



Psychopathology, psychopharmacological properties, decision-making capacity to consent to clinical research and the willingness to participate among long-term hospitalized patients with schizophrenia



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ABSTRACT

Many studies discuss factors related to the decision-making capacity to consent to clinical research (DMC) of patients with schizophrenia. However, these studies rarely approached willingness to participate and the association between psychopharmacological properties (e.g., antipsychotic-induced side effects) and DMC. This study aimed to explore factors related to DMC and willingness to participate in patients with schizophrenia. All 139 patients with schizophrenia were assessed with the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and other measures. A linear regression model was used to find the predictors of MacCAT-CR scores. A logistic regression model was used for exploring the predictors of willingness to participate. Patients with more severe negative symptoms performed poorly in DMC outcomes. In addition, females, those with fewer years of education and reduced cognitive function are more likely to experience difficulties in decision-making. Forty-three subjects (30.4%) chose to participate. Patients with higher level of positive symptoms, longer length of stay, higher burden of anticholinergics and users of atypical antipsychotics were more likely to participate in a clinical study which aimed to “enhance cognition”. These findings suggest that research investigators should consider many variables for patients who require more intensive screening for impaired DMC.

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1. Introduction

Schizophrenia is a chronic debilitating disease affecting many domains of function, the core symptoms of which consist of impaired cognition; positive symptoms featuring hallucinations, delusions and loosening association; and negative symptoms including emotional apathy, social withdrawal and lack of drive (Crow, 1985; Gelder et al., 1996; Matza et al., 2006). Considerable attention has been devoted to decision-making capacities related to research (DMC) among schizophrenia patients, as these patients are noted to have more impaired DMC than nonpsychiatric comparison subjects (Cohen et al., 2004; Appelbaum, 2006; Jeste et al., 2006). To identify patients with impaired DMC necessitating further education and remediation is paramount; a useful screening

instrument with which to assess DMC is therefore needed for clinical practice and related research (Appelbaum, 2006). Thus, the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum and Grisso, 2001) which includes 4 components: understanding, appreciation, reasoning and expression of a choice, was developed to evaluate the DMC of subjects in clinical studies, and this rating scale has been commonly used in people with schizophrenia (Carpenter et al., 2000; Dunn et al., 2002; Moser et al., 2002; Stroup et al., 2005). Among schizophrenia patients, clinical psychopathology was determined to be related to DMC in numerous studies (Moser et al., 2002; Kovnick et al., 2003; Stroup et al., 2005), several of which found that negative symptoms—rather than positive symptoms—were significantly associated with the understanding scores of the MacCAT-CR (Moser et al., 2002; Stroup et al., 2005; Candilis et al., 2008). However, our pilot study found both positive and negative symptoms to be significantly associated with the understanding and appreciation scores of the MacCAT-CR (Lan et al., 2013). Nevertheless, methodologies were limited by the heterogeneity of

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subjects' characteristics (Stroup et al., 2005), relatively small sample sizes (Moser et al., 2002; Candilis et al., 2008), and a failure to use regression models to control for important related confounders, e.g., age and sex, in all previous research including our pilot study (Lan et al., 2013).

In addition to psychopathology, educational level has been found to be associated with DMC in individuals with schizophrenia (Dunn et al., 2006b; Candilis et al., 2008), though inconsistent results were present (Palmer and Jeste, 2006). In a study enrolling hospitalized patients with schizophrenia, the duration of hospitalization was found to have a negative association with DMC (Kovnick et al., 2003). Moreover, a number of studies have revealed that cognitive deficit is associated with impaired DMC (Stroup et al., 2005; Palmer and Jeste, 2006; Dunn et al., 2007; Palmer and Savla, 2007). Of particular interest, factors related to cognition and memory that might lead to impaired DMC, such as dosages and types of antipsychotics (Faber et al., 2012), dosages of benzodiazepine and dosages of anticholinergics (Mintzer et al., 2010), have not been explored in prior studies. It is worth investigating whether the pharmacological properties of psychotropic agents affect DMC among schizophrenia patients because further effective strategies concerning the recruitment of research subjects might be tailored to patients on different regimes of treatment.

Meanwhile, identifying factors associated with the decisions that participants make about whether to take part in a hypothetical study is an important step in providing useful clues in further studies designed to clarify subjects' concerns and avoid misunderstandings during the process of recruitment. One study reported that the willingness to participate in schizophrenia research differed between those with prior research experience and those without (Kaminsky et al., 2003). Prior studies found the willingness to take part in a clinical study was negatively associated with levels of the perceived risk of participation (Roberts et al., 2002; Dunn et al., 2009), and positively with higher levels of education, higher cognitive function and lower psychotic level, and higher scores of MacCAT-CR on certain scales (Candilis et al., 2006). A study enrolling schizophrenia patients and psychiatrists indicated that monetary incentives, physicians' recommendations and family preferences seemed to influence patients' participation decisions (Roberts et al., 2002). Yet there were unexplored issues in these studies: long-term hospitalized patients were not included, the effects of psychotropic medications on willingness remained unclear, and some of these studies did not use regression models to control for related confounders.

In the U.S., at present, long-term hospitalization is rare. However, in certain East Asian countries, such as Taiwan, China, Japan and Korea, long-term hospitalization systems for mentally ill patients still exist (Phillips, 2001; Hanzawa, 2012). Compared with shorter-term inpatients, longer-term patients with severe mental illness have more striking features of "thought disorder" (Sakiyama et al., 2002), more pronounced cognitive deficits (Heinik, 1996; Sarto et al., 2002), more severe negative symptoms (Heinik, 1996) and poorer social functioning; all of which still persist even after patients are discharged (Harvey et al., 2010). A study in China found greater lengths of stay for schizophrenia patients are associated with more extensive negative symptoms and social isolation (Wu et al., 2013). These findings indicate long-term schizophrenia inpatients harbor unique characteristics that may affect their independent living. The issue of DMC thus warrants investigation among long-term hospitalized schizophrenia patients as they are faced with the aforementioned disadvantages in global functioning. To our knowledge, however, until just recently, only one study enrolling 27 long-term inpatients in the U.S. has explored the issue of DMC with MacCAT-CR (Kovnick et al., 2003).

The current study aimed to explore the relationship between a number of factors and DMC using a regression model among long-term hospitalized schizophrenia patients. This study asked whether the severity of positive symptoms is negatively associated with DMC in a linear regression model; and (2) whether patients with higher daily doses of antipsychotics, benzodiazepines or anticholinergics present with impaired DMC. We also aimed to clarify unexplored factors related to subjects' DMC in prior studies, such as type of antipsychotics used and patients' willingness to participate in a hypothetical clinical study.

2. Methods

2.1. Participants

Supplement 3 describes the background of the long-term stay of psychiatric patients in Taiwan and the nature of the study site and subjects in this study. We recruited patients in a public psychiatric hospital, Yuli hospital, Ministry of Health and Welfare in Taiwan which accommodates about 2500 long-term psychiatric patients (1) who met the diagnostic criteria for schizophrenia or schizoaffective disorder according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV); (2) whose scores on the Chinese version (Guo et al., 1988) of the Mini-Mental State Examination (MMSE) (Folstein et al., 1975) were greater than 20; and (3) who had at least 3 years of education. Participants were excluded from this study if they refused to be evaluated or had an acute psychotic episode that required a hospital transfer. The patient sample included 139 subjects.

2.2. Procedures

Supplement 3 describes in detail the use of MacCAT-CR and relevant interventions safeguarding subjects' rights. The study design was reviewed by the Institutional Review Board (IRB) of Yuli Hospital. Before the study began, we explained the content of this research to subjects according to the principles of informed consent, in which a "hypothetical study" related to memory enhancement was emphasized. The study began in January 2011 and was completed in June 2012.

2.3. Measures

2.3.1. MacCAT-CR

Participants were audio recorded during their assessment using the Chinese version (Lan et al., 2013) of the MacCAT-CR (Appelbaum and Grisso, 2001). A detailed validation of this Chinese version has been reported elsewhere (Lan et al., 2013). The MacCAT-CR was used herein to assess 4 components: an understanding of the nature of the research project and its procedures (5 sections, a total of 13 items); an appreciation for the effects of participation (3 sections); the ability to think rationally about participation (4 sections); and the ability to choose (1 item). Three research assistants who had been trained to conduct a semi-structured MacCAT-CR interview according to standardized in-structive sentences (Supplement 1), completed the interviews and audio recordings for all patients. The original authors of the MacCAT-CR (Appelbaum and Grisso, 2001) described a hypothetical 6-week double-blind placebo-controlled randomized trial, which we modified to an exploration of the effectiveness of a memory-enhancing drug for cognitive deficits (Appendix B). A certified psychiatrist (BJW) who had been trained to score the MacCAT-CR completed these ratings after listening to all of the interviews using the rating guidelines of a revised and validated back-translated Chinese version of the MacCAT-CR (Supplement

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