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博士論文

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Controlled Trial

(社会資源の自己学習プログラムが統合失調症外来患者の陰性症状と
生活の質に与える影響：無作為化比較試験)

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Impacts of a Self-directed Social Resources Study Program on Negative Symptoms and Quality of Life in Schizophrenia Outpatients: A Randomized Controlled Trial

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SELF-DIRECTED STUDY PROGRAM ON SOCIAL RESOURCES

Keywords: Schizophrenia, Negative symptoms, Quality of life, Social participation

To clarify whether a self-directed study program on social resources improves negative symptoms, quality of life (QOL), and social participation among outpatients with schizophrenia. Eighty-six participants were randomly divided into intervention and control groups. In addition to the usual day programs, the intervention group participated in a self-directed study program on social resources once a week for eight weeks. The control group participated only in the usual day programs. Negative symptoms and QOL were assessed at baseline and post-intervention using the Positive and Negative Syndrome Scale (PANSS) and the WHO Quality of Life-BREF (WHOQOL-BREF), respectively. Social participation was also assessed. After the intervention, there were no significant differences in the PANSS negative symptoms and WHOQOL-BREF total scores between the two groups. Within-group, PANSS negative symptom scores significantly improved in the intervention group ($p < 0.05$), but not in the control group. The WHOQOL-BREF physical health subscale scores improved significantly only in the intervention group ($p < 0.05$). Social participation remained unchanged between the intervention and control groups. The results suggest that a self-directed study program on social resources may be useful for improving negative symptoms and physical QOL in outpatients with schizophrenia. The findings highlight the potential of such interventions to bridge the existing gap in psychosocial rehabilitation strategies for this population.

INTRODUCTION

After 1990, psychiatric day programs experienced a decline in Europe and the United States, with new support services such as Assertive Community Treatment, Individual Placement and Support, and social clubs replacing them (1). Prolonged stays within psychiatric day programs can lead to institutionalism, erecting barriers to social participation for patients (1). The institutionalized patients restrain themselves, live a passive life, and lose their initiative (2, 3). In Japan, the number of psychiatric day programs within medical settings increased from 1988 to 2011, stabilizing thereafter (4). According to a 2008 survey of psychiatric day programs, 72% of patients were diagnosed with schizophrenia, of which 75% engaged for over a year, and 43% within this subgroup participated for a cumulative span of 5 years and more (5). Japan's landscape is marked by a prevalence of extended program durations. As mentioned by Hoge et al. (1), the Ministry of Health, Labor and Welfare of Japan (5) emphasized the problem of long stays in psychiatric day programs without sufficient social participation by the patients.

Schizophrenia is a psychiatric syndrome characterized by positive symptoms, such as hallucinations, delusions, and disorganized speech; negative symptoms, such as decreased expressiveness and avolition; and cognitive deficits involving impaired executive functions, memory, and speed of mental processing. Negative symptoms are especially associated with poor quality of life (QOL) and reduced social participation (6). Conventional psychopharmacological methods, while fundamental, demonstrate limited efficacy against negative symptoms (6, 7, 8). The active use and efficacy of psychosocial treatments focused on improving negative symptoms are expected (9, 10, 11). Therefore, the quest for efficacious strategies to mitigate negative symptoms remains paramount.

Psychosocial treatments were administered as both group- and individual-based interventions. In Japan, psychiatric day programs include these interventions. Recently, self-directed learning has been introduced in the education sector and is reported to be more effective than passive learning (12, 13). Self-directed study is a form of active behavior that can improve the negative symptoms including decreased expression and avolition. Therefore, in this intervention study, we attempted to improve the negative symptoms, QOL, and social participation of long-term participants of psychiatric day programs by developing a self-directed study program centered on social resources.

This study aimed to clarify whether a self-directed study program centered on social resources holds the

potential to improve negative symptoms, QOL, and social participation among outpatients with schizophrenia who have been long-term participants in psychiatric day programs.

MATERIALS AND METHODS

Trial design and setting

This study was designed as a multicenter randomized controlled parallel group trial (allocation ratio 1:1) and was conducted at four psychiatric day programs within psychiatric hospitals in Japan: three private hospitals and one public hospital in the Hyogo prefecture.

Participants

Inclusion criteria for study participation were as follows: 1) diagnosis of schizophrenia (F2), based on the International Statistical Classification of Diseases (10th Revision); 2) engaged in psychiatric day programs for more than one year; and 3) participation in day programs at least once a week within the four weeks before the study.

Participants were recruited through referrals from the attending clinical staff at the psychiatric day programs where the study was conducted.

Psychiatric day programs usually provide group-based social skills training, cognitive behavioral therapy, patient psychoeducation, employment support, and group activities, such as recreation, sports, and cooking, for three or six hours per day, five days per week.

Intervention

Intervention group. In addition to the usual psychiatric day programs, the intervention group participated in a self-directed study program on social resources for 10-20 minutes once a week for eight weeks.

The authors originally developed a self-directed program on social resources using Microsoft PowerPoint. All slides were reviewed for content validity by two psychiatrists and one occupational therapist with more than 10 years of clinical experience and who were not involved in the study.

For each of the seven themes (housework, medical care, work, leisure, peer support, prevention of long-term care, and others), social resource services related to each theme were presented using slides. Each session, from the first to sixth, consisted of two themes. The seventh and eighth sessions consisted of a review of the seven themes (Table I). At the end of the session, slides were presented to encourage participants to proactively access the social services of their choice, and in addition, they were informed that the day programs staff would play a supportive role. Each session was conducted in a short time (10-20 minutes).

Table I. Themes and social resource services of self-directed study program from the first to sixth session

Theme/ Social resource service	Session number (n)	
1. Housework		
Home help service	(1)	(5)
Food delivery service		
2. Medical care		
Home-visit nursing care	(1)	(2)
Psychiatric day programs		
3. Work		
Support for transition to employment		
Support for continuous employment Type A and Type B	(2)	(3)
Public employment security office		
Local vocational centers for persons with disabilities		
4. Leisure		
Community activity support center	(3)	(4)
Culture center		
5. Peer support		
Self-help group		
Community activity support center	(4)	(5)
Elderly club		
6. Prevention of long-term care		
Outpatient day long-term care		(6)
Outpatient rehabilitation		
7. Others		
Activities to do inside the house		(6)
Activities to do outside the house		

Note. The seventh and eighth session consisted of a review of the seven themes.

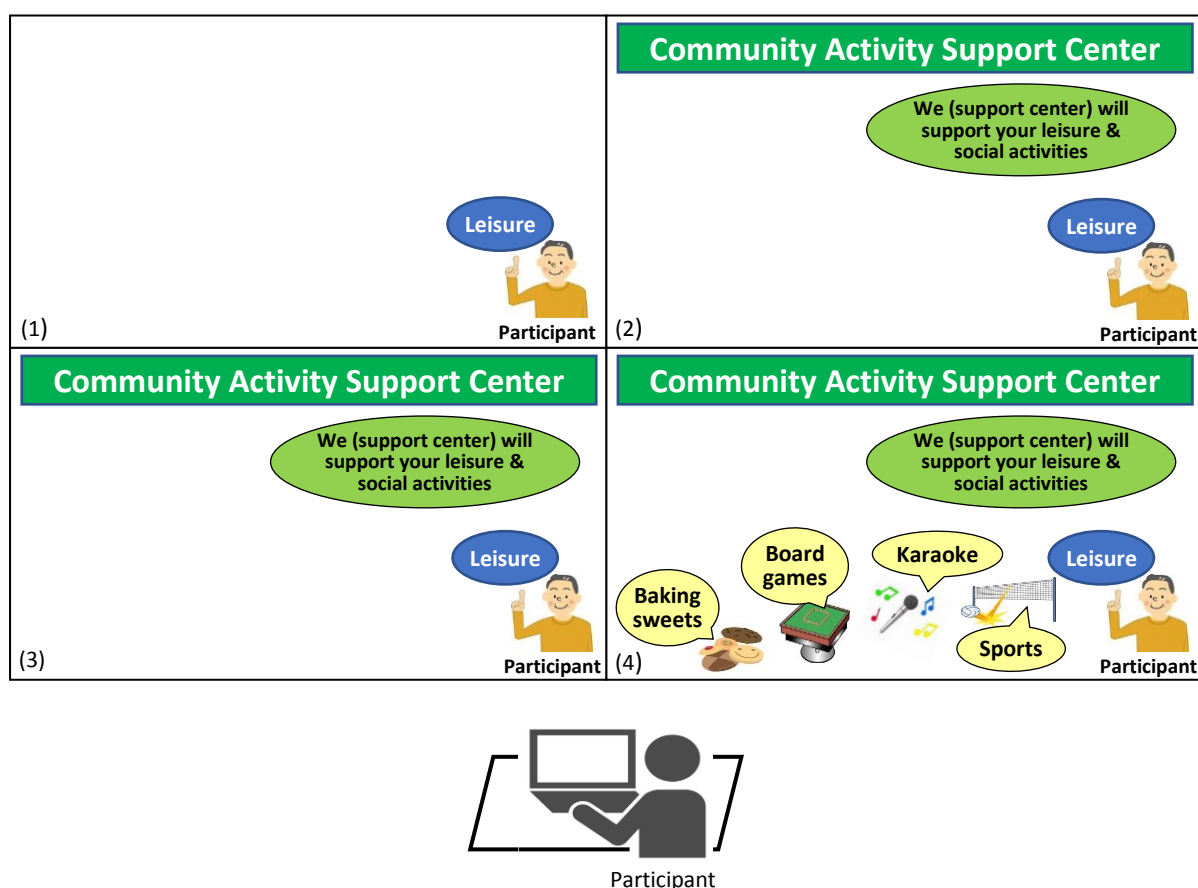


Figure 1. An example of slides used in self-directed study program; Community Activity Support Center in Leisure

Note. When participant want to know about leisure (first click) (1), the second participant's click begins with an illustration that a community activity support center is a social resource service related to the theme of leisure (2). The third click shows a chatting activity with friends (3), the fourth click shows a baking sweets activity, the fifth click shows a board game activity, the sixth click shows a karaoke activity, and the seventh click shows a sports activity (4).

A thematic social resource service was presented in a single PowerPoint slide, on which the content and activities being implemented were inserted each time the participant pressed the Enter button. An example is shown in Figure 1. The first click occurs when a participant wants to know about leisure (Figure 1-1), their second click begins with an illustration that a community activity support center is a social resource service related to the theme of leisure (Figure 1-2). The third click shows a chatting activity with friends (Figure 1-3), the fourth click shows a baking sweets activity, the fifth click shows a board game activity, the sixth click shows a karaoke activity, and the seventh click shows a sports activity (Figure 1-4).

For inquiries concerning the program, day-programs staff offered responses akin to those provided during conventional day programs.

Control group. The control group participated only in conventional psychiatric day programs.

Outcomes

Both the intervention and control groups were evaluated using the following assessments, which were performed at baseline and post-intervention (8 weeks from baseline).

Positive and Negative Syndrome Scale. Negative symptom severity was measured using the Japanese version of the Positive and Negative Syndrome Scale (PANSS) (14). PANSS negative symptoms comprises 7 items (15, 16), each item is rated on a seven-point Likert scale, rating from 1 (absent) to 7 (extreme). Assessments were conducted by experienced psychiatrists who were unaware of participant group assignments.

WHO Quality of Life-BREF. QOL was assessed using the Japanese version of the WHO Quality of Life - BREF (WHOQOL-BREF) (17). The WHOQOL-BREF comprises 26 items; each item is rated on a five-point Likert scale from 1 (not at all, very dissatisfied, very poor) to 5 (an extreme amount, very satisfied, very good). The higher the score, the better the participants' QOL. Items 3, 4, and 26 are reverse scored.

Social participation and time spent in day programs. To assess social participation, the participants were asked if they had initiated new social activities such as working or going to school. If they had initiated new activities, this would be expected to result in a decrease in time that they spent in day programs. Therefore, we examined the time spent in day programs.

Randomization

Randomization was performed using an Excel table of random numbers (no stratification factors were used), and participants were assigned to either the intervention or control group at each site.

Statistical analysis

The data of participants who participated in the self-directed study program with usual day programs (intervention group) and those who participated only in conventional day programs (control group) more than six times during the 8-week intervention periods were analyzed. The background data of the participants in the two groups were compared using the chi-square test or t-test. For the PANSS and WHOQOL-BREF scores, the scores of the intervention and control groups were compared using the Mann-Whitney U test, whereas the baseline and post-intervention scores within each group were compared using the Wilcoxon signed-rank test. If there was a significant difference in the PANSS negative symptoms, the sub-items were also examined. For the time spent in day programs, percentages between groups and within each group were compared using a t-test. If the data were not normally distributed, the Mann-Whitney U test or Wilcoxon signed-rank test was used. Statistical analyses were performed using Statcel3 for Excel 2011 (The Publisher OMS, Saitama, Japan); p-values of less than 0.05 were considered statistically significant.

Ethics approval

This study was approved by the Ethics Committee of the Kobe University Graduate School of Health Sciences (approval number: 269-2014). The ethics committee of each institution approved this study. Written informed consent was obtained from all participants.

RESULTS

The recruitment and participation process is illustrated in Figure 2. From the pool of 121 potentially eligible participants, 86 were ultimately included in the study, while 35 declined to participate. Subsequently, 43 patients were randomly allocated to the intervention group and 43 to the control group. At baseline, a total of seven participants withdrew from the study. In the intervention group, four participants declined to participate, and one participant secured employment. In the control group, two participants declined to participate. Six participants dropped out during the intervention period. In the intervention group, three participants exhibited irregular participation. Similarly, in the control group, two participants did not engage consistently and one participant did not participate after the intervention; therefore, post-intervention evaluation was not possible. Thus, 73 patients were assessed post-intervention: 35 in the intervention group and 38 in the control group.

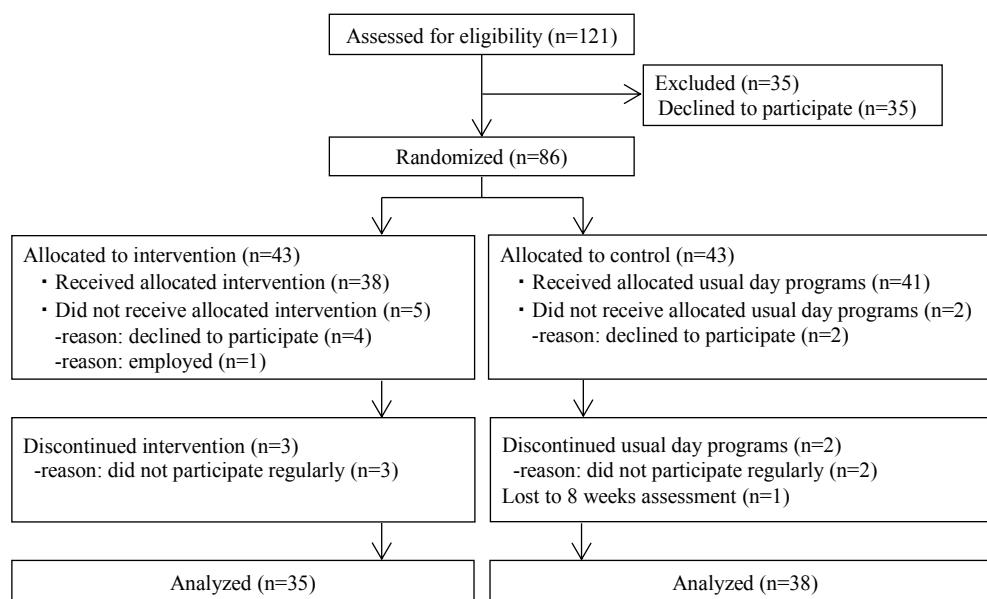


Figure 2. Study flowchart

Table II. PANSS negative symptom scores, WHOQOL-BREF scores, and the time spent in day programs

	Intervention group (N=35)		Control group (N=38)		Difference			
	Pre	Post	Pre	Post	Pre	Post	Intervention	Control
	Median (IQR)				Between groups		Within-groups	
PANSS negative symptoms								
Total score	18 (13)	15 (11)	15.5 (11.5)	14 (13.3)	0.791	0.765	0.031*	0.089
Blunted affect	2 (3)	2 (3)	2.5 (2)	2 (3)	0.843	0.973	0.317	0.096
Emotional withdrawal	3 (2)	2 (2)	2 (2.3)	2 (2.3)	0.433	0.541	0.011*	0.058
Poor rapport	2 (2)	2 (2)	2 (2)	2 (2)	0.405	0.480	0.157	0.317
Passive social withdrawal	3 (2)	2 (1)	2.5 (3)	2 (2.3)	0.335	0.261	0.058	0.132
Lack of spontaneity	3 (2)	2 (2)	2 (2)	2 (2.3)	0.657	0.780	0.408	0.739
Motor retardation	2 (2)	2 (2)	2 (2)	1.5 (2)	0.471	0.675	0.151	0.317
Active social avoidance	2 (1)	1 (2)	2 (2)	1.5 (2)	0.732	0.674	0.257	0.480
WHOQOL-BREF								
Total score	80 (8)	80 (12)	81 (9.3)	77.5 (12)	0.719	0.459	0.650	0.121
Physical health	21 (6)	22 (5)	21.5 (4)	21.5 (5)	0.343	0.579	0.015*	0.902
Psychological health	18 (4)	17 (5)	18 (3.3)	17.5 (3.3)	0.803	0.925	0.864	0.235
Social relationships	9 (3)	9 (2)	9 (2)	9 (2)	0.839	0.892	0.694	0.769
Environmental	24 (7)	25 (4)	26 (6.5)	24.5 (4.3)	0.535	0.363	0.785	0.090
	Mean (SD)							
Social participation evaluated by the time spent in day programs (%)	47.7 (28.1)	46.2 (29.0)	54.3 (26.4)	52.4 (24.0)	0.299	0.212	0.629	0.173

Note. PANSS, Positive and Negative syndrome Scale; WHOQOL-BREF, WHO Quality of Life-BREF; %, percentage of participation time in total day-program time. *p < 0.05.

The mean age was 54.6 ± 13.5 in the intervention group and 49.1 ± 10.4 in the control group. There were 21 men and 14 women in the intervention group, and 26 men and 12 women in the control group. Age and gender were not significantly different between the groups, with p values of 0.051 and 0.453, respectively.

Table II shows PANSS negative symptom scores, WHOQOL-BREF scores, and the time spent in day programs of the groups. The baseline evaluation scores for negative symptoms, QOL, and the time spent in day programs did not differ between groups. After 8 weeks, no significant differences were found between groups in any of these scores. Within-groups, PANSS negative symptom scores decreased significantly from baseline in the intervention group (median [IQR]: 18 [13] to 15 [11], $p = 0.031$), while no significant change was found in the control group. The score in the emotional withdrawal item decreased significantly from baseline only in the intervention group (median [IQR]: 3 [2] to 2 [2], $p = 0.011$). WHOQOL-BREF physical health scores also showed significant improvement only in the intervention group (median [IQR]: 21 [6] to 22 [5], $p = 0.015$). No significant change in the time spent in day programs were observed during the intervention period in either group. None of the participants in either group participated in social activities such as working or going to school during the intervention period.

DISCUSSION

This study reports the results of the first randomized controlled trial of a self-directed study program on social resources developed to improve negative symptoms, QOL, and social participation of outpatients with schizophrenia who were long-term participants of psychiatric day programs. While no substantial differences emerged in PANSS negative symptom scores, WHOQOL-BREF total scores, or social participation between the intervention and control groups post-intervention, the intervention group exhibited noteworthy improvements in PANSS negative symptom scores, emotional withdrawal items, and WHOQOL-BREF physical subscale scores.

PANSS negative symptom scores did not differ significantly post-intervention between the intervention and control groups, whereas we observed an improvement in PANSS negative symptom scores only in the intervention group. These positive changes in negative symptoms among long-term participants in psychiatric day programs greatly hold clinical significance for the following reasons: 1) these participants have endured prolonged negative symptoms, 2) their social engagements have been limited, and 3) negative symptoms were associated with poor social participation (6). Several systematic review (11, 18, 19) reported that psychosocial treatments did not easily result in improvements in the negative symptoms of schizophrenia. In our study, therefore, it is significant that the self-directed study program which is a psychosocial treatment, showed a trend toward improvement.

Hoshii et al. (20) reported that participant-chosen activities in occupational therapy improved the PANSS positive symptoms and general psychopathology scores of inpatients with chronic schizophrenia compared to therapist-chosen activities in occupational therapy. They stated that having the participants' experiences brought about by their own choices, rather than by others, were important for improving their symptoms. In this study,

participants also experienced through their self-directed behavior. Both interventions improved the symptoms in patients with chronic schizophrenia. On the PANSS subscales, significant improvements were found in positive symptoms and general psychopathology in the study by Hoshii et al., and in negative symptoms in our study. The differences in findings between the two studies might be due to differences in participant characteristics, including disease processes, psychopathology, and living status (inpatient or outpatient).

PANSS negative symptoms include blunted affect, emotional withdrawal, poor rapport, passive social withdrawal, lack of spontaneity, motor retardation, and active social avoidance (15). There was a significant improvement in the emotional withdrawal item among the seven sub-items, suggesting that the improvement in the emotional withdrawal item may have contributed to the improvement in PANSS negative symptom scores.

The self-directed study program did not affect WHOQOL-BREF total scores in outpatients with schizophrenia who were long-term participants of psychiatric day programs; however, an effect on the WHOQOL-BREF physical health subscale was observed. Patients with chronic schizophrenia are often found to report intense physical discomfort (21). This self-directed study program is structured in such a way that its patients have easy access to information about social resources, and this program intervention may help these patients to have a better outlook on the future and take the next step forward, both physically and psychologically.

The remarkable results of this study were the favorable changes in negative symptoms and physical QOL that occurred in outpatients with chronic schizophrenia after a short intervention period. Therefore, the self-directed study programs were important for the participants. Furthermore, this study had few dropouts, demonstrating the feasibility of providing a computer-based, self-directed study program for outpatients with chronic schizophrenia. Furthermore, while one-on-one learning programs between patients and therapists are expensive, this self-directed study program can be implemented at the patient's own pace and at a low cost, as the patient uses a computer alone. Therefore, we believe that this program can be easily incorporated into various day programs.

Nevertheless, certain limitations warrant consideration. 1) There may have been a regional bias. 2) Medication was not controlled. 3) The relationship between physical QOL and actual physical activity was not examined. Addressing these limitations would enhance the clinical significance of this study. To maximize benefit, enhancing intervention frequency and duration stands as a potential avenue for future exploration.

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