

Quality of life in Schizophrenia patients with and without adequate pharmaceutical care: A randomized controlled study

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ARTICLE INFO

Keywords:

Schizophrenia
Psychotropic drugs
Prescribing indicators
Quality of life

ABSTRACT

Introduction: Schizophrenia is a complicated mental illness manifesting in a variety of disturbing clinical presentations in an individual, resulting in varying treatment results and poor Quality of Life (QoL). This study was aimed at assessment and comparison of QoL in patients with and without provision of pharmaceutical care and evaluation of the drug utilisation pattern among the patients.

Materials and methods: A randomized controlled study was conducted among 104 patients fulfilling the eligibility criteria, randomly assigned to control and interventional group, with 52 patients in each group. At baseline and follow up, QoL scores were compared using the WHOQOL-BREF questionnaire for each group. Patient counselling was provided to the intervention group.

Results: Schizophrenia was prevalent in females (56.2%) and 34.4% were below 30 years. Factors such as marital, employment, education, socio-economic status were influenced. Post-follow up WHOQOL-BREF scores among the intervention group were found to be significant as compared to that of the control group.

Conclusion: There is improvement in the domain wise mean and total QoL scores in Schizophrenia patients in the interventional group as compared to that of the control group at the follow up.

1. Introduction

1.1. Background

Mental health affects the significant facets of life and psychiatric illness, as defined by The American Psychiatric Association are a group of disorders that interfere with the cognitive functions, behavioural pattern and emotional and mental well-being of an individual.¹ “Schizophrenia is a complex, chronic mental state disorder characterized by an array of symptoms including delusions, hallucinations, un-stuck speech or behaviour and impaired psychological feature ability”. The first onset of the un-wellness, followed by its chronic course, build it into a disabling disorder for several patients and their families. Incapacity usually results from negative symptoms characterized by the loss or deficits and psychological feature symptoms like impairment in attention and executive function along with the memory deficits.

People with Schizophrenia typically experience auditory hallucinations, which can be abusive or often involve criticism on their action,

discussions among themselves. All these can indirectly lead to the development of strange beliefs or delusions. Many patients also have thought disorder and negative symptoms. While negative symptoms may be less troubling to the patient, they can be very distressing and unmanageable to the family and dear ones. Schizophrenia can be classified into subtypes according to the balance of symptoms that a patient experiences. Mild symptoms can occur in healthy people and are not associated with illness.²

Schizophrenia is a low prevalence disorder. Gender differences were not observed in prevalence. Globally, prevalent cases rose from 13.1 (95% UI: 11.6–14.8) million in 1990 to 20.9 (95% UI: 18.5–23.4) million cases in 2016. Schizophrenia contributes 13.4% years of life lived with disability to burden of disease globally.³

Schizophrenia affects 1% of the population in all cultures. It affects men and women equally, but the onset is often later in women than in men. Schizophrenia is characterized by positive, negative and cognitive symptoms. Positive and Negative symptoms affects patients’ families; therefore, it is important for physicians to provide guidance to all

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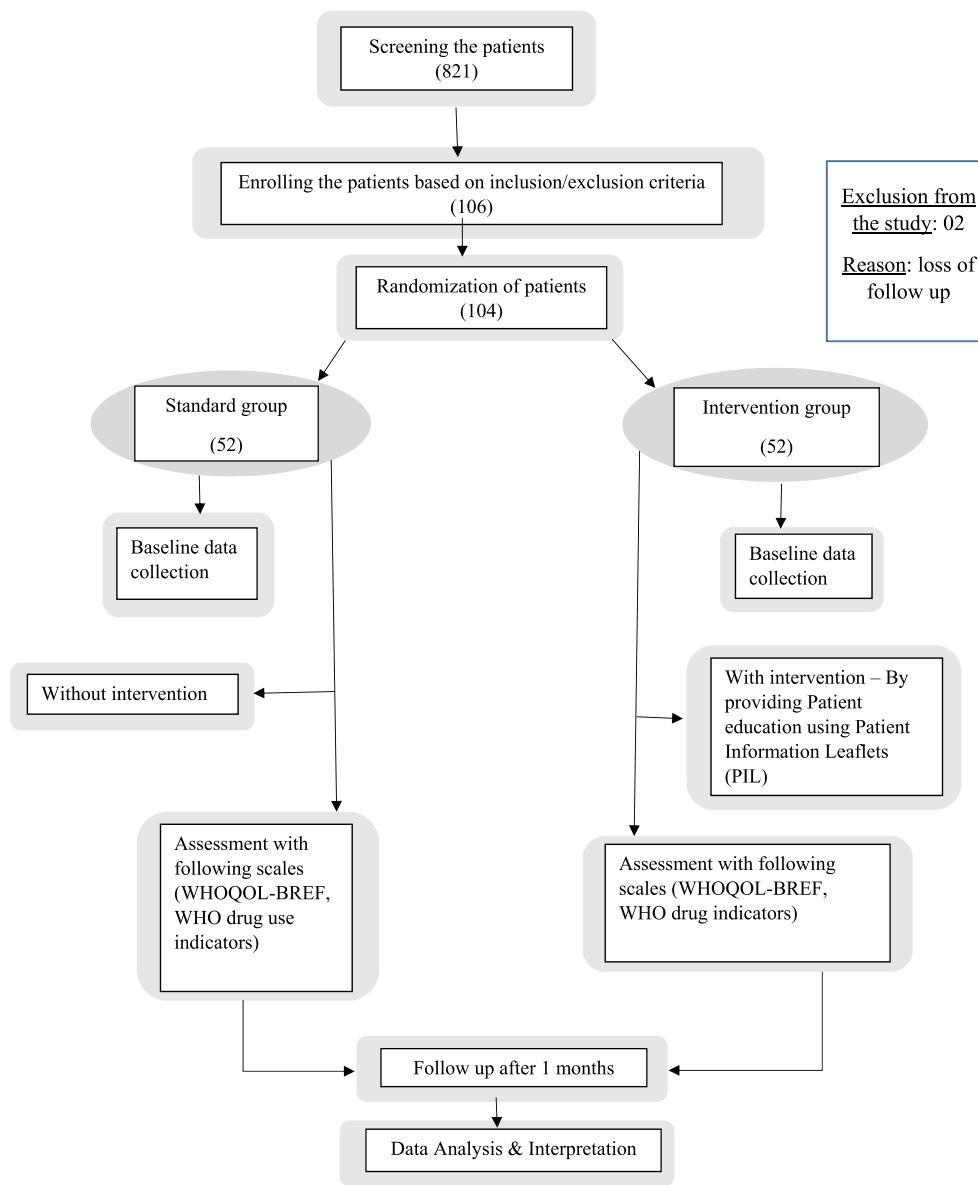
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<https://doi.org/10.1016/j.cegh.2022.101208>

Received 10 August 2022; Received in revised form 15 December 2022; Accepted 26 December 2022

Available online 30 December 2022

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Flow chart of study procedure at baseline to follow-up.

persons affected by the disease. Psychosocial and family interventions can improve outcomes. Most of the antipsychotics have neurologic or physical side effects (e.g., weight gain, hypercholesterolemia, diabetes) and can be symptomatically managed by medications. There is a 10% lifetime risk of suicide in patients with Schizophrenia.

Unemployment is not favourable to the health of the general population (Bartley 1994), and it is an important part of the social exclusion faced by the seriously mentally ill particularly in developed countries (Boardman et al., 2003). In the United Kingdom (UK), there has been very little change in the last 10 years in the proportion of adults with a psychotic disorder being employed. This contrasts with the increase in the employment rate in the general population along with those physical disabilities.^{4,5}

Low educational level, however, has a negative impact on the quality of life in Schizophrenia patients. Positive affect and a sense of personal control and empowerment tend to improve quality of life, while perceived stigma is related to a lower quality of life.⁶

Three fields are identified here which may contribute to the difficulties of Schizophrenic patients to achieve an adequate quality of life. (i) It is obvious that schizophrenic patients living in the community have

additional needs and fewer personal and environmental resources than healthy people. (ii) They have a serious dilemma related to the participation in social engagements due to the stigma attached to Schizophrenia. (iii) They have occasional difficulties in adequately identifying and expressing their needs.⁷

The World Health Organization Quality of Life Scale BREF version (WHOQOL-BREF) is used for patients with Schizophrenia. Scores of various Schizophrenia patients and their relation with those of global functioning, psychiatric symptoms, disability and social support can range between small and large. There were significant differences between groups of patients with schizophrenia in the WHOQOL-BREF. Patients who were anxious, disabled, lacked social support and used more social services scored significantly lower in some or all WHOQOL-BREF domains. Changes in WHOQOL-BREF scores were positively associated with changes over time in global functioning by means of social & mental support and use of healthcare services.^{8,9}

1.2. Objectives

This study is mainly focused on.

- Assessment of Quality of Life in Schizophrenia patients by providing means of pharmaceutical care through patient counselling and patient education

2. Materials and methods

This study was conducted for 6 months (November 2020 to April 2021), in Department of Psychiatry, KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre Belagavi. Simple randomization method was used among 104 patients who met eligibility criteria and were assigned to control and interventional group. Schizophrenia patients of both the genders, aged above 18 years and whose relatives are willing to give informed consent were involved in the study. Patients with history of malignancy, pregnant and lactating women were excluded from the study.

The QoL of Schizophrenia patient was calculated by the WHO Quality of Life Scale-Brief (WHOQOL-BREF), is a subset of 26 items covering 4 domains: physical health, psychological functioning, social relationship and environment, in addition to two individually scored items about an individual's overall perception of quality of life and health¹⁰ (Permission ID: 374,500). The four domain scores are scaled in a positive direction between 1 and 5 with higher scores indicating a higher quality of life.

2.1. Randomization method

SNOSE Method is used, wherein randomization bunch is composed on a paper, kept in an obscure fixed envelope, marked with a number which is opened by investigator once the patient has agreed to take part and afterward relegates the treatment bunch likewise.

3. Procedure

Refer Flow chart of the procedure in previous page.

4. Intervention

All the patients included in the study were followed with telephonic calls and follow up visits to Psychiatry outpatient and inpatient departments. The study subjects that belonged to the control group received the standard therapy from the Psychiatrist whereas those belonging to the intervention group received standard care as well as pharmaceutical care from the clinical pharmacist regarding the management of Schizophrenia, how it affects Quality of Life and recovery from the disease. Patient information Leaflets were provided to the patients during patient education.

5. Outcome measures

5.1. Primary outcome

Improvement in post-follow up QoL scores among the intervention group as compared to that of control group.

6. Sample size determination

Based on pilot study on both groups i. e experiment and control. The change in QOL after one month was calculated. Based on changes in QOL, the sample size was calculated. The sample size was taken in each group was 52 with 1% α -error and 5% β -error (95% power). The formula was

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 (2S^2)}{d^2}$$

$$n = \frac{4.262^2 (49.33)}{41.084^2}$$

$$n = \frac{18.16(98.66)}{1687.8}$$

$$n = 106 \text{ samples}$$

Table 1
Comparison of baseline sociodemographic characteristics among control and intervention groups.

Demographic profile	Experiment group	%	Control group	%	Total	%	χ^2	p-value
Age groups								
≤30yrs	20	38.46	17	32.69	37	35.58	2.6430	0.4500
31–40yrs	16	30.77	16	30.77	32	30.77		
41–50yrs	7	13.46	13	25.00	20	19.23		
≥51yrs	9	17.31	6	11.54	15	14.42		
Mean	36.75		36.79		36.77			
SD	12.20		12.41		12.25			
Gender								
Male	25	48.08	29	55.77	54	51.92	0.6160	0.4320
Female	27	51.92	23	44.23	50	48.08		
Educations								
No	6	11.54	8	15.38	14	13.46	6.4010	0.1710
Primary	13	25.00	20	38.46	33	31.73		
Secondary	18	34.62	14	26.92	32	30.77		
Graduate	15	28.85	8	15.38	23	22.12		
PG	0	0.00	2	3.85	2	1.92		
Occupations								
Employed	14	26.92	18	34.62	32	30.77	0.7220	0.3950
Unemployed	38	73.08	34	65.38	72	69.23		
Marital Status								
Married	33	63.46	33	63.46	66	63.46	0.0000	1.0000
Unmarried	19	36.54	19	36.54	38	36.54		
SES								
Lower	0	0.00	2	3.85	2	1.92	18.604	0.0010*
Lower middle	28	53.85	16	30.77	44	42.31		
Middle	1	1.92	14	26.92	15	14.42		
Upper Lower	9	17.31	12	23.08	21	20.19		
Upper middle	14	26.92	8	15.38	22	21.15		
Total	52	100.00	52	100.00	104	100.00		

Table 2
Comparison of baseline and follow up WHOQOL BREF scores between the control and intervention group.

Groups	Variables	Treatment times	Mean	SD	Mean Diff.	SD Diff.	% change	t-value	p-value	
Intervention group	Quality of life	Baseline	185.06	37.84						
		Follow-up	241.48	37.05	-56.42	46.3	-30.49	-8.774	0.0001*	
	Physical	Baseline	44.75	13.78						
		Follow-up	60.56	13.14	-15.81	15.1	-35.32	-7.538	0.0001*	
	Psychological	Baseline	43.46	13.09						
		Follow-up	58.38	10.31	-14.92	14.0	-34.34	-7.657	0.0001*	
	Social relationships	Baseline	47.62	13.21						
		Follow-up	57.37	12.18	-9.75	14.5	-20.48	-4.831	0.0001*	
	Environmental	Baseline	49.23	12.92						
		Follow-up	65.17	14.94	-15.94	15.5	-32.38	-7.415	0.0001*	
	Control group	Quality of life	Baseline	187.8	39.52					
			Follow-up	203.81	42.09	-15.96	51.7	-8.50	-2.225	0.0305*
Physical		Baseline	45.00	12.87						
		Follow-up	50.88	13.17	-5.88	17.7	-13.08	-2.395	0.0203*	
Psychological		Baseline	43.60	11.98						
		Follow-up	48.04	13.05	-4.44	14.8	-10.19	-2.156	0.0358*	
Social relationships		Baseline	48.60	13.40						
		Follow-up	49.75	11.89	-1.15	15.8	-2.37	-0.525	0.6013*	
Environmental		Baseline	50.65	12.27						
		Follow-up	55.13	15.57	-4.48	13.8	-8.85	-2.331	0.0237*	

Where,

$$Z\alpha = 2.58 \text{ at } 1\% \alpha \text{ error}$$

$$Z\beta = 1.682 \text{ at } 5\% \beta \text{ error}$$

$$d = \text{margin of error} = 41.084$$

$$S = \frac{S_1 + S_2}{2}$$

7. Sampling method

Simple Random sampling with Random number method.

8. Data collection

The data was collected from case sheets, previous medical records, medications history, current medication, family and social history, educational qualifications, occupation, and assessing quality of life. Predesigned Google forms were used for data collection and documentation.

9. Statistical analysis

SPSS (IBM version 22.0) was used to generate the results. Repeated measures ANOVA was used to compare the patients' domain-wise health related Quality of Life and the Paired Sample t -test to compare Pre-intervention and Post-intervention overall Quality of Life. Descriptive statistics are being used to highlight the sociodemographic variables of the study population.

10. Results

Among 110 patients who were enrolled in the study, 104 patients successfully completed it. Mean age of study population was 36.77% years and the difference in the population of male ($n = 54$) and female participants ($n = 50$) in the control and intervention group of the study was not significantly seen. Total percentage of 31.73% of the participants were found to have received primary education and prevalence of married individuals was found to be higher than the unmarried patients. Sociodemographic distribution of the study participants in control and intervention group is displayed in Table 1. There is no significance between the study groups as far as baseline characteristics are concerned, except for the individual socioeconomic status.

The domain wise WHOQOL-BREF mean scores were seen to be

significantly improved in all the four domains and the total quality of life ($p < 0.005$). Comparison of intervention group and control group with baseline and follow-up QoL and its dimension scores by independent t -test are displayed in Table 2.

The percentage change in the QoL scores of intervention group shows improvement in the overall well-being with % change of 30.49% in overall QoL followed by domain wise change as shown in Table 2.

11. Discussion

Distribution of sociodemographic factors like age, education, economic status and employment amongst the diseased population is being evaluated and reported through several studies. The clinical pharmacist intervention was found to have a significant influence on the impaired psychosocial and physical health. Extrapyramidal adverse effects of the antipsychotics resulted into Trihexyphenidyl hydrochloride being the most commonly prescribed drug on performing the drug utilization evaluation. This study had 51.92% ($n = 54$) male patients and 48.08% ($n = 50$) female patients with the mean age of patients being 36.77 years with a higher number of married participants. Similarly, Guedes de Pinho et al. through a descriptive epidemiological, observational cross-sectional study among 268 patients who fulfilled ICD-10 criteria for Schizophrenia in the eight hospitals of Portugal, showed that most of the participants were male (63.4%). The mean age being 36.77 years with maximum percentage of study participants equal to 35.58% being in the age group of ≤ 30 yrs, which was found to be comparable to the descriptive study performed by Elza Munjely et al. with a mean age of 34.8 years. Regarding the marital status of the subjects the results contradict with the present study having higher percentage of unmarried individuals (62.3%). The number of unemployed study participants amounting to 90.3% of the samples ($n = 242$) was found to be comparable to our study with 69.23% ($n = 72$)^{9, 11}

In Schizophrenia patients, cognitive dysfunction, psychological disturbances and their effect on physical and overall well being secondary to a varied range of clinical manifestations of the disorder account to the diminished quality of life. They in turn have an impact on the efficiency of the patients right from minute daily activities to bigger tasks and duties in jobs resulting in loss of employment. The drug related problems, specifically adverse drug reactions caused due to pharmacotherapy leads to additional effect on their QoL.

Directed with an objective of assessing the health related quality of life in patients affected with Schizophrenia, this study defines the crucial facets of an individual's well-being with the help of domains of WHOQOL-BREF namely physical condition, psychological health, social

interactions and environmental factor before and after providing intervention. Significant improvement was seen in the physical health domain followed by psychological health post-follow up.

On the contrary, Ram Solanki et al. demonstrated that the quality of life as per the average domain scores of QoL scale used was lower in the schizophrenia patients, especially in the social relationship domain for which isolated behaviour, indifference, lack of motivation, unemployment in several cases and symptoms in patients along with the social stigma around the mental health might be a possible explanation, through a cross sectional study in a outdoor attending patients of psychiatry department in a hospital. The study correlated with the psychopathology and their QoL. The randomized controlled studies that compare the significance domain wise QoL of patients before and after clinical pharmacist intervention is provided, are not very commonly observed^{12,13},

The study lays emphasis on the role of Clinical Pharmacists in upgrading the overall quality of life in the Schizophrenia through assessment of the domain wise and total QoL scores pre and post-intervention.

12. Limitations of the study

- Inconsistent patient flow during the COVID pandemic and time constraints were major limitations of the study.
- This study helps assess the QoL in Schizophrenia at baseline and follow up but does not correlate the deterioration of the QoL with presence of drug related problems, adverse effects and lack of awareness about the illness in the patients.
- The Quality of Life of the study participants is being measured by generic measure rather than disease-specific measures.

13. Conclusion

The study shows significant improvement in the post-follow up domain wise and total QoL of the intervention group as compared to that of control group, indicating the scope of patient education and counselling and its impact on the recovery of the patients in future studies. Drug utilization evaluation was performed with the help of drug use indicators. Except for the percentage of medicines prescribed by generic names, the drug prescription pattern was determined to be consistent with WHO prescribing indicators. (Result: 1.05%).

Funding

This research received no specific grant from any funding agencies in the public, commercial, or not-to-profit sectors.

Author credit statement

Dr. Jovin Joshy: Writing- Original Draft, Visualization. **Dr. Aparna Joshi:** Formal Analysis, data curation. **Dr. Saloni R. Jain:** Methodology, Investigation. **Dr. Keziah Anna Mathew:** Resources, Writing-Review & editing. **Aishwarya C. Hiremath:** Conceptualization, Supervision. **Dr. Bheemsain V. Tekkalaki:** Validation, Project administration.

Registration

This Randomization study was initiated after approval from the Institutional Ethics Committee of KLE College of Pharmacy, Belagavi, Karnataka, India. (Ref No; KLECOP/680 (20)/2020/21).

Protocol

Clinical Trial Registration number: SCHIZO2021.

Declaration of competing interest

The authors declare that there are no conflicts of interest.

Acknowledgement

We would like to thank Dr. Niranjana S Mahantashetti, Principal of JN Medical College, Dr.S.B. Patil, Superintendent of KLE's Dr. Prabhakar Kore Charitable Hospital, Belagavi, Dr.M.V Jali, MD of KLEs Dr. Prabhakar Kore Hospital & Research Centre, Belagavi, Dr. Sunil S. Jalalpure, Principal of KLE College of Pharmacy, Belagavi, Dr. Sameeran S. Chate, Department Head of Psychiatry and Department of Statistics, USM-KLE, Belagavi.

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