Effects of adherence therapy by psychiatric nurses for people with schizophrenia in Japan : A randomized controlled trial

博士論文（要約）

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（統合失調症を持つ人に対する精神科看護師によるアドヒアランス・セラピーの効果：無作為化比較試験）

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論文の内容の要旨

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Background

Non-adherence to antipsychotic medications among people with schizophrenia increased rates of symptomatic relapse and hospitalization, and non-adherence is associated with negative impacts on functioning and the course of the illness. The mean rate of non-adherence among people with schizophrenia is around 45%, and 75% of people with schizophrenia stop medication within two years of hospital discharge. It is important to prevent relapse among people with schizophrenia. Relapses can be prevented by enhancing treatment adherence among patients as a means of illness self-management.

Factors affecting adherence in people with schizophrenia are patient-related factors, clinician-related factors, medication-related factors, and environmental factors. The adherence therapy program addresses medication problems for individual patients. Adherence therapy has been developed to be provided by nurses and is based on cognitive behavioral therapy and motivational interviewing. The aim of adherence therapy is to achieve a joint decision or concordance about medications between patients and therapists. Although some results of previous studies showed that adherence therapy was largely effective in improving adherence to treatment and clinical outcomes for people with schizophrenia, the effects of adherence therapy have been slightly inconsistent. Further studies are required to examine the intervention effects of this therapy. The effect of adherence therapy has not been tested in a randomized controlled trial among people with schizophrenia in Japan.

Objective

A randomized controlled trial was conducted to examine the effects of adherence therapy by psychiatric nurses on improving psychotic symptoms and enhancing medication adherence among hospitalized people with schizophrenia in Japan.

Method

Participants were inpatients at five Japanese hospitals in Fukushima, Miyagi, Nara, Fukuoka, and Kumamoto who were diagnosed with schizophrenia or schizoaffective disorders. The subjects (n = 81) were introduced to the researcher by administrators of each hospital, and 53 eligible participants were randomly assigned to an intervention group (n = 27) or a control group (n = 26) stratified by the hospital.

The author made an authorized translation of the latest adherence therapy manual into Japanese.

Psychiatric nurses received adherence therapy training for at least six hours. The adherence therapy program was delivered for the participants in the intervention group on a face-to-face and one-on-one basis by trained psychiatric nurses. They received eight sessions over an eight-week period. Treatment phases in the adherence therapy program were engagement (first session), assessment (first and second sessions), intervention (third through seventh sessions), and evaluation (eighth session). Sessions were delivered during outpatient visits for patients who were discharged midway through the intervention. The participants in the control group received treatment as usual at their hospitals during the study.

Participants in the intervention and control groups completed the same questionnaire at the entry in the study (baseline), eight weeks after the baseline assessment (post-intervention), and sixteen weeks after the baseline assessment (follow-up). Semi-structured interviews about psychotic symptoms were also conducted. Primary outcomes were

1. psychotic symptoms (based on the Oxford University version of the Brief Psychiatric Rating Scale [BPRS]); and
2. medication adherence (based on the Drug Attitude Inventory [DAI]).

Secondary outcomes were

1. insight (based on the Birchwood Insight Scale for psychosis [BIS]);
2. self-efficacy (based on the Self-Efficacy for Community Life scale [SECL]);
3. treatment satisfaction (based on the Treatment Satisfaction Questionnaire for Medication [TSQM]); and
4. client satisfaction (based on the Client Satisfaction Questionnaire [CSQ]).

Participants, intervention providers, and evaluators were not blinded to the allocation after assignment.

The analyses were conducted on an intention-to-treat basis for the primary and secondary outcome variables in the total sample. The intervention effect was tested by using a repeated measures analysis of variance as an interactive effect between two groups (the intervention and control groups) and three occasions (baseline, post-intervention, and follow-up). Per-protocol analyses were also conducted in a similar way, excluding the participant in the intervention group who did not receive intervention. Two subgroup analyses were conducted: (1) intervention effect on medication adherence in two subgroups classified based on the severity of psychotic symptoms at the baseline assessment; and (2) intervention effect in two subgroups classified based on the degree of medication adherence.

Written informed consent was obtained from all participants. The study's aim and plan were reviewed and approved by the Research Ethics Committee of the Faculty of Medicine/Graduate School of Medicine, the University of Tokyo, and the Ethics Committee of Kyushu University.

Results

A total of 25 psychiatric nurses in five hospitals were recruited in the present study and delivered adherence therapy to inpatients with schizophrenia. Their average number of years working in psychiatry was 8.0 years.

In the participant flow, one participant in the intervention group did not receive intervention and was excluded from the analyses. The primary analysis was intention-to-treat and involved 52 participants.

Forty-one participants remained for the per-protocol analysis. The drop-out rate was 22.6% of all participants.

There was no significant difference between the intervention group and the control group in the demographic and medical characteristics of participants, including the score of psychotic symptoms (BPRS) and medication adherence (DAI) at baseline ($p > 0.05$). The rate of non-adherent participants was 42.3% in both groups.

No significant intervention effect was observed on psychotic symptoms ($p > 0.05$) or medication adherence ($p > 0.05$) as primary outcomes. Psychotic symptoms and medication adherence improved at follow-up in both groups. As secondary outcomes, no significant intervention effect was observed for the total score and any subscale of insight, any component of treatment satisfaction for medication, or client satisfaction ($p > 0.05$). While a significant intervention effect was only observed for the SECL subscale score of treatment-related behavior ($p < 0.05$), there were no significant effects on the other subscale and total scores of self-efficacy ($p > 0.05$).

The results of subgroup analysis showed no significant intervention effect for medication adherence among participants with severe symptoms or in those with mild symptoms at baseline ($p > 0.05$). Similarly, there was no significant intervention effect for psychotic symptoms among participants with positive adherence or in those with negative adherence at baseline ($p > 0.05$).

The mean time of sessions was 38.1 minutes per session and the average of total contact time was 5.1 hours.

Discussion

This study showed that there were no significant intervention effects from the current adherence therapy program for the psychotic symptoms and medication adherence of people with schizophrenia. A significant intervention effect was observed only for self-efficacy on treatment-related behavior. Adherence therapy might not be effective for improving psychotic symptoms or medication adherence among inpatients with schizophrenia in Japan, while it may enhance self-efficacy on treatment-related behavior.

The current program of adherence therapy for people with schizophrenia was not significantly effective for psychotic symptoms and medication adherence as primary outcomes. These effect size for psychotic symptoms and medication adherence were much smaller than those reported in previous studies. It may be that it was difficult to find positive intervention effects because the severity of psychotic symptoms in this study was less than in previous studies.

A significant intervention effect was observed for the SECL subscale score of treatment-related behavior, while there were no significant effects on the other secondary outcomes.

The effect size for self-efficacy on treatment-related behavior was relatively large (0.62) in the total sample at follow-up. It was shown that adherence therapy could enhance self-efficacy on treatment-related behavior of people with schizophrenia. Further studies on the effect of adherence therapy on self-efficacy are needed.

On the other hand, there was no significant effect on insight. Because a different outcome measure of insight (Schedule for Assessment of Insight) was used in previous study, these results were difficult to

compare with results from this study. In this study, the participants of both groups did not show high insight at follow-up. In the previous study which showed improvements in insight, the participants were followed up over 18 months. Insight might not have been changed during the brief therapy implemented in this study (16-week follow-up). Further studies with the same measurement and the same length of follow-up are needed in the future.

Although there was no significant effect on treatment satisfaction (TSQM), a previous study showed that satisfaction with medication treatment was significantly improved by adherence therapy. A possible reason for this difference was that adherence therapy did not lead to prescription changes in this study.

There was no significant difference on client satisfaction between the intervention group (adherence therapy) and the control group (treatment as usual). The effect sizes for client satisfaction (CSQ) of this study were 0.31 at post-intervention and 0.42 at follow-up in the total sample, although they were not significant.

In this study, improvements in insight, treatment satisfaction, and client satisfaction among people with schizophrenia were not found.

Limitations

Participants might not have been representative of people with schizophrenia in Japan, and the indicator of medication adherence was assessed only by a self-report. Further research with a greater number of participants is needed, particularly patients with schizophrenia whose adherence is poor and who use a combination of subjective and objective indicators to evaluate their medication adherence.

In this study, while the drop-out rate was almost the same as in previous studies, effect sizes were smaller than in previous studies which showed positive effects of adherence therapy. The needed sample size would have been larger than in this study.

The mean time of sessions and the average of total contact time were slightly shorter than in the previous study. In addition, the length of adherence therapy training for nurses was shorter than in previous studies. Further intervention studies with the same amount of training time as indicated in the original manual and the same amount of session time as in the previous study are needed.

Conclusion

The present study failed to show that there were positive effects of adherence therapy for improved psychotic symptoms and medication adherence among people with schizophrenia, while it showed that self-efficacy for treatment-related behavior improved after the intervention.