

# **CLINICAL TRIAL PARTICIPATION: ATTITUDES OF INDIAN SCHIZOPHRENIC PATIENTS WITH DEPRESSIVE SYMPTOMS**

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## **ABSTRACT**

### ***BACKGROUND & OBJECTIVES***

In clinical trials, the informed consent process intends to provide information to the individuals about the risks, rights, and benefits of participation. However, obtaining informed consent from subjects with diminished mental abilities and impaired capacity to consent has been a challenge for many researchers. In addition, little is known about the willingness of Indian schizophrenic patients with depressive symptoms to participate in psychiatry research. The present study was designed to understand the attitudes of Indian schizophrenic patients with depressive symptoms regarding clinical trial participation.

### ***METHODS***

This interview-based study was conducted on fifty patients aged 18–65 years who met the DSM-IV diagnostic criteria for schizophrenia, and who had depressive symptoms as defined by a score of  $\geq 7$  on the Montgomery–Asberg Depression Rating Scale (MADRS). The patients were asked to pretend that they were potential candidates for a hypothetical trial involving an antipsychotic drug, and were given the following three questions to express their attitudes towards clinical trial participation: 1). Is there a need for clinical trials in India? 2) As a study subject you will receive monetary reimbursement per visit. Do you feel you should be reimbursed? Why? 3) What is your level of convenience with respect to travel/stay at the hospital for clinical trial procedures? All of the fifty patients completed the interview-based study. Agree/disagree/do not know options were used to assess the attitude assessment sections.

## *RESULTS*

Attitudes toward clinical research were positive. All (100 %) patients were of the opinion that clinical trials should be conducted in India. When asked about thoughts on monetary reimbursements per visit, twenty eight (56%) patients agreed to the fact that such reimbursement for research participation should be offered for their time off from work to attend study visits. The remaining twenty two (44 %) patients felt that their participation would be for societal benefits and for receiving an additional care for their concerned disease. Regarding convenience, all patients chose to travel once a week to the study site and 76% of them agreed to hospitalization for trial-related procedures.

## *CONCLUSION*

The attitudes of Indian schizophrenic patients with depressive symptoms were indicative of their willingness to participate in psychiatry research. Conducting a study with a large sample using structured interviews should validate the results of this study.

## **KEYWORDS**

schizophrenia; depression; patient attitudes; clinical trial; reimbursement

## **BACKGROUND & OBJECTIVES**

In clinical trials, the informed consent process intends to provide information to the individuals about the risks, rights, and benefits of participation<sup>1</sup>. For ethical research conduct, various national and international guidelines<sup>2</sup>, including the Indian Council of Medical Research (ICMR) in India<sup>3</sup>, highlight the need of obtaining informed consent from individuals willing to participate in clinical trials.

People with schizophrenia are known to have cognitive and emotional impairment, further resulting in therapeutic misconception- the tendency to confuse research participation with mental health treatment. This is more commonly witnessed in countries like India where research and clinical care often occur together in the same setting, and overall low levels of health literacy make people less discerning<sup>4</sup>. Acquiring informed consent for clinical trial participation from such patients with diminished mental abilities and impaired capacity to consent has been a challenge for many researchers<sup>5</sup>. In addition, little is known from the past studies about the willingness of Indian schizophrenic patients with depressive symptoms to participate in research. Therefore, the present study was designed to understand the attitudes of Indian schizophrenic patients with depressive symptoms toward clinical trial participation.

## **METHODS**

This interview-based study was conducted in the Department of Psychiatry, LTMG Sion Hospital, Mumbai, India during 2014- early 2015. It comprised of fifty patients (24 men, 26 women) aged 18–65 years who met the DSM-IV diagnostic criteria for schizophrenia, and who had depressive symptoms as defined by a score of  $\geq 7$  on the Montgomery–Asberg Depression Rating Scale (MADRS)<sup>6</sup>. Written informed consent was obtained from each patient after making them understand the study details. The study received favorable opinion from an independent Ethics Committee.

After obtaining consent for the actual study, the investigator asked each patient to pretend that he/she was a potential candidate for another research study, and read through a detailed informed consent document for a hypothetical trial of an antipsychotic drug. The investigator, thereafter, gave the following three questions to the patients to express their attitudes towards clinical trial participation:

- 1) Is there a need for clinical trials in India?
- 2) As a study subject you will receive a monetary reimbursement of Rs. 500 per visit. Do you feel you should be reimbursed? Why?
- 3) What is your level of convenience with respect to travel/stay at the hospital for clinical trial procedures?

All of the fifty patients who had expressed initial willingness to participate completed the interview-based study. All interviews were conducted by the same interviewer. Agree/disagree/do not know options were used to assess the attitude assessment sections.

## **RESULTS**

### *DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE PATIENTS*

Fifty Indian schizophrenic patients with depressive symptoms and with the mean age of  $32.02 \pm 11.631$  years participated in this interview-based study (24 men, 48 % and 26 women, 52 %). Total scores on the MADRS were  $13.16 \pm 4.287$  (Table 1).

**Table 1. Demographic and clinical characteristics of the patients (n = 50)**

Characteristics	n (%) or mean
Age	32.02 ± 11.631
Sex	
Male	24 (48 %)
Female	26 (52 %)
Total score of MADRS	13.16 ± 4.287
<i>MADRS, Montgomery–Asberg Depression Rating Scale.</i>	

### *ATTITUDES REGARDING CLINICAL TRIALS IN INDIA*

Attitudes toward clinical research were positive. All patients were of the opinion that clinical trials should be conducted in India since they assess the safety and effectiveness of new medicines that may possibly result in better health outcomes as compared to older medicines currently available in India.

### *ATTITUDES REGARDING MONETARY REIMBURSEMENT*

When patients were asked about their thoughts on monetary reimbursements of Rs. 500 per visit, twenty eight (56%) patients agreed to the fact that such reimbursement for research participation should be offered for their time off from work to attend study visits. The remaining twenty two (44 %) patients felt that their participation would be for societal benefits and for receiving an additional care for their concerned disease (Table 2).

### *ATTITUDES REGARDING CONVENIENCE*

All patients (100 %) chose to travel once a week to the hospital for trial-related procedures. Participants were also asked to outline their points of view on hospitalization. Nearly 38 (76 %) patients showed their willingness to get hospitalized, while some (20 %) denied. Others (4 %) expressed that the opinion of their spouse and family members should be taken into consideration while getting admitted for trial procedures (Table 2).

## **DISCUSSION**

Clinical trials are the primary means by which new treatment approaches are assessed in medicine<sup>7</sup>. One of the most crucial factors in a trial's success is the subjects' willingness to participate in the study<sup>8</sup>. Although extensive literature on clinical trial participation among

various populations is available, there is a dearth of studies focusing on specific attitudes of mentally-ill patients in India toward psychiatry research.

In this study, responses to three simple questions have generated information that helped us understand the willingness of Indian schizophrenic patients with depressive symptoms to participate in psychiatry research.

**Table 2. Attitudes of patients toward clinical trials, monetary reimbursement and convenience (n = 50)**

<b>Attitudes of patients toward clinical trials</b>				
<b>Sr. No.</b>	<b>Responses</b>	<b>Agree n (%)</b>	<b>Disagree n (%)</b>	<b>Do not know n (%)</b>
1)	There is a need for clinical trials in India	50 (100.00)	0 (0.00)	0 (0.00)
<b>Attitudes of patients toward monetary reimbursement</b>				
1)	Monetary reimbursement for trial patients should be offered for their time off from work to attend visits.	28 (56.00)	22 (44.00)	0 (0.00)
2)	No reimbursement requirement, trial participation is for societal benefits and for receiving an additional care for concerned disease.	22 (44.00)	28 (56.00)	0 (0.00)
<b>Attitudes of patients toward convenience</b>				
1)	Weekly travel to hospital for trial procedures	50 (100.00)	0 (0.00)	0 (0.00)
2)	Willingness to get hospitalized for trial procedures	38 (76.00)	10 (20.00)	2 (4.00)

Edlinger *et al.* have reported positive attitudes regarding psychiatry research in patients with schizophrenia or depression<sup>9</sup>. In support of this, all of the respondents from our study had a positive attitude towards research, and were of the opinion that clinical trials should be conducted in India since they assess the safety and effectiveness of new medicines that may

possibly result in better health outcomes as compared to older medicines currently available in India.

Breitkopf *et al* have stated that offering reimbursement can lead individuals to consent to research participation against their own decision, particularly in vulnerable populations<sup>10</sup>. On the other hand, studies conducted by Roberts *et al.* have demonstrated that individuals with schizophrenia show selfless attitudes toward research. They participate in trials to help society, to facilitate scientific development, and to help others with the illness (present and in the future)<sup>11, 12</sup>. Also, Chong *et al.* found two main reasons for patients' voluntary participation<sup>13</sup>; 1) the possibility that I might get well; 2) I'm helping other patients like myself. In our case, about 56% of the total number of patients felt that monetary reimbursements for research participation should be offered for their time off from work to attend study visits, whereas the remaining (44 %) were of the opinion that trial participation is for societal benefits and for receiving an additional care for concerned disease.

Furthermore, this study assessed patients' attitudes toward convenience with respect to travel/stay at the hospital. All patients chose to travel once a week to the site and 76% of them agreed to hospitalization for trial-related procedures.

In summary, the participating patients' attitudes were indicative of their willingness to participate in psychiatry research. Future research calls for larger samples and structured interviews to validate the results of this study.

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