

Generalized Anxiety Disorder in Adolescents Treated with Homoeopathy: A Randomized, Single-Blind, Placebo-Controlled Trial

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Abstract: Generalised Anxiety Disorder is one of the anxiety disorders getting substantial rise but seldom diagnosed clinically in today's society leading to low self esteem and disabling them from social interactions and academic achievement among adolescents. Common reasons are family, peer pressure, insecurities, friends, health & competition among peers in school performance. *Aim:* To assess the efficacy of homeopathic treatment of GAD among adolescents (11-17 years) in comparison with cognitive behavioral therapy (placebo group). *Objectives:* To study the clinical presentation of GAD among adolescents (11-17 years); To identify the various ailments leading to GAD among adolescents (11-17 years); To compare the pre score and post score of GAD among adolescents (11-17 years) with GAD questionnaire by APA in both groups. *Result:* 62 subjects are divided according to the criteria of results as recovered, improved and not improved. Out Of 31 patients in the study group 12 recovered, 16 improved and 3 not improved. Out of 31 subjects in the control group 4 recovered, 18 improved and 9 not improved. *Conclusion:* Efficacy of treatments is assessed through improvement of cases seen in no. of follow ups of both groups, where homeopathic treatment showed good results in the initial follow ups.

Keywords: GAD, CBT, RCT, Study Group, Placebo Group

1. Introduction

The word anxiety derives from the Latin substantive *angor* and the corresponding verb *ango* (to constrict). A cognate word is *angustus* (narrow) [1].

The word anxiety is derived from the Latin "*anxietas*" (to choke, throttle, troubled in mind). Anxiety is considered excessive or pathological when it arises in the absence of challenge or stress, when it is out of proportion to the challenge or stress in duration or severity resulting in psychological, social, occupational, biological, and other impairment [2]. Generalised anxiety disorder (GAD) is one of the anxiety disorders with uncontrollable worry about different events.

A study conducted by NIMHANS in 2011 to know whether anxiety disorders associated with a more severe form of bipolar disorder in adolescents revealed that compared with others, adolescents with anxiety had more

life time suicidal ideation, more number of episodes, lower physical, psychological, and subjective quality of life, and lower global functioning. Among adolescents with bipolar disorder, anxiety disorders are associated with poorer course, lower quality of life, and global functioning and also stressed on recognition of this disorder and treatment. It also states that the age of onset with mean 9.5 with SD 3.5 [3].

A prospective study conducted by Russell PS Indian journal paediatrics in 2013 on suicidal behavior in anxiety disorders among adolescents in a rural community population in Vellore revealed GAD (adjusted OR = 5.65) [4].

An article published in the journal of BMC psychiatry in 2014 titled "The relationships between perfectionism, pathological worry and generalised anxiety disorder were investigated in a clinical sample where treatment of perfectionism found that there is significant associations exist between certain dimensions of perfectionism, pathological

worry and GAD. It also stated that such findings have clinical relevance for the assessment of individuals with GAD, and provide impetus for future research to explore whether treatment of perfectionism can ameliorate GAD symptomatology [5].

Definition: Generalised anxiety disorder in children is defined as one who often experience unrealistic worries about different events or activities for at least 6 months with at least 1 somatic complaint. The diffuse nature of the anxiety symptoms differentiates it from other anxiety disorders. Worries in children with GAD usually centre's on concerns about competence and performance in school and athletics [6].

Epidemiology: Youth with GAD seems to worry about everything, including grades, homework, performance in sports and other activities, relationships, health, family and world events. Children with GAD are extremely self-conscious and perfectionist who spends countless hours and energy on school projects for fear of making mistakes or perform poorly and struggle with more intense distress than is evident to parents or others around them [7].

Prevalence: Boys and girls are equally affected before puberty, when GAD becomes more prevalent in girls. The prevalence of GAD ranges from 2.5–6% of children [6].

ICD-11 classification: Generalized anxiety disorder is included in international classification of diseases-11 under anxiety disorders or fear related disorders of mental, behavioral or neuro-developmental disorders (6B00) [8]. Sigmund Freud's (1926) revised theory of anxiety, and to make these consonant with a super ordinate focus on the ego and its functions, led her to consider problems such as the "choice of neurosis" and "motives" for defense. In fact, she distinguished four principal motives for defense against the drives:

- (1) Superego anxiety (or guilt),
- (2) Objective anxiety (in children),
- (3) Anxiety about the strength of drives,
- (4) Anxiety stemming from conflicts between mutually incompatible aims.

On the basis of her extensive observations of and psychoanalytic work with young children, Anna Freud later developed the concept of developmental line, a variegated developmental schedule that permitted the clinician-researcher to follow important changes in sexual, aggressive, and social developmental "lines" from infancy to adolescence [9].

2. Several factors Impact on GAD

2.1. Genetics & Environment

Evidence from family studies of anxiety suggests that the environment, not genetics, is primarily responsible for the development of a specific anxiety disorder. In addition to providing evidence for a strong familial component to anxiety, the results of family studies suggest that this component may be largely disorder-specific. For example,

Noyes, Clarkson, Crowe, Yates, and McChesney (1987) showed that first-degree relatives of individuals with GAD had an increased risk for GAD, but not panic disorder, in comparison to control families [10].

Several factors like type of bond established between parents and child from infancy, environment at home and lasting love built-up by parents and their habits, overprotection, favoritism and rejection among other siblings by the parents affect personality of child. ⁽¹²⁾ lity of child. ⁽¹²⁾ The retrospective report of anxious adults has indicated that anxious behaviors may be identifiable from an early age. For example, adults with GAD commonly report being anxious all of their lives (Rapee, 1991). Three sources of environmental influence that may be of importance in the development of anxiety disorders are:

- (1) Environmental support of avoidance,
- (2) Transmission of threat and coping information, and
- (3) External environmental events.

In a task (Hudson & Rapee, 2001), Children were given a moderately stressful puzzle task, and their mothers' behavior during the task was assessed. Clear differences were identified in degree of involvement between mothers of anxious children and mothers of non-anxious children. Mothers of children with anxiety disorders gave more help and were more intrusive with their help during the task than were mothers of nonanxious children [10].

2.2. Order of Birth

The child's serial order among siblings has an influence on the individual's personality and patterns of behavior. The two important of which are the sex of the child and how individual feel about the roles they are expected to play.

For e.g. A first born girl who is expected to help with the household work and with the care of young siblings may resent the fact at the boys in the family have fewer domestic duties and are granted privileges and given opportunities denied to her. First born may resent the pressure of parents to live up to their expectations or having to act as a model for younger siblings.

A second or later born boy may resent being bossed by an older sibling or being treated as the 'baby of the family'. Second born often interpret inferior complexity which often discourages the development of leadership qualities. Resent due to comparison with other sibling. They are underachievers due to poor parental expectations and plagued by feeling of parental neglect.

A later born usually lack willingness to assume responsibilities. They are spoiled by extra attention during early childhood. They are dependent and irresponsible. They are willful [12].

2.3. Diagnosis of GAD

A diagnosis of GAD requires that the child's excessive anxiety and worry cause significant distress or impairment in daily life. To receive a diagnosis, the child/adolescent must have shown excessive anxiety and worry, occurring more

days with any of the symptoms mentioned in DSM-5 criteria for GAD [13].

Symptoms of GAD: (Diagnostic and Statistical Manual 5, Adapted from the American Psychiatric Association) [11].

- 1) Many worries about things before they happen ("What if..." thoughts)
- 2) Many worries about friends, family, school, or activities
- 3) Frequent thoughts and fears about safety of self and/or safety of parents
- 4) Excessive worry about being away from home
- 5) Clingy behavior with family members
- 6) Reassurance seeking or repeatedly asking the same question in an effort to feel less worried

2.4. Other Somatic Complaints

- 1) Frequent stomachaches, headaches, or other physical complaints
- 2) Muscle aches or tension
- 3) Sleep disturbance
- 4) Lack of concentration
- 5) Being easily fatigued
- 6) Restlessness
- 7) Irritability [13]

J. T. Kent reads: "Each medicine produces particular effects in the body of man and no other medicinal substance can create any that are precisely similar." [14].

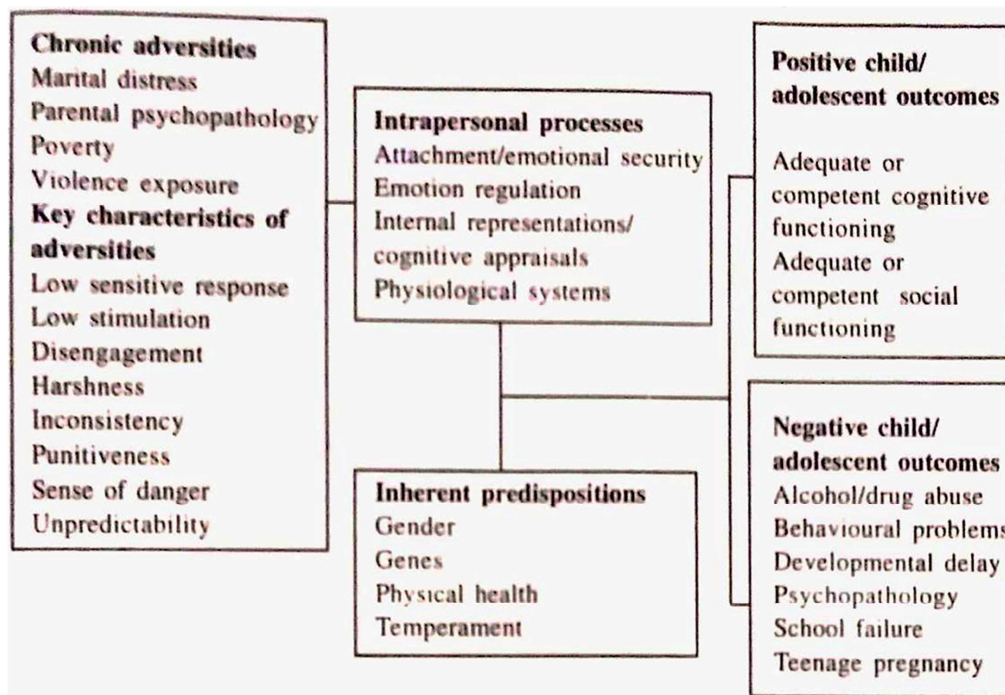


Figure 1. Factors affecting behavior in normal child development [12].

3. Methodology

Materials used: Case Proforma, GAD Questionnaire, Consent form, Modified kuppuswamy scale.

3.1. Method

3.1.1. Type of Research

A Prospective case study.

3.1.2. Sampling Design

Single Blind Randomized Controlled Trail.

3.1.3. Setting

Belgaum, Karnataka.

3.1.4. Details of Study Subjects

The subjects will be selected from schools; OPD's and satellite camps of A. M. Shaikh homoeopathic medical college and hospital of Belgaum, based on the inclusion and

exclusion criteria.

(i). Inclusion Criteria

- 1) Subjects from 11-17 years of both sexes of all socio-economic status are considered.
- 2) Subjects who obtain 14-40 points on GAD Scale by APA are included.

(ii). Exclusion Criteria

- 1) Subjects with any endocrinal diseases like hyperthyroidism, Cushing syndrome etc.
- 2) Subjects with developmental disorders like autism spectrum disorders, and other congenital syndromes (Down's syndrome etc.).
- 3) Subjects with other co-morbid anxiety disorder like Obsessive- compulsive disorder, panic disorder, separation anxiety disorder.
- 4) Subjects with other mood disorders and bipolar disorders.

3.1.5. Participant Subjects

(i). Size of Sample

On the basis of study design, size of sample is 62.

A total of 62 subjects of both sexes from 11-17 years of age are selected for this study based on the GAD questionnaire. These 62 subjects are randomized through chit method into a Control group, consisting of 31 subjects who are given placebo along with counseling and another is Study group, consisting of 31 subjects who are given homeopathic medicine based on constitution.

(ii). Duration of the Study

1.6 year. Each case is followed for one year.

(iii). Follow up

Follow up of cases once in a month for one year based on the improvement of subject's condition.

3.1.6. Result Criteria

(i). Recovered

If there is absence of symptoms for at least 3 months duration and improvement in their school performance is seen after 6 months of follow up.

(ii). Improved

If there is absence of symptoms for at least 3 months duration but recurrence of symptoms present after 6 months of follow up.

(iii). Not Improved

Complaints did not show reduction in the intensity and frequency and sense of well being at general level.

3.2. Statistical Methods Employed

Chi – Square test.

Ethical issues involved in the study: Ethical clearance had been obtained from the institution for this “Role of

individualised homeopathic medicine in management of generalized anxiety disorder in adolescents age group - a randomized, single-blind, placebo-controlled study.”

4. Observation and Results

This randomized control trial conducted between 1st May 2020 to 30th November 2021 in the age group of 11-17 years in both sexes. Each case is followed for one year.

Age Incidence:

Table 1. Age Incidence in Study Group.

Sl. No.	Age in years	No. of subjects	Percentage %
1.	11-12	5	16.1%
2.	13-14	15	48.3%
3.	15-16	11	35.4%
	Total	31	100%

Table 2. Age Incidence in Control Group.

Sl. No.	Age in years	No. of subjects	Percentage
1.	11-12	4	12.9%
2.	13-14	20	64.5%
3.	15-16	7	22.5%
	Total	31	100%

Table 3. Sex Incidence in Study Group.

Sl. No.	Sex of subjects	No. of subjects	Percentage (%)
1.	Male	14	45.1%
2.	Female	17	54.8%
3.	Total	31	100 %

Table 4. Sex Incidence in Control Group.

Sl. No.	Sex of subjects	No. of subjects	Percentage
1.	Male	13	41.9%
2.	Female	18	58%
3.	Total	31	100 %

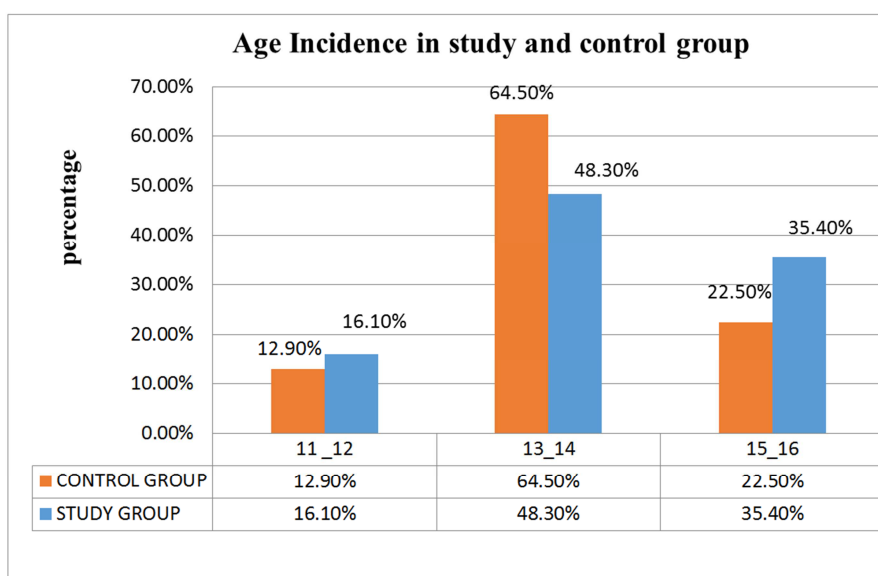


Figure 2. Bar graph showing age incidence in study and control group.

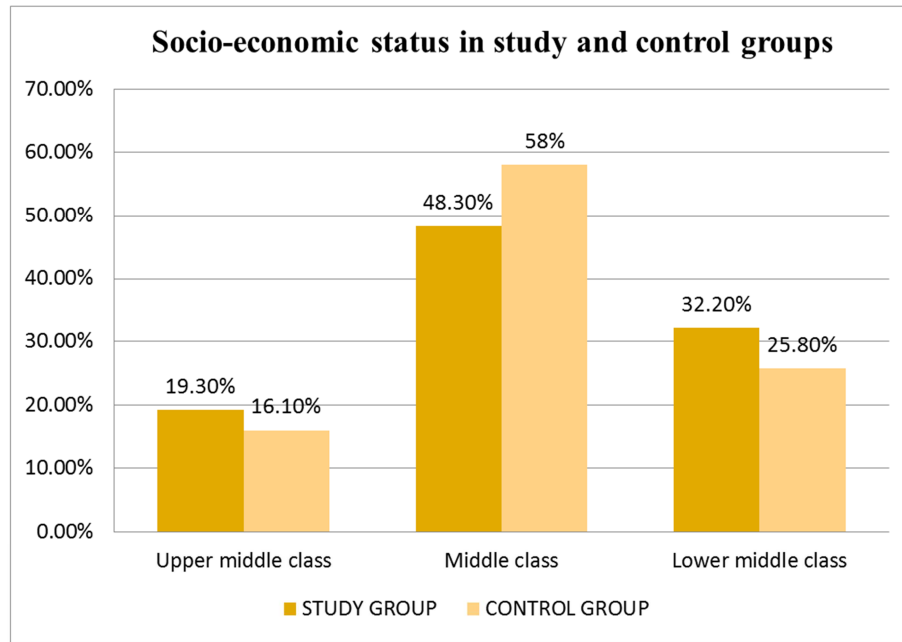


Figure 3. Bar graph showing socio-economic status in study and control groups.

Table 5. Incidence of socio-economic status.

socio-economic status	Study group	Percentage %	Control group	Percentage %	Percentage %(average)
Upper middle class	6	19.3%	5	16.1%	17.7%
Middle class	15	48.3%	18	58%	53.15%
Lower middle class	10	32.2%	8	25.8%	29%
Total	31	100%	31	100%	100%

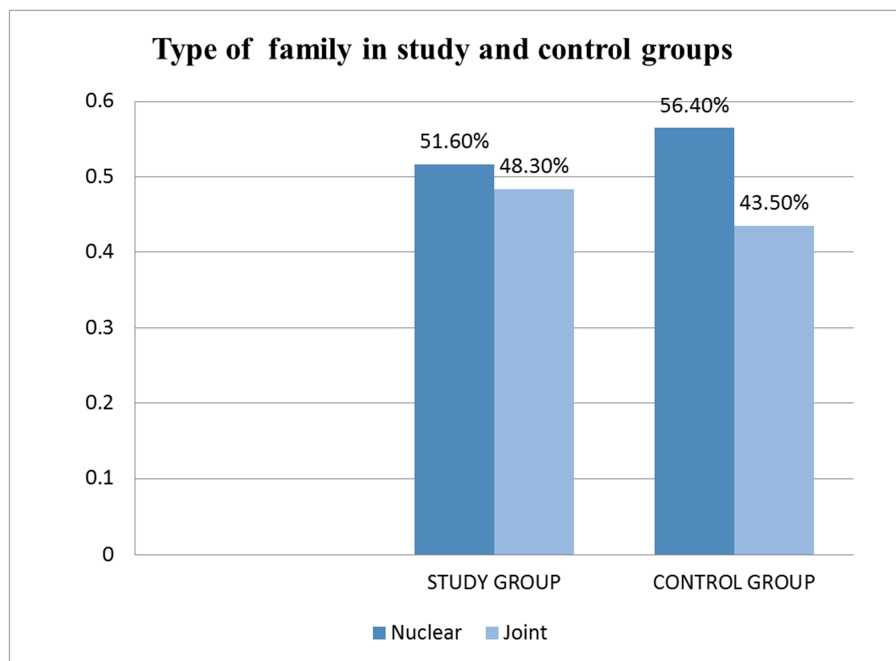


Figure 4. Bar graph showing type of family in study and control groups.

Table 6. Incidence of family type.

Type of family	Study group	Percentage %	Control group	Percentage %	Percentage %(average)
Nuclear	16	51.6%	19	61.2%	56.4%
Joint	15	48.3%	12	38.7%	43.5%
Total	31	100%	31	100%	100%

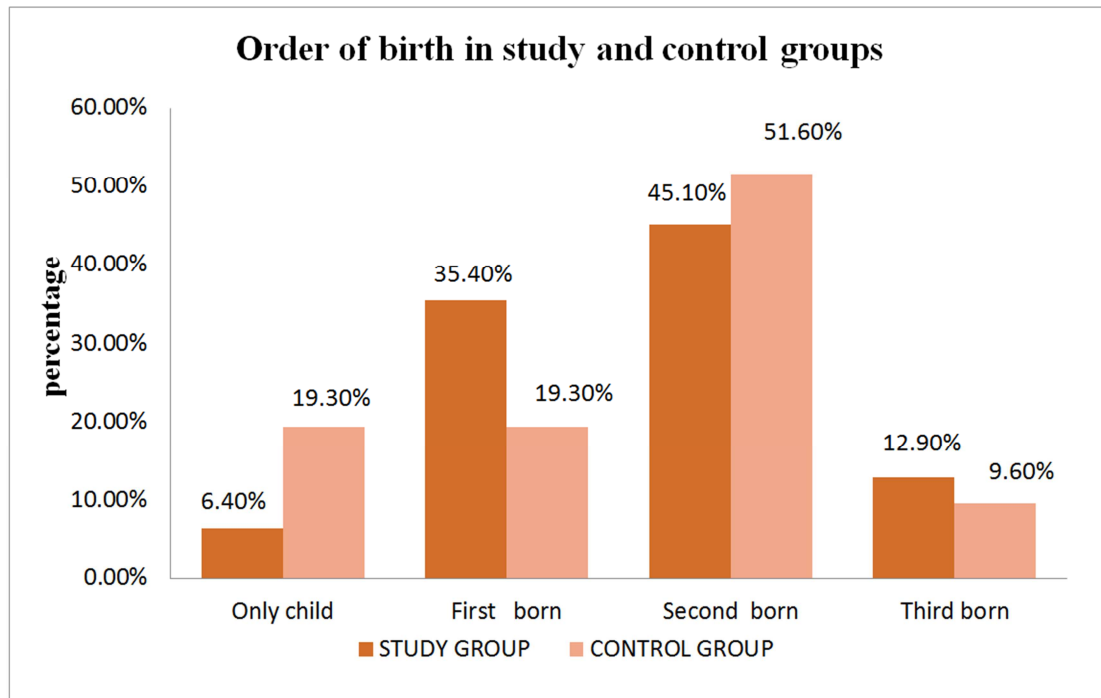


Figure 5. Bar graph showing order of birth in study and control group.

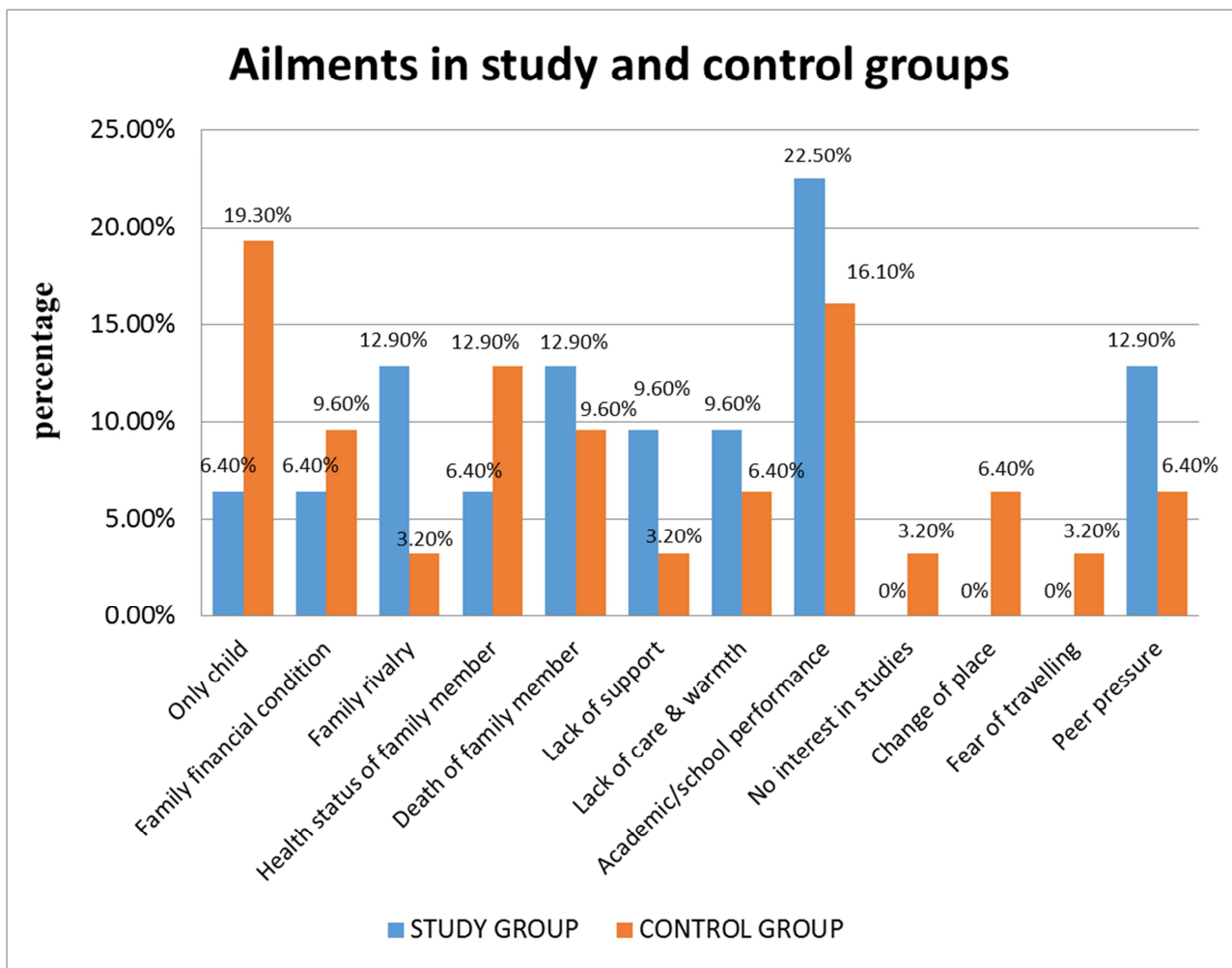


Figure 6. Bar graph showing ailments in study and controls groups.

Table 7. Incidence of Order of birth.

Order of birth	Study group	Percentage %	Control group	Percentage %	Percentage % (average)
Only child	2	6.4%	6	19.3%	12.8%
First born	11	35.4%	6	19.3%	27.3%
Second born	14	45.1%	16	51.6%	48.3%
Third born	4	12.9%	3	9.6%	11.2%
Total	31	100%	31	100%	100%

Table 8. Ailments of GAD.

Sl. no.	Ailments	Study group	Percentage %	Control group	Percentage %	Percentage % (average)
1.	Only child	2	6.4%	6	19.3%	12.8%
2.	Family financial condition	2	6.4%	3	9.6%	8%
3.	Family rivalry	4	12.9%	1	3.2%	8%
4.	Health status of family member	2	6.4%	4	12.9%	9.6%
5.	Death of family member	4	12.9%	3	9.6%	11.2%
6.	Lack of support	3	9.6%	1	3.2%	6.4%
7.	Lack of care & warmth	3	9.6%	2	6.4%	8%
8.	Academic/school performance	7	22.5%	5	16.1%	19.3%
9.	No interest in studies	0	0%	1	3.2%	1.6%
10.	Change of place	0	0%	2	6.4%	3.2%
11.	Fear of travelling	0	0%	1	3.2%	1.6%
12.	Peer pressure	4	12.9%	2	6.4%	9.6%
13.	Total	31	100%	31	100%	100%

Table 9. Presenting complaints.

Sl. No.	Presenting complaints	Study group	Percentage %	Control group	Percentage%	Percentage% (average)
1.	Sleeplessness	3	9.6%	4	12.9%	11.2%
2.	Restlessness	4	12.9%	2	6.4%	9.6%
3.	Palpitations	2	6.4%	3	9.6%	8%
4.	Irritability	2	6.4%	2	6.4%	6.4%
5.	Difficult concentration	3	9.6%	4	12.9%	11.2%
6.	Headache	4	12.9%	3	9.6%	11.2%
7.	Twitching of muscle	2	6.4%	1	3.2%	4.8%
8.	Cramps in fingers	1	3.2%	2	6.4%	4.8%
9.	Fatigue	2	6.4%	4	12.9%	9.6%
10.	Recurrent cold	2	6.4%	0	0%	3.2%
11.	Constipation	3	9.6%	3	9.6%	9.6%
12.	Irregular menses	1	3.2%	0	0%	1.6%
13.	Leucorrhea	2	6.4%	3	9.6%	8%

Table 10. Indicated homeopathic remedies.

Sl. no	Indicated medicine	No. patients	Percentage %
1.	Natrum muraticum	6	19.35%
2.	Calcarea carbonicum	4	12.9%
3.	Lycopodium	3	9.67%
4.	Pulsatilla	3	9.67%
5.	Causticum	2	6.45%
6.	Magnesium muraticum	2	6.45%
7.	Arsenicum album	2	6.45%
8.	Sulphur	2	6.45%
9.	Gelsemium	2	6.45%
10.	Silicea	2	6.45%
11.	Staphysagria	2	6.45%
12.	Phosphorous	1	3.22%

Table 11. No. of sessions of CBT.

Sl. No.	No. of sessions of CBT	No. of subjects	Percentage %
1.	4 sessions	5	16.1%
2.	5 sessions	11	35.4%
3.	6 sessions	14	45.1%
4.	7 sessions	1	3.2%

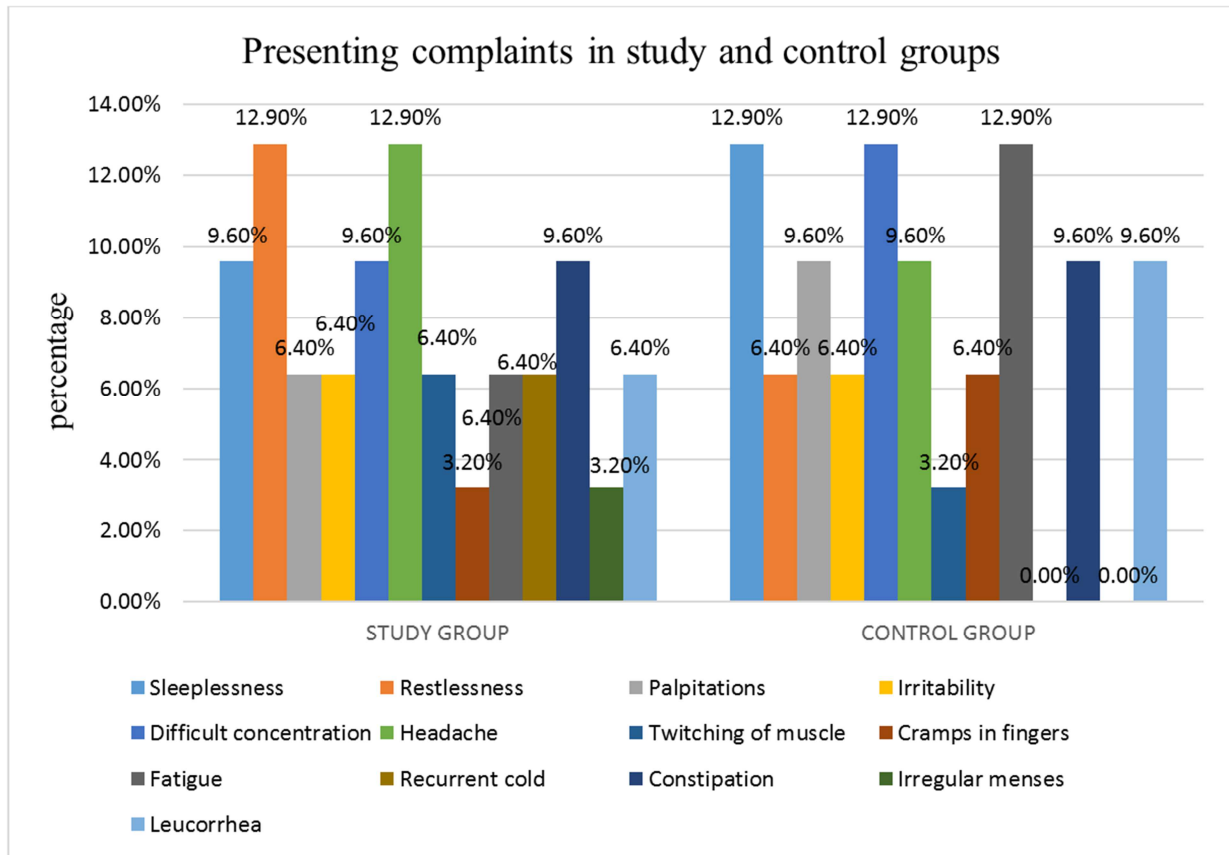


Figure 7. Bar graph showing presenting complaints in study and control group in percentage.

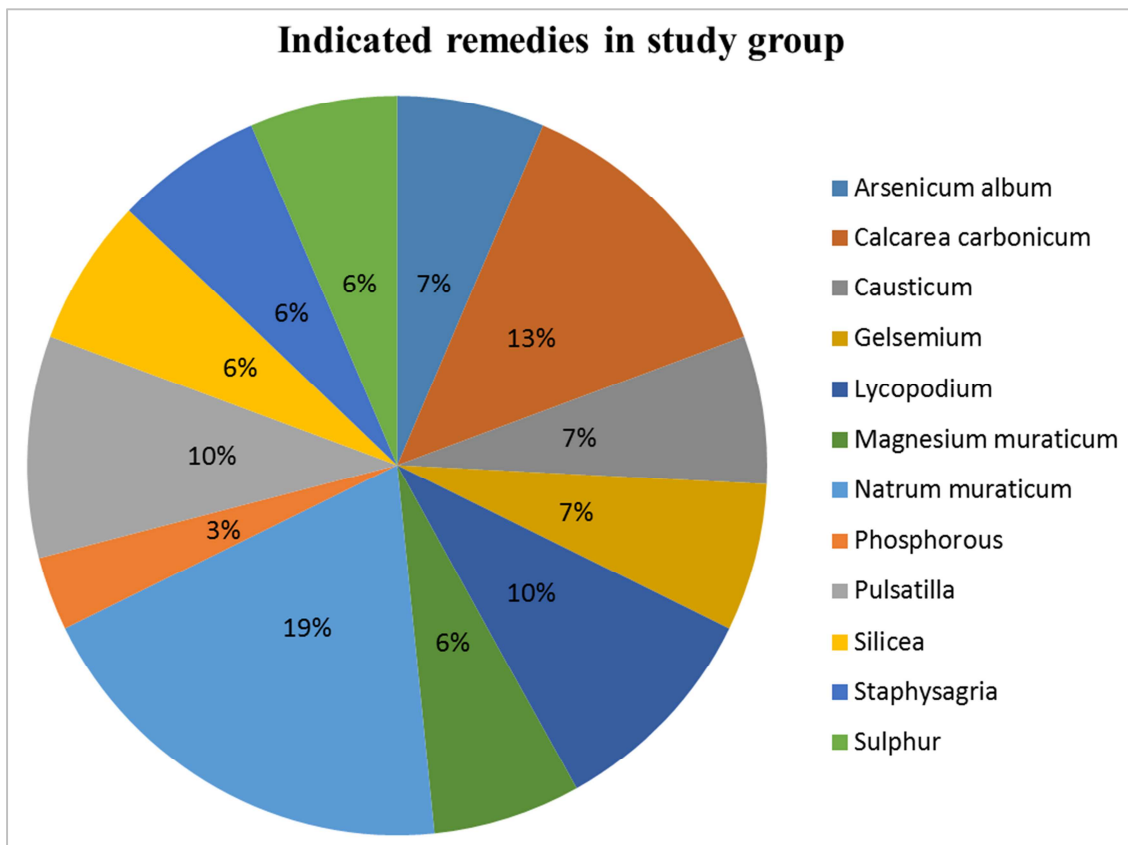


Figure 8. Pie chart showing indicated remedies in study group.

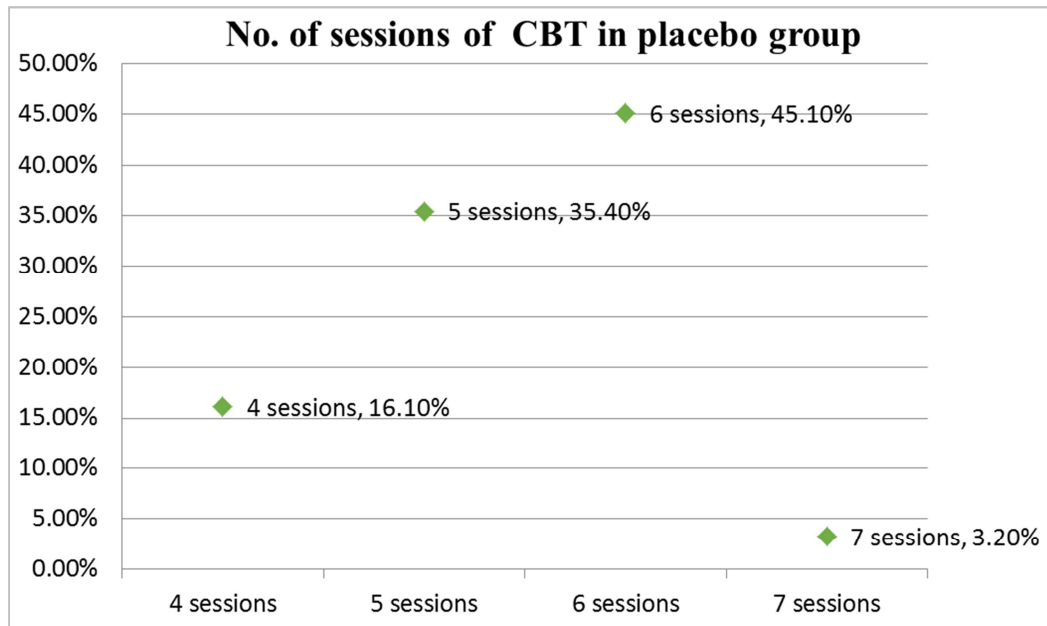


Figure 9. Graph showing no. of session of CBT in placebo group.

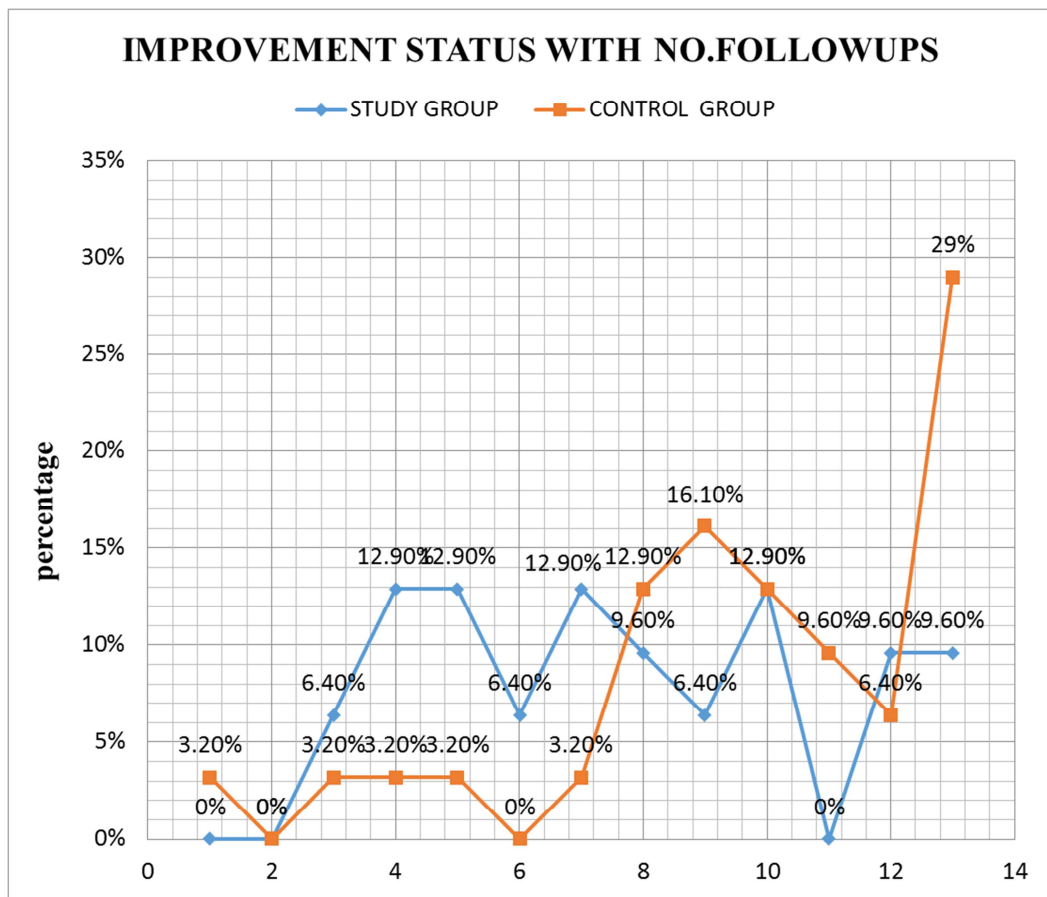


Figure 10. Graph showing improvement status with no. of follow up.

Table 12. Statistical analysis of pre and post score in study group.

SEVERITY	PRE SCORE	PERCENTAGE%	POST SCORE	PERCENTAGE %
MILD (0-14)	0	0%	12	38.7%
MODERATE (15-27)	9	29.1%	14	45.1%
SEVERE (28-40)	22	70.9%	5	16.1%

Table 13. Statistical analysis of pre and post score in control group.

Severity	Pre score	Percentage %	Post score	Percentage %
MILD (0-14)	0	0%	4	12.9%
MODERATE (15-27)	14	45.1%	14	45.1%
SEVERE (28-40)	17	54.8%	13	41.9%

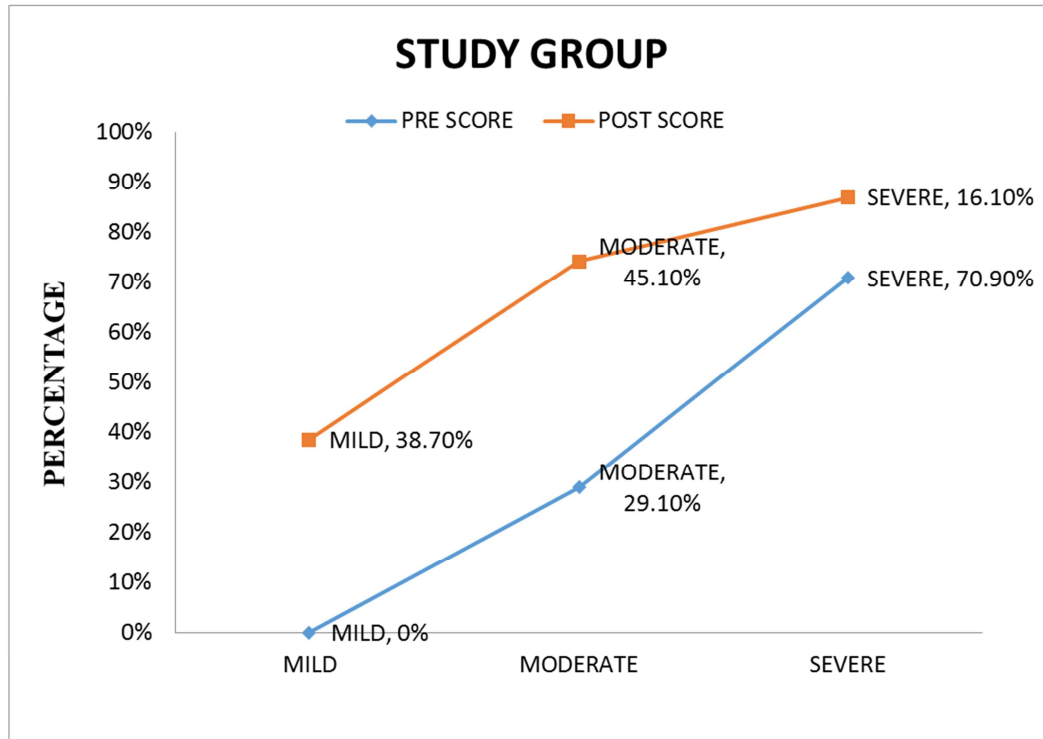
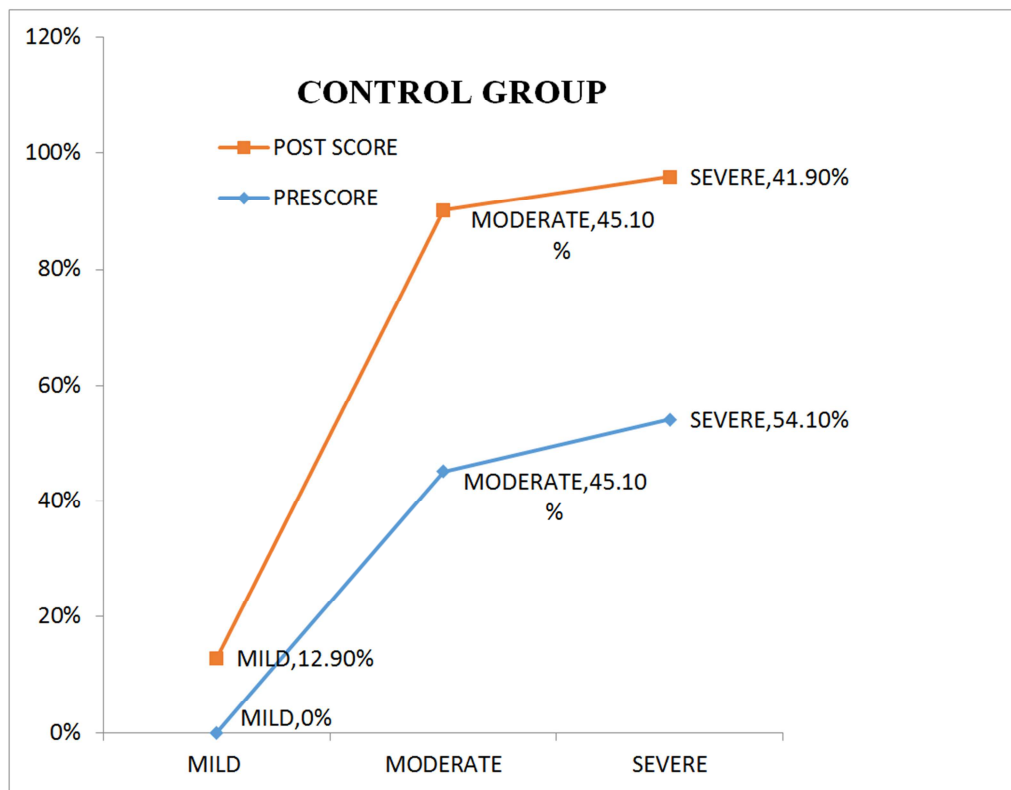
**Figure 11.** Graph showing study group.**Figure 12.** Graph showing control group.

Table 14. Comparing the efficacy of homeopathic treatment and control group through changes seen in No. of follow-ups taken.

Sl. No.	Status with followups	Study group		Control group	
		No of cases	Percentage	No of cases	Percentage
1	RECOVERED IN 1 ST FP	0	0%	1	3.2%
2	RECOVERED IN 2 ND FP	0	0%	0	0%
3	RECOVERED IN 3 RD FP	2	6.4%	1	3.2%
4	RECOVERED IN 4 TH FP	4	12.9%	1	3.2%
5	RECOVERED IN 5 TH FP	4	12.9%	1	3.2%
6	RECOVERED IN 6 TH FP	2	6.4%	0	0%
7	IMPROVED IN 1 ST FP	4	12.9%	1	3.2%
8	IMPROVED IN 2 ND FP	3	9.6%	4	12.9%
9	IMPROVED IN 3 RD FP	2	6.4%	5	16.1%
10	IMPROVED IN 4 TH FP	4	12.9%	4	12.9%
11	IMPROVED IN 5 TH FP	0	0%	3	9.6%
12	IMPROVED IN 6 TH FP	3	9.6%	2	6.4%
13	NO IMPROVEMENT	3	9.6%	9	29%

5. Discussion

GAD is a psychosomatic illness with increasing severity but seldom diagnosed in adolescents. There is a need to explore this disorder if neglected, leads up in depression, suicidal ideations, and other anxiety disorders affecting social interactions leading to underachievement in adolescents. The aim of this randomized control trial is to reveal the efficacy of homeopathic treatment of Generalised anxiety disorder in adolescents (11-17 years) with cognitive behavioral therapy (placebo) in control group by using the pre and post score with GAD scale by APA. The secondary objectives are to know clinical presentations, ailments leading to GAD.

Analysis of pre and post score in study group & control groups: GAD assessment in the study group before the homeopathic treatment showed that 70.9% (22 subjects) with severe score & 29.1% (9 subjects) are with moderate score which changed after intervention to mild of 38.7% (12 subjects), moderate score of 45.1% (14 subjects) and severe of 16.1% (5 subjects).

GAD assessment in the control group before the CBT showed that 54.8% (17 subjects) with severe score & 45.1% (14 subjects) are with moderate score which changed after intervention to mild of 12.9% (4 subjects), moderate score of 45.1% (14 subjects) and severe of 41.9% (13 subjects).

Average assessment of GAD in both study and control group before the intervention shows that 37.1% (23 subjects) with severe score & 62.8% (39 subjects) are with moderate score which changed after intervention to mild of 25.8% (16 subjects), moderate score of 45.1% (28 subjects) and severe of 29% (18 subjects).

As the questionnaire has only 3 criteria where mild was from 0 to 14 points, where the subjects with absence of symptom also come under this criterion. Post treatment score did not fulfill all the 10 symptoms of questionnaire, some subject's covered 5 to 6 symptoms only. This gives us the idea that the subjects are in the moderate criterion showing improvement. Recovered subjects did not have any symptoms after 3 months of follow up. However there might be reverting of symptoms depending on external stimuli.

6. Limitations of the Study

- 1) As this study is of 1.6 year, though cases recovered showing no symptoms during the study span, there is always a chance for remission of symptoms due to the triggering factor.
- 2) The cases showed no improvement was due to the limitation of the RCT protocol, hence there cannot be any intervention against this procedure followed.
- 3) Miasmatic analysis was not conducted because of the less stipulated time and lack of family history analysis which can be carried out in a longitudinal study.
- 4) The most common cause of GAD is a positive family history of GAD which wasn't highlighted in this study.

7. Conclusion of the Study

This research is an experimental study to know the efficacy of homeopathic treatment of GAD in adolescents in comparison to cognitive behavioral therapy in placebo group on an ethical basis.

Adolescence is crucial stage, as the limbic system developing during this stage, is sensitized by sex hormones (estrogen and testosterone) making them prone for anxiety. In this 21st century, handful of gadgets, social media influence, nuclear families and peer pressure, drives adolescents to struggle with their own will to survive. Being a masked disorder in adolescents, GAD is overlooked by most pediatricians due to its vague symptoms.

This research can be the torch bearer to cognize how various factors like socioeconomic status of parents, family type, order of birth of the child, lack of company, and health status of family member, school performance, parental issues and peer pressure contribute in the development of GAD in adolescents. This study proved how environmental issues affect the abilities of an adolescent in various spheres by deranging health landing him/her in a disease state i.e. psychosomatic illness. This study also disclosed suicidal ideation in 3 subjects.

This study revealed that clinical presentation of GAD might not be only one symptom as mentioned in GAD DSM-

5 criteria, most adolescents in the study presented with headache, difficult concentration and indigestion on & off during the follow ups. Paving the way in understanding pathophysiology of GAD as mentioned in the literature, this research avails us how anxiety affects the immune system & hormone imbalance in adolescents. Yet, the exact pathogenesis behind this emotion is unclear. Average assessment of GAD in both study and control group before the intervention shows that 37.1% with severe score & 62.8% are with moderate score which changed after intervention to mild of 25.8%, moderate score of 45.1% and severe of 29%.

As an observation through this research, most subjects showed passive and passive aggressive behavioural communication which might indicate their proneness to GAD.

Going through the effects of homeopathic remedies on human body in the study group, we can clearly confirm that anxiety showing mental, emotional and physical symptoms can be treated effectively based on individual constitution. Therapeutic utility of CBT for GAD is also understood through this study. This research invokes a hope for treating such masked psychiatric illnesses with homeopathic similimum. Homeopathy being a holistic system of medicine makes us to understand the emotional pathology of remedies by psychosomatic presentation of symptoms which was stressed by Dr. Samuel Hahnemann.

8. Recommendation for Further Study

- 1) A further study of GAD with homeopathic remedies can be done with the investigations of serotonin levels providing an evidence based research.
- 2) There is a need for a longitudinal study to understand the complete emotional aetiopathogenesis of GAD among adolescents.
- 3) There are no proper researches on GAD among children and adolescents in India. There is a need for exploratory study of GAD in India among children and adolescence due to its increasing severity.
- 4) Further studies can be carried out to know the relation between behavioral communication & GAD in the adolescents.

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