

Original Research Article

Volume 14 Issue 03

March 2025

A CLINICAL STUDY TO ASSESS THE IMPROVEMENT OF AFFECT IN PATIENTS DIAGNOSED WITH SCHIZOPHRENIA USING HOMOEOPATHIC REMEDIES - A STUDY PROTOCOL

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ABSTRACT

Aim & Objective

Schizophrenia is a complex mental disorder marked by distortions in perception, thinking, and affect, including heightened negative affect (NA) and diminished positive affect (PA). This study aims to evaluate the effectiveness of individualized homoeopathic medicines in the Management of affect in schizophrenia patients. The objectives include assessing the impact of these medicines on improving positive affect and reducing negative affect using the PANAS score. Additionally, the overall symptom intensity will be evaluated by using the PANSS scale. Homoeopathic treatment with its minute potentised form are look forward to bring a significant improvement in the affect of persons diagnosed with schizophrenia

Materials and Methods

This protocol is a single-arm prospective clinical trial to identify the effectiveness of Homoeopathic Medicine in improving the affect of persons with schizophrenia. Affect will be measured using the PANAS scale at baseline and at the 3rd, 6th, 9th, and 12th months. Symptom severity will be assessed using the PANSS scale during the same intervals. The

study outcomes will be analysed statistically, with the Friedman test used to evaluate changes in PANAS and PANSS scores. P-value if shows ≤ 0.05 will be considered as statistically significant value.

Discussion and Conclusion

The study explores the potential of homoeopathic interventions as a complementary treatment for affective disturbances in schizophrenia. Homoeopathic holistic approach may offer an alternative to conventional treatments, which often come with side effects and financial burdens. Findings could provide preliminary evidence supporting individualized homoeopathic medicine as a cost-effective, non-invasive option for improving affect and overall quality of life in schizophrenia patients. Further randomized controlled trials are recommended to validate these outcomes and establish stronger evidence for clinical practice.

Keywords

Schizophrenia, affective disturbances, Positive and Negative Affect Schedule (PANAS), Positive and Negative Syndrome Scale (PANSS), Homoeopathy.

1. INTRODUCTION

Schizophrenia is a chronic mental health disorder that profoundly impacts cognitive, emotional, and social functioning. A key aspect of this disorder is the disruption of affect, which encompasses the immediate and subjective experience of emotion. Affect can manifest as positive affect (PA) and negative affect (NA), representing distinct emotional states. PA involves emotions like enthusiasm and vigor, while NA encompasses distressing emotions such as anger and nervousness. These emotional disturbances are prevalent in schizophrenia and are closely linked to the disorder's cognitive impairments, such as deficits in attention, memory, executive functioning, and social cognition.⁽¹⁾ They affect daily functioning, self-esteem, and interpersonal relationships. They also hinder social, professional, and familial responsibilities by impairing concentration, motivation, and task engagement, often leading to social withdrawal and isolation.⁽²⁾ Such impairments exacerbate the illness course and highlight the need for new treatment strategies.

Conventional treatments for schizophrenia, including antipsychotic drugs, mood stabilizers, and cognitive-behavioral therapy (CBT), focuses on symptom management. However, these approaches often come with limitations such as secondary blunted affect, long-term side

effects, and only partial efficacy in improving emotional and social functioning.⁽³⁾ This highlights the need for additional therapeutic interventions that address the multidimensional nature of schizophrenia.

The homoeopathic system of medicine offers a holistic approach to treating schizophrenia by addressing its physical, emotional, and mental dimensions. Homeopathy is known for its cost-effectiveness, minimal side effects, and potential to improve emotional stability and social functioning.⁽⁴⁾ While homoeopathy's efficacy has been explored for various mental health conditions, its specific impact on the affective disturbances in schizophrenia remains under-researched.

This study proposes to gauge the effectiveness of homoeopathic medicines to improve the affective symptoms of schizophrenia. An article indicates that individuals with schizophrenia typically demonstrate diminished positive affect alongside heightened negative affect⁽⁵⁾

Observational studies suggest that, schizophrenia spectrum disorders are characterized by elevated NA across different measures and samples throughout the world and characterized by stably low PA/elevated anhedonia.⁽⁶⁾

One study mentions that individuals with schizophrenia who experience mood alterations have a notable effect on their professional lives. Negative affect (NA) can impede concentration, causing challenges in completing tasks. Reduced positive affect (PA) leads to decreased motivation, impacting productivity. Moreover, social anxiety contributes to withdrawal from social interactions, making it difficult to collaborate effectively in professional environments.⁽⁷⁾ In a systematic review, blunted affect might contribute to suicide indirectly by influencing risk factors like emotional withdrawal, depressive symptoms, feelings of hopelessness, low self-esteem, and negative self-evaluation.⁽⁸⁾ Another research revealed that inadequate social functioning in individuals with schizophrenia was connected to increased levels of negative affect (NA) and social anxiety. Conversely, stronger trait positive affect (PA) was correlated with improved social functioning. These findings imply that schizophrenia is characterized by diminished PA and heightened NA, which are consists feature of the illness.⁽⁹⁾

The studies which reinforce the efficacy of Homoeopathy for improvement of affect in schizophrenia are limited. An observational study on the treatment of schizophrenic patients demonstrated the beneficial effects of homoeopathic medicine.⁽¹⁰⁾ The more effective

medications for treating schizophrenia patients in this study were determined. A clinical study showed that receiving homeopathic medication significantly reduced the symptoms of paranoid schizophrenia. ⁽¹¹⁾ The studies demonstrated the efficacy of homeopathic interventions for persons with schizophrenia, there is a notable absence of research within homoeopathy that specifically examines the individual monitoring and tracking of affective symptoms progress. This emphasizes the importance of undertaking such investigations within the field of homoeopathy

By targeting emotional disturbances, homoeopathy has the potential to enhance patients' quality of life, reduce dependency on conventional medications, and promote social and professional reintegration. The findings of this study could contribute to developing adjunctive therapeutic strategies that complement existing treatments, addressing the unmet needs of schizophrenia patients and offering a promising avenue for future mental health care.

MATERIALS AND METHODS

The research study will be an open-label single-arm clinical trial which is planned to conduct at National Homoeopathy Research Institute in Mental Health (NHRIMH), Kottayam, Kerala, India. The individualised homoeopathic intervention will be given by the Principal Investigator and Psychiatrist will be approached for the case diagnosis of each subject. In maintaining follow-ups, supportive assistance if required shall be provided by the Principal Investigator. The study protocol was made in accordance with the Helsinki Declaration on human experimentation and Good Clinical Practices in India. The medicines proposed to be used during the study will be from known homoeopathic pharmacopoeia preparations. Clearance from the ethical committee and scientific advisory committee will be obtained before undertaking the study. This study protocol is registered with the Clinical Trial Registry of India (CTRI/2024/09/073577). The protocol was designed based upon the guidance and approval by the Institutional Ethical committee and scientific advisory board.

RATING SCALES USED IN THE STUDY

Positive and Negative Affect Schedule (PANAS) is the assessment scale used in studies of affect in clinical as well as non-clinical groups. Brief self-report form with good psychometric quality brings about information on Positive (PA) and Negative (NA) affect. It is a 10-item scale each for positive and negative affect. The assessment rating scale scores of positive and

negative affect ranges from 10-50. Mean score is 33.3 for positive affect and 17.4 for negative affect ⁽¹⁾. Increased PA score reveals experiences of enthusiasm, control, commitment, strength, and activity, low level of PA score is represented by sadness and lethargy. High NA indicates shame, worry, fear, irritability, and hostility, whereas individuals with low in NA are typically calm and relaxed. Positive Affect Scores ranges from 10 to 50, with high score represents higher levels of positive affect. Mean Scores: 33.3 (SD \pm 7.2) Negative Affect Scores can range from 10 – 50, with lower scores representing lower levels of negative affect. Mean Score: 17.4 (SD \pm 6.2)

The Positive and Negative Syndrome Scale (PANSS) is a standardized clinical interview is used to measure the severity of schizophrenia symptoms and the presence of positive and negative psychopathology symptoms. PANSS is one of the most widely used psychometric instruments for assessing psychotic illness. PANSS has 30 items that are commonly aggregated into three primary domains: positive, negative, and general psychopathology. The PANSS is used in clinical trials of schizophrenia and other disorders to ensure the reliability of study measures and sensitivity to changes in clinical trials. ⁽¹²⁾

SCREENING AND ENROLLMENT

Subjects who are presenting with schizophrenia symptoms from Out Patient Department (OPD) and other Peripheral units of NHRIMH, Kottayam, will be screened by using the verbal screening questions. On fulfilling the required scoring, the case will be referred to concerned investigator and consultant psychiatrist for further confirmation of diagnosis and enrolment.

RECRUITMENT PROCESS AND INCLUSION CRITERIA

Patients who present with symptoms of schizophrenia at OPD and peripheral camps of the NHRIMH, Kottayam will be screened by using verbal screening form, Positive and Negative Affect Schedule (PANAS) scale and The Positive and Negative Syndrome Scale (PANSS) at baseline. The screening question form will be retained by the investigator. Psychiatrist will be consulted for the diagnosis. Patients who meet the inclusion criteria will be given a detailed explanation of the study project needs and shall be invited to participate in study trial. A written informed consent will be taken from each patient and then, subjects qualified as per inclusion criteria will be enrolled. Detailed case-taking will be done in the standardised case record format. Basic routine investigations along with specific investigations will be applied to the subjects as per the need to rule out any serious medical conditions.

Persons with Schizophrenia are eligible if they are: aged between 19 - 65 years, with both sexes, cases falling under the ICD 10 diagnostic criteria for SCHIZOPHRENIA. Subjects will be assessed at baseline with Positive and Negative Affect Schedule (PANAS) scale and The Positive and Negative Syndrome Scale (PANSS)

SAMPLE SIZE

By assuming the recovery with Individualized Homoeopathic individualised medicine came up in previous studies and due to unavailability of data with similar studies the sample size of 30 is selected. By Considering 15% drop out rate, 35cases can be enrolled in the study.

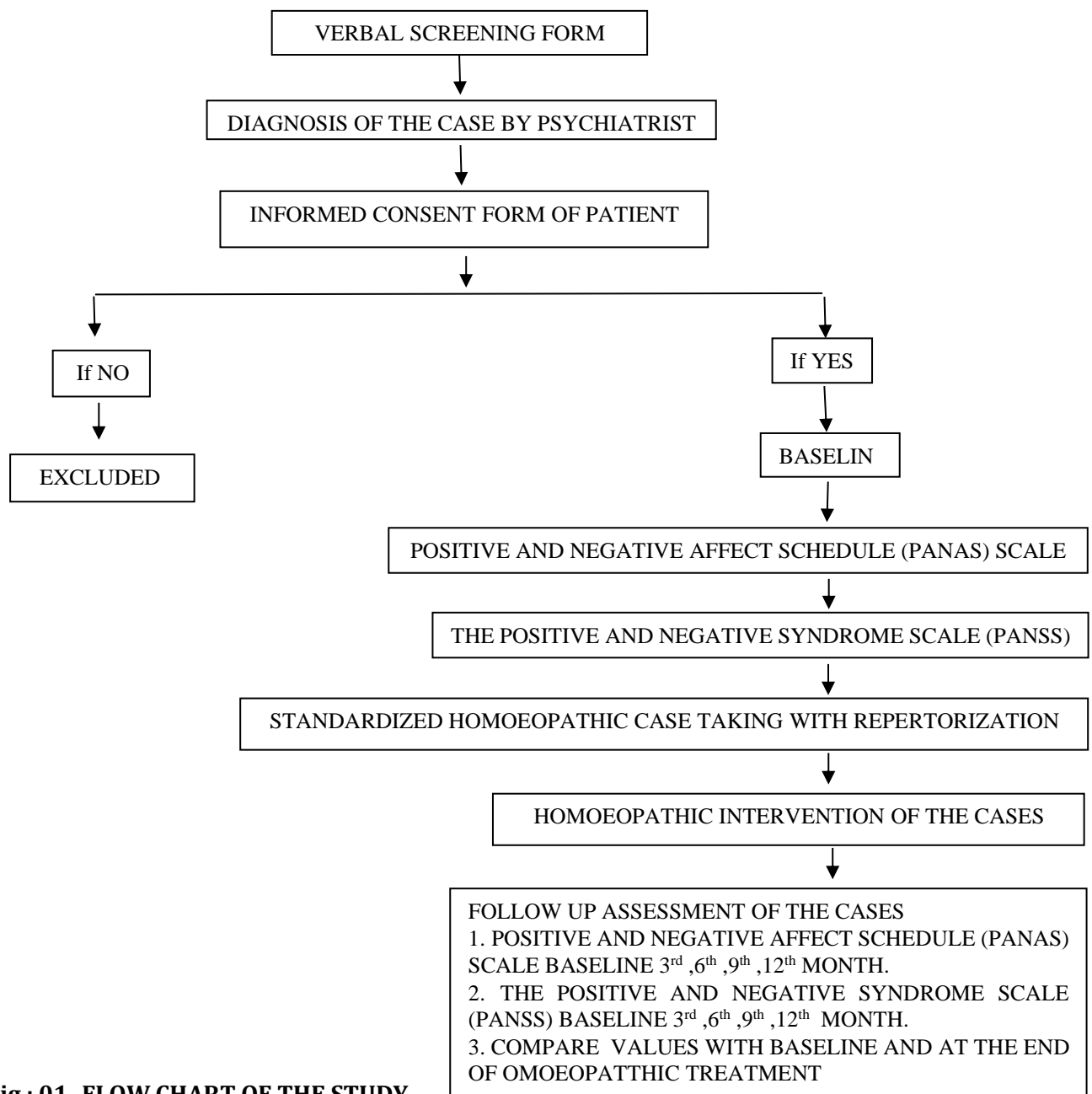


Fig : 01- FLOW CHART OF THE STUDY

INTERVENTION

An in-depth interview with the patient and bystanders will be conducted by the investigator and the case details will be recorded in the given Case Recording format (CRF). Based on further analysis and evaluation, totality will be formed. Repertorisation will be done based on the totality of symptoms using the latest homeopathic software. The similimum will be selected based on individualization of the patient as per the repertorial result, in consultation with Materia Medica. The dose and repetition of medicine will be done according to the principles of homoeopathy. The psychiatrist will be consulted for any emergencies in the patient's condition. The potency of the individualized homoeopathic medicine will be moderated as per the requirement of the case. If improvement in case stops after a particular period, the next indicated homoeopathic medicine will be repeated. If no change takes place, case will be reviewed and a new remedy will be considered. In case of any acute conditions occurring during the study, an acute indicated homoeopathic remedy will be considered based on acute totality.

OUTCOME MEASURES

Primary outcome will be improving the affect in schizophrenia patients using Positive And Negative Affect Schedule (PANAS) Scale at the baseline and at every 3 months and comparing the scores at end of the treatment. The secondary outcome, to perceive the overall improvement in SCHIZOPHRENIA symptoms using the Positive and Negative Syndrome Scale (PANSS) Scale.

CRITERIA FOR BASELINE AND FOLLOW UP ASSESSMENT

Assessment of this schizophrenia clinical trial study subjects will be done using PANSS scale at the baseline and every month. For assessment of affective symptoms, PANAS Scale will be used for assessment at baseline and every 3 months and at the end of the study. Positive Affect score ranges from 10 to 50, the higher score represents the higher level of positive affect. 10 to 21 low Positive affect, 21 to 32 Average Positive affect, 32+ High Positive Affect. Negative Affect Score can range from 10 to 50, whereas lower scores representing lower levels of negative affect. < 18 low Negative affect 18-28 Average Negative affect, 28+ High Negative affect. Laboratory investigations will be done as per the need of the patient to exclude in any suspected serious medical conditions. The results at baseline and at the end

of the study would be compared and evaluated to determine how well a person's affective symptoms can be improved through individualized homoeopathic medicine. Details of study timeline are given in the below Table.:

Table 1: Timeline of the research study

TIME	STUDY PERIOD						CLOSE OUT
	Enrol ment	MONTHS					
		3	6	9	12	EVERY MONTH	
Eligibility screening	+	-	-	-	-	-	-
Informed consent of the patient	+	-	-	-	-	-	-
Homoeopathic Intervention	+	+	+	+	+	+	-
Assessment of Verbal screening Form	+	-	-	-	-	-	-
PANAS	+	+	+	+	+	+	+
PANSS	+	+	+	+	+	+	+

Diagnostic Criteria for SCHIZOPHRENIA (ICD-10)

- (a) Thought echo, thought insertion, thought withdrawal, or thought broadcasting.
- (b) Delusion of control, Delusion of influence, or passivity related to body or limb movements, specific thoughts, actions, or sensations; or delusional perception.
- (c) Hallucinations voices which were commenting on the patient's behavior, discussing about the patient among themselves, or voices originating from parts of the body.
- (d) Persistent delusions which are culturally inappropriate or impossible (e.g., superhuman powers or communication with aliens).

(e) Persistent hallucinations in any modality, accompanied by fleeting delusions, over-valued ideas, or occurring daily for weeks or months.

(f) Thought disorder leading to incoherence, irrelevant speech, or neologisms.

(g) Catatonic behavior such as excitement, posturing, waxy flexibility, negativism, mutism, or stupor.

(h) Negative symptoms (e.g., apathy, blunted emotions, poor speech) leading to social withdrawal, not due to depression or medication.

At least one clear symptom from groups (a) to (d), or

At least two symptoms from groups (e) to (h).

These symptoms must be present for most of the time over a period of one month or more. If symptoms last less than one month, the condition should be initially diagnosed as acute schizophrenia-like psychotic disorder and reclassified as schizophrenia if symptoms persist.

DATA COLLECTION

Standardized Case record format for the study and Excel spread sheet will be used for data collection. Data recording will be done through validated questionnaires and tools for outcome measures, such as PANAS and PANSS. Apart from these psychological, physical, clinical, and demographic information of the patient will be noted. Comparison of PANAS And PANSS will be scored at baseline, 3rd month, 6th month, 9th month, and 12th month.

Table No.2: Format of Data collection

SYMPTOMS	BASELINE	3 RD	6 TH	9 TH	12 TH	P VALUE

STATISTICAL ANALYSIS

The data will be statistically analysed using the appropriate statistical analysis software. The changes in the positive and negative affect scores of the participants assessed using Friedman test for PANAS Scale. PANSS total score were also assessed using the Friedman test. Scores of the scales at baseline, 3rd month, 6th month, and 12th month will be considered for scoring. If P value becomes ≤ 0.05 will be considered as statistically significant

2. DISCUSSION

Changes in affective symptoms of schizophrenia which is characterised by heightened negative affect and diminished positive affect. Dysfunctional affectivity is very much common in schizophrenia spectrum disorders (SSD) and can significantly affect various aspects of life, including the progression of the illness, treatment outcomes, and overall well-being. studies suggest that blunted affect might contribute to suicide indirectly by influencing risk factors like depressive symptoms, emotional withdrawal, low self-esteem, negative self-evaluation, and feelings of hopelessness. The proper evaluation and treatment for schizophrenia are required along with clinical management and assessment scales. The patients, fulfilled the ICD 10 criteria for diagnosis with age more than 18 years, who can speak and read English, and completion of informed consent will be taken for the study. The assigned sample size is 35 to be enrolled in 6 months period. At the end of the study, the data's obtained through standard rating scales will be recorded in the excel sheet for further study. The schizophrenia has poor positive affect so an interventional studies required to consider affect as one of the parameters for judging its effectiveness.

3. CONCLUSION

This protocol also aims to assess and equate the affective symptoms of persons with schizophrenia. This study also highlights on general improvement in symptoms of persons with schizophrenia. The study aims to assess initial treatment outcomes in schizophrenia, feasibility, safety of administering, psychological and therapeutic count for the management of schizophrenia and improving the affect of in schizophrenia and aims to minimize the risk of publication bias and selective outcome reporting bias.

The negative factor from this study is the limited sample size and no comparative group.

4. ACKNOWLEDGEMENT

Authors acknowledge Dr.R.Bhuvaneswari Officer incharge, Dr.R.Sitharthan Principal and Dr.N.D.Mohan, Psychiatrist of NHRIMH for their constant support. Authors also Acknowledge

Kerala University of Health sciences at Thrissur for giving the critical review on this research proposal and helped in disseminating this knowledge.

5. COMPETING INTERESTS

None

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