Original article

Efficacy of modified compliance therapy for schizophrenia patients

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BACKGROUND: Schizophrenia requires a large share of medical resources due to its early onset and chronic and severe nature. Compliance therapy is a therapy specifically designed to improve concordance with treatment for those with major mental illnesses. The aim of present study was to determine whether compliance therapy improves drug adherence and consequently makes better global functioning and improves quality of life in schizophrenic patients. **METHODS**: This randomized controlled clinical trial study was done in Noor Hospital in 2008-2009. Patients were randomly assigned to receive the intervention consisting of 8 sessions of compliance therapy, or the control treatment consisting of an equal number of sessions of supportive counseling. All patients were evaluated by Heinrichs Quality of Life scale, Global Assessment of Functioning (GAF) scale, and Positive and Negative Symptoms Scale (PANSS) at baseline, third month and sixth month after intervention. **RESULTS:** 76 schizophrenic patients who met criteria of study were enrolled in the trial. Our data showed a significant main effect for interaction of group and time for GAF scale, Heinrichs Quality of Life scale and PANSS. **CONCLUSIONS:** The findings of our study showed that compliance therapy can improve not only global functioning but also quality of life in schizophrenic patients. In addition, PNASS was improved during the six months follow-up in compliance therapy group.

KEYWORDS: Schizophrenia, Heinrichs Quality of Life Scale, Global Assessment of Functioning, Positive and Negative Symptoms Scale, Compliance Therapy

BACKGROUND

Schizophrenia, affecting nearly 1% of the world's population, is manifested by chronic psychosis and social, occupational, behavioral and cognitive impairments.[1] This debilitating psychiatric disorder requires a disproportionate share of medical resources due to its early onset and chronic and severe nature.[2] Deficits in adaptive functioning varying between problems in basic activities of daily living to troubles maintaining competitive employment.[3] Cognitive deficits rather than the positive or negative symptoms of schizophrenia predicted poor performance in basic activities of daily living.[4] In recent studies, it was shown atypical antipsychotic medications can improve neurocognitive performance,[5-8] although significant cognitive deficits is still remained.[6] On the other hand, compliance with antipsychotic medication is generally poor which is along with a substantial increase in re hospitalizations and a generally poorer outcome in people with psychotic disorders.[9,10] 90% of patients will relapse within the first five years of treatment following an acute episode which is mainly because of discontinuation of effective antipsychotic drug therapy.[11] It was reported that up to 80% of people with psychosis are non-compliance or sub-optimal treatment adherence[12] and if patients were completely compliant with their medication, relapse rates would fall to about 15%.[13] Several effective psychosocial interventions such as family therapy,[14] compliance therapy[15] and psychoeducational approaches[16] are currently available for the treatment of schizophrenia. Compliance therapy is a therapy specifically designed to improve concordance with treatment for those with major mental illnesses, but its effectiveness in patients with schizophrenia is controversial.[15] It is a cognitive behavior intervention with techniques adapted from motivational interviewing and psycho-education therapies.[17] Kemp et al. described "compliance therapy" causes to better drug compliance, attitudes to treatment, and insight at final of intervention;[18,19] however, some studies did not confirm it.[20] By this study, we aimed to determine whether compliance therapy improves drug adherence and consequently make better global functioning and improve quality of life in schizophrenic patients.

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METHODS

Subjects

Study subjects were 76 inpatients and outpatients in psychiatric clinic and ward of Isfahan Noor Hospital. They were invited to participate in this study after controlling the following inclusion criteria: 1) Patients with the diagnosis of schizophrenia or schizoaffective disorder according to the Clinical Interview for DSM-IV (SCID);[21] 2) Patients who were in remission phase of disease; 3) Age between 18 and 65 with fluent Persian reading and writing; 4) No evidence of organic disturbance or mental retardation; 5) No history of substance abuse or dependence based on DSM-IV criteria; 6) Giving written informed consent at least by first relative family member. The exclusion criterion was absence for more than three sessions of eight sessions.

Design and procedures

The study used a randomized, controlled clinical trial design and patients were randomly assigned to receive compliance therapy or supportive counseling (control). It was done from March 2008 to September 2009. At the screening visit, after providing demographic data and written informed consent approved by the Medical Ethics Committee of the Isfahan University of Medical Sciences, eligible subjects were randomly assigned to intervention or control group (1:1).

Our modified cognitive-behavioral program was based around these therapeutic strategies: evaluation, solving problems of medical therapy, timing of treatment, identifying conflicts of treatment, discussion about the attitudes and attentions to treatment, and following treatment in future. Based on our previous experiences, in addition to these sessions there were discussions with two subjects such as false beliefs and attitudes about the disease and its medications, and describing discrimination between true beliefs and superstitions and their effects on disease treatment for patients and their families. This intervention consists of eight sessions, lasting 30-60 minutes, at first every two weeks and then monthly for six months.

The control group received an equal number and design of sessions of supportive counseling. It is a form of therapy for mental disturbances employing non-specific counseling, guidance and encouragement to develop the patient's own resources; but does not specifically focus on any aspects of psychotherapy.

Efficacy assessments

All patients were evaluated for quality of life, global functioning, and positive and negative symptoms at initial, third month and sixth month follow up of intervention. Global functioning was assessed using Global Assessment of Functioning (GAF) scale.[22] The overall level of functionality on a scale from one to 100 on the basis of the clinician's judgment about the patient's psychological and occupational functioning is assessed by this instrument. We determined quality of life using the Heinrichs Quality of Life scale,[23] a 21 items scale which rated 0-6. The scale is rated by semi-structured interview providing information on symptoms and functioning in the last four weeks from beginning of the trial. Dimensions such as interpersonal relations and social network (eight questions), instrumental role functioning (four questions), intrapsychic foundations (seven questions) and common objects and activities (two questions) were scored by this instrument. The Positive and Negative Symptoms Scale (PANSS) was used to measure symptomatology,[24] a 30-item scale which is divided into three subscales: negative symptoms (seven items), positive symptoms (seven items) and general psychopathology (16 items). Each item was rated from one (absent) to seven (extreme).

The translation and back-translation method was used to make the Persian translation of PANSS and Heinrichs Quality of Life Scale valid. PANSS and Heinrichs Quality of Life Scale were translated by two psychiatrists to Persian and then two other bilingual psychiatrists translated the same text to first language. Translated texts were evaluated by the translation team for final decision.

Statistical analysis

The Student's t-test and chi-square test were used for initial comparison of variables between groups. Group differences between prior to the third months and at the end of 6 months intervention were examined using repeated measures ANOVA. P-values less than 0.05 were considered significant. Data were analyzed using SPSS 17.0 software (SPSS Inc., Chicago, IL, USA).

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RESULTS

76 schizophrenic patients who met criteria of study were enrolled to the trial. The demographic and clinical characteristics of the two treatment groups are showed in table 1. There were no statistically significant socio-demographic differences between compliance therapy group and the control group on any of these variables except educational level at the time of initial assessment. The numbers of illiterate patients in compliance therapy and control group were two and nine, respectively, which was statistically

significant (p = 0.022). The two treatment groups' mean scores on measures of GAF scale, Heinrichs Quality of Life scale, and PANSS at the initial, third months and sixth months are presented in table 2. Moreover, the difference between the mean (± SD.) score of GAF scale, Heinrichs Quality of Life scale, and PANSS was significant at the initial of study but for GAF, repeated measures ANOVA revealed a significant main effect for group, a non-significant main effect for time, and a significant interaction of group and time (Figure 1). Likewise, for Heinrichs Quality of Life a significant main effect for group, a significant main effect for time, and a significant interaction of group and time was indicated (Figure 2). For PANSS repeated measures ANOVA revealed a significant main effect for group, a significant main effect for time, and a significant interaction of group and time (Figure 3). The results of the repeated measures of ANOVA for all scores were adapted by considering the educational level difference between the two groups (Table 3).

Table 1. Socio-demographic and Clinical Characteristics of 76 Schizophrenic patients receiving compliance therapy or non-specific counseling at initial of study

Characteristics	Treatment group (N = 38)	Control group (N = 38)	P-value
Age, mean ± SD	29.9 ± 9.27	31.1 ± 10.35	0.617
Sex:			
Male	26 (68.42)	26 (68.42)	1
Female	12 (31.57)	12 (31.57)	
Marital status:			
Single	31 (81.57)	30 (78.94)	0.77
Married	7 (18.42)	8 (21.05)	
Education:			
Literate	36 (94.73)	29 (76.31)	0.022
Illiterate	2 (5.26)	9 (23.68)	
Hospitalization during recent year:			
1	11 (28.94)	23 (60.52)	
2	16 (42.1)	8 (21.05)	0.114
≥ 3	11 (28.94)	7 (18.42)	

All variables are number (%) unless otherwise indicated.

Table 2. Frequency and Mean (± SD) score of Global Assessment of Functioning (GAF), Heinrichs Quality of Life scale and Positive and Negative Symptoms Scale (PANSS) at the initial, third months and sixth months

SCALE	Intervention Mean ± SD	Control Mean ± SD	P-value
GAF			
Before intervention	58.7 ±11.6	52.1 ± 8.1	0.001
At 3 months	67.3 ± 10.6	47.6 ± 11.7	0.001
At 6 months	72.4 ± 11.4	44.2 ± 12.9	0.001
Heinrichs Quality of Life			.
Before intervention	68.2 ± 21.8	51.3 ± 16.9	0.009
At 3 months	83.1 ± 19.9	44.1 ± 12.5	0.001
At 6 months	101.2 ± 17.2	44.8 ± 15.6	0.001
PANSS			
Before intervention	54.1 ± 15.6	77.7 ± 17.4	0.001
At 3 months	51.1 ± 13.8	79.3 ± 18.2	0.001
At 6 months	44.9 ± 10.8	77.5 ± 20.1	0.001

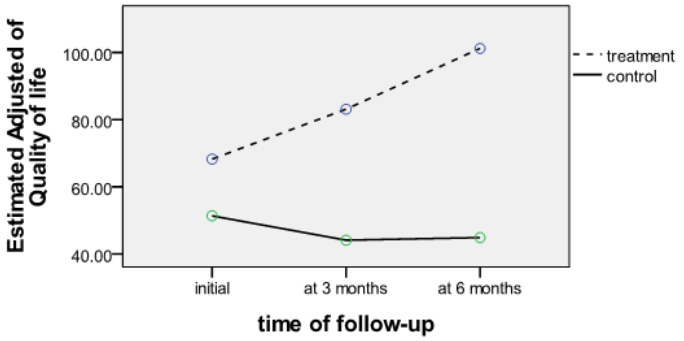

Figure 1. Quality of life over six months in schizophrenia patients receiving camp or non-specific counseling

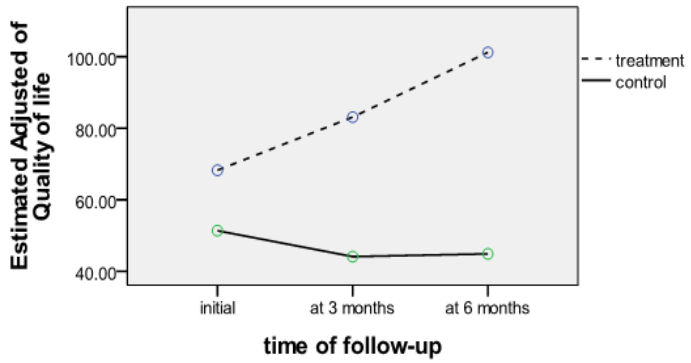

Figure 2. Quality of life over six months in schizophrenia patients receiving compliance therapy or non-specific counseling

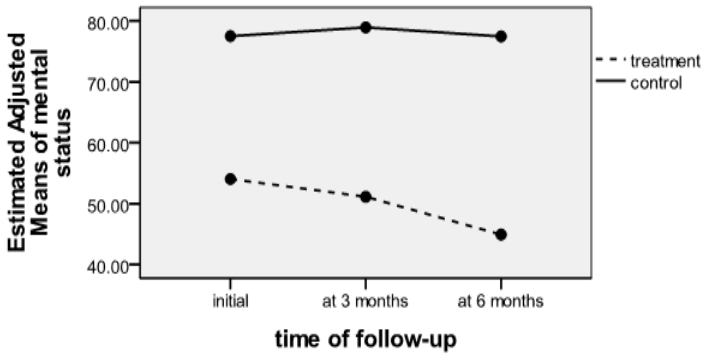

Figure 3. Positive and negative symptom scale over six months in schizophrenia patients receiving compliance therapy or non-specific counseling

Table 3. Summarizes of Global Assessment of Functioning (GAF), Heinrichs Quality of Life scale and Positive and Negative Symptoms Scale (PANSS) scores in the patients based on 3 and 6 month follow-up controlling for educational level using ANCOVA repeated measure

Main Effects	F-test	d.f.	p-value
GAF:			
Follow-up (time effect)	1.82	(2.73)	0.168
Intervention (group effect)	75.1	(1.74)	< 0.001
Follow-up * Intervention (interaction effect)	31.1	(2.73)	< .001
Heinrichs Quality of Life:			
Follow-up (time effect)	16.2	(2.73)	< 0.001
Intervention (group effect)	141.4	(1.74)	< 0.001
Follow-up * Intervention (interaction effect)	29.6	(2.73)	< 0.001
PANSS			
Follow-up (time effect)	6.59	(2.72)	0.002
Intervention (group effect)	74.7	(1.73)	< 0.001
Follow-up * Intervention (interaction effect)	3.39	(2.72)	0.039

DISCUSSION

We used Clinical Interview for DSM-IV (SCID) for diagnosing the subjects and assessed the efficacy of intervention by assessing the GAF scale mean score, Heinrichs Quality of Life scale mean score and PANSS mean score. Our findings showed that although the differences between the mean scores were significant at the initial of study, compliance therapy can improve not only global functioning but also quality of life and positive and negative symptoms in schizophrenic patients, during the six months follow up while it became worsen in the control group, which is relevant from significant interaction of group and time. In addition, the numbers of illiterate patients in compliance therapy and control group was statistically significant but the results of the repeated measures of ANOVA for all scores were adapted by considering the educational level difference between the two groups.

There had been a little evidence to evaluate whether the intervention can improve the compliance of prescribed drugs in psychotic patients.[25] The interventions which have been used for this purpose consisted of educational,[26,27] behavioral[28] and cognitive-behavioral interventions.[21] Because in our society, cultural beliefs have a notable effect on patients' beliefs about their illness and treatment, we used cultural concepts as a part of discussion about the attitudes and attentions to treatment in compliance therapy; this was a new idea in our study.

Kemp et al. reported the positive effect of compliance therapy on patients with schizophrenia throughout the six[18] and 18[19] months follow-up. Moreover, improved insight and global functioning and decreasing rate of readmission and more cost effectiveness were showed in compliance therapy group.[19] Furthermore, in a published review article about compliance therapy in schizophrenia by McIntoch et al.[16] from all relevant randomized clinical trials, they only included O'Donnell[20] study according to the criteria of their survey which revealed that compliance therapy may not assist these patients. In fact, positive and negative symptoms, global functioning, insight, quality of life and average number of hospital day were not statistically different between compliance and non-compliance therapy groups in their study.[20]

There are some issues which interfere with the compliance in schizophrenic patients, especially in our study. In Diana et al. study[29] that was about predictors of noncompliance in patients with schizophrenia, it was shown that different factors determined compliance in schizophrenic patients such as patients' beliefs about their illness and treatment, side effect and cost of treatment, family or social support, and ease or difficulty in access to treatment. In our study, an attempt was made to match these variables in both groups; however, this was not completely possible. Another problem which has been challenged in similar studies is definition of compliance and methods by which it has been assessed.[30-32] There is not a consensus on what the compliance means. In our study, this was an indirect composite measure based on information from global functioning, quality of life, and positive and negative symptoms. Different ways has been used measuring compliance such as physician judgment, patients' self report, pill count and blood and urine analysis, although none of them is entirely acceptable.[25] In our study, like Kemp et al. study,[18] we relied on the self reports evaluation for measure of compliance which is not ideal. Finally, the modern mental health care has moved from 'compliance' to 'concordance' model during recent years. The supporters of this model are of the opinion that patients, themselves, should have the right to make decision to stop or continue their medication even though it is against the physician's decision. The important matter is helping them making an appropriate decision.[33]

In conclusion, as our study established noncompliance with antipsychotic drugs which is obviously a main avoidable reason of relapse in patients with psychotic disorders, so to address this matter more studies are needed considering the discussed factors to enhance the schizophrenic patients' tendency towards taking medication.

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