

The Effect of a Psycho-Educational Program on Psychiatric Symptoms, Drug Attitude and Treatment Satisfaction of Patients with Schizophrenia

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Abstract

The purpose of this study was to determine the effect of a Comprehensive Psycho-Educational Approach and Scheme Set (COMPASS) for patients with schizophrenia who were treated with risperidone long-acting injectable (RLAI), on their psychiatric symptoms, drug attitudes, and treatment satisfaction levels. Participants were sixty-five patients at thirteen hospitals in Japan who met ICD-10 F2 criteria for schizophrenia or schizo-affective disorder and were treated with RLAI. A correlational study design was used to measure the effect of the COMPASS on the psychiatric symptoms, drug attitudes, and treatment satisfaction levels of patients treated with RLAI. Using the following evaluation indicators: The Subjective Satisfaction to Treatment Scale (SSTS), Brief Psychiatric Rating Scale (BPRS), Global Assessment of Functioning (GAF), Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS), and Drug Attitude Inventory-10 (DAI-10), measurements were taken at the beginning of the program (baseline), at the end of the program, and six months after (end-point). Data analysis included descriptive statistics, Mann-Whitney U test or Wilcoxon signed-rank test, and Spearman's rank correlation coefficient. Significant differences were observed in BPRS total ($p < 0.001$), sub-scales of BPRS positive ($p < 0.001$), BPRS negative ($p < 0.01$), BPRS affective ($p < 0.01$), and GAF ($p < 0.001$). However, there was no significant change in subscale of BPRS manic, DAI-10, DIEPSS, or SSTS but significant positive correlations were found between SSTS and DAI-10 and GAF at baseline; a negative correlation was found between SSTS and BPRS. The findings of the study suggested the benefit of using the COMPASS in conjunction with RLAI to decrease patients' psychiatric symptomatology and improve treatment satisfaction. In addition, patient satisfaction was found to be an important factor to be considered by the psychiatrist.

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Keywords

Schizophrenia, Long-Acting Injection, Psycho-Education, COMPASS (Comprehensive Psycho-Educational Approach and Scheme Set), Adherence, Satisfaction Level

1. Introduction

Non-adherence to medication is a major problem in the treatment of schizophrenia. One of the most important treatment methods for patients with poor medication adherence to antipsychotics is the use of long-acting injectable (LAI) medications [1]. LAI has proven to be beneficial in assisting with the prevention of relapse, reduction of readmission rates and alleviation of suicide attempts for patients diagnosed with schizophrenia and poor medication adherence [2] [3]. Similarly, psycho-educational programs for both patients and family members have been found to be effective in preventing relapse [4] [5] and promoting emotional expression [6].

In a randomized study by Guo *et al.* [7], they compared 2 groups of patients diagnosed with early stage schizophrenia. One group received medication only and the other group received medication and a psychosocial intervention program. Those patients receiving both medication and psychosocial intervention had a lower rate of treatment discontinuation or change, a lower risk of relapse, and improved insight, quality of life (QOL), and social functioning. Swelieh *et al.* [8] studied medication adherence and treatment satisfaction of 131 patients diagnosed with schizophrenia. The findings revealed a correlation between treatment satisfaction level, psychiatric scores and medication adherence. Depot antipsychotic drugs are thought to reduce relapse rates by improving adherence [9]. Lee *et al.* [10] revealed that combined therapy with a psychosocial intervention for relapse prevention could be effective in maintaining medication compliance, and that discontinuation of long-acting atypical antipsychotics might be predictive of the next relapse.

Further research is needed to validate the benefits and impact of administering a psycho-education program such as Comprehensive Psycho-educational Approach and Scheme Set (COMPASS) to patients with schizophrenia who are treated using LAI antipsychotics. The COMPASS was developed by Zhao *et al.* [11] for patients diagnosed with schizophrenia and who were treated with RLAI. This is an original psychoeducational program supporting treatments with RLAI and evaluating subjective treatment satisfaction, transition of symptoms, and effectiveness in preventing symptomatic relapse.

The aim of this study was to determine the effect of COMPASS a psycho-educational program for patients with schizophrenia, who were treated with RLAI and the patient's psychiatric symptoms, drug attitude and level of treatment satisfaction.

2. Methods

2.1. Research Design

A correlational study was designed with defined variables focused on the effect of the COMPASS on the symptomatology, attitudes, and satisfaction of sixty-five participants completing the process for data collection.

2.2. Procedure for Data Collection

A complete description of all procedures was provided to the patients who were informed of the goal of treatment (return to everyday life with biweekly administration of RLAI), the need for administration of oral medication during the first four weeks after initiation of RLAI, and the potential risk of adverse events with RLAI. This effect was similar to that works on the balance of chemical substances which act on the nervous system in patient's brain. Both RLAI and oral medication are administered at the beginning of treatment in an effort to quickly decrease symptomatology. Each patient was informed of the costs of RLAI and other important information. Informed consent was obtained from each of the participants. Patients were followed for a 6-month period. During this time the COMPASS program was continuously implemented throughout the transition phase (introduction of RLAI) and to the observation phase which was done six months after the introduction of the RLAI.

2.3. Setting and Subjects

Twelve psychiatric hospitals were private and one was a University hospital in Japan.

Criteria for participant selection included: Patients diagnosed with schizophrenia or schizoaffective disorder based on International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) F2 criteria; were between the ages of 20 - 70 years old; had no systemic or neurologic diseases, including disturbances of hematopoiesis; had no history of electroconvulsive therapy within the past 6 months prior to study enrollment; were not pregnant; were not dependent on any substances other than nicotine during the 5 years before enrollment; had no communication difficulty; and could not be switched to RLAI monotherapy. No patient was excluded from the study because of a medical condition at baseline.

Of the 113 patients who qualified for the study, 48 failed to complete the procedure for data collection, or had exacerbation of psychiatric symptoms.

2.4. Description of the Psycho Educational Program

The name *COMPASS* was created by combining letters from the words, *COM* prehensive *Psycho*-educational Approach and Scheme Set (The *COMPASS* is free to download from <http://j.mp/COMPASS-eng>).

This is comprised of three chapters: *Chapter one* is targeted for patients in the acute phase. In this chapter, disease symptomatology (positive and negative symptoms, cognitive dysfunction), characteristics of conventional treatment (oral medication) and treatment using RLAI are discussed. The strength of the treatment with RLAI in preventing relapse is emphasized. *Chapter two* focuses on the recovery phase. This chapter addresses self-awareness of physical condition (including symptoms of schizophrenia and treatment-related adverse events), mental condition (self-assessment for screening of depression), and coping strategies to prevent relapse. *Chapter three* relates to those preparing to be discharged. In this chapter, patients reconfirm the advantages and disadvantages of treatment with RLAI, learn about social resources which will support daily life in the community, discuss concrete ways in which they could participate in their community, and prioritizes their own hopes and dreams.

All patients in the study had to complete chapter one prior to proceeding to RLAI monotherapy. Furthermore, in order to enhance the patients understanding of the material, clinicians adjusted the teaching times of chapters two and three to meet the learning needs of individual patients.

2.5. Evaluation Indicators

Several instruments were used as indicators to measure the effects of the *COMPASS* as a psycho-educational program on the psychiatric symptomatology, treatment satisfaction, and patient attitudes towards treatment. Measurements were taken at study baseline (time point when the patient's transition of prescription to RLAI monotherapy was completed) and over the following 6 months (observation period for evaluating treatment continuation of RLAI).

- *Subjective Satisfaction Treatment Scale (SSTS)*. The SSTS was developed by Zhao, one of the researchers in the study. This scale measures, from zero to seven from 1 (completely dissatisfied) to 7 (completely satisfied), using the following four questions: 1) One's perception of the efficacy of RLAI, 2) the difficulty due to side effects of RLAI, 3) Daily life activities, and 4) overall satisfaction to RLAI treatment. This self-administered questionnaire was completed by both the patients and clinicians.
- *Brief Psychiatric Rating Scale (BPRS)*. The BPRS assesses positive, negative and affective symptoms including 18 symptom constructs (*i.e.* hostility, suspiciousness, hallucination, grandiosity). The clinicians rate the patient's behavior and enters a number that ranges from 1 (not present) to 7 (extremely severe) for each symptom construct.
- *Global Assessment of Functioning Scale (GAF)*. Clinicians used the GAF scale to rate a person's overall level of functioning from 1 to 100, using a numeric score to represent the severity of that person's psychological symptoms and/or daily functioning. The three areas examined by the GAF are: Psychological—obsessions, panic attacks, etc. Social and Interpersonal—maintaining friendships, personal hygiene, etc. and Occupational—work attendance, ability to follow directions, etc.
- *Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS)* [12]. Clinicians used the DIEPSS to assess drug induced movement disorders. This consists of questions aimed to detect nine representative symptoms of Parkinsonism including sialorrhea, gait disturbance, hesitation to start walking (freezing), bradykinesia,

muscle rigidity, tremors, loss of vital facial expression (*i.e.*, mask-like face), akathisia and dyskinesia. Questions on the questionnaire used non-technical words. Patients' self-assessment for each item of the questionnaire (*i.e.*, the presence or absence of the symptoms and their severity) was scored using a 5-point scale.

- *Drug Attitude Inventory-10 (DAI-10)*. The DAI-10 consists of 10 questions rated by a patient to evaluate an individual's perception of their medication and correlating experience. This was modified in this study like the following question: "I feel more normal on medication" (from DAI-10), to the question item of the DAI-10 like "I feel more normal when I am on RLAI treatment".

2.6. Ethical Considerations

The research study design and procedures followed the clinical study guidelines and were approved by the Ethics Committees of Fujita Health University. All patients and clinicians provided informed consents to participate this study.

2.7. Statistical Analysis

Analyses of data included comparing the means and standard deviations of the BPRS, GAF, DIEPSS, DAI-10 and SSTS scores at baseline, prior to the administration of the COMPASS and at end point of the study. Those scores that changed from baseline to the 6-month endpoint with differences between improved and non-improved adherence groups were tested using the Mann-Whitney U test or Wilcoxon signed-rank test. Spearman's rank correlation coefficient was used to test the association between the SSTS and these previously described scores. The level of significance was set at $p < 0.05$.

3. Results

A total of 65 patients comprised the sample of the study. Average age was 44.13 (SD = 3.81) years old: There were 32 women and 33 men. Women patients' average age was 47.48 (SD = 13.86) years old, and 40.97 (SD = 13.19) years old for men.

3.1. Change of Evaluation Indicators

Analysis comparing the baseline scores prior to the COMPASS and initiation of RLAI, and at endpoint (6-months following the program and RLAI treatment) showed that the means and standard deviations of the Evaluation Indicators (BPRS, GAF, DIEPSS, DAI-10, SSTS) indicated a significant decrease in the Total BPRS ($p < 0.001$), sub-scale of BPRS positive ($p < 0.001$), BPRS negative ($p < 0.01$), BPRS affective ($p < 0.01$), and increase in GAF ($p < 0.001$). However, there were no significant changes in the BPRS Manic, DAI-10, DIEPSS, and SSTS total (see [Table 1](#)).

Table 1. Change of the evaluation indicators before and after implementation.

		Baseline (N = 65)		Endpoint (N = 65)		Z	p
		Mean	SD	Mean	SD		
BPRS	Total	38.57	14.18	32.28	10.16	-4.65	0.00
	Positive	11.78	5.28	9.29	4.03	-3.07	0.00
	Negative	10.22	3.97	8.49	3.41	-2.50	0.01
	Affective	8.28	3.27	6.74	2.69	-2.77	0.01
	Manic	4.29	2.67	3.88	2.32	-1.30	0.19
GAF		49.60	13.62	57.95	15.62	-3.23	0.00
DIEPSS		2.55	3.59	1.91	2.67	-0.76	0.45
DAI-10		5.51	4.44	5.23	5.03	-0.08	0.94
SSTS total		28.57	12.00	31.92	9.30	-1.10	0.27

Mann-Whitney U test. Brief Psychiatric Rating Scale (BPRS), functioning was evaluated using Global Assessment of Functioning (GAF), and extrapyramidal side effects were evaluated using Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS), and Drug Attitude Inventory-10 (DAI-10) were rated by clinical senior psychiatrists at baseline and 6 months study endpoint. Subjective Satisfaction to Treatment Scale (SSTS) in patient was evaluated by patient.

3.2. Relations between Each Evaluation Indicator and Improved Situation in DAI-10

The patients whose scores improved on the DAI-10 following the COMPASS ($p < 0.01$) were classified as the improved group. However, within this group, no significant difference was observed in the BPRS, GAF, DIEPSS and SSTS total at the endpoint (see [Table 2](#)).

3.3. Correlation between DAI-10 and Evaluation Indicators before and after the Implementation of COMPASS

At baseline, prior to the COMPASS, significant positive correlations were found between DAI-10 and SSTS total ($p < 0.01$), and GAF ($p < 0.01$) and a significant negative correlation was recognized between DAI-10 and BPRS total ($p < 0.01$), and between SSTS total and BRPS total ($p < 0.05$).

Six months later, at the completion of COMPASS intervention, a significant positive correlation was observed between DAI-10 and SSTS total ($p < 0.01$) and between SSTS total and GAF ($p < 0.05$). Significant negative correlations were found between SSTS total and BPRS total ($p < 0.01$) and DIEPSS ($p < 0.05$) (see [Table 3](#)).

Table 2. Relations between each evaluation indicators and improved situation in DAI-10.

	Improved (N = 24)		Not improved (N = 41)		Z	p
	Mean	SD	Mean	SD		
BPRS total	32.54	7.61	32.13	11.37	-0.81	0.42
GAF	55.46	15.85	59.41	15.30	-1.48	0.14
DIEPSS	1.67	2.78	2.05	2.60	-1.13	0.26
DAI-10	7.42	3.31	3.95	5.38	-2.80	0.01
SSTS total	34.46	6.03	30.44	10.43	-1.59	0.11

Mann-Whitney U test. Brief Psychiatric Rating Scale (BPRS), functioning was evaluated using Global Assessment of Functioning (GAF), and extrapyramidal side effects were evaluated using Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS), and Drug Attitude Inventory-10 (DAI-10) were rated by clinical senior psychiatrists at baseline and 6 months study endpoint. Subjective Satisfaction to Treatment Scale (SSTS) in patient was evaluated by patient.

Table 3. Correlation between DAI-10 and evaluation indicators before and after implementation (N = 65).

Baseline	DAI-10	SSTS total	DIEPSS	BPRS	GAF
DAI-10	1.000				
SSTS total	0.354**	1.000			
DIEPSS	0.047	-0.102	1.000		
BPRS total	-0.294*	-0.263*	0.129	1.000	
GAF	0.360**	0.326**	-0.106	-0.559**	1.000
Endpoint	DAI-10	SSTS total	DIEPSS	BPRS	GAF
DAI-10	1.000				
SSTS total	0.584**	1.000			
DIEPSS	-0.184	-0.253*	1.000		
BPRS total	-0.24	-0.359**	0.080	1.000	
GAF	0.189	0.260*	-0.071	-0.585**	1.000

Spearman rank correlation coefficient; * $p < 0.05$, ** $p < 0.01$; Brief Psychiatric Rating Scale (BPRS), functioning was evaluated using Global Assessment of Functioning (GAF), and extrapyramidal side effects were evaluated using Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS), and Drug Attitude Inventory-10 (DAI-10) were rated by clinical senior psychiatrists at baseline and 6 months study endpoint. Subjective Satisfaction to Treatment Scale (SSTS) in patient was evaluated by patient.

3.4. Comparison of Satisfaction Levels between Patients versus Psychiatrists

No significant difference was found in the treatment satisfaction level (SSTS) between scores derived from patients and from clinicians (psychiatrists) except the side effects (see **Table 4**).

3.5. Changes in Satisfaction Levels in Patients and Psychiatrist

Regarding the comparison of satisfaction levels before and after the implementation of COMPASS, patients did not show any changes in overall scores on the SSTS and SSTS subscale of SSTS effect, side effects, and life. However, clinicians (psychiatrists) showed significantly higher scores on the SSTS subscales: effect ($p < 0.05$) and life ($p < 0.001$) at the completion of the COMPASS (see **Table 5**).

4. Discussion

Compared to baseline measurements, positive, negative and affective symptoms of the BPRS, and GAF (the level of psychological symptoms and social and occupational functioning) were improved following the COMPASS and treatment with RLAI at the endpoint measurement scores. However, the Drug-Induced Extrapyramidal Symptom, overall attitude toward RLAI treatment, satisfaction level as evaluated by DIEPSS, DAI-10, and SSTS, did not show significant change.

Table 4. Comparison between patients and psychiatrists on sub-scale of the SSTS.

		Patients (N = 65)		Psychiatrists (N = 56)		Z	p
		Mean	SD	Mean	SD		
Baseline	Effect	4.61	1.38	4.75	1.18	-0.27	0.79
	Side effect	4.71	1.66	5.20	1.29	-2.61	0.01
	Life	4.69	1.40	4.55	1.19	-0.63	0.53
	Overall	4.59	1.41	4.95	1.09	-1.75	0.08
Endpoint	Effect	4.82	1.21	5.11	1.17	-1.46	0.14
	Side effect	5.00	1.51	5.36	1.43	-1.79	0.07
	Life	4.88	1.35	5.16	1.07	-1.50	0.13
	Overall	4.77	1.25	5.13	1.01	-0.73	0.47

Wilcoxon signed-rank test, Subjective Satisfaction to Treatment Scale (SSTS) in patient was evaluated by patient and psychiatrist. SD = standard deviation.

Table 5. Comparison between on sub-scale of the SSTS before and after implementation.

		Baseline		Endpoint		Z	p
		Mean	SD	Mean	SD		
Patients (N = 65)	Effect	4.61	1.38	4.82	1.21	-0.83	0.40
	Side effect	4.71	1.66	5.00	1.51	-1.19	0.23
	Life	4.69	1.40	4.88	1.35	-0.62	0.54
	Overall	4.59	1.41	4.77	1.25	-0.80	0.42
Psychiatrists (N = 56)	Effect	4.75	1.18	5.11	1.17	-2.15	0.03
	Side effect	5.20	1.29	5.36	1.43	-0.92	0.36
	Life	4.55	1.19	5.16	1.07	-3.19	0.00
	Overall	4.95	1.09	5.03	1.05	-0.86	0.39

Wilcoxon signed-rank test, Subjective satisfaction to treatment scale (SSTS) in patient was evaluated by patient and psychiatrist. SD = standard deviation.

The patients whose DAI-10 scores improved after completing the COMPASS and initiating RLAI treatment were classified as the improved group. However, no significant difference was observed in the scores of BPRS, GAF, DIEPSS and SSTS total.

Significant positive correlation was found between DAI-10/SSTS and GAF at the baseline. A significant negative correlation was observed between DAI-10/SSTS and BPRS; it was presumed that if psychiatric symptoms are more severe, overall attitude toward RLAI treatment and satisfaction level is also lower.

Significant positive correlations were found following completion of the COMPASS between SSTS level and GAF. A significant negative correlation was observed between SSTS level and DIEPSS/BPRS. This indicates a negative relationship between medication satisfaction level, the severity of psychiatric symptoms and the adverse events of extrapyramidal symptoms.

Previous studies [13] [14] have found that psychiatric symptoms affect social functioning as well as QOL. Kim JH, Kim MJ [15] suggested that adverse effects, particularly extrapyramidal side effect (EPS) and akathisia, are significantly associated with subjective well-being, implying the necessity to develop rational strategies to control these variables effectively. It also suggested that EPS and akathisia continue to be major adverse effects associated with a low level of subjective well-being in patients receiving risperidone. Helldin *et al.* [16] suggested that patients who had no interference from symptoms in their daily functioning found their life better, had a superior insight and were more positive to treatment. In addition, Xia *et al.* [17] reported that patients with schizophrenia receiving psychoeducation are more likely to be satisfied with mental health services and have improved QOL. Aki *et al.* [18] suggested that the patient's QOL could be predicted by the life skills measured by a family member and suggested that active treatment for depressive and negative symptoms might be recommended to improve the patient's QOL and life skills. An earlier study [19] also supports the value of patients' attitudes towards antipsychotic treatment at hospital discharge. Therefore, patient education is important in order to provide appropriate information to the patient, and patients' better understanding about basic information of their illness and treatments, including not only pharmacological treatments but also psychosocial approach to mental health, at the time of the first medical examination. Moreover, it was considered necessary to focus on the patient's dysfunctions due to illness, side effects, psychiatric symptoms, psychological symptoms, social and occupational functioning in order to support a patient in the Psycho-educational Program.

Regarding the comparison of the satisfaction level before and after the implementation of COMPASS, patients did not show any changes in their perception of the efficacy of RLAI, side effects, daily life activities and overall satisfaction level scores. However, psychiatrists showed significantly higher scores on satisfaction levels with their perception of the efficacy of RLAI and daily life activities following six months of monitoring changes compared to baseline measurements.

As a result, it seemed important to recognize that there is difference between value of the patient and psychiatrist in the satisfaction level. The importance of patient relationships and communication was confirmed by the difference in SSTS scores between the psychiatrist and patients six months after initiating the program. Psychiatrists concluded that the satisfaction level had significantly improved, although the patient responses did not reflect the same effect.

5. Conclusion

The findings of the study suggested the benefit of using the COMPASS in conjunction with RLAI to decrease patients' psychiatric symptomatology and improve treatment satisfaction. The importance of patient relationships and communication was confirmed by the differences in SSTS scores between the psychiatrist and patients six months after initiating the program. This finding indicates the need for psychiatrist to careful attention to patient satisfaction level. Inclusion of a psycho-educational program along with RLAI is recommended to enhance patient's quality of life.

Implications of the Study

The findings of the study suggest that educational programs combined with standardized medical interventions can be effective in treating certain psychiatric and mental health conditions. Patient satisfaction of treatment, attitudes toward medication and treatment, including psychiatric symptomatology are important considerations when determination of effects of interventions are evaluated. Implications for research include the use of clinical follow-up which should be more organized so as not to lose (drop-out) participants in the study. During the 6-

month period, forty-eight participants failed to comply with the protocol resulting in their disqualification. This drop-out rate can be avoided.

Limitations

The findings of the study indicate the need to further study the benefit of the COMPASS by comparing medication adherence, re-hospitalization and quality of life of patients who received only RLAI treatment.

The generalizability of the study was limited by the sample size and lack of a control group, which would have strengthened the ability to determine the impact of the COMPASS. Furthermore, the DAI-10 rating scale is typically used with patients receiving oral treatment and not for hypodermic medication administration.

One of the immediate findings of the study is the consideration of providing treatment individualized for each patient to evaluate degree of satisfaction. It became clear that different psycho-educational approaches based on drug attitudes could not be assured.

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Disclosure

The authors report no conflicts of interest in this work.

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