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MULTICOMPONENT INTERVENTION PROGRAM ON MEDICATION ADHERENCE, REPORTED SIDE EFFECTS AND GENERAL FUNCTIONING AMONG CAREGIVERS OF PATIENT RECEIVING ANTIPSYCHOTICS

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ABSTRACT

Objectives: *This study was conducted to estimate the medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotic medication, to determine the effect of a multicomponent intervention program on medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics and to find the association of medication adherence, reported side effects and general functioning with selected socio personal variables.* ***Methods:*** *A quantitative research approach and one group pre test post test design were adopted. Using convenience sampling, 80 caregivers of patient receiving antipsychotic medication who attended psychiatric outpatient department were enrolled in the study. Socio personal proforma, Clinician rating scale, Glasgow antipsychotic side effect scale and Lawton instrumental activities of daily living scales were used to collect the data.* ***Results:*** *Findings of the study showed a significant difference in the pre and post test results of medication adherence ($z = 4.256$) at $p<0.001$, reported side effects ($z = 4.302$) at $p<0.001$ and general functioning ($z = 4.218$) at $p<0.001$ scores after the multicomponent intervention program. The study also found that, there was no significant association between medication adherence, reported side effects and general functioning with the selected socio personal variables.* ***Conclusion:*** *The study concluded that multicomponent intervention program helps to provided medication adherence, management of antipsychotic side effects and improved the general functioning among caregivers of patient receiving antipsychotics.* ***Keywords:*** *Multicomponent intervention program, Medication adherence, Reported side effects, General functioning, Caregivers of patient receiving antipsychotics.*

INTRODUCTION

Antipsychotics, also known as neuroleptics, are the first line pharmacological intervention for severe mental illnesses such as schizophrenia and other psychotic disorders. First generation antipsychotics are known as typical antipsychotics, were introduced in the year 1950 and second generation drugs known as atypical antipsychotics that introduced clozapine in the year 1970. These two generations of medication block the dopamine receptors in the brain, whereas atypical medication tends to act on serotonin receptors[1]. Antipsychotic drugs have become the cornerstone of treatment for psychiatric disorders.

These are effective in reducing psychotic symptoms, relapses and psychosocial functioning. However, nonadherence to medication is one of the biggest problems that increases rehospitalisation and psychotic symptoms[2]. Thus, lack of adherence to pharmacological treatment is associated with worsening of symptoms and decrease prognosis. Whereas, various patient related factors are responsible for nonadherence such as age, lack of insight, negative attitude towards treatment and substance use. The family related factors are ignorance of benefits and unrealistic expectations. The illness related factors are aggressive behaviour and cognitive impairments[3]. The health related factors are negative impact on adherence and lack of supervision. Antipsychotic medications can produce various adverse effects that may significantly affect the quality of life that causes distress. These produce own spectrum of adverse reactions such as extra pyramidal side effects, weight gain, seizures, hypotension, hyperlipidaemia and increased risk of diabetes mellitus. Most common extra pyramidal symptoms include acute dystonia, akathisia, tardive dyskinesia, neuroleptic malignant syndrome and parkinsonism, which develop within hours after initiating doses of antipsychotics[4]. Activities of daily living (ADLs) are the fundamental skills required to perform activities independently without any assistance. The activities of daily living were introduced by Sidney Katz in 1950 and it is used as an indicator of a person who had normal general functioning. The dependence may happen if there is any difficulty to perform the activities of daily living[5]. The inability to accomplish essential activities may lead to poor quality of life. Psychoeducation is an evidence based therapeutic intervention for patients and family members to provide information to cope with illness. Psychoeducation can be done on group or one to one basis. It has been emphasized as an evidence based practice with various beneficial health outcomes[6]. It has the first choice of strategies to provide medication adherence, management of side effects and improve general functioning of patient receiving antipsychotic medications. It could increase patients responsibility to face the illness and it allows to participate with treatment regimens actively.

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Statement Of the Problem

A study to assess the effect of a multicomponent intervention program on medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics at psychiatric outpatient department of a selected tertiary care hospital in Ernakulam district, Kerala.

Objectives

- To estimate the medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotic medication.
- To determine the effect of a multicomponent intervention program on medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics.
- To find the association of medication adherence, reported side effects and general functioning with selected socio personal variables.

Operational Definitions

- **Medication adherence**: Refers to the extent to which a patient takes prescribed medications according to the dosage and frequency, recommended by the psychiatric consultants.
- **Side effects:** Refers to effect of a drug, chemical and other medications that are in addition to its intended effect, especially harmful or unpleasant that are reported by caregivers.
- **General functioning:** Refers to the physical, social and psychological wellbeing that involves in activities of daily living.
- **Caregivers:** Refer to family members or significant others who are actively involved in caring of patient who are receiving antipsychotics for minimum 6 months and accompanies the patient more than 6 months for continuing treatment in selected setting.
- **Chronic psychotic disorders:** Refer to selected chronic mental illness such as bipolar affective disorder, schizophrenia, and other psychotic disorders diagnosed by psychiatrist using ICD 10 guidelines.
- **Multicomponent intervention:** Refers to information, education and communication (IEC) given for 30 - 45 minutes to the caregivers of patient receiving antipsychotic medication. which includes medication adherence, benefits, associated factors, management of antipsychotic medication side effects and remedies to improve general functioning among caregivers of patient receiving antipsychotic medication. It aims to provide medication adherence, management of antipsychotic medication side effects and improve general functioning.

Assumptions

a. Patients receiving antipsychotics may face nonadherence to medication.
b. Patients receiving antipsychotic generally experience some side effects.
c. Patients receiving antipsychotic may affect with poor general functioning.
d. Multicomponent intervention program may provide medication adherence, manage antipsychotic side effects and improve general functioning.

Hypotheses

H1: There is a significant difference in the average medication adherence, reported side effect and general functioning scores after the multicomponent intervention program on the experimental group.

H2: There is a significant association of selected socio personal variables with medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics.

METHODOLOGY

Research approach: Quantitative research approach

Research design: Pre experimental design (one group pre test post test design)

Variables

Outcome variables

Medication adherence, reported side effects and general functioning

Socio personal variable: Age in years, gender, religion, marital status, educational status, occupation, type of family, relationship with the patient and duration of stay with the patient

Setting of the study

Psychiatric outpatient department of M.O.S.C. Medical college hospital, Kolenchery

Population

Target population: Caregivers of patient receiving antipsychotic medication in Ernakulam district

Accessible population: Caregivers of patient receiving antipsychotic medication from the selected setting of M.O.S.C. Medical college hospital, Kolenchery

Sample and sampling technique

Sample: Caregivers of patient receiving antipsychotic medication from the selected setting who met the inclusion criteria

Sampling technique: Convenience sampling technique

Sample size: 80 caregivers of patient receiving antipsychotic medication from the selected setting

Sample Selection Criteria Inclusion Criteria:

a. Patients with psychiatric disorders receiving antipsychotic medication more than 6 months from a selected tertiary care centre.
b. The patient those who have nonadherence on medication,

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mild to severe side effects of antipsychotic medications and impaired in general functioning will be selected for study.

c. Adult family members or significant others who are actively involved in caring of patients with chronic psychiatric disorders for more than 6 months and accompanies the patient for
continuing treatment in the selected setting.

Exclusion Criteria

a. Caregivers who have physical or mental illness which incapacitate them to participate in the study.

Tools and Techniques

Socio personal Proforma: Socio personal proforma for caregivers of patient receiving antipsychotic medication including age in years, gender, religion, marital status, educational status, occupation, type of family, relationship with the patient, duration of stay with the patient.

Clinician Rating Scale (CRS): It is a standardized scale used for assessing the medication adherence of patient receiving antipsychotic medication. The scale has 7 items scored from one to seven. The maximum score is 7 and minimum score is 1. The score is 3 or above indicates adherence and 2 or less than 2 indicates non adherence. The reliability of the tool was established by using Cronbach's alpha method and tool was found to be reliable with r= 0.83.

Glasgow Antipsychotic Side Effect Scale (GASS): Glasgow antipsychotic side effect scale used for assessing the reported side effects of patient receiving antipsychotic medication. The scale has 22 items rated from 0 - 3. The maximum score is 63 and minimum score is 0. A score between 43 - 63 indicates severe side effects, 22 - 42 indicates moderate side effects and 0 - 21 indicates absent or mild side effects. The reliability of the tool was established by test retest method and tool was found to be reliable with r= 0.82.

Lawton Instrumental Activities of Daily Living (IADL) Scale: Lawton Instrumental Activities of Daily Living Scale (IADL) used for assessing the general functioning of patient receiving antipsychotic medication. The maximum score is 8 and minimum score is 0. A score 8 indicates high function and 0 indicates low function. The reliability of the tool was established by test retest method and tool was found to be reliable with r=0.88.

Ethical Considerations: Approval was obtained from the institutional ethics committee of Malankara Orthodox Syrian Church Medical College Hospital, Kolenchery. Informed consent was obtained from the subjects.

Pilot Study

The pilot study was conducted among 15 subjects who met the inclusion criteria. The study was found to be feasible in terms of time, money and manpower resources

Data Collection Process

The study was conducted after obtaining ethical clearance from the institutional ethics committee. Formal administrative permission was obtained from the Administrative Director, M.O.S.C. Medical College Hospital and Principal, M.O.S.C. College of Nursing. Totally 150 caregivers of patient receiving antipsychotics were screened from psychiatric outpatient department as per the inclusion criteria. In that 80 participants were selected by convenience sampling technique. After a brief self introduction by the researcher, the purpose of the study were explained to the subjects. The subjects were allowed to read the participant information sheet and made provision to clarify the doubts for informed consent. One group pre test post test design were selected for the study. The pre test was done by using socio personal proforma, Clinician rating scale for assessing medication adherence, Glasgow antipsychotic side effect scale for assessing side effects of antipsychotic medications and Lawton instrumental activities of daily living scale. The caregivers of patient who had medication nonadherence, mild to severe antipsychotic side effects and impaired general functioning were selected for the study. The multicomponent intervention program were administered for 30 - 45 minutes by using flash cards and booklets. The reinforcement was given by the researcher once in every week for the period of 30 days. The supervised multicomponent intervention program follow up was done at seven days of interval for the caregivers of patient receiving antipsychotics. The post test was done at the end of month (4th week) to reassess the medication adherence, reported side effects and general functioning to check the effect of multicomponent intervention program. The Confidentiality was ensured during and after the study.

Plan for Data Analysis

For assessing the effects of a multicomponent intervention program on medication adherence, reported side effects and general functioning, Wilcoxon signed rank statistics was performed as data violated the normality. For determining the association of medication adherence, reported side effects with socio personal variables Fisher's exact test/ Chi square test was performed as data follows normality, Kruskal Wallis test/ Mann whitney U test was used to find the association between general functioning with socio personal variables as data violates normality. The p value <0.05 was considered as to be statistically significant.

Results

The median and interquartile range score of medication adherence 3 (Q1 = 2, Q3 =4), reported side effects 35 (Q1 = 28, Q2 = 38) and general functioning 4 (Q1 = 2, Q3 =5) among patient receiving antipsychotic medication (Table 1, Table 2 & Table 3). The median score of medication adherence after multicomponent intervention program was (4.5) significantly higher than the median score of medication adherence (2) before the multicomponent intervention program. Therefore, there was a statistic significant difference between the adherence score between before and after the intervention (z = 4.256) at p<0.001 (Table 4). The

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median score of reported side effects after the multicomponent intervention program was (13.50) significantly reduced in the median score of reported side effects (37) before the multicomponent intervention program. Therefore, there was a statistical significant difference in the reported side effects score between before and after the intervention (z = 4.302) at p<0.001 (Table 5). The median general functioning pre test score before the multicomponent intervention program was (3) significantly lower than the median general functioning post test score (6) after the multicomponent intervention program. Therefore, there was a statistical significant difference in the general functioning score between before and after the intervention (z = 4.218) at p<0.001 (Table 6). The study also found that, there was no significant association between medication adherence, reported side effect and general functioning with the selected socio personal variables. Hence the study concluded that multicomponent intervention program helps to provided medication adherence, management of antipsychotic side effects and improved the general functioning among caregivers of patient receiving antipsychotics.

Table 1: Median and Interquartile range of medication adherence among caregivers of patient receiving antipsychotics

Variable	Median	Q1	Q3
Medication adherence (Score ranges from 01- 07)	03	02	04

Table 2: Median and Interquartile range of reported side effects among caregivers of patient receiving antipsychotics

Variable	Median	Q1	Q3
Reported side effects Score ranges from (13 - 48)	35	28	38

Table 3: Median and Interquartile range of general functioning among patient receiving antipsychotic medication.

Variable	Median	Q1	Q3
General functioning Score ranges from (0 - 7)	04	02	05

Table 4: Median, Interquartile range and Wilcoxon signed rank test of pre and post test score of medication adherence

Time points	Median (Q1, Q3)	Wilcoxon signed rank Statistic (z)	p-Value
Pre test	2 (2, 3.5)	4.256	**p<0.001***
Post test	4.5 (4, 6)		

*Significant (p< 0.05)

Table 5: Median, Interquartile range and Wilcoxon signed rank test of pre and post test score of reported side effects

Time points	Median (Q1, Q3)	Wilcoxon signed rank Statistic (z)	p-Value
Pre test	37 (35, 41)	4.302	**P<0.001***
Post test	13.50 (10, 18)		

*Significant (p< 0.05)

Table 6: Median, Interquartile range and Wilcoxon signed rank test of pre and post test score of general functioning

Time points	Median (Q1, Q3)	Wilcoxon signed rank Statistic (z)	p-Value
Pre test	**3 (1, 4)**	**4.218**	**P<0.001***
Post test	**6 (6,7)**		

*Significant (p< 0.05

DISCUSSION

The present study revealed the score of medication adherence 3 (Q_1 = 2, Q_3 =4) among caregivers of patient receiving antipsychotics and 55% of subjects were had adherent to medication and 45% of subjects were had nonadherence to medication. This finding is supported by Vieta E[7] to assess the perceptions of potential reasons for nonadherence to medication among psychiatrists. This study estimated that 57% of bipolar patients was partially nonadherent with medication. A wide range of nonadherence rates have been reported for patients with unipolar depression were (10% - 75%), anxiety was (57%), schizophrenia was (20% - 72%) and

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attention deficit hyperactivity were (50% - 75%). The present study revealed the score of reported side effects 35 (Q1 = 28, Q2 = 38) among caregivers of patient receiving antipsychotics and 86.30% were having moderate side effects, 07.50% were having severe side effects and 06.30% were not having any side effects of antipsychotic medications. This finding is supported by Marco Dibonaventura[8] to assess the impact of medication side effects of patients with schizophrenia. This study reported that majority of patients had at least one side effect due to the medication were (86.19%). The most commonly reported side effects were difficulty in concentration(32.2%), restlessness (28.2%), weight gain (25.8%), and insomnia (25.1%). The present study revealed the score of general functioning 4 (Q1 = 2, Q3 =5) among caregivers of patient receiving antipsychotics. This finding is supported by Reema Samuel[9] to assess the prevalence of instrumental activities of daily living dysfunction in people with schizophrenia. The study found that 2% patients were completely independent in activities of daily living. The present study revealed that there is a statistically significant difference in the adherence score between before and after the intervention ($p<0.001$). This finding is supported by Jeffrey M. MD[10] to assess the patient centered and sustainable antipsychotic medication adherence intervention program. The researcher found that there was a significantly improved adherence score ($p<0.001$) before and after the intervention program. The present study revealed that there is a statistically significant difference in the reported side effects score between before and after the intervention ($p<0.001$). An experimental study was conducted by Pope et al[11] to assess the adverse effects of antipsychotic medication among patients with schizophrenia. The study reported that there was a statistically significant difference in pre and post test scores ($p=0.001$). The present study revealed that there is a statistically significant difference in the general functioning score between before and after the intervention ($p<0.001$). This finding is supported by Eman S. Soliman[12] to assess the impact of psychoeducation program on quality of life of schizophrenic patients and caregivers. This study reported that there was a high statistical significant difference between patients received psychoeducation program ($p=0.015$) and not received psychoeducation program ($p=0.28$). There is no significant association found in medication adherence score with socio personal variables. This finding was supported by Zaid Demoz[13] found that there was no statistical significant association between marital status and adherence level. There was no significant association found in reported side effect score with socio personal variables. This finding was supported by Sayali Devidas Dambhe[14] found that there was no significant association ($p<0.05$) in age, gender, education status and occupation. There was no significant association found in general functioning score with socio personal variables. This finding was supported by Ken Yamauchi[15] there was no significant association found in the general functioning score and duration of stay with the patient.

NURSING IMPLICATIONS

Nursing Practice

- Play in primary prevention by facilitating early detection and management of medication nonadherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics
- Identify the areas where the caregivers of patient receiving antipsychotics need more help, support and confidence building.
- Play a supportive role in caregivers of patient receiving antipsychotics for their emotional issues.
- Mass health education camping should be organized regularly by the health teams to provide education on medication nonadherence, reported side effects and general functioning.

Nursing Education

- Suggest incorporating the mental health issues among caregivers of patient receiving antipsychotic medications regarding early identification, and its management in the nursing curriculum.
- Train the student nurses to identify the factors affecting medication adherence, reported side effects and general functioning among caregivers of patient receiving antipsychotics based on which appropriate nursing interventions can be a planned for patients and caregivers.

Nursing Administration

- Develop psycho education protocols for educating the caregivers of patient receiving antipsychotics for identifying and managing the medication nonadherence, side effects of antipsychotic medications and general functioning.
- Nurse administrator should take the initiative in organizing continuing education programs regarding various aspects of medication nonadherence, side effects of antipsychotic medications and general functioning.
- Appropriate teaching learning material need to be prepared and made available for nurse.

Nursing Research

- Based on the findings of the present study, further studies should be encouraged to improve the medication adherence, reported side effects and general functioning in patients with suitable intervention packages need to be developed.
- The findings of the present study can be considered as a cornerstone for future researches.

CONCLUSION

The study concluded that multicomponent intervention program helps to provided medication adherence, management of antipsychotic side effects and improved the general functioning among caregivers of patient receiving

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antipsychotics.

Conflict of interest

There are no relevant conflicts of interest

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