

# Study Protocol

## **Protocol on to assess the effectiveness of planned teaching on knowledge regarding to adverse effect of antipsychotic agents among caregivers of schizophrenia patient**

### **ABSTRACT**

**BACKGROUND OF THE STUDY:** The involvement of caregivers in treatment has been known as an vital part of mental health care. The enlarged emphasis on caregiver partaking has been to some extent driven by the shift from hospitals to primary provision of schizophrenia care in the community, where caregivers are more broadly involved in supporting consumers.

**OBJECTIVES:** 1. To assess the pre-test knowledge regarding adverse effect of antipsychotic agent among caregivers of schizophrenia patients 2. To evaluate the effectiveness of planed teaching programme on knowledge regarding to antipsychotic agent among caregiver of schizophrenia patients. 3. To find out the association between post-test knowledge score with regards to adverse effect of antipsychotic agent regarding to adverse effect among caregivers of schizophrenia patients.

**MATERIAL AND METHODS:** Pre-experimental, one group pretest and post-test design to assess the effectiveness of planed teaching on knowledge regarding adverse effect of antipsychotic agents and their response during the adverse effect among caregivers of schizophrenia patients. In this study total 100 caregivers of schizophrenia patient who full fill the inclusion criteria. **EXPECTED RESULTS:** This study is planned to assess the effectiveness of planed teaching on knowledge regarding to adverse effect of antipsychotic agents among caregivers of schizophrenia patients. There will be significant association between pre-test and post-test knowledge with regards to antipsychotic agents among schizophrenia patient's caregivers. **CONCLUSION:** The conclusion will be drawn from the outcomes.

**KEYWORDS:** Schizophrenia, effectiveness, planned teaching, knowledge, caregiver, antipsychotic agents, patients.

## INTRODUCTION

Antipsychotics, also known as neuroleptics, are a class of psychotropic drugs used primarily to manage psychosis (including delusions, hallucinations, paranoia, or thought disorders), primarily in schizophrenia but also in a number of other psychotic disorders.(1) First-generation antipsychotics are dopamine receptor antagonists (DRAs) and are known as typical antipsychotics. Second-generation antipsychotics are serotonin-dopamine antagonists and are also known as atypical antipsychotics.(2) Antipsychotic drugs generally produce extrapyramidal symptoms as a side effect. Extrapyramidal symptoms are caused by dopamine blockade or fatigue in the basal ganglia; This dopamine deficiency often mimics idiopathic pathology of the extrapyramidal system. Less recognized is that extrapyramidal symptoms are also associated with several non-antipsychotic agents, including some antidepressants, lithium, various anticonvulsants, antiemetics, and, rarely, oral contraceptives. Extrapyramidal symptoms caused by these agents are indistinguishable from extrapyramidal symptoms caused by neuroleptics.(3) The extrapyramidal sign is a side effect of antipsychotic drugs when the patient is receiving treatment for schizophrenia. Such signs include dystonia (continuous twitching and twitching of muscles), akathisia (may manifest as muscle restlessness), parkinsonism (characteristic signs such as stiffness), bradykinesia (slowing down), tremors and intermittent dyskinesia (irregular, jerky motion).(4)

Schizophrenia is a chronic brain disease. When schizophrenia is active, symptoms can include delusions, hallucinations, disorganized speech, thinking problems, and lack of motivation. (5) People with schizophrenia require lifelong treatment(6) People with schizophrenia can appear as if they have lost touch with reality, causing significant suffering to the individual, their family and friends. If left untreated, the symptoms of schizophrenia can be persistent and disabling.(7) While schizophrenia can occur at any age, the median age of onset tends to be in the late teens and early 20s for men and in the late 20s and early 30s for women. Schizophrenia is rarely diagnosed in someone under the age of 12 or over 40.(8) Lognathan and Murthy found gender differences in stigma experienced by patients with schizophrenia. Men report that their experience of stigma is most acute in their workplace. Women have reported experiences of

stigma in relation to marriage, pregnancy and childbirth.(9) Antipsychotics are a group of remedies that are mostly used to treat mental health illnesses such as schizophrenia.(10)

Caregivers often experience a significant burden of illness with their clients. Previous research exploring caregiver experiences in the broader schizophrenic population has demonstrated significant objective and subjective burdens of providing informal care, particularly on mental health and the day-to-day functioning of caregivers.(11) It is important to grow an understanding of caregiver involvement in such decisions because they often have a detailed view of the lives of mental health consumers and can provide valuable information about the effects of drugs.(12)

## **BACKGROUND OF THE STUDY**

Antipsychotic drugs are given to control symptoms of schizophrenia such as hallucinations and strange or paranoid behavior. These medications are calming without sedation or reduced alertness. A number of antipsychotic drugs are divided into two generations: first-generation drugs and second-generation drugs. Side effects of first-generation drugs include weight gain, diabetes, high blood pressure, heart disease and other complications. The side effects of second-generation antipsychotics vary between different agents, but weight gain has been shown to be one of the most troublesome complications. These drugs tend to stimulate appetite and the result is often significant weight gain.(13)

Antipsychotic drugs are chemicals that affect the brain and nervous system in a variety of ways and are often used in psychiatric practice to treat a wide variety of schizophrenia. The use of antipsychotics has reduced the number of patients hospitalized for mental illness by up to 50% in the United States. Researchers from around the world compared various family interventions to increase caregiver knowledge of antipsychotics, their side effects, and prevent relapse, concluding that psychoeducational interventions were more effective in increasing knowledge and reducing stress among caregivers. Psychoeducational intervention is a systematic approach based on the needs of the patient and family. Psychoeducation mainly emphasizes on increasing patient and family knowledge about schizophrenia, overcoming schizophrenia, and managing the side effects of psychotic drugs.(14)

## **NEED FOR THE STUDY**

Caregivers are notable individuals who care for relatives with schizophrenia and caregivers must have the option to know the signs and indications identified with the results of antipsychotic tranquilizers so they can make an opportune move to identify early impacts, unfavorable responses and at last aides in early treatment and recuperation. Schizophrenic patients ordinarily take long haul prescriptions for which patients themselves can't think a lot about their meds, how they work, and how incidental effects happen. Along these lines, include relatives in the treatment interaction to assist them with getting viable patient consideration and guard patients as conceivable from incidental effects.(15)

Really focusing on somebody with schizophrenia can influence relational intricacies. It takes up the majority of your profession time and energy. The obligation of families to furnish care for individuals with schizophrenia has expanded in the course of recent many years. This is mostly because of the pattern of local area care and de-hospitalization of schizophrenic patients. (12)

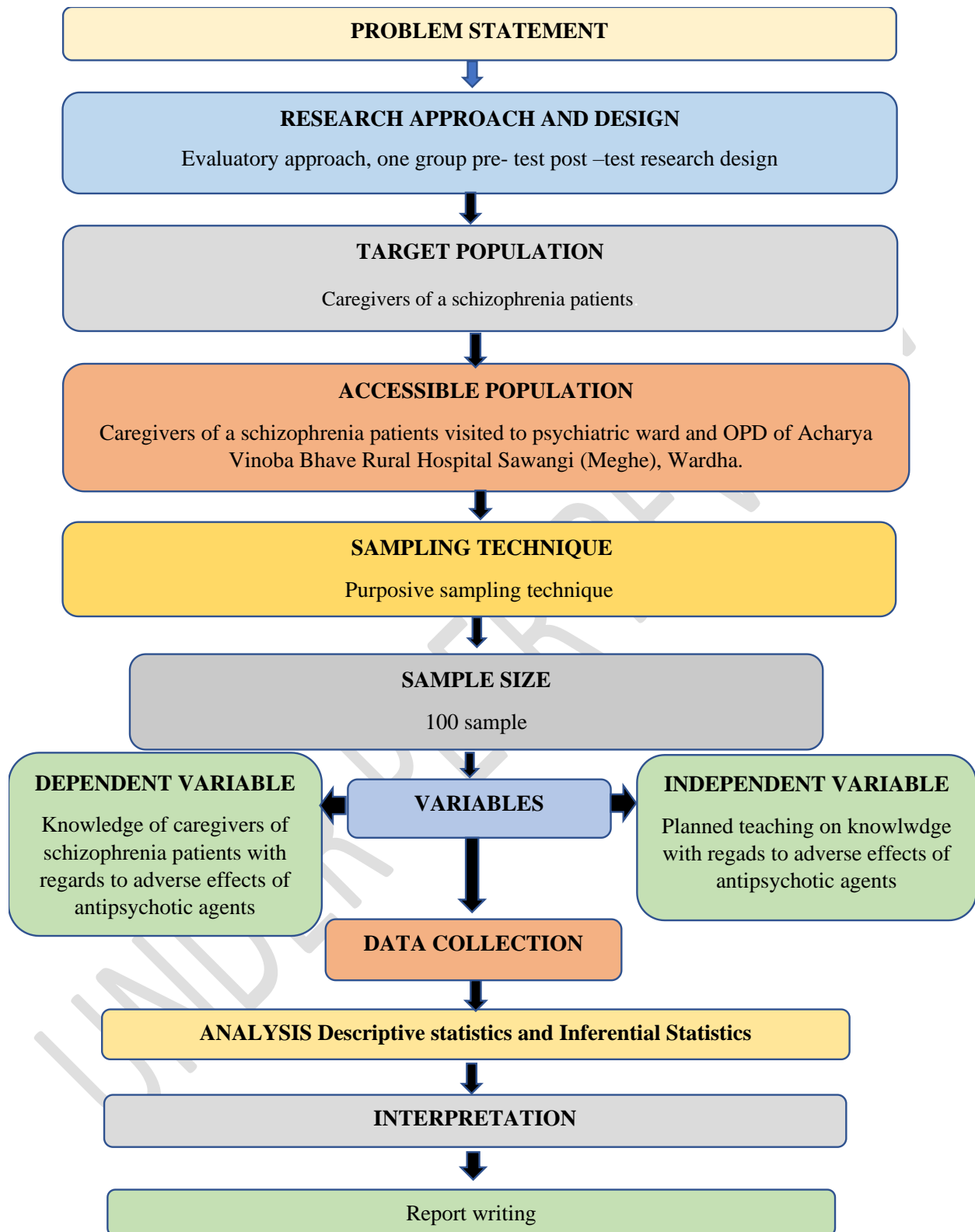
## **METHODOLOGY:**

The study will be based on evaluatory research approach with One group, pre-test post-test research design. The study will be carried out Acharya Vinoba Bhave Rural Hospitals in Sawangi (Meghe), Wardha. A purposive sampling technique will be used. Data will be collected from caregivers of schizophrenia patient by self-structured questionnaire will be assess the effectiveness of planned teaching on knowledge regarding adverse effect of antipsychotic agents. Investigator will take permission from the concern authority of the selected hospital. Then she will approach to the sample. She will introduce herself and inform them about the nature of the study so as to ensure better co-operation during the data collection. The investigator will approach the care givers of schizophrenia patients and will explain the proposed study and how it will be beneficial for them. Investigator will take their willingness to participate in the study. Investigator will make the sample comfortable and will orient them to study. She will administer the questionnaire with interview method to them. Doubts will be clarified. Once the questionnaire is completed investigator will collect them back from each sample. Each sample will require maximum time of 30 minutes to complete the questionnaire.

After the pre test the planned teaching will be giving on same day by the investigator. Post test will administer with the same questionnaire on 7<sup>th</sup> day. The collection of data will perform

within the stipulated time. After the data gathering process the investigator will thank all the study samples as well as the authorities for their co-operation.

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**Fig.-1 Schematic presentation of one group pretest posttest design for the present study**

### **INCLUSION CRITERIA:**

- Caregivers of schizophrenia patients receiving antipsychotic drugs.
- Caregivers who are taking care of the patient from 6 weeks and above.
- Those who can read and write Marathi.
- Person who are willing to participate in the study.

### **EXCLUSION CRITERIA:**

- Caregivers who is expose to the similar type of study during 1 yrs

### **SAMPLE SIZE:**

In this study sample size will be 100.

Daniel formula for sample size :

$$n = Z^2 * P * (1-p) / d^2$$

Where,

Z is the level of significance at 5% i.e.

95% confidence interval = 1.96

P = prevalence of schizophrenia = 2.5% = 0.025

d = Derived error of margin = 3% = 0.03

$$n = 1.96^2 * 0.025 * (1 - 0.025) / 0.03^2 = 104.04 = 100$$

### **LIMITATION:**

This study is limited to caregivers of schizophrenia who are receiving antipsychotic agents and also those care givers who is giving care to the schizophrenia patient from 2 years.

### **DATA MANAGEMENT AND MONITORING:**

The demographic variable are Age, gender, education status, occupational status, previous information about antipsychotic drugs, relationship with the patients, duration of illness, duration of antipsychotic drugs among caregivers the schizophrenia patient. Assess the effectiveness of planned teaching on knowledge regarding adverse effect of antipsychotic agents. One group pre-test and post-test will be taken for study.

### **STATISTICAL ANALYSIS:**

Statistical analysis will be done by descriptive and inferential statistics.

### **EXPECTED OUTCOMES/RESULTS:**

The study is planned to assess the effectiveness of planned teaching on knowledge regarding to adverse effect of antipsychotic agents among caregivers of schizophrenia patient. There will be significant association between pre-test and post-test knowledge regarding adverse effect of antipsychotic drugs and also with the demographic variables.

### **DISCUSSION:**

In a review led in Shiraz, Iran, on the impact of psychoeducational intercessions for relatives on guardian trouble and mental indications in schizophrenic patients, the review investigated the adequacy of family psychoeducation in decreasing patient manifestations and family trouble. guardian. Seventy Iranian outpatients determined to have schizophrenic issue and their guardians were haphazardly allotted to either the exploratory (n = 35) or control (n = 35) gatherings. Patients in the test bunch got treatment with antipsychotic drugs and a psychoeducational program was coordinated for their guardians. The psychoeducational program comprises of ten hour and a half meeting held more than five weeks (two meetings each week). Every guardian took part in 10 meetings (more than five weeks) at pattern, following a medical procedure and one month from there on. Approved device was utilized to survey the clinical status of the patient and guardian trouble. Contrasted and the benchmark group, the case bunch showed a huge decrease in manifestation seriousness and parental figure trouble both following a medical procedure and after one month. These discoveries likewise propose that transient requirements based psychoeducational mediations for relatives of Iranian patients with schizophrenic issues can further develop results for patients.(16)

One more review was directed on the adequacy of self-training module on information on the results of antipsychotic drugs among wellbeing experts of mental patients. An example of 100 guardians from mental patients was chosen utilizing a designated inspecting strategy and a pre-test post-test bunch configuration was utilized in this review. Organized surveys and self-

concentrate on modules. Information on the results of antipsychotic drugs on parental figures of mental patients 94 (94%) had a low degree of information, 6 (6%) had a moderate degree of information. The base score is 1 and the greatest score is 10. Evaluation of post-test information about the symptoms of antipsychotic drugs on parental figures of mental patients 3 (3%) had a normal information score and 10 (10%) had a decent information score, 66 (66%) had an excellent information score an information level score and 21 (21%) each had an awesome information level score. The determined t-esteem is 48.41 and the classified p-esteem is 0.05. In this way, it is measurably deciphered that oneself review module on information about the results of antipsychotic drugs.(15)

## **CONCLUSION**

Conclusion will be drawn from the statistical analysis.

## **CONSENT**

Caregivers written consent has been collected and preserved by the author in accordance with international or university standards (s).

## **ETHICS ASPECTS:**

Study was approved by the institutional Ethics Committee (letter no- DMIMS (DU)/IEC/2021/296) and the study will be conducted with the ethical guidelines by institutional Ethics Committee on Human research.

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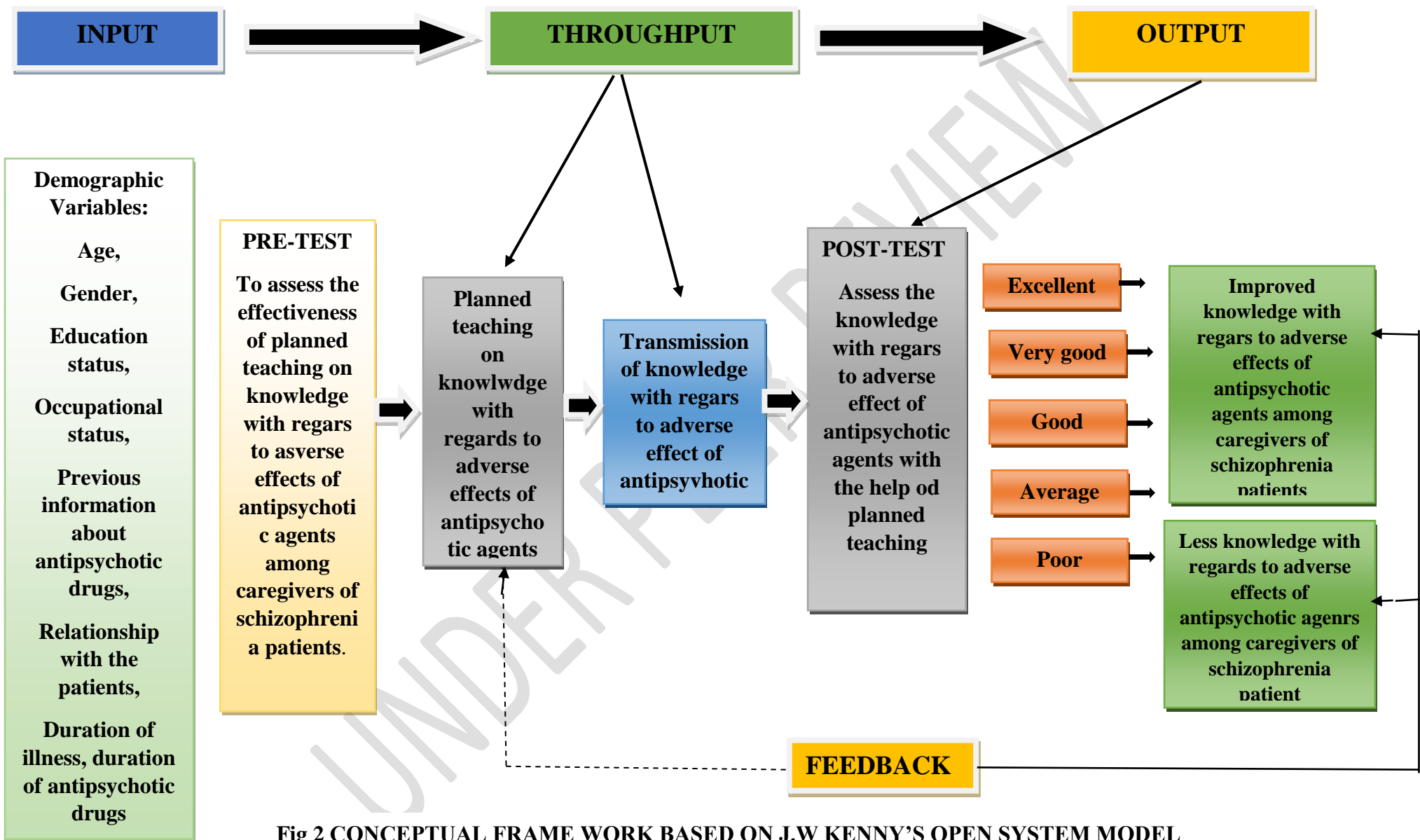


Fig 2 CONCEPTUAL FRAME WORK BASED ON J.W KENNY'S OPEN SYSTEM MODEL

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