



# International Journal of Homoeopathic Sciences

E-ISSN: 2616-4493

P-ISSN: 2616-4485

[www.homoeopathicjournal.com](http://www.homoeopathicjournal.com)

IJHS 2024; 8(2): 163-169

Received: 15-03-2024

Accepted: 22-04-2024

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## Effectiveness of homoeopathic medicines in LM potency by using Kent's repertory for the management of generalized anxiety disorder: A randomized controlled study

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**DOI:** <https://doi.org/10.33545/26164485.2024.v8.i2c.1133>

### Abstract

Generalized Anxiety Disorder (GAD) is characterized by feelings of intense unease, stress, or apprehension about daily life. The present investigation intends to evaluate the therapeutic efficacy of selected homoeopathic medicines (Arm A) from Kent's Repertory in L.M potency to placebo (Arm B) in the treatment of GAD using the Spielberger STAI-Y scale assessment. Both men and women aged between 18-40 years were selected for the studies at the IPD / OPD from RVS Homoeopathic Medical College and Hospital, Sulur, Coimbatore, Tamilnadu. The result shows that in Arm A (N=32), improved (75%), moderate (12.5%), and 6.25% had a severe level of anxiety. The Arm B (N=32), 56.25% are moderate, 25% have severe anxiety and 12.5% have improved, respectively according to the level of anxiety on the post-test STAI-Y anxiety scale. The most frequently prescribed homoeopathic medicine was *Argentum nitricum* (N=6). The result found there is a statistical difference in the score of ARM A, pre-test STATE score (M=48.17, SD=11.68) and post-test STATE (M=28.34, SD=10.28) and pre-test TRAIT score (M=51.50, SD=13.42) and post-test TRAIT (M=31.50, SD=11.60), indicated a significant difference (<0.05) in the first & final scores in intervention Arm A. In conclusion, the homoeopathic medicines selected from Kent's repertory in LM potency were adequate for the treatment of GAD.

**Keywords:** Spielberger STAI-Y Scale, anxiety disorder, argentum nitricum, kent's repertory, placebo

### Introduction

Anxiety is one of the most common mental illnesses interfering with the quality of life and work. It involves one's body's perceptions of self and relationship with others, making it a foundational concept in the study of human behaviour [1]. Anxiety derives from the Greek word root meaning "to press tight". Anxious is related to the Latin word "Angere", which means "to strangle" and "to distress". It is also related to the anguish described as "acute pain, suffering or distress" [2]. An anxiety disorder covers various conditions, from panic disorders to agoraphobia to obsessive-compulsive disorder [3]. Generalized anxiety disorder (GAD) is marked by excessive, exaggerated anxiety and worry about everyday life events for no apparent reason [4]. GAD causes feelings of intense anxiety, worry, or nervousness about everyday life [5]. GAD is the most common anxiety disorder in older in younger adults; other anxiety disorders are less common [6]. The prevalence of GAD among women is double that of men and higher in younger persons [7].

State-Trait Anxiety Inventory (SATI) has been used extensively in clinical anxiety research since its development by Spielberger *et al.* in 1970, and the STAI was revised in 1983 (STAI-Y) [8-12]. State anxiety is the anxiety self at present cross-section moment (state) as a transitory emotional response to a stressful situation and is exemplified by, I feel, anxious now. Trait anxiety is the habitual tendency to be anxious in general (a trait), an enduring personality characteristic that could predispose persons and is exemplified by, I often feel, anxious [13]. STAI-Y has been widely used clinically to assess anxiety in medical and psychiatric populations via self-report of the presence and severity of current anxiety symptoms and generalized propensity to be anxious [14-17].

Several biological, psychological and social risk factors for anxiety disorders have been identified for older adults [18]. Anxiety often begins in adolescence or early adult life, and the condition is diagnosed much more commonly in women than men [19]. Anxiety is an emotion, and subjective individual experience comes under neurosis [20] homoeopathic medicines and psychotherapy are helpful in the treatment of Generalized Anxiety Disorder (GAD) [21]. The clinical research evidence on homoeopathy in the treatment of anxiety and GAD were systematically reviewed [22-26].

Difficulty in potency selection is one of the major pitfalls for beginners in practicing homoeopathy. L.M scale, currently known as Fifty-Millesimal (L.M) potency, is now increasingly accepted as the safest scale with maximum advantages. Dr Pierre Schmidt of Geneva names potencies prepared under this method as 50 Millesimal potencies because the material part of the medicine was said to decrease by 50000 times for each degree of dynamization [27]. The present study aims to assess the therapeutic effect of selected homoeopathic medicines from Kent's Repertory in L.M potency compared to placebo in the management of GAD using the Spielberger STAI-Y scale.

**Null hypothesis (H0):** There is no significant difference in result between Arm A of patients receiving Homoeopathic medicines using Kent's repertory and Arm B of patients receiving placebo.

**Alternative hypothesis (H1):** There will be a significant difference in results between Arm A of patients receiving Homoeopathic medicines using Kent's repertory and Arm B of patients receiving placebo.

## Materials and Methods

### Study design

Randomized Controlled Study-Single Blinded.

### Study population

Both men and women aged between 18-40 years were selected at the IPD/OPD from RVS Homoeopathic Medical College and Hospital, Sular, Coimbatore, Tamil Nadu, from November 2016 to May 2018.

### Study setting

The IPD/OPD from RVS Homoeopathic Medical College and Hospital, Sular, Coimbatore, Tamil Nadu, India

### Study duration

The study was conducted for 18 months (12 months for enrollment, 4 months for follow-up, and two months for data collection and compilation). The patient's follow-up was done at the interval of 7-14 days, as per the status of the case, for a minimum duration of 4 months.

### Sample size

A total number of 75 participants were screened, out of which 64 cases fulfilled the inclusion criteria, which were randomly allocated by using computer-based randomization ([www.randomizer.org](http://www.randomizer.org)) into the following two arms.

### Intervention

Arm A: (N=32 cases) Received homoeopathic medicines selected based on the totality of symptoms using Kent's

repertory in LM potency from Hompath Classic 8.0 version with due consultation Materia Medica.

### Frequency and repetition

As per the guidelines in the 6th edition of Organon of Medicine [28].

Arm B: (N=32 cases) Received Placebo

### Medicine dispensing

The pharmacist was instructed to serve either placebo or LM potency medicines to the indicated persons [29-31].

### Follow up

The follow-up of the cases was done at an interval of 7-14 days, as per the severity of the case for four months. They were also asked to report even before the scheduled date in the event of experiencing any troublesome symptoms or severe illness. In addition, they were made aware of the necessity of being faithful to the follow-up schedule. At each follow-up, the patient's improvement was evaluated in detail with particular references to changes in general well-being, changes in the presenting symptoms, and the appearance of any new symptoms. In addition to that, vital signs, mental status examination and cross-checking of the self-assessment anxiety work diary (Based on the DSM-IV Diagnostic criteria questionnaire) were also done. After carefully evaluating the follow-up criteria, the remedy was repeated in the same potency or change in the potency.

### Selection criteria

#### Inclusion criteria

1. Age groups of (18 years to 40 years).
2. Cases of both sexes were included in this study.
3. Patients from all socioeconomic statuses were considered for the study.
4. A patient suffering from GAD was collected as per DSM-IV Diagnostic criteria.
5. Patients suffering from moderate and severe levels of anxiety are only included.

#### Exclusion criteria

1. Cases with an unclear picture of the disease.
2. Patients suffering from other psychiatric disorders and medical illnesses.
3. Patients with irregular follow-ups.
4. Patient suffering from mild levels of anxiety.

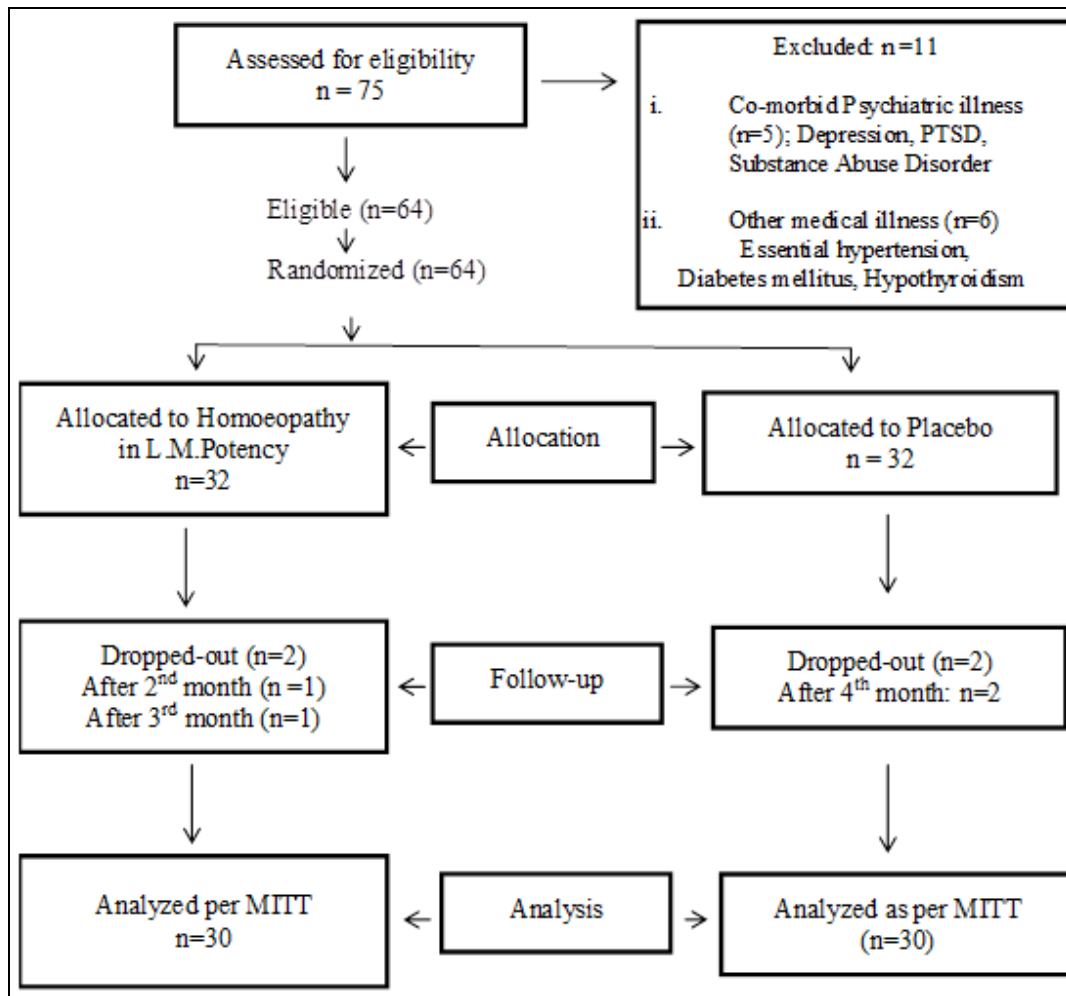
#### Data collection procedure and instrument used

1. Case taking Performa
2. DSM-IV Diagnostic criteria questionnaire [32, 33]
3. STAI Y Form [34]
4. Kent's repertory in HOMPETH CLASSIC software (version 8.0) Dr Jawahar J Shah, (2000-2005).

#### Plan of analysis/statistical tools

To compare STAI pre and post-treatment scores for both groups paired t-test was applied using SPSS 20.0 version. Independent t-test was applied to compare the pre and post-treatment scores between the two treatment groups. Data analysis was done using a Microsoft Excel sheet based on STAI-Y pre and post-test scores before and after treatment of GAD and symptomatic assessment.

#### Study flow chart



PTSD: Post Traumatic Stress Disorder; MITT: Modified Intention to Treat

**Ethical consideration**

Ethical clearance was obtained from the institutional ethical committee of Homoeopathy University, Jaipur.

**Results**

In this study, the maximum prevalence of GAD was observed in the age group of 18-21. i.e. (32.81%), followed by the age group of 22-25 (18.75%), 30-33 (15.62%), 34-37 (12.5%), 26-29 (10.93%) whereas the minimum was observed in the age group of 38-40 (9.37%), respectively. As per the gender, out of 64 cases, the maximum prevalence of GAD was observed in females, i.e. (62.5%) and then in males, i.e. (37.5%) and shown the distribution according to the marital status. The higher prevalence of GAD was observed in students, i.e. N=23 (34.94%), then followed by private jobs N=13 (20.13%), housewives N=9 (14.06%), professionals N=7 (10.94%), businessman N=5 (7.81%), laborer N=4 (6.25%), government jobs N=2 (3.13%), where the lower incidence of GAD was observed in social worker N=1 (1.56%) from this study. The distribution of GAD cases according to family history shows that total number of patients having a positive psychiatric family history (N=43) and without were family history (N=21). According to the food habits, cases (N=57) were non-vegetarian and (N=7) were vegetarian, respectively.

The distribution according to the level of anxiety based on the pre-test STAI-Y score given in Figure. 1., shows cases (N=44) with a moderate level of anxiety and cases (N=20)

with a severe level of anxiety. The selected homoeopathic medicine prescribed for Arm A (N=32) is given in Table 1.

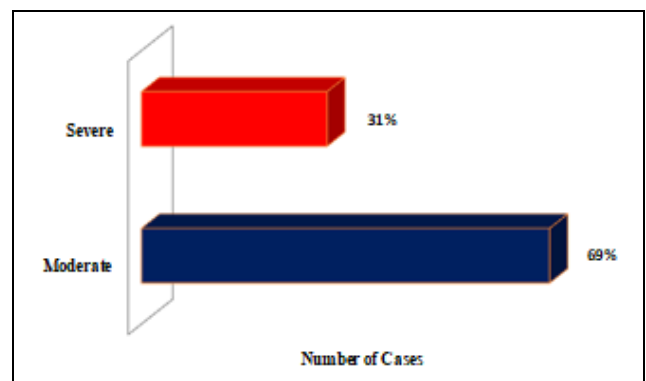


Fig 1: Level of anxiety

Table 1: Distribution of medicine prescribed for 32 cases of gad in arm a medicine prescribed to no of cases in percentage (%)

Medicines prescribed	No. of cases with GAD	No of cases in Percentage (%)
<i>Argentum nitricum</i>	06	18.75
<i>Natrum muriaticum</i>	04	12.5
<i>Pulsatilla nigricans</i>	04	12.5
Phosphorus	04	12.5
<i>Silicea terra</i>	04	12.5
<i>Gelsemium sempervirens</i>	03	9.38
<i>Lycopodium clavatum</i>	03	9.38
<i>Arsenicum album</i>	02	6.25
Sulphur	02	6.25

**Table 2:** Distribution of cases of GAD according to the result obtained from STAI-Y scale pre-test (Arm-A)

No of cases (n)	Moderate	Severe
Arm A	20	12
Arm B	24	08

According to the level of anxiety observed in the pre-test STAI-Y Anxiety Scale from Arm-A, the result shows that out of 32 cases of GAD, 31.25% with a moderate and severe level of anxiety with 18.75% respectively. Out of 32 cases of GAD according to the level of anxiety on the pre-test STAI-Y Anxiety Scale in Arm-B, the result shows that 37.5% are moderate and 12.5% have a severe level of anxiety respectively in Table 2.

**Table 3:** Distribution of cases of GAD according to the result obtained from STAI-Y scale post-test

No. of Cases (n)	Improved	Moderate	Severe	Drop out
Arm-A	24	04	02	02
Arm-B	04	18	08	02

Out of 32 cases of GAD according to a level of anxiety on the post-test STAI-Y Anxiety Scale in Arm-A, the result shows that 12.5% are moderate, 6.25% have a severe level of anxiety, and 75% have improved, with 6.25% drop-out cases respectively. According to the level of anxiety observed in the post-test STAI-Y Anxiety Scale from Arm-B, the result shows that out of N=32 of GAD, 56.25% are

moderate, 25% has a severe level of anxiety, and 12.5% has improved, with 6.25% drop-out cases respectively Table.3. To accomplish the goal, a paired t-test was done for each Arm (N=32) to calculate the difference before and after the treatment score, and a paired sample t-test was carried out to know the difference in the mean of both Arms. In this study, a sample size of 64 was taken for the pre-test STAI Y assessment. Out of 64 cases of GAD, the statistical analysis was done for the sample size of N=60, after considering the four drops out during the study. So the degree of freedom (n1+n2-1) is 58 {Arm A; N=30 (DF=N-1=29), Arm B; N=30 (DF=N-1=29)}, the level of significance is < 0.05.

**Table 4:** Mean value and SD for pre-test and the post-test score of State and Trait for Arm A

Arm-A	N	Mean	SD	SE
State Pre-Test	32	48.17	11.68	2.13
State Post-Test	30	28.34	10.28	1.88
Triat Pre-Test	32	51.50	13.42	2.45
Triat Post-Test	30	31.50	11.60	2.11

SD: Standard Deviation; SE: Standard Error

**Table 5:** Mean value and SD for pre-test and post-test score of State and Trait for Arm B

Arm-B	N	Mean	SD	SE
State Pre-Test	32	46.56	9.00	1.64
State Post-Test	30	42.17	10.76	1.97
Triat Pre-Test	32	49.20	9.16	1.67
Triat Post-Test	30	43.47	11.50	2.10

**Table 6:** Paired sample t-test for an unequal variance for Arm A (State & Trait)

Arm-A	Mean	SD	SE mean	95% Confidence Interval of the Difference		T	DF	Sig. (2-Tailed)
				Lower	Upper			
State Pre & Post Test	19.83	8.12	1.49	16.79	22.88	13.32	29	.000
Triat Pre & Post Test	20.00	9.65	1.76	16.39	23.60	11.35	29	.000

**Table 7:** Paired sample t-test for an unequal variance for Arm B (State & Trait)

Arm-A	Mean	SD	SE mean	95% Confidence Interval of the Difference		T	DF	Sig. (2-Tailed)
				Lower	Upper			
State Pre & Post Test	44.00	5.77	1.05	2.24	6.55	4.18	29	.000
Triat Pre & Post Test	57.33	7.10	1.30	3.08	8.39	4.42	29	.000

The mean value and standard deviation for Arm A & Arm B are given in Table 4 and Table 5 separately for the STAI-Y, STATE and TRAIT assessment scores for pre-test and post-test. The study result shows that there is a statistical difference in the score of ARM A, pre-test State score (M=48.17, SD=11.68) and post-test State (M=28.34, SD=10.28) and pre-test TRAIT score (M=51.50, SD=13.42) and post-test Trait (M=31.50, SD=11.60). The results of the paired sample t-test for the unequal variance for Arm A (State & Trait) indicate a significant positive difference (<0.05) in the first & final scores in intervention Arm A, given in Table 6. The analysis shows that the mean & SE value for state pre & post-test is 19.83±1.49 and TRAIT pre & post-test is 20.00±1.76 in Arm A, which supports the null hypothesis. Further, the level of Anxiety was improved for maximum cases after the homoeopathic medications were provided in Arm A.

A paired sample t-test for an unequal variance for Arm B is shown in Table.7 (State & Trait), suggesting that there is no significant difference (< 0.05) in the pre & post-test scores of State and Trait assessment scale in Arm-B. The analysis

shows that the mean & SE value for State pre & post-test is 44.00±1.05 and Trait pre & post-test is 57.33±1.30 in Arm B. State and Trait score p-value (<0.05) indicates a significant difference between the State and Trait score in Arm-A, the intervention group, treated with homoeopathic medicine, compared to Arm-B, the control group with placebo. Further, the result shows a significant improvement according to the State and Trait scale in intervention Arm A (Individualized medicines with aid of synthesis repertory) compared to the control group with placebo, i.e. Arm B.

**Discussion**

In the present study, every patient was subjected to screening by DSM IV GAD eligibility criteria baseline assessments followed by recruitment in the trial. Further, laboratory investigations were performed, blood routine, urine routine, thyroid profile, and ECG if necessary. No serious adverse events were observed and reported during the study period, but four cases were dropped due to the irregular follow-up.

**Age incidence:** In this study, the maximum incidence of GAD between the age group of 18-21 was observed. This result correlates with Kaplan and Sadock the onset of GAD begins from childhood to adulthood, with the median age of onset being approximately 31 years. It is worth including the age of onset variable in the study of psychiatric conditions [35]. Generalized anxiety disorder (GAD) is the most common anxiety disorder and is as common, or more common, in older as in younger adults; other anxiety disorders are less common [36]. GAD develops during early adulthood and late adolescence, with an average age of 25-30 years for the first sign [37].

**Sex incidence:** In the present study, higher cases of GAD were observed in females compared to males. This result confirmed the higher prevalence of anxiety in females than males [38].

**Marital status:** The study shows that the maximum incidence of GAD cases was observed in married persons. This result was simultaneous with a world mental health survey that marital distress is a risk factor for both anxiety and mood disorders for both men and women. Still, it does not clarify whether gender differences in the prevalence of anxiety-mood disorders are more significant among the married than the never-married due to role strains and role constraints [39]. Thus the study also supported the present observation.

**Occupation:** The highest incidences of GAD were observed among students in this study. Anxiety disorders are the most prevalent psychiatric problems among college students with approximately 11.9% a national mental health survey reported the mean age for GAD was 20 years. It may start experiencing symptoms while in college [40]. The present finding also reproduces the same.

**Family history:** Maximum GAD cases seen in showing positive family history. The present finding supported by the result of a positive family history of anxiety disorders may represent an important environmental etiologic factor in the development of GAD [41].

**Food Habits:** It was observed that the maximum GAD incidence was seen in non-vegetarians rather than vegetarians. Vegetarians displayed elevated prevalence rates for anxiety disorders and depressive disorders from the earlier study. However, there is no incidence of a causal role of a vegetarian diet in the aetiology of mental disorders [42]. It shows that higher fruit and vegetable intake was associated with lower fear severity and concluded that non-refined grains, vegetables and alcohol intake appeared to be the driving variables related to the total MDS score and depression/anxiety [43].

**Indicated medicine in Arm A:** In this study, the most frequently prescribed homoeopathic medicine was Argentum nitricum. Homoeopathic remedies are used in the treatment of GAD [44]. Further, the level of Anxiety was improved for maximum cases after the homoeopathic medications were provided in Arm A. Homoeopathic remedy Argentum nitricum of 30 C potency after chronic administration in rodents and concluded that Argentum nitricum had anxiolytic effects. Still, the use of low doses

and high dilutions is advocated to avoid toxicity. [45] The result obtained from this present study shows an effect of homoeopathic treatment for GAD cases in Arm A. Homoeopathic treatment may be effective in the management of patients with GAD. These findings were confirmed by Bonne *et al.*, which resulted in the effect of homoeopathic treatment on mental symptoms of GAD didn't differ from that of placebo and concluded that improvement in both conditions was substantial. [46] Spiel Berger State-Trait Anxiety Inventory STAI-Y evaluation using pre-test & post-test and follow-up pattern and the findings suggest that homoeopathic therapy can be an effective method to treat anxiety and depression disorders. [47] The present study finding also proves that prescribed homoeopathic medicine for treatment affects GAD, based on the results obtained from STAI-Y assessment, pretest and post-test score. The result obtained from his study showed an effect of homoeopathic treatment on mental symptoms of GAD and didn't differ from that of a placebo and concluded that improvement in both conditions was substantial [48].

**STAI-Y Assessment:** The state-trait anxiety inventory form Y is a brief self-rating scale to evaluate state and trait anxiety. Detection of pervasive anxiety "proneness" and current symptoms 20 STAI-Y represents a significant and commendable development in the conceptualization and measurement of anxiety. Research with the STAI has enormously contributed to recognising the importance of distinguishing between the intensity of anxiety as a transitory emotional state and individual differences in anxiety as a relatively stable personality trait. In the present study, Arm A (State & Trait) indicates a significant positive difference (<0.05) in the pre & post-test scores in homoeopathic intervention. The two assessment scores from Arm B (placebo) suggest no significant difference in the pre & post-test scores of the State and Trait assessment scale. Placebo is not considered to have any specific effect; effects seen in Arm B are due to the additive effects of the natural course of the disease and the non-specific effects. [48] The data of this study shows that the applied homoeopathic treatment may be effective in managing patients with GAD. The scope of treatment includes both somatic manifestations of anxiety and the most profound vital discomfort affecting the subject [49]. Further the results shown significant differences between the levels of anxiety symptoms on pre and post-assessment (Psychomorbidity Assessment Scale-PAS) and individualized homoeopathic medicine was found effective in reducing anxiety symptoms in patients and same were conformed in the present study. The average (STAI) State score at visit 2 decreased by more than 6 points. In contrast, the stai-trait score decreased by more than 3 points and suggested that treating anxiety and sleep disorders with homoeopathic-complex medicine can produce notable improvements even in a short period. The observed effects were not affected by sex, age or baseline anxiety [50]. The present study shows that the p-value (<0.05) corresponding to pre & post-test State and Trait score, which indicates that there is a significant difference between the State and Trait score and improvement in Arm-A, treated with homoeopathic medicine, as compared to Arm B, the control group with placebo.

## Conclusion

This study highlights that GAD was more prevalent in

females than males in the age group of 18-21 years. Further, homoeopathic medicines selected from Kent's repertory in LM potency were effective for treating GAD, and the analysis shows an improvement in the levels of anxiety for Arm-A than Arm-B using STAI-Y.

### Implication

Homoeopathy medicines can formulate a positive change in people suffering from these distressing states of mind and behaviour by reducing their anxiety levels and thus making patients capable of dealing with stressful situations. The basic purpose of this study is to provide early engagement with psychiatric services to minimize the effective cost of treatment and maximize a better prognosis. These could be of great help in mental health services.

### Acknowledgments

We sincerely thank the Principal, RVS Homoeopathy Medical College and Hospital, Kumarakottam, Sullur, Coimbatore, for the permission of this study and the teaching faculty of Homoeopathy University, Jaipur, Rajasthan, India, for their PhD guidance.

### Declaration of patient consent

Patient consent is not required as the patient's identity is not disclosed or compromised.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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**How to Cite This Article**

Narayanan PD, Bhinda A, Shaktvipiya Y, Sharma V. Effectiveness of homoeopathic medicines in LM potency by using Kent's repertory for the management of generalized anxiety disorder: A randomized controlled study. *International Journal of Homoeopathic Sciences*. 2024;8(2):163-169.

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