



Longitudinal informed consent competency in stable community patients with schizophrenia: A one-week training and one-year follow-up study

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ABSTRACT

Objective: This study explores the efficacy of a one-week informed consent information training process for improving competence to provide consent in stable community patients with schizophrenia over a one-year follow-up period.

Method: A one-week training session designed to enhance competence to provide informed consent for research was conducted. The training was guided by a research protocol that provided detailed explanations of each major conceptual unit. Participants were followed for one year, and comprised 50 stable community outpatients with schizophrenia who were randomly assigned to either an intervention group (IG, $n = 33$) or a control group (CG, $n = 17$) that did not receive any training. The Chinese Mandarin MacArthur Competence Assessment Tool-Clinical Research (MacCAT-CR) was used to assess competence for informed consent pre-training (baseline), post-training (one week later), and at the end of one year.

Results: A repeated measures analysis comparing the IG and CG at pre-training, post-training and the one-year follow-up revealed significant improvements in the Understanding and Appreciation subscale following the one-week training. However, by the end of one year, scores returned to baseline levels, with the exception of the Appreciation subscale, which was below baseline. There were significant main effects across time on the Appreciation and Reasoning subscales, indicating considerable changes over time. The CG showed no significant changes from pre-training to one week later or at one-year follow-up for all subscales.

Conclusions: The capacities of understanding and appreciation can be improved in stable community patients with schizophrenia after one week of training; however, this training effect is not sustained one year later. The results suggest that more intensive or periodic trainings may be needed to maintain long-term competence levels in patients with schizophrenia, particularly with regard to their capacity to appreciate the nature and consequences of study participation.

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1. Introduction

Informed consent requires that individuals understand and freely consent to participate in research, including clinical trials. Informed consent is a process that optimally occurs in the context of an investigator-participant relationship that is characterized by trust and honesty. It consists of the following elements: communication of accurate and balanced information to a potential participant with adequate decisional capacity (Appelbaum and Grisso, 2001), who is situated so as to be

able to make a voluntary decision (Appelbaum et al., 2009). Research has shown that the quality of the consent process and other contextual variables (Roberts and Roberts, 1999) can affect participants' decision-making capacities. For example, one study found that a consent process that addressed the deficits in memory and attention experienced by patients with Alzheimer's Disease improved their understanding of informed consent disclosures for participation in early phase AD research; however, the intervention did not affect measures of appreciation or reasoning (Rubright et al., 2010). Another study showed that most patients with schizophrenia who initially demonstrated impaired decision-making capacity were later judged capable of making an adequate decision after participating in a focused educational intervention (Carpenter et al., 2000). In another schizophrenia study, there was a greater likelihood of improvement in patients' understanding when

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Table 1

Demographic characteristics of the participants in the intervention group (IG) and the control group (CG).

Variable	IG (n = 33)		CG (n = 17)		t/X ²	P
	Mean	S.D.	Mean	S.D.		
Age	39.42	(9.36)	39.41	(11.47)	−0.004	0.997
Educational level (years)	12.39	(2.98)	11.82	(2.63)	−0.667	0.508
Schizophrenia history (months)	196.70	(104.45)	201.76	(139.01)	0.145	0.885
Gender						
Male, N (%)	18	(54.5)	9	(52.9)	0.012	0.914
Female, N (%)	15	(45.5)	8	(47.1)		
PANSS positive	9.61	3.07	9.29	2.73	−0.353	0.726
PANSS negative	10.48	3.50	9.18	2.48	−1.371	0.177
PANSS general	21.55	4.54	22.00	5.32	0.317	0.753
psychopathology						
PANSS total	41.64	9.12	41.06	9.02	−0.213	0.832
CGI-S	1.67	0.82	1.82	0.95	0.608	0.546
MCCB speed of processing	44.95	8.21	48.53	12.87	1.198	0.237
MCCB attention/vigilance	43.24	10.67	42.82	9.80	−0.135	0.893
MCCB working memory	46.73	9.93	43.88	11.97	−0.842	0.407
MCCB verbal learning	41.21	12.66	45.76	20.17	0.979	0.332
MCCB visual learning	42.42	12.65	45.18	15.08	0.682	0.498
MCCB reasoning and problem solving	44.12	10.64	42.76	14.33	−0.379	0.706
MCCB social cognition	45.15	12.58	49.53	15.68	1.071	0.289

Note: P values were calculated using the independent t-test and chi-square test.

S.D. = standard deviation; PANSS = Positive and Negative Syndromes Scales score; CGI-S = Clinical General Impression-Severity Scale; MCCB = Measurement and Treatment Research for Improving Cognition in Schizophrenia (MATRICS) Consensus Cognitive Battery (MCCB).

the training program utilized disclosures of information through DVD rather than printed text (Jeste et al., 2009). One preliminary study found that a web-based tool enhanced the informed consent process in schizophrenia research (Harmell et al., 2012). Competence for informed consent to research is often impaired in schizophrenia, as this disorder is associated with cognitive deficits and symptoms that may hinder understanding, appreciation and reasoning (Appelbaum, 2006).

Consent-related abilities may fluctuate with the course of an illness. In the CATIE study of treatment in schizophrenia, most participants showed stable or improved consent-related abilities over time, yet approximately one-fourth of them experienced substantial worsening, and 4% of the participants ranked below the study's capacity threshold for enrollment (Stroup et al., 2011). Little is known about the long-term efficacy of training interventions directed at improving competence for informed consent to research. The importance of identifying efficacious procedures is underscored by the recognition that participants whose capacity declines over the course of long-term studies may not be able to judge or protect their own interests.

The current study is the first long-term prospective study to assess the relationship among competence for informed consent, training efficacy and time, studying stable community-based patients with schizophrenia at multiple follow-up points: pre-training (baseline), post-training (1 week later), and the end of one year. The study addresses the following two research questions:

1. Could one week of training improve competence for informed consent in stable community patients with schizophrenia?
2. Will the impact of the training be maintained at one-year follow-up?

2. Method

2.1. Subjects

50 stable, community-based outpatients between the ages of 18 and 65 years, diagnosed with schizophrenia using the Structured Clinical Interview for DSM-IV Disorders (SCID-IV) (First et al., 1997), participated in the current study. The patients were divided randomly into two groups with a ratio of 2:1. The intervention group (IG, n = 33) received informed consent training for 20 min daily over a one-week period; the control group (CG, n = 17) participated only in a non-cognitively oriented rehabilitation treatment in the community. Both groups were Han Chinese and recruited from the three-city community of Beijing in 2013.

Specific inclusion criteria were:

- a) being able to read and write Chinese fluently;
- b) not hospitalized, in a stable phase of illness for at least 6 months, and maintaining current antipsychotic and other concomitant psychotropic medications for at least 3 months, to minimize symptomatic instability;
- c) no more than a “moderate” severity rating on hallucinations, delusions, and any negative symptom, or on positive formal thought disorder items (e.g., PANSS Conceptual Disorganization item score) of the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987), as in the MCCB validation study (Nuechterlein et al., 2008);
- d) extra pyramidal symptom total scores, as assessed by the Simpson–Angus Scale (Simpson and Angus, 1970), less than 6;
- e) a minimal level of depressive symptoms, as reflected by a PANSS depression score less than 4.

Exclusion criteria were:

- a) refusal to provide informed consent;
- b) diagnosis of schizoaffective disorder or comorbidity with other mental disorders;
- c) substance dependence in the past 6 months;
- d) positive results on a laboratory toxicology screen performed during the study;
- e) report of recent alcohol consumption during any study visit;
- f) diagnosis of dementia or other neurodegenerative disorder, known genetic disorder with neuropsychiatric effects, or central neurologic system trauma;
- g) diagnosis of other neurologic disorder (e.g., epilepsy or Tourette's syndrome);
- h) significant head injury or other brain injury leading to cognitive impairment;
- i) intellectual disability (premorbid IQ < 70);
- j) ever having received ECT treatments;
- k) hypnotics and anticholinergic agents taken within 5 metabolic half-lives.

Table 2

Results for each group (IG and CG) by time (pre-training, post-training and one-year follow-up) for the MacCAT-CR.

Variable	Pre-training				Post-training				One year follow-up			
	IG M	S.D.	CG M	S.D.	IG M	S.D.	CG M	S.D.	IG M	S.D.	CG M	S.D.
Understanding	18.67	(6.18)	17.31	(5.49)	20.79	(6.99)	17.19	(6.34)	18.48	(6.33)	18.13	(4.43)
Appreciation	3.67	(1.78)	3.56	(2.10)	4.39	(1.75)	4.00	(2.13)	3.12	(1.95)	4.00	(2.13)
Reasoning	4.73	(1.77)	5.06	(2.02)	5.76	(1.80)	5.06	(1.88)	4.30	(1.81)	4.13	(2.06)
Expressing a Choice	2.00	(0.00)	2.00	(0.00)	2.00	(0.00)	2.00	(0.00)	2.00	(0.00)	2.00	(0.00)

Note: MacCAT-CR = MacArthur Competence Assessment Tool for Clinical Research; S.D. = standard deviation.

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