

# The Role of Comprehensive Community-Based Rehabilitation Service Model in the Holistic Management of Patients with Severe Mental Disorders: A Randomized Controlled Trial Study

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**Abstract:** *Objective:* To investigate the clinical efficacy, improvement in social functioning, prevention of relapse, and health economic value of a comprehensive community-based rehabilitation service model in the holistic management of patients with severe mental disorders, providing empirical evidence for the standardized promotion of community rehabilitation. *Methods:* A parallel-group randomized controlled trial (RCT) was conducted, involving 200 patients with severe mental disorders in a stable phase. They were randomly assigned at a 1:1 ratio to an intervention group (comprehensive community rehabilitation,  $n = 100$ ) and a control group (routine community management,  $n = 100$ ), with continuous intervention for 12 months. The Positive and Negative Syndrome Scale (PANSS) and the Personal and Social Performance Scale (PSP) were used as primary outcome measures to compare differences in symptom improvement, social functioning, relapse rate, medication adherence, hospitalization status, and medical expenses between the two groups. *Results:* After 12 months of intervention, the PANSS total score in the intervention group ( $43.0 \pm 6.8$ ) was significantly lower than that in the control group ( $47.9 \pm 7.5$ ), while the PSP score ( $66.0 \pm 8.0$ ) was significantly higher than that in the control group ( $60.8 \pm 7.3$ ), with statistically significant differences ( $p < 0.001$ ). The relapse rate in the intervention group (10.0%) was significantly lower than that in the control group (22.0%), while the medication adherence rate (83.0%) was significantly higher than that in the control group (68.0%). The hospitalization rate, number of hospitalization days, and annual total medical expenses were all significantly lower in the intervention group than in the control group ( $p < 0.05$ ). *Conclusion:* The comprehensive community-based rehabilitation service model can effectively improve psychiatric symptoms and social functioning in patients with severe mental disorders, reduce the risk of relapse and hospitalization, and save medical costs. It represents an efficient and promotable core intervention strategy for the holistic management of severe mental disorders.

**Keywords:** Severe mental disorders; Community rehabilitation; Holistic management; Randomized controlled trial; Social functioning; Prevention of relapse

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## 1. Introduction

Severe mental disorders are a class of psychiatric illnesses that significantly impair patients' social functioning and quality of life, including schizophrenia, bipolar disorder, and schizoaffective disorder. These disorders are characterized by prolonged courses, high relapse rates, and severe disability, imposing a heavy burden on patients, their families, and society. The traditional hospital-centered treatment model often leads to repeated hospitalizations, social isolation, and escalating care burdens, and has become increasingly inadequate in meeting patients' long-term rehabilitation needs <sup>[1]</sup>. China's management standards for severe mental disorders have explicitly incorporated community rehabilitation into the core components of whole-course management, while the "Integrated Mental Health Rehabilitation Initiative" further mandates the establishment of a continuous, integrated, and accessible community rehabilitation service system <sup>[2,3]</sup>.

Community rehabilitation services for mental disorders aim to facilitate patients' reintegration into society by improving their self-care abilities, social adaptation and participation, and employment skills. These services employ a comprehensive approach integrating psychiatry, rehabilitation therapy, psychosocial interventions, social work, community support, and volunteer services to provide lifelong care, health education, functional training, and social support, thereby enhancing patients' overall health. However, current community rehabilitation services often suffer from fragmentation, inadequate professional capacity, and poor hospital-community coordination, lacking evidence-based evaluations of comprehensive service models <sup>[4]</sup>. This study employed a randomized controlled trial (RCT) to investigate the clinical efficacy, social functioning improvements, and health economic value of comprehensive community rehabilitation in whole-course management of patients with severe mental disorders, providing evidence for policy optimization and clinical implementation.

## 2. Subjects and methods

### 2.1. Study design

A parallel-group randomized controlled trial (RCT) was conducted following CONSORT guidelines <sup>[5]</sup>. Participants were recruited from outpatient community rehabilitation service sites affiliated with our hospital. Assessors were blinded, and participants were randomly assigned to intervention and control groups in a 1:1 ratio.

### 2.2. Subjects

#### 2.2.1. Inclusion criteria

Patients aged 18–65 years meeting DSM-5 diagnostic criteria for severe mental disorders, with stable conditions and basic communication abilities <sup>[6]</sup>.

#### 2.2.2. Exclusion criteria

Severe physical illnesses, substance dependence, or inability to cooperate with follow-up.

#### 2.2.3. Sample size calculation

Based on a previous effect size (Cohen's  $d = 0.65$ ) for PSP score improvements in community rehabilitation, with  $\alpha = 0.05$ , power  $(1-\beta) = 0.80$ , and accounting for a 15% dropout rate, 90 participants per group were

required<sup>[7]</sup>. Thus, 200 patients (100 per group) were planned for recruitment.

### 2.3. Interventions

The intervention group received comprehensive community rehabilitation, including medication management and adherence training, symptom monitoring and relapse prevention, social skills training, vocational rehabilitation, family support, and peer support<sup>[8–10]</sup>. The control group received standard community management under national basic public health service guidelines, including regular follow-ups, medication supervision, and basic health guidance<sup>[2]</sup>.

### 2.4. Outcome measures

The Positive and Negative Syndrome Scale (PANSS) assessed psychiatric symptom severity, comprising 30 items divided into three subscales: positive symptoms (7 items), negative symptoms (7 items), and general psychopathology (16 items), with a 7-point rating scale (1–7)<sup>[11]</sup>. Higher total scores indicate greater symptom severity. The Personal and Social Performance Scale (PSP) evaluated social functioning across four domains: socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behavior, using a 100-point scale. Higher scores indicate better social functioning<sup>[12]</sup>. The Morisky Medication Adherence Scale assessed medication adherence with four items on a 4-point scale, with scores  $\geq 3$  indicating good adherence<sup>[13]</sup>. The WHO Quality of Life-BREF (WHOQOL-BREF) evaluated quality of life across 26 items in four domains: physical health, psychological health, social relationships, and environment<sup>[14]</sup>. The Caregiver Burden Inventory (CBI) assessed caregiver burden across 24 items in five domains: time-dependent burden, developmental burden, physical burden, social burden, and emotional burden<sup>[15]</sup>.

### 2.5. Statistical analysis

Data were analyzed using SPSS 26.0 with repeated measures ANOVA,  $\chi^2$  tests, and *t*-tests<sup>[16]</sup>. A *p*-value  $< 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Baseline characteristics of participants

A total of 200 patients were recruited, with all completing the study (0% dropout rate). Baseline data showed no statistically significant differences in demographic or clinical characteristics between the two groups (*p*  $> 0.05$ ), indicating comparability. See **Table 1**.

**Table 1.** Comparison of baseline characteristics between groups

Characteristic	Intervention group(n = 100)	Control group(n = 100)	<i>p</i> value
Age (years, mean $\pm$ SD)	41.8 $\pm$ 10.8	42.0 $\pm$ 11.0	0.876
Gender (male/female)	62/38	59/41	0.614
Disease duration (years, mean $\pm$ SD)	8.2 $\pm$ 4.0	8.5 $\pm$ 4.3	0.582
Diagnosis (schizophrenia/bipolar/schizoaffective)	72/20/8	70/23/7	0.897
Baseline PANSS total score (mean $\pm$ SD)	52.0 $\pm$ 8.5	51.8 $\pm$ 9.0	0.892
Baseline PSP score (mean $\pm$ SD)	58.0 $\pm$ 10.0	58.5 $\pm$ 9.5	0.753

## 3.2. Primary outcome measures

### 3.2.1. Improvement in psychiatric symptoms (PANSS)

By referring to **Table 2**, repeated measures analysis of variance revealed statistically significant effects for between-group differences ( $F = 16.8, p < 0.001$ ), time ( $F = 120.5, p < 0.001$ ), and their interaction ( $F = 8.2, p < 0.001$ ). By the 12-month mark, the intervention group exhibited an average reduction of 4.9 points in the total PANSS score compared to the control group, with an effect size of  $d = 0.68$ .

**Table 2.** Changes in total PANSS scores of patients in the two groups ( $\bar{x} \pm s$ )

Time point	Intervention group (n = 100)	Control group (n = 100)	Intergroup difference (95% CI)	p value	Effect size(d)
Baseline	52.0 ± 8.5	51.8 ± 9.0	-	-	-
3 months	48.5 ± 8.0	49.9 ± 8.5	-1.4 (-2.8, -0.1)	0.042	0.18
6 months	46.0 ± 7.2	48.4 ± 8.0	-2.4 (-3.8, -1.0)	< 0.001	0.32
12 months	43.0 ± 6.8	47.9 ± 7.5	-4.9 (-6.3, -3.5)	< 0.001	0.68

### 3.2.2. Recovery of social functioning (PSP)

According to **Table 3**, the PSP scores in the intervention group showed a continuous upward trend, with an average increase of 5.2 points compared to the control group at 12 months. This difference was statistically significant ( $p < 0.001$ ), with an effect size of  $d = 0.65$ .

**Table 3.** Changes in PSP Scores for Both Groups of Patients ( $\bar{x} \pm s$ )

Time Point	Intervention group (n = 100)	Control group (n = 100)	Inter-group difference (95% CI)	p value	Effect size (d)
Baseline	58.0 ± 10.0	58.5 ± 9.5	-	-	-
3 months	60.5 ± 9.0	58.8 ± 8.5	1.8 (0.3, 3.2)	0.018	0.2
6 months	63.0 ± 8.5	59.8 ± 7.8	3.2 (1.8, 4.6)	< 0.001	0.41
12 months	66.0 ± 8.0	60.8 ± 7.3	5.2 (3.8, 6.6)	< 0.001	0.65

### 3.2.3. Relapse rate

During the study period, 10 cases (10.0%) in the intervention group experienced relapse, compared to 22 cases (22.0%) in the control group. The  $\chi^2$  test indicated a statistically significant difference ( $\chi^2 = 4.56, p = 0.033$ ). The relapse rate in the intervention group decreased by 12 percentage points, with a relative risk reduction of 54.5% (RR = 0.455, 95% CI: 0.221–0.935).

The criteria for determining relapse of severe mental disorders in this study were based on the “Work Specifications for the Management and Treatment of Severe Mental Disorders (2018 Edition)” and the general definitions used in similar community rehabilitation studies both domestically and internationally<sup>[17,18]</sup>. Relapse was determined if any of the following criteria were met:

- (1) Significant worsening of psychiatric symptoms, with a  $\geq 20\%$  increase in the total Positive and Negative Syndrome Scale (PANSS) score compared to the baseline or recent stable value at enrollment, or the emergence of prominent psychotic symptoms such as hallucinations, delusions, behavioral disorganization, or agitation.
- (2) The need to adjust the dosage or type of antipsychotic medication, or initiate emergency intervention or outpatient intensive treatment due to acute exacerbation of the condition.

- (3) Unplanned hospitalization or compulsory medical treatment due to deterioration of psychiatric symptoms.
- (4) The occurrence of significant self-injury, suicide attempts, or violent impulsive behavior requiring emergency medical intervention.

### 3.3. Secondary outcome measures

#### 3.3.1. Medication adherence

At the end of the study, 83 patients (83.0%) in the intervention group had good medication adherence, compared to 68 patients (68.0%) in the control group. The difference between the groups was statistically significant ( $\chi^2 = 5.24, p = 0.022$ ).

#### 3.3.2. Hospitalization status

The hospitalization rate and the average length of hospital stay per person in the intervention group were significantly lower than those in the control group, with an average reduction of 8.7 days in hospital stay and a decrease rate of 32.8%. Refer **Table 4**.

**Table 4.** Comparison of hospitalization status between the two groups of patients

Indicator	Intervention group (n = 100)	Control group (n = 100)	Intergroup difference (95% CI)	p value
Hospitalization rate (%)	15	30	-15.0 (-25.1, -4.9)	0.004
Hospital days per person (days, mean $\pm$ SD)	17.8 $\pm$ 14.5	26.5 $\pm$ 19.2	-8.7 (-13.2, -4.2)	< 0.001

The hospitalization rate and the average length of hospital stay per person in the intervention group were significantly lower than those in the control group, with an average reduction of 8.7 days in hospital stay and a decrease rate of 32.8%.

#### 3.3.3. Medical expenses

The annual total medical expenses in the intervention group were significantly lower than those in the control group, with an average savings of 850 yuan per case and a decrease rate of 10.8%. Refer **Table 5**.

**Table 5.** Comparison of annual medical expenses between the two groups (Yuan,  $\bar{x} \pm s$ )

Cost type	Intervention group (n = 100)	Control group (n = 100)	Intergroup difference (95% CI)	p value
Outpatient cost	1400 $\pm$ 475	1600 $\pm$ 530	-200 (-320, -80)	0.001
Hospitalization cost	3750 $\pm$ 3150	4350 $\pm$ 3800	-600 (-1350, 150)	0.115
Medication cost	1900 $\pm$ 420	1950 $\pm$ 450	-50 (-160, 60)	0.368
Total cost	7050 $\pm$ 3500	7900 $\pm$ 4100	-850 (-1550, -150)	< 0.001

## 4. Discussion

### 4.1. Key findings and mechanism analysis

This study, based on a randomized controlled trial with 200 samples, confirms that the comprehensive

community rehabilitation service model holds significant advantages in the whole-course management of severe mental disorders.

(1) Superior symptom control

The intervention group showed a 4.9-point reduction in the total PANSS score compared to the control group, with particularly notable improvements in negative symptoms. This is closely related to the multidimensional rehabilitation interventions covering medication side effect management, cognitive training, and emotional regulation <sup>[9]</sup>.

(2) Significant social function reconstruction

The PSP score increased by 5.2 points, with an effect size of  $d = 0.65$ , indicating substantial improvements in patients' interpersonal interactions, self-care, and social participation. This long-term cumulative effect benefits from systematic life skills and social skills training <sup>[10]</sup>.

(3) Effective reduction in relapse risk

The relative risk of relapse decreased by 54.5%, validating the core gatekeeper role of community rehabilitation in breaking the "hospital-community revolving door" <sup>[19]</sup>. The decline in relapse rate is directly related to improved medication adherence, underscoring the importance of long-term continuous management <sup>[18]</sup>.

(4) Good cost-effectiveness

Although the difference in hospitalization expenses was not statistically significant ( $p = 0.115$ ), outpatient expenses decreased significantly, and total expenses dropped by 10.8%, demonstrating that community rehabilitation can effectively conserve healthcare resources while ensuring therapeutic efficacy <sup>[20,21]</sup>.

## 4.2. Methodology and limitations

Although the sample size of this study was reduced to 200 cases, it had sufficient statistical power (Power = 0.93) based on effect size calculations. The study's limitations include its single-center design, which limits the generalizability of the results, and a follow-up period of 12 months, with the long-term effects (e.g., beyond 2 years) requiring further cohort observation <sup>[22]</sup>.

## 5. Conclusion

This study systematically evaluated the application value of the comprehensive community rehabilitation service model in the whole-course management of patients with severe mental disorders through a 12-month randomized controlled trial with a total sample size of 200 cases. The results showed that compared to the conventional community management model, comprehensive community rehabilitation can achieve significant improvements in multiple key dimensions, including mental symptom control, social function recovery, medication adherence enhancement, relapse risk reduction, and alleviation of hospitalization and medical burdens. This provides solid empirical support for the "hospital-community-family" integrated whole-course management.

In summary, the comprehensive community rehabilitation service model aligns with the chronic, recurrent, and long-term management needs of severe mental disorders. It can permeate the entire process from consolidation after the acute phase, maintenance, rehabilitation, to social reintegration, serving as an indispensable key component in the whole-course management system. This model is safe, effective, and

economically feasible, making it suitable for standardized and large-scale promotion in primary mental health services. In the future, efforts should be made to strengthen multi-sectoral collaboration, improve the construction of community rehabilitation talent teams, and enhance the two-way referral mechanism between hospitals and communities to promote the deep integration of community rehabilitation and whole-course management, thereby comprehensively improving the level of rehabilitation services for severe mental disorders in China and assisting patients in better returning to their families and society.

## Disclosure statement

The authors declare no conflict of interest.

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