

“A Open Label Clinical Study – To Ascertain The Effect Of Homoeopathic Medicines In Cases Of Psycho-Somatic Disorder With Miasmatic Approach”

Dr. Sanjeev Kumar Srivastava^{1*}, Dr. Sunil Kumar²

¹Ph.D. Scholar, Tania University

²Professor-Dept. of Organon Of Medicine, Sri Ganganagar Homoeopathic medical college, Hospital and research Institute, Tania University

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ABSTRACT

Background: Psychosomatic illnesses challenge this paradigm because they present physically, but are thought to have, at least in part, a psychological origin. Psychosomatic disorder, also called psycho physiologic disorder, is a condition in which psychological stresses adversely affect physiological (somatic) functioning to the point of distress. Aim: To ascertain the effectiveness of homoeopathic remedies in cases of Psycho-somatic disorder. Objective: 1. To measure changes in symptom severity, quality of life and overall well-being. 2. To assess of psychological factors in cases of Psycho-somatic disorder. 3. To assess the miasmatic background in the cases of Psycho-somatic disorder. Methods & Results: A prospective single-arm clinical trial involved 100 patients suffering from Psychosomatic disorder at OPD of B R V Homoeo Clinic And Research Unit Prayagraj. Psychosomatic Symptom Scale (PSSS) is a questionnaire used to assess psychosomatic symptoms with score was utilized to gauge improvement. The average score before treatment (2.78) decreased to (1.54) after treatment, resulting in a mean difference of 1.24. The calculated t-value (13.77) was greater than the critical value (0.78) at a 5% significance level ($p < 0.0001$), indicating a highly significant enhancement. Conclusion: Customized homoeopathic treatments led to a statistically significant reduction in psychosomatic disorder and associated symptoms. The findings indicate that homoeopathy presents a safe, effective, and non-invasive option for addressing psychosomatic disorder. Keywords: psychosomatic disorder, Psychosomatic Symptom Scale (PSSS) Homoeopathy, Constitutional Treatment, Single Arm Clinical Trial, Miasmatic Analysis, Symptom Score, Clinical Improvement.

Aim: To ascertain the effectiveness of homoeopathic remedies in cases of Psycho-somatic disorder

Objective:

1. To measure changes in symptom severity, quality of life and overall well-being.
2. To assess of psychological factors in cases of Psycho-somatic disorder.
3. To assess the miasmatic background in the cases of Psycho-somatic disorder.

Materials & Methods:

A. STUDY SETTING:

The study will be carried out at outpatient department OPD of B R V Homoeo Clinic And Research Unit Prayagraj (UP).

B. SELECTION OF SAMPLES:

Minimum 100 patients will be taken from 0 to 60 years of age from OPD and IPD of B R V Homoeo Clinic and Research Unit Prayagraj (UP)

C. INCLUSION CRITERIA: Both sexes of age group 20-70years. Clinically diagnosed cases of psychosomatic disorder on the basis of symptoms and investigations. Both new and recurrent cases of psychosomatic disorder. Patient who will give consent and willing to participates in the study.

D. EXCLUSION CRITERIA: Patients suffering from other systemic diseases. Dropout patients. Patients having any other Psychosomatic disorder. Patients not willing to participate in the study.

E. STUDY DESIGN:

Perspective Open label Clinical study

F. INTERVENTION: Appropriate Homoeopathic medicine will be chosen on basis of totality of symptoms including patient's constitution type, susceptibility and specific food considering the Homoeopathic principles. A thorough assessment will be done considering not only the physical symptoms but also psychological and social factors including patient's emotional state, stressors, lifestyle, and environmental influences. Miasmatic influences will be considered in understanding the underlying predisposition to Psychosomatic disorder the optimal potency and dosage will be determined for each patient. Regular Follow-up sessions will be allowed for assessment and adjustment of the treatment plan.

G. SELECTION OF TOOLS: Case taking on standard case taking format. Data compilation and statistical analysis. Relevant literature review from books, internet, journals. Homoeopathic repertories will be utilized if required. To diagnose Psychosomatic disorder commonly used investigations are done

H. BRIEF PROCEDURE: Detailed and through case taking of each and every case of patient will be taken. Relevant investigative procedure such as laboratory investigation will be done in cases as per the need of the case. Evaluation of symptoms and framing of the totality in accordance with homoeopathic principles. Miasmatic background of each case will be analyzed as per the direction of Hahnemann and other stalwarts. Selection of medicine by Homoeopathic Materia Medica in accordance with fundamental cause and totality of symptoms. Repertory will be used if necessary. Each case will be assessed periodically to follow up the remedy reaction through clinical assessment, expert opinion as well as relevant investigation.

I. DATA COLLECTION Minimum 100 (Hundred) cases with complaints of Psychosomatic disorder was assessed for the outcome of treatment.

J. CASE RECORDING One standard case record format will be prepared for maintaining the clinical profiles of the patients.

K. SELECTION OF MEDICINE After thorough case taking selection of individualized homoeopathic medicine will be done on the basis of totality of symptoms.

L. SELECTION OF POTENCY: Selection of potencies, doses and administration of medicines will be done on the guidelines prescribed by Dr. Hahnemann in “ORGANON OF MEDICINE”.

M. REPETITION SCHEDULE: The medicine will be repeated on the basis of principles laid down by Dr. Hahnemann in his ORGANON OF MEDICINE as per the case demands.

N. FOLLOW UP: After presenting individualized Homoeopathic Medicine and providing other instructions, the patient will be asked to report at suitable intervals preferably after every 2 – 4 weeks. At each time a detail follow up record will be maintained as improvement or worsening of the case.

O. ASSESSMENT RESULT: It is difficult to formulate definitive assessment criteria, but the case will be assessed in terms of their presenting symptoms, physical signs, quality of life, overall well-being and clinical findings along with the laboratory investigations.

P. STATISTICAL TECHNIQUES AND DATA ANALYSIS: Descriptive Statistics: The result will be represented by patient’s demographics, symptom scores, and treatment outcomes. Regression Analysis: Investigate associations between prognostic factors and treatment response.

Q. Outcome assessment & Result: The response of the patient will be documented after the administration of medicine according to the totality of symptoms. Standardized scales will be used to assess the symptom severity and quality of life. The percentage changes of symptoms score obtained from Psychosomatic Symptom Scale (PSSS) is a questionnaire used to assess psychosomatic symptoms, meaning physical symptoms that are thought to be caused or exacerbated by psychological factors. It's a self-reported scale where individuals rate how frequently they experience various physical symptoms and psychological distress. The PSSS is a 26-item scale that includes somatic (physical) and psychological subscales. 1= Never, 2= A few times a month, 3=A few times a week, 4=A few times a month

$$\text{Percentage} = \frac{\text{Score at Baseline} - \text{Score at the end}}{\text{Score at Baseline}} \times 100$$

Outcome of the treatment was measured in gradation as:

Marked Improvement	70 %
Moderate Improvement	10%
Mild Improvement	10%
Worse	05%
Status que	05%

Research Hypothesis:

1 Null Hypothesis- There is no significant difference in the effectiveness of homoeopathic remedies for Psycho-somatic disorder.

2 Alternative Hypothesis- Homoeopathic remedies are effectiveness result in improved symptom relief and overall well-being for patients with Psycho-somatic disorder. At 5%level of significance.

Observations & Results: Data was recorded via a case proforma and presented in charts.

CHART- 1 Percentage distribution acc. to Age

CHART- 2 Percentage distributions as per economic condition

CHART- 3 Percentage distributions as per Marital status

CHART -4 Percentage distribution as per risk actors

CHART 5 Percentage distribution of 100 cases as per presenting complaint

CHART 6 Percentage distribution of 100 cases as per medicines prescribed

CHART 7 Percentage distributions of 100 cases as result outcome

Statistical analysis & results: A paired t-test was conducted for “Homoeopathic management in Psychosomatic disorder”

via comparing before & after scores collected from the studied sample. There was a significant difference in the scores, of Before (M = 2.78, SD = 0.73) & After (M = 1.54, SD = 0.50) conditions: $t(99) = 13.77, p = .000$.

According to statistical analysis, t value i.e. 13.77 is $>$ t table value i.e. 2.000, which suggests that the null hypothesis (H_0) is rejected at 5% level of significance. Thus alternative hypothesis (H_1) is accepted, i.e. after receiving homoeopathic medicines patients of Psychosomatic disorder show statistically significant importance.

Paired Samples Test

Pair	Paired Differences Mean Std. Deviation	t	df	Sig. (2-tailed)	95% Confidence Interval of the Difference				
					Std. Error Mean	Lower		Upper	
Pair 1	VAR00001 - VAR00002	1.24	0.616	.090	1.06	1.04	13.77	99	.000

Discussion: The key observations and findings of the study are summarized below

AGE INCIDENCE: Maximum incidence was seen in age group 21- 40 years.

ECONOMIC CONDITION: Maximum among urban population as compared to rural population

RISK FACTOR: Psychosomatic Disorder were found to be maximum among stress, anxiety and past medical condition.

PRESENTING COMPLAINT: Maximum cases were of Eczema, IBS, Migraine.

MEDICINES PRESCRIBED: Cases were treated with Sepia and Nat Mur, Sulphur followed by Ars Alb, Graphitis, Psori. Merc. Sol, after repertorization.

SEVERITY OF SYMPTOMS PER PSYCHOSOMATIC SYMPTOM SCALE (PSSS) SCALE: Severity of complaint, before t/t, maximum cases were under the grade 1 and 2 with never or few times a month.

OUTCOME ASSESSMENT: Around 70 cases (70%) showed marked improvement, 10 cases (10%) showed moderate improvement, 10 cases (10%) showed mild improvement, 05 cases (05%) worse and 05 cases (05%) were in status quo in cases of Psychosomatic Disorder.

Conclusion: Homoeopathic treatments exhibited statistically significant enhancements in Psychosomatic disorder and associated symptoms, affirming their efficacy in the management of Psychosomatic disorder.

Future reference: This study should be conducted with large sample size for long duration.

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