3 months of study onset (n=143) were compared to patients not subject to psychosocial therapy throughout follow up (n=4268), using parametric tests. Symptom severity and social autonomy at 6 months from baseline were compared between patients undergoing psychoeducation (n=117) and patients not subject to psychosocial therapy, matched (1:1) on propensity scores. Patients who initiated psychosocial therapy were significantly younger, more severely ill and used less often antipsychotic drugs than patients in the reference group. At 6 months, patients who initiated psychoeducation and their matched referents did not differ significantly in terms of symptom severity, but their level of improvement in social autonomy was significantly greater (p=0.005). In routine clinical practice, psychoeducation in addition to antipsychotic drugs provides some benefit among schizophrenia patients, particularly in terms of social autonomy.

#### 1. Introduction

Despite disagreement about recovery rates, remission in schizophrenia is now considered as an achievable objective of treatment. Remission encompasses both symptom remission and improvement of psychosocial aspects in patients' lives (e.g., well-being, quality of life). This distinction is important, as impairment in psychosocial aspects may persist beyond symptom remission and despite efficacious antipsychotic drugs (Jorgensen et al., 2015; Roe et al., 2011). Psychosocial therapies may modify self-experience and improve metacognition in patients with schizophrenia (Lysaker et al., 2011a, 2010). Several types of psychosocial interventions have been developed to improve the specific cognitive or functional impairment features of schizophrenia (Kern et al., 2009; Medalia and Choi, 2009; Patterson and Leeuwenkamp, 2008; Roder et al., 2011): social skills training (Kopelowicz et al., 2006), cognitive remediation therapy (McGurk et al., 2007; Wykes et al., 2011), cognitive behavioral therapy

(Jauhar et al., 2014; Jones et al., 2012; Morrison, 2009), psychoeducation (Lincoln et al., 2007), and family therapy (McWilliams et al., 2010), to name a few. These psychosocial therapies have demonstrated some benefit at cognitive and symptomatic levels for patients with schizophrenia: metacognition (Kopelowicz et al., 2006; Lysaker et al., 2011b), cognitive deficits (Wykes et al., 2011), thought disorders, or negative symptoms (Klingberg et al., 2011; Morrison, 2009), social autonomy (Cochet et al., 2006), prevention of relapse (Gumley et al., 2006). They might also improve patients' well-being (Penn et al., 2004) or adherence to medication (Barkhof et al., 2012).

However, the benefit of psychosocial interventions has been nearly exclusively assessed through Randomized Clinical Trials (RCTs) (Jauhar et al., 2014; Lincoln et al., 2007; Pilling et al., 2002; Wykes et al., 2011; Xia et al., 2011). Although RCTs are the gold standard for measuring the efficacy of medical interventions as provided under ideal conditions, it is often difficult to extrapolate findings to routine clinical practice (Depp and Lebowitz, 2007). RCTs of psychosocial therapies

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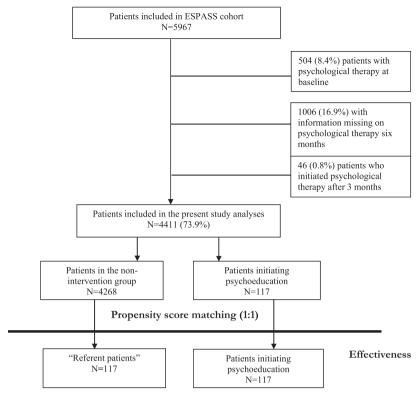


Fig. 1. Flowchart of patients included in the ESPASS study and in the study analyses.

usually take place in specialized centers for treatment of schizophrenia, where healthcare providers are highly trained clinicians and where human and technical resources are more numerous. Therefore, little is known about patients who actually receive psychosocial therapies in real life. In addition, participants enrolled in RCTs are carefully selected and homogeneous (Jones et al., 2012; Stirman et al., 2003). The question of generalization from results of RCTs is of particular importance for psychoeducation which involve several types of programs and practices. Also, psychoeducation may be easier to implement across psychiatric teams, as opposed to cognitive-based therapies. In contrast to RCTs, observational studies provide the opportunity to explore those patients undergoing psychosocial therapies in routine clinical practice. They also provide the opportunity to measure the impact of psychosocial therapies in a more heterogeneous sample of patients, hence extending the scope for generalization of study results (Fleischhacker and Goodwin, 2009).

The present study aimed to (1) describe the real-life prescribing patterns for psychosocial therapies among patients with schizophrenia, and (2) assess the impact of psychosocial therapies on schizophrenia symptoms and social autonomy in routine clinical practice, with a focus on psychoeducation. Based on previous data published on psychoeducation (Xia et al., 2011), we hypothesized that the improvement of schizophrenia symptoms and social autonomy would be higher in patients receiving psychoeducation.

#### 2. Materials and methods

Data were drawn from the "Enquête Sur les Prescriptions antipsychotiques et sur l'Autonomisation et la Socialisation des patients Schizophrènes" (ESPASS) cohort, a non-interventional, observational prospective cohort study including schizophrenia patients at the time of antipsychotic medication initiation or of a change in antipsychotic medication (Leguay et al., 2010; Limosin et al., 2008; Nordon et al., 2014).

After complete description of the study to the patients, verbal consent was obtained for all patients included. The study design was approved by the French National Order of Physicians ("Ordre National des Médecins") and the French commission on data computerization and personal freedoms ("Commission Nationale d'Informatique et des Libertés").

#### 2.1. Study participants

Between January 2005 and April 2006, 985 psychiatrists – 649 working in public settings and 336 working in private settings throughout France – included 5967 schizophrenia patients consecutively, on the following inclusion criteria: (a) age ≥18 years, (b) diagnosis of schizophrenia according to the Diagnostic and Statistical Manual of Mental Disorders criteria, fourth edition (American Psychiatric Association., 2000), (c) need for antipsychotic medication initiation or a change in antipsychotic medication in the normal course of care as decided by the psychiatrist, and (d) consent to participate. The investigators (psychiatrists) included their own patients when appropriate and all medical decisions were left at their discretion in order to adhere to real-life conditions and to maximize the scope for generalizing the results.

For the present study, we restricted the original ESPASS population to patients with available data on psychosocial therapy prescription at baseline and during follow-up. In addition, we excluded patients who had already received psychosocial therapy at baseline or who initiated the psychological intervention after the 3-month visit.

#### 2.2. Measures

Data was collected by the psychiatrists during the visit corresponding to recruitment (baseline) and in follow-up visits at 1 month, 3 months and 6 months.

#### 2.2.1. Intervention and outcome measures

The intervention of interest was the initiation of any psychosocial therapy. Patients who initiated psychosocial therapy within the first 3 months from study onset were identified as belonging to the "inter-

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