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A Randomized Clinical trial to Evaluate Reduction of DASS-21 Stress Score in Psychosomatic Disorders using Mind-Ailments from as an Eliminative Rubric

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ABSTRACT: **Background**: Psychosomatic disorders arise when persistent psychological stress adversely affects bodily functions, primarily mediated by the hypothalamic-pituitary-adrenal (HPA) axis. In the homoeopathic medical science, the cause of the illness plays a key role in selecting a remedy, uniquely considering how the mind plays a role in health and illness. This study aims to evaluate the reduction of DASS-21 'Stress' scores by comparing 3rd-grade versus 1st-grade remedies, utilizing the 'Mind Ailments from' as an eliminative rubric in cases of psychosomatic disorders using Synthesis repertory.

Material and Methods: A prospective, randomized, single-blind clinical study was conducted at Bharati Vidyapeeth Homoeopathic Medical College and Hospital. The study included 52 patients (aged 18-60) with psychosomatic diseases and baseline DASS-21 stress scores > 15. Participants were equally divided into Group A (3rd-grade remedies, n=26) and Group B (1st-grade remedies, n=26). Outcomes were measured using DASS-21 and Psychosomatic Symptoms Questionnaire (PSQ-39) scales before and after the intervention. The Mann-Whitney U test was used for between group comparisons and the Wilcoxon signed-rank test for within-group variation.

Result: Both treatment cohorts shows statistically significant within-group reductions in psychological and physiological distress ($p < 0.01$). Between-group comparisons established the statistical superiority of the first-grade remedy intervention. The first-grade cohort achieved a mean DASS-21 score reduction of 11.92 ± 1.44, compared to 7.31 ± 1.38 in the third-grade cohort. Similarly, the mean PSQ-39 score reduction was 36.04 ± 3.50 for the first-grade group versus 19.08 ± 2.38 for the third-grade group. First-grade interventions yielded marked (21.15%) and moderate (23.08%) clinical improvements, whereas third-grade interventions predominantly yielded mild (36.54%) improvements.

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Conclusion: While both remedy grades provided statistically significant amelioration of symptoms, First-grade remedies selected using Synthesis Repertory with "Mind–Ailments from" as an eliminative rubric produced greater reductions in DASS-21stress score and PSQ-39 scores. Patients receiving first-grade remedies showed predominantly moderate-to-marked clinical improvement, whereas third-grade remedies showed mainly mild improvement. These findings underscore the critical importance of efficacy of remedy grading in clinical practice, advocating for the prioritization of first-grade indications to optimize patient outcomes and enhance the quality of life in individuals suffering from psychosomatic disorders.

INTRODUCTION

Stress

Stress is a psychophysiological reaction that happens when environment demands exceed a individuals ability to adapt and maintain homeostasis. Chronic distress initiates a cycle of allostatic load, causing neurobiological deterioration and weakening the body's regulatory systems, which increases susceptibility to both mental and physical illnesses. This is heavily mediated by the hypothalamic-pituitary-adrenal (HPA) axis.[1]

Psychosomatic disorder

The Greek terms "psyche," which means "mind" or "soul," and "soma," which means "body," are the source of the word "psychosomatic." The word was originally used in 1818 by the German psychiatrist Heinroth. [2] The major physiological and psychological effects of ongoing negative stress and underlying emotional distress are the main cause of psychosomatic disorders.[3] Psychosomatic disorders, are referred as psychophysiological disorders, arises when physical bodily functions are adversely affected by psychological stress.[5] Inappropriate activation of the autonomic nervous system and endocrine glands by emotional stress can result in physical symptom such as chronic pain, gastrointestinal disorders, respiratory issues, sleep disorders, anorexia nervosa, and headaches. It is important to remember that conditions like heart disease and hypertension can develop or worsen as a result of excessive and ongoing stress, anxiety, or emotional distress.[4] psychosomatic pathology is driven by an intricate combination of environmental pressures, individual cognitive appraisal, and underlying biological vulnerabilities.[11]

Psychosomatic disorders and Homoeopathy

A state of complete physical, mental, and social well-being is called health. By this definition, homeopathy is the only medical approach that takes into account the function of the mind in health and sickness.[6] The 6th edition of Organon of Medicine highlights the role of mental health in disease. According to §225 psychosomatic disease can develop from long lasting emotional states like anxiety, stress, fear, and depression, which may impact physical health. 4 Causation plays a key role in homoeopathy. Choosing a homoeopathic remedy mainly depends on the cause of the illness.[7]

Repertorial approach:

Synthesis Repertory

Cases are repertorized using the Synthesis Repertory (Repertorium Homoeopathicum Syntheticum) compiled by Dr. Frederik Schroyens and first published in 1987.[13] The main source is the Sixth American edition of Kent's Repertory.[14] It follows the philosophical background of "Generals to Particular".[15]

Gradation of remedies:

1st Grade : BOLD CAPITAL [4 marks]

2nd Grade : Bold small [3 marks]

3rd Grade : Italics [2 marks]

4th Grade : Ordinary Roman [1 mark] [14]

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Eliminating Method of Repertorization

Dr. Margaret Tyler and John Weir introduce this method of repertorization.[16]

According to this method choose the most important symptom in the patient, preferably a general one, without which you cannot consider a prescription. Place this symptom at the top, with other symptoms arranged below it in order of importance. When repertorizing, include only those medicine that cover this main symptom. You can then refer to additional rubrics and add them only to those medicines. [13]

Gradation of Remedy:

Gradation of remedies refers to its value in both provers and patients. Dr. Boenninghausen is credited with developing the method for evaluating or grading remedies. This grading is based on how often a symptom appears during proving, reproving, and clinical verification. Gradation shows how each remedy is individually assessed for a specific symptom or rubric. Different repertories use various grades and typography to indicate these differences. [14]

DASS-21 Assessment Scale:

Lovibond & Lovibond created the 42-item Depression Anxiety Stress Scale (DASS) in 1995. To save time during the assessment procedure, a 21-item reduced version (DASS-21) was later created.[9] While this instrument is not designed to yield a definitive categorical clinical diagnosis[10]. The stress subscale clearly identifies signs of psychological tension, physical arousal, and agitation. The 'Stress' subscale specifically quantifies a dimension of continuous nervous arousal and low threshold for frustration.[8] In psychosomatic cases, stress is a key factor that can cause or worsen physical problems. The DASS-21 helps clinicians identify these emotional states, enabling them to offer early psychological support in conjunction with physical care.[9]

Psychosomatic Symptom Questionnaire (PSQ-39):

The PSQ-39 is an assessment tool adapted from the initial 47-item inventory developed by Lacourt et al. During the validation phase of the Persian translation, scale was streamlined to 39 items. The instrument is designed to comprehensively measure the severity of a patient's psychosomatic complaints using seven day recall period. The 39 items are clustered into 7 distinct physiological and cognitive domains: Cardiorespiratory, Musculoskeletal, Psychological, Gastrointestinal, General, Body balance and Globus.[12]

AIM AND OBJECTIVES

Aim

To study the Reduction of DASS-21 'Stress' score in 3rd Grade vs. 1st Grade Remedy using 'Mind-Ailments from' as an Eliminative Rubric in Psychosomatic Disorders.

Objective:

To evaluate the difference in the stress score from DASS-21 scale between 3rd grade and 1st grade remedies using the rubric Mind-Ailment from in cases of psychosomatic disorders.

MATERIAL AND METHODS

1. **Study setting:** The study was conducted at Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital OPD, as well as in various rural and urban camps organized by the hospital.
2. **Selection of Sample:** 52 cases of both genders in the age group 18 – 60 years and fulfilling the inclusion and exclusion criteria were enrolled for the study. Two equal groups was created from the cases.

   Group A: Patient receiving 3rd Grade Remedy

   Group B: Patient receiving 1st Grade Remedy
3. **Case Definition:** Individuals age ranging 18-60 years irrespective of genders having psychosomatic disorder and not on any psychotropic medication for the same and having the stress score > 15 on DASS-21 scale and willing to give consent for the study was considered.

4. **Inclusion and exclusion criteria:**

Inclusion Criteria:

- Patients with complaints of psychosomatic disorders assessed by PSQ-39 scale was included.
- Individuals of age 18-60 years was included.
- Patients with both genders.
- Patients having stress score > 15 on DASS-21 scale.
- Patients were willing to take part in the study.

Exclusion Criteria:

- Patient with serious psychological, gross pathological disease was not considered.
- Patients which are on some psychotropic medications was not considered.
- Patients having stress score > 33 on DASS-21 scale was excluded.
- Patients who were not able to come for regular follow up.

5. **Study Design:** It was a Prospective, Double Arm, Randomized Single blind Clinical Study.

6. **Randomization:** The randomization was done by computer-generated randomization. After randomization, the cases were allocated into two equal groups Group A (n=26): Patient receiving 3rd Grade Remedy and Group B (n=26): Patient receiving 1st Grade Remedy

7. **Investigations:** Investigations were done as per need of the case.

8. **Intervention:** Following a thorough assessment of the patient's condition, a chosen treatment employing the Mind-Ailments as an eliminative rubric were given orally at potencies of 30, 200, 1M, etc., according on the patient's needs. The medication was administered sublingually as a globule, powder, or liquid. The patient is offered guidance for improved mental health in addition to the medication or placebo.

9. **Duration of Study:** Study was carried out for 18 months.

10. **Selection of tools:**

    a) Cases were repertoriesed by using Synthesis Repertory.

    b) Drugs were acquired from standard pharmacy and were preserved in as per the guidelines in the Homoeopathic Pharmacopoeia; Medicines were stored in Bharati Vidyapeeth Homoeopathic Pharmacy, Katraj, Pune-411043. Liquid was stored in an amber colored glass bottle kept in a dark place, under appropriate temperature away from sunlight and humidity condition.

11. **Drug administration:** Oral route only.

12. **Drug dispensing:** It was dispensed in globules and powder form.

13. **Outcome Assessment:** The outcomes were assessed using the PSQ-39 scale and DASS-21 scale before and after treatment

14. **Data Collection**: All the participants were subjected to an initial screening according to the case definition. The data was collected using a case record form as a tool. 52 Patients with psychosomatic diseases were studied at Bharati Vidyapeeth deemed to be university homoeopathic medical college and hospital.

15. **Follow up criteria:** All patients were closely monitored and any symptomatic or clinical changes was carefully documented. Five follow-ups were scheduled every 15 days unless if necessary, in any other conditions where patient feels the necessity to be approached earlier.

16. **Statistical Analysis**: The Mann-Whitney U test was used for between group comparisons and the Wilcoxon signed-rank test for within-group variation
17. **Trial registration:** This clinical study was registered with the Clinical Trials Registry of India (CTRI No.: CTRI/2024/10/075935).
18. **Ethical approval and informed consent:** The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune. Written informed consent was obtained from all participants prior to enrollment in the study.

OBSERVATION AND RESULTS

Demographic Characteristics of patients

Table 1: Gender-wise and Group wise-distribution of patients

Characteristic	Number of Patients (n)	Percentage (%)
Gender		
Female	27	51.92
Male	25	48.08
Group allocation		
1st Grade Remedy	26	50.00
3rd Grade Remedy	26	50.00

Table 2: Distribution of patients according to age

Age group	3rd grade remedy		1st grade remedy	
	Number of patients	Percentage	Number of patients	Percentage
20-30	11	21.15%	16	30.77%
30-40	9	17.31%	8	15.38%
40-50	6	11.54%	0	0.00%
50-60	0	0.00%	2	3.85%

Baseline Demographic Characteristics of patients are summarized in Tables 1 and 2

The study enrolled a total of 52 patients, who were evenly divided, with 26 patients receiving 1st grade remedy and 26 patients receiving 3rd grade remedy. The overall cohort demonstrated a balanced gender distribution, comprising 27 females (51.92%) and 25 males (48.08%). Age distribution showed variation between the treatment arms, with highest proportion of participants falling within the 20-30 years demographic for both 1st grade (30.77%) and 3rd grade (21.15%) cohorts.

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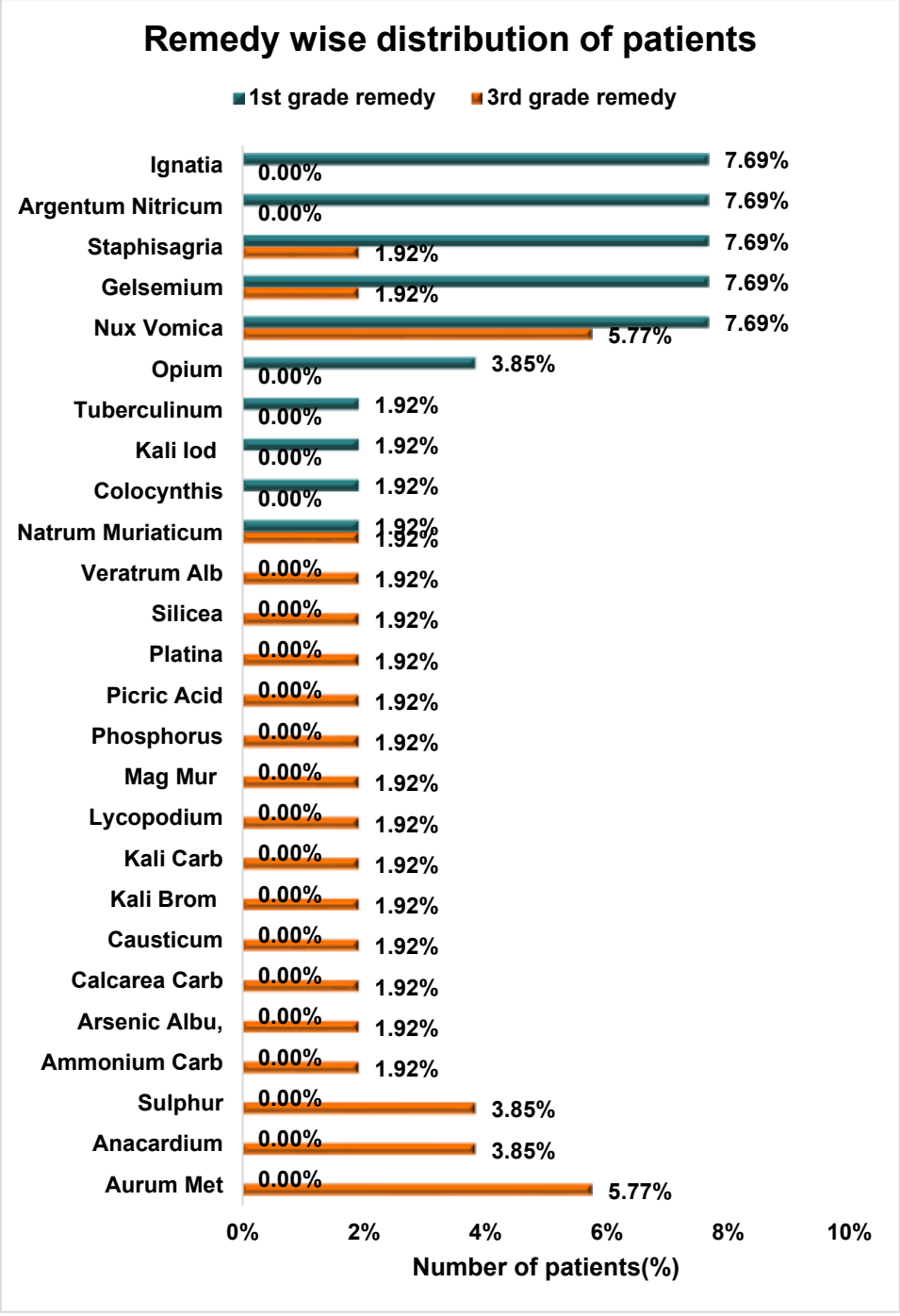


Figure 1: Remedy-wise distribution of patients.

Figure 1 illustrates the frequency of specific homoeopathic remedies prescribed across both treatment groups. In the 1st grade remedy cohort, prescriptions were highly concentrated among a few key medicines, with Ignatia, Argentum nitricum, Staphisagria, Gelsemium, and Nux vomica each prescribed to 7.69% of the patients. Conversely, the 3rd grade remedy selections demonstrated a broader, more scattered distribution, where Nux vomica and Aurum metallicum were the most frequently indicated remedies prescribed to 5.77% of the patients, followed by Sulphur and Anacardium (3.85%).

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Effect of Remedies on DASS-21 stress Score

Table 3: Wilcoxon signed-rank test **of the DASS-21 stress score**

Group	Time	N	Median(IQR)	Test Statistic Value	P-Value
First grade remedy	Before treatment	26	28.00(4.00)	Standardized test statistic= -4.541	p-value**<0.01
	After treatment	26	16.00(4.00)		
third grade remedy	Before treatment	26	28.00(4.00)	Standardized test statistic= -4.552	p-value**<0.01
	After treatment	26	20.00(4.00)		

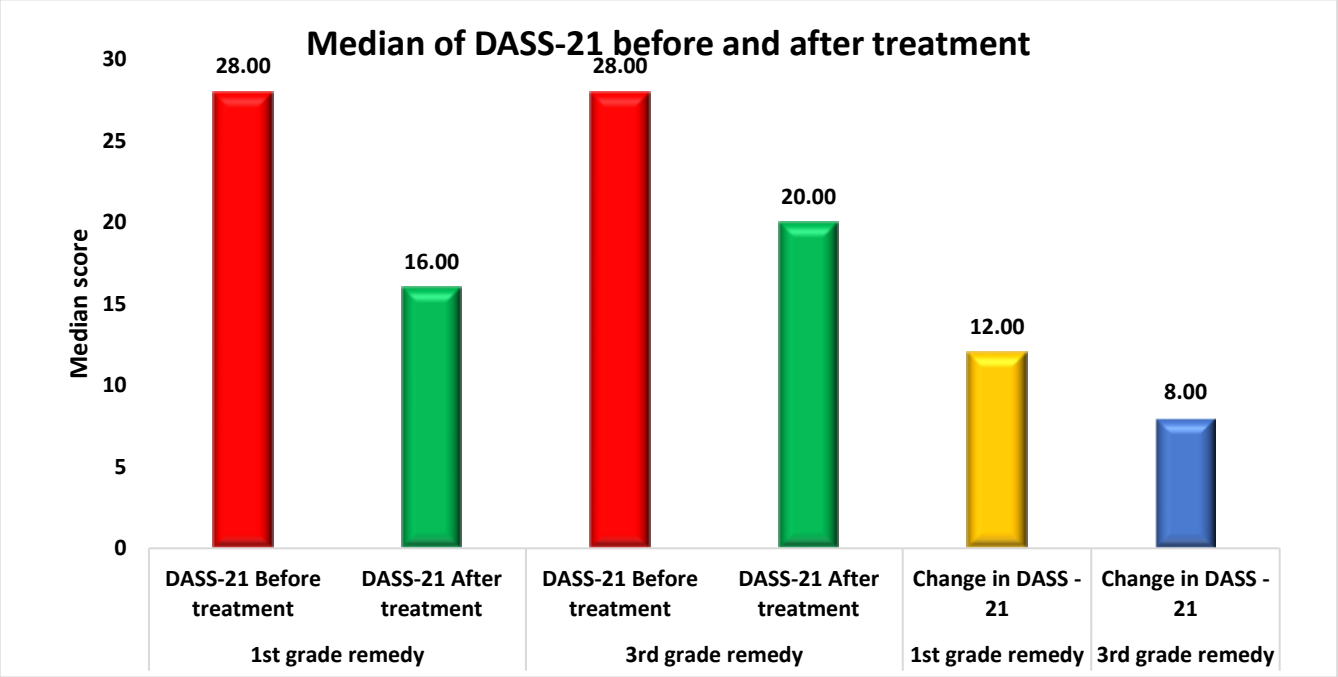


Figure 2: Bar diagram representing the median of DASS-21 stress score before and after treatment.

Table 3 and Figure 2 detail the statistical outcomes of a Wilcoxon signed-rank test evaluating the efficacy of 1st grade remedies versus 3rd grade remedy by analysing pre and post treatment scores on the DASS-21 score. Both 1st grade and 3rd grade remedy groups (n=26 each) presented a baseline median DASS-21 score 28.00 (IQR=4.00). Following the intervention, the 1st grade remedy group demonstrated a highly significant reduction to a median score of 16.00 (IQR=4.00). Similarly the 3rd remedy group exhibited a significant decrease to a median of 20.00 (IQR=4.00). Wilcoxon signed-rank analysis showed statistically significant within-group changes in both groups (1st grade: Z = -4.541, p<0.01; 3rd grade: Z = -4.552, p<0.01). The 1st grade remedy yielded substantially greater median score reduction 12 points compared to the 3rd grade remedy 8 points.

Table 4: Mann-Whitney test of the change in DASS-21 score for the two groups of medicines, first and third grade remedy group

Medicine	N	Mean±Sd of change in DASS 21 score	Median (IQR)	Test statistic and P-value
1st grade remedy	26	11.92±1.44	12.00(2.50)	Standardized test statistic=-6.135, p-value**<0.01
3rd grade remedy	26	7.31±1.38	8.00(2.00)	

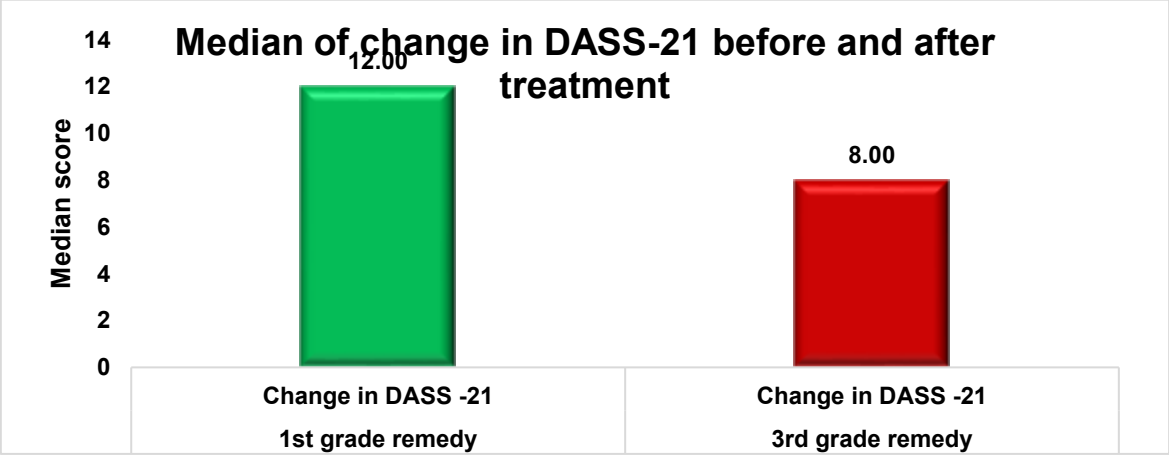


Figure 3: Median of change in DASS-21 before and after the treatment.

A Mann-Whitney U test was conducted to compare the magnitude of change in DASS-21 stress score between two groups (Table 4, Figure 3). The 1st grade remedy cohort (n=26) achieved a mean score reduction of 11.92 ± 1.44, with a median change of 12.00 (IQR=2.50). IN contrast, the 3rd grade remedy cohort (n=26) recorded a significantly lower mean reduction of 7.31 ± 1.38 and a median change of 8.00 (IQR=2.00). The analysis yielded a standardized test statistic of -6.135 and a p-value of <0.01, demonstrating a highly statistically significant difference between the two groups.

Effect of Remedies on PSQ-39 Score

Table 5: Wilcoxon signed-rank test **of the Psychosomatic Symptoms Questionnaire (PSQ-39)**

Group	Time	N	PSQ-39 Median(IQR)	Test Statistic Value	P-Value
1st grade remedy	Before treatment	26	99.00(6.25)	Standardized test statistic= -4.469	p-value**<0.01
	After treatment	26	64.00(3.25)		
third grade remedy	Before treatment	26	99.00(26.00)	Standardized test statistic= -4.541	p-value**<0.01
	After treatment	26	79.00(27.25)		

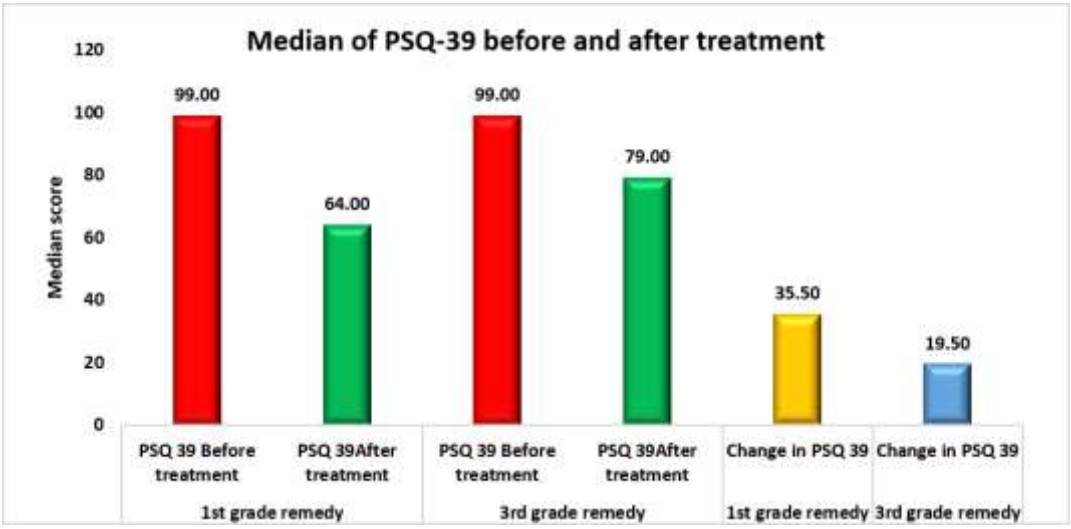


Figure 4: Bar diagram representing the median of PSQ-39 before and after treatment.

Table 5 and Figure 4 demonstrate a significant reduction in PSQ-39 scores following treatment in both groups. In the 1st grade remedy group, the median PSQ-39 score decreased from 99.00 (IQR=6.25) at baseline to 64.00 (IQR=3.25) after treatment, whereas in 3rd grade remedy group it decreased from 99.00 (IQR=26.00) to 79.00 (IQR=27.25). Wilcoxon signed-rank analysis showed statistically significant within-group changes in both 1st grade ($Z = -4.469$, $p < 0.01$) and 3rd grade ($Z = -4.541$, $p < 0.01$) remedy groups. The corresponding median reduction were 35.50 and 19.50 points, respectively.

Table 6: Mann-Whitney test of the change in PSQ-39 score for the two groups of medicines, first and third grade remedy group

Medicine	N	Mean±Sd of change in PSQ-39 score	Median (IQR)	Test statistic and P-value
1st grade remedy	26	36.04±3.50	35.50(4.25)	Standardized test statistic=-6.246, p-value**<0.01
3rd grade remedy	26	19.08±2.38	19.50(1.00)	

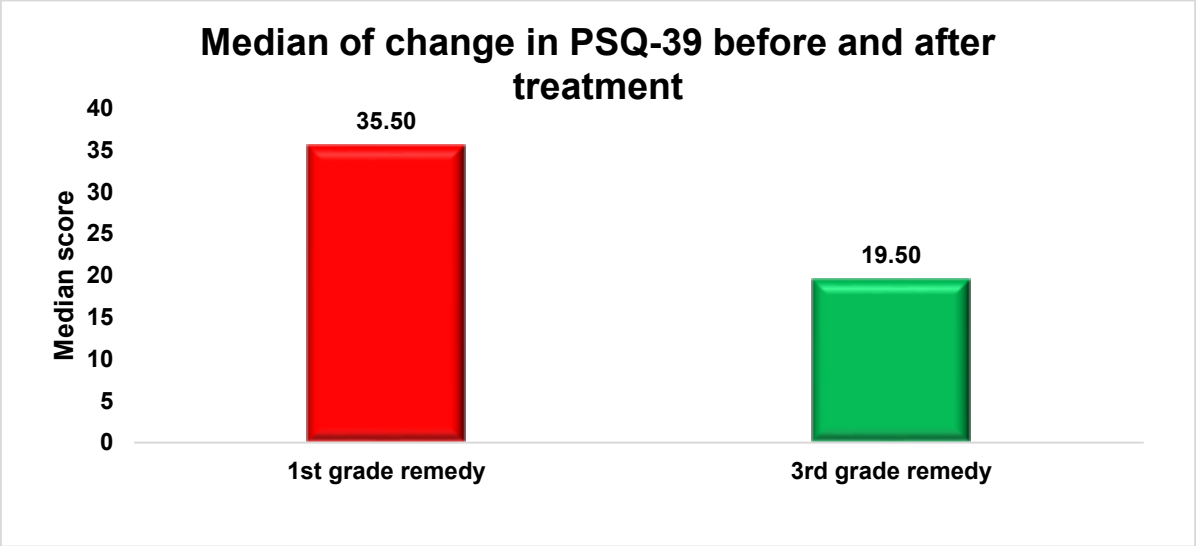


Figure 5: Median of change in PSQ-39 before and after the treatment

Table 6 and Figure 5 present the between group comparison of changes in PSQ-39 scores. The 1st grade remedy group demonstrated a greater reduction in PSQ-39 than the 3rd grade remedy group, with mean change of 36.04 ± 3.50 and 19.08 ± 2.38, respectively. The median (IQR) reduction was 35.50 (4.25) in 1st grade remedy group and 19.50 (1.00) in 3rd grade remedy group. The Mann-Whitney U test indicated a statistically significant difference in the magnitude of change between the groups (standardized test statistic = -6.246, $p < 0.01$).

Overall level of improvement of patients

Table 7: Distribution of patients by level of improvement.

Improvement Level	1st grade remedy		3rd grade remedy	
	Number of patients	Percentage	Number of patients	Percentage
Marked	11	21.15%	0	0.00%
Mild	3	5.77%	19	36.54%
Moderate	12	23.08%	7	13.46%

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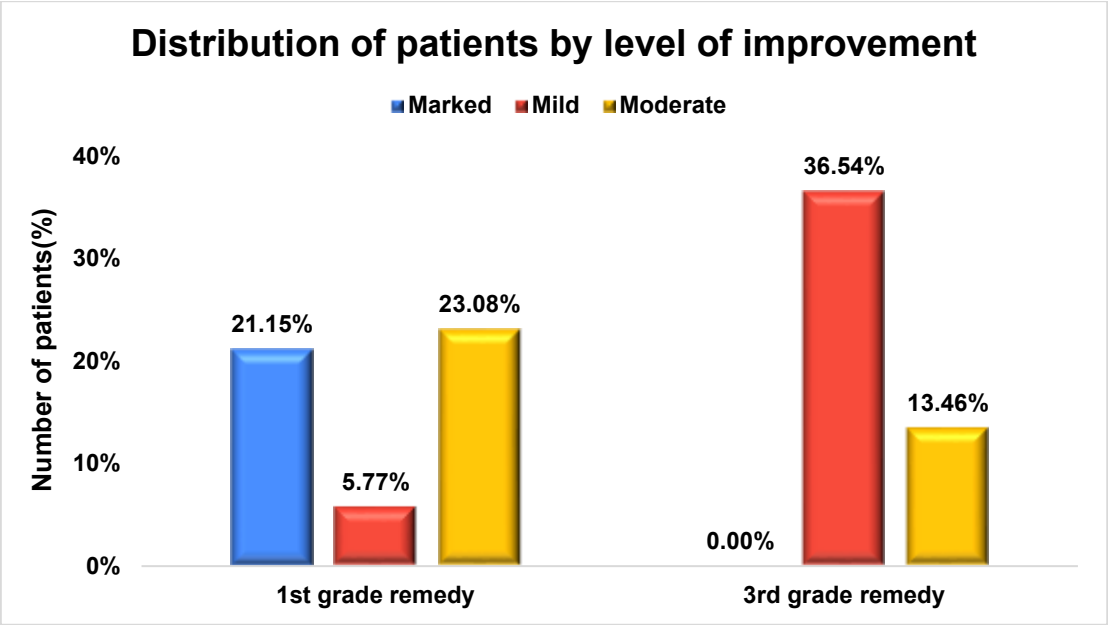


Figure 6: Bar diagram representing the distribution of patients by level of improvement.

Table 7 and Figure 6 shows the distribution of clinical improvement which highlights a distinct disparity in therapeutic efficacy between the two interventions. Patients in the 1st grade remedy cohort predominantly achieved robust clinical outcome, characterized by moderate (23.08%) and marked (21.15%) improvements, with only 5,77% exhibiting a mild response. In contrast the 3rd grade remedy yielding Mild (36.54%) and Moderate (13.46%) improvements, with none achieving marked recovery (0.00%). These comparative distribution patterns substantiate that the 1st grade remedy provides superior clinical potency in mitigating psychosomatic symptoms and reducing stress.

DISCUSSION

A single-blind, randomized clinical trial was conducted at Bharti Vidyapeeth Homoeopathic Medical College and Hospital, Pune, to evaluate the comparative efficacy of first-grade versus third-grade remedies in reducing DASS-21 stress score in psychosomatic disorders. Utilizing the 'Mind-Ailments from' as an eliminative rubric from Synthesis repertory. 52 patients meeting strict inclusion criteria were randomized into two equal cohorts: Group A patients receiving 3rd grade remedy and Group B patient receiving 1st grade remedy. Every patient's case was taken in detail. After that case was repertorized by the eliminating method of repertorization using synthesis repertory. A follow up was conducted in 10 to 15 days and as per the need of the case. Therapeutic outcomes were quantified using the DASS-21 stress scale and PSQ-39 scale. To assess therapeutic effectiveness, non-parametric statistical analysis were employed, utilizing the Wilcoxon signed-ranked test for within-group variance (pre and post treatment) and the Mann-Whitney U test to determine between group comparative significance.

RESULT:

Both treatment cohorts exhibited highly significant within-group reduction in DASS-21 stress scores following the intervention ($p < 0.01$). The 1st grade remedy group's median DASS-21 stress score decreased from 28.00 (IQR = 4.00) to 16.00 (IQR = 4.00), whereas the 3rd grade group's median score decreased from 28.00 (IQR = 4.00) to 20.00 (IQR = 4.00). Between group analysis utilizing the Mann-Whitney U test confirmed the statistical of the first grade remedy ($p < 0.01$). Patients in 1st grade remedy cohort achieved a significantly greater mean score reduction (11.92±1.44; median = 12.00) compared to 3rd grade cohort (7.31±1.38; median = 8.00).

This therapeutic divergence was corroborated by the Psychosomatic Symptom Questionnaire (PSQ-39) data. The 1st grade remedy group demonstrated a substantially higher mean symptom reduction (36.04±3.50; median = 35.50) than the 3rd grade remedy group (19.08±2.38; median = 19.50), yielding a highly significant between-group difference ($p < 0.01$).

Overall, the results indicate that both remedy groups are effective in reducing stress and psychosomatic symptoms. However, the 1st grade remedies are more significant than 3rd grade remedies from the rubric Mind- Ailments from in reducing the stress score from DASS-21 scale in cases of psychosomatic disorders.

CONCLUSION

This evaluation of 52 patients with psychosomatic disorders demonstrates that while both 1st and 3rd grade remedy significantly alleviate psychological distress, 1st grade remedy yield substantially superior clinical outcomes. While repertorization utilizing the 'Mind-Ailments from' as an eliminative rubric within the Synthesis repertory, the cohort receiving 1st grade remedies achieved maximum score reduction of DASS-21 stress score and PSQ-39 scale score, reflecting moderate to marked therapeutic improvement. In contrast, 3rd grade remedy group exhibited predominantly mild responses. These findings underscore the critical importance of remedy grading in clinical practice, advocating for the prioritization of first-grade indications to optimize patient outcomes and enhance the quality of life in individuals suffering from psychosomatic disorders.

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Conflict of interest:

The authors declare no conflict of interest.

Author contributions:

Dr. Tejaswinee Arun Mhaisale: Conceptualization of the study, study design, data collection, investigation, data analysis, interpretation of results, preparation and drafting of the manuscript.

Dr. Priya R Sheth: Conceptualization of the study, supervision of the study, guidance in study design and methodology, manuscript review and revision, and correspondence with the journal as the corresponding author.

Dr. Monali T Thopte: Contribution to manuscript preparation, critical review of the manuscript, and revision of the final manuscript.

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