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An Open Label Clinical Trial Showing Effectiveness of Individualized Homoeopathic Medicine in Generalized Anxiety Disorder (GAD) Amongst Patient Attending at District Health Centre

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Abstract

GAD is one of the most common mental disorders up to 20% of adults are affected by anxiety disorder each year which is characterized by excessive nervous, anxiety, worry, irritable etc. GAD lifetime prevalence of roughly 5%-6% and 12-month prevalence of 2%-3%. Risk factors are high levels of stress, a history of personal or family psychiatric issues and traumatic life events. Objectives of this study to show effectiveness of individualized homoeopathic medicine amongst patients of generalized anxiety disorder. It is an open label observational study. 25 cases (11 severe, 8 moderate and 6 mild cases) of GAD are selected at Birsingha SHD, Vidyasagar RH, Ghatal, Paschim Medinipur, West Bengal. Selected individualized homoeopathic medicine as per homoeopathic posology and also maintains GAD-7 score before, during and after treatment. Results are tabulated and mean score between those before treatment and after 1 year treatment compared using t-test difference of two means. This study shows 22 cases (88%) normal limit and 3 cases (12%) severe to mild after treatment. Individualized homoeopathic medicine significantly reduces GAD-7 score. This study shows the effectiveness of individualized homoeopathic treatment in GAD.

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Introduction

GAD is one of the most common mental disorders up to 20% of adults are affected by anxiety disorder each year. GAD is characterized by excessive, uncontrollable worry, with a significantly higher prevalence in women, and a median age of onset typically in the late teens to mid-20.GAD is twice as common in women as in men. Increased prevalence is associated with being middle-aged (35–54), divorced/separated/widowed, unemployed, or having a low household income. The disorders stems from a combination of genetic factors (hereditary basis), environmental factors (stressors), and neurobiological factors (e.g., neurotransmitter dysregulation). According to new data released by World Health Organization more than 1 billion people are living with mental health disorders such as anxiety. As per ICD 11, anxiety is defined as apprehensiveness or anticipation of future danger or misfortune accompanied by a feeling of worry, distress, or somatic symptoms of tension. The focus of anticipated danger may be internal or external. Generalized anxiety disorder is characterized by at least 6 months of persistent and excessive anxiety and worry. Diagnostic criteria in the Diagnostic & Statistical Manual of Mental Disorders, 5th edition (DSM-5) include the following:

- Excessive anxiety and worry for at least 6 months.
- Difficulty controlling the worrying

The anxiety is associated with 3 or more of the following symptoms for at least 6 months:

- Restlessness, feeling keyed up or on edge.
- Being easily fatigued.
- Difficulty in concentrating or mind going blank, irritability.
- Muscle tension.
- Sleep disturbance.
- Irritability.
- The anxiety results in significant distress or impairment in social and occupational areas.
- The anxiety is not attributable to any physical cause.

In order to discuss how to deal with worry, anxiety, and GAD, we need to establish clear definitions of these terms. Most people tend to use the words "worry" and "anxiety" interchangeably, which can make it a challenge to differentiate between them in practical terms. Worry is a cognitive process: it occurs in the mind. Worry involves mentally anticipating and preparing for potential negative outcomes in the future. Whereas worries take place in the mind, anxiety occurs in the body. Anxiety is the general name for a varied number of physical sensations that people experience when they're in danger or feel threatened in some way. Although we've discussed anxiety disorders in general, the focus of this workbook is on one particular anxiety disorder, generalized anxiety disorder, or GAD. Contrary to its name, the primary symptom of GAD isn't anxiety, but rather excessive and uncontrollable worry about day-to-day events. In GAD, worry is chronic, meaning excessive worry has been present for at least six months and isn't solely due to a stress-or in the person's life. There are six physical symptoms that people with GAD can experience, although only three must be present to meet the criteria for diagnosis: • Feeling restless, keyed up, or on edge • Being easily fatigued • Difficulty concentrating or mind going blank • Irritability • Muscle tension • Sleep disturbances. These physical symptoms are experienced chronically, meaning that they are present more days than not for at least six months. Finally, worry and anxiety symptoms need to cause significant distress and impairment in a person's daily life in order to meet the criteria for a GAD diagnosis (American Psychiatric Association 2013).Childhood anxiety occurs in about 1 in 4 children at some time between the ages of 13 and 18 years. The median age at onset is 11 years. However, the lifetime prevalence of a severe anxiety disorder in children ages 13 to 18 is approximately 6%. The general prevalence in children under 18 years is between 5.7% and 12.8%. The prevalence is approximately twice as high among women as among men. Generalized Anxiety Disorder (GAD) is a common, chronic condition with a 12-month prevalence of approximately 2% to 5% in the general population, affecting nearly 3% to 6% over a lifetime. The exact mechanism is not entirely known. Anxiety can be a normal phenomenon in children. Stranger anxiety begins at 7 to 9 months of life. Noradrenergic, serotonergic, and other neurotransmitter systems appear to play a role in the body's response to stress. The serotonin system and the noradrenergic system are common pathways involved in anxiety. Many believe that low serotonin system activity and elevated noradrenergic system activity are responsible for its development. Therefore, selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine

reuptake inhibitors (SNRIs) are the first-line agents for its treatment. Generalised anxiety disorder assessment (GAD-7) is the default measure for anxiety. This scale was originally developed to assess the severity of anxiety symptoms in generalised anxiety disorder only.

GAD-7 consists of:

Over the last two weeks how often have you been bothered by the following problems? (Use tik to indicate your answer)	Not at all	Several days	More than half in the days	Nearly every days
1. Feeling nervous,anxious or on edge	0	1	2	3
2.Not being able to stop or control worrying	0	1	2	3
3.Worrying too much about different things	0	1	2	3
4.Trouble relaxing	0	1	2	3
5.Being so restless that it is hard to …still	0	1	2	3
6.Becoming easily annoyed or irritable	0	1	2	3
7.Feeling afraid, as if something awful might happen	0	1	2	3

(Total score T= --- +---+---+---)

The main objectives of this study to find out the effectiveness of individualised homoeopathic medicine amongst patients of Generalised anxiety disorder.

Specific objective:

- To recruit patients from OPD using GAD-7 score for classification into mild, moderate and severe anxiety.
- To compare the mean GAD-7 score before and after 1 year of treatment.

Method

It is an open label observational study where 25 cases of GAD are selected at Birsingha SHD, Vidyasagar RH, Ghatal, Paschim Medinipur, West Bengal. After case taking, repertorisation with miasmatic consideration finally selected constitutional homoeopathic medicine as per homoeopathic posology and also maintains GAD-7 score before, during and after treatment (4 weeks interval). Results are tabulated and mean score between those before treatment and after 1 year treatment compare using t-test difference of two means.After treatment change at least four (4) points in scale indicates meaningful improvements. A decrease of six (6) or more points is considered a significant clinical change based on the reliable change index.

Master Chart:

SL NO.	NAME	AGE	SEX	GUIDING SYMPTOMS	SELECTED REMEDIES	FOLLOW UP
1.	AK	30yrs	F	Patient feels very restless, can't stay in one place, perfectionist, fastidiousness, feels very weakness without cause.	Ars alb 30/ 2 doses B.D.	Placebo and Ars. Alb 30 /1 dose ,repeat after 5 months
2.	SM	27 yrs	F	Patient is very obstinate,unmoved by apology,constant changing,Headstrong,Desire fried food, Offensive smell in urine.	Nitric acid 200/ 1dose O.D.	Placebo and Nitric acid 200/1 dose ,repeat after 6 months

3.	SK	32 yrs	M	Patient very irritable, fastidious,easily anger, H/O alcoholism and night watching, loss of ambition, Desire spicy food.	Nux vom 30 /2 doses B.D.	Placebo and Nux vom 30 /1 dose ,repeat after 4 months
4.	KR	45 yrs	F	Patient is very sympathetic, fastidious, animal and nature lover, enjoy the rain & thunderstorm, F/H of cancer.	Carcinosin 200/1 dose O.D.	Placebo and Carcinosin 200 /1 dose ,repeat after 7 months
5.	TD	60 yrs	F	Excessive cold sweat, feels suffocation, desire air rapidly, chilly patient, easily exhausted, G.I. complaints better after eructation.	Carbo veg 30/2 doses B.D.	Placebo and Carbo veg 30 /1 dose ,repeat after 5 months
6.	KS	36 yrs	F	Complaint after vaccination, desire as well as intolerance of onion, dreams of falling, perspiration lying on the side, very religious.	Thuja occ. 200/1 dose O.D.	Placebo and Thuja occ. 200 /1 dose ,repeat after 7 months
7.	PM	17 yrs	M	Patient repeats everything said to it, fears arrest on account of a supposed crime, feet in continued motion, sensitive to noise.	Zinc. met 200/ 1 dose O.D.	Placebo and Zinc. met.200/1 dose ,repeat after 6 months
8.	PG	37 yrs	F	Sensation of a band around head, all discharge very offensive, middle of the tongue deep cracked, vindictive, loves fat & salt.	Nit. Acid 30/2 doses O.D.	Placebo and Nitric acid 30 /1 dose ,repeat after 8 months
9.	MR	25 yrs	M	Fear of death and predict the day, music is unbearable, makes her sad, fear of future, crowd, crossing in the street, bitter taste in every things except water.	Aconite 200/2doses O.D.	Placebo and Aconite 200 /1 dose ,repeat after 4 months
10.	TC	48yrs	F	Fleshy women at climacteric , slightest emotion causing palpitation, desire for company, violent rush of blood to head with vertigo.	Calc ars 200/1 dose O.D.	Placebo and Calc. ars 200 /1 dose ,repeat after 8 months
11.	RS	26 yrs	F	Great loquacity, mentally and physically feels very exhausted after sleep, can't tolerate tight clothing anywhere, sleep in left-lateral position, can't tolerate excessive heat & cold.	Lachesis 200/1 dose O.D.	Placebo and Lachesis 200 /1 dose ,repeat after 7 months

12.	AM	37 yrs	F	Fear of death, of being left alone, think refuses to take medicine, great thirst, drinks much but little at a time, great exhaustion after the slightest exertion.	Ars alb 200/2 doses B.D.	Placebo and Ars alb 200 /1 dose ,repeat after 6 months
13.	KL	58 yrs	M	All symptoms feels better while riding in a carriage, sensitive to noise, pain, desire fried food, chilly patient.	Nit acid 200/1 dose O.D.	Placebo and Nitric acid 200 /1 dose ,repeat after 5 months
14.	MP	39 yrs.	F	As if a strange person where at her side,dislike meat & potato, dreams of dead person, stool after breakfast, sweat only on uncovered parts.	Thuja occ. 200/ 1 dose O.D.	Placebo and Thuja occ. 200 /1 dose ,repeat after 7 months
15.	SA	33 yrs	M	Uneasiness respecting health, fear of death, grief after lost of dearest friend, sweat during and after last meal, sleeplessness from over excitement.	Nitric acid 200/ 1 dose O.D.	Placebo and Nitric acid 200 /1 dose ,repeat after 5 months
16.	SM	23 yrs	F	F/H of inflammatory disorder, cancer, cosmopolitan attitude, prefers sleep in genu-pectoral position, all symptoms aggravated by sea side.	Carcinosin 200/ 1 dose O.D.	Placebo and Carcinosin 200 /1 dose ,repeat after 9 months
17.	KP	19 yrs	F	Slightest cause irritates her, ferocious, hasty speech, longing for acids & wine, very chilly pt.	Heper Sulph 200/ 2 doses B.D.	Placebo and Heper sulph 200 /1 dose ,repeat after 6 months
18.	AM	59 yrs	F	Hurried & rapid talking, tongue moist & flabby with profuse thirst, perspiration profuse & offensive, after perspiration feels weak, breath & body smell foul.	Merc sol 200/1 dose O.D.	Placebo and Merc sol. 200 /1 dose ,repeat after 7 months
19.	PB	64 yrs	M	Hopeless, despair to recovery, very chilly patient, wants warm clothing even in summer, profuse perspiration and after perspiration feels better.	Psorinum 200/1 dose O.D.	Placebo and Psorinum 200 /1 dose ,repeat after 5 months
20.	SD	38 yrs	F	Desire to use foul language, fear of dog, desire milk & potato, tendency to catches cold, F/H of COPD.	Tuberculinum 200/1 dose O.D.	Placebo and Tuberculinum 200 /1 dose ,repeat after 6 months

21.	LS	31 yrs	F	Feels as if going insane or being paralyzed, hopeless, despair of recovery, H/O delayed milestone development, hereditary tendency to alcoholism.	Syphillinum 200/1 dose O.D.	Placebo and Syphillinum 200 /1 dose ,repeat after 8 months
22.	BP	26 yrs	F	Weak memory, loss the threads of conversation, time passes too slowly, fear in the dark & of some one behind her, sleep in knee-chest position, feels better at the seashore.	Medorrhinum 200/ 1 dose O.D.	Placebo and Medorrhinum 200 /1 dose ,repeat after 7 months
23.	SK	15 yrs	M	Anxiety with palpitation, slight mental effort produces hot head, sense of weight on top of head, loss of appetite when over-worked, intolerance of milk.	Calc carb 200/1 dose O.D.	Placebo and Calc carb 200 /1 dose ,repeat after 6 months
24.	KB	45 yrs	F	Dread of death when alone, great restlessness & prostration, face deathly pale, cachectic look, unquenchable thirst, drinks often but little at a time, water disagrees.	Ars alb 200/ 2 doses O.D.	Placebo and Ars. Alb. 200 /1 dose ,repeat after 7 months
25.	AB	65 yrs	M	Dirty filthy people, prone to skin affection, aversion to being washed, early morning diarrhoea, Hot patient, desire sweet things.	Sulphur 30 / 1 dose O.D.	Placebo and Sulphur 30 /1 dose ,repeat after 9 months

GAD-7 Master Chart:

Sl no.	Name of patients	Age	Sex	Before treatment	After 4 wks	After 4 wks	After 4 wks	After 4 wks	After 4 wks	After 4 wks	4 wks	4 wks	4 wks	4 wks	4 wks	Difference between before and after treatment
1	AK	30	F	17	14	12	11	10	10	9	9	8	8	7	7	7	10
2	SM	27	F	17	15	14	12	12	12	11	10	8	8	7	6	6	11
3	SK	32	M	17	15	15	14	13	13	13	11	9	7	6	6	6	11
4	KR	45	F	16	13	12	11	10	10	10	8	7	6	5	4	4	12
5	TD	60	F	16	13	12	11	10	9	9	9	7	6	5	4	4	12
6	KS	56	F	16	12	11	10	9	8	8	6	5	4	4	4	4	12
7	PM	17	M	16	13	12	10	9	9	7	6	5	4	3	3	3	13
8	PG	37	F	15	12	11	10	9	8	8	7	6	5	4	4	4	11
9	MR	25	M	15	12	11	10	9	7	7	6	6	5	4	4	4	11
10	TC	48	F	15	12	11	10	10	8	8	6	5	5	4	3	3	12
11	RS	26	F	15	13	12	11	10	9	9	7	6	5	3	2	2	13
12	AM	37	F	14	12	11	10	8	8	6	5	4	4	4	4	4	10

13	KL	58	M	14	12	11	10	9	9	8	7	6	5	3	3	3	11
14	MP	39	F	13	11	10	9	8	8	7	6	5	4	4	4	4	9
15	SA	33	M	12	10	9	8	7	7	7	6	5	4	4	4	4	8
16	SM	23	F	12	10	9	7	6	6	6	5	4	4	4	4	4	8
17	KP	19	F	12	10	9	8	8	7	7	7	6	5	4	3	3	9
18	AM	59	F	11	9	8	7	6	6	6	5	5	4	4	4	4	7
19	PB	64	M	11	9	8	8	7	7	6	6	6	5	4	3	3	8
20	SD	38	F	9	7	6	6	5	5	5	5	4	4	4	4	4	5
21	LS	31	F	8	6	6	5	5	5	5	5	4	4	4	4	4	4
22	BP	26	F	8	7	6	6	5	5	5	5	4	4	3	3	3	5
23	SK	15	M	7	6	5	5	4	4	4	4	3	3	3	3	3	4
24	KB	45	F	6	5	5	4	4	4	3	3	3	3	2	2	2	4
25	AB	65	M	5	4	4	3	3	3	3	3	2	2	2	2	2	3

GAD values before treatment has a mean score of 12.7 ± 8.19 (n=25) and GAD values have mean score after 1 year treatment as 3.8 ±1.2 (n=25). The t statistic for the difference in 2 means computes to $= \frac{x_1 - x_2}{SE\ x_1 - x_2} =$ 3.78, while table value for **α** = 0.05, and degree of freedom = 24 is 2.064. So the difference in the mean scores is statistically significant at 95% confidence interval.

Table showing frequency distribution of patient's showing different catagories of GAD:

GAD with grading	Before Treatment no.(%)	After Treatment no.(%)
Severe Anxiety >15	11(44%)	0
Moderate Anxiety > 11-14	08 (32%)	0
Mild Anxiety >05-09	06 (24%)	03 (12%)
Normal <4		22 (88%)

Table showing frequency distribution of patient's showing different catagories of GAD according to gender:

GAD	No. Of Male patient's (%)	No. Of Female Patient's (%)
	08 (32%)	17 (68%)

This study shows 11 cases severe GAD, 8 cases moderate GAD and 6 mild GAD cases are marked improvement and showing gradually decreasing GAD-7 score. There were 11 (44%)) patients suffering from severe generalised anxiety disorder before treatment. After treatment there were no cases of severe generalised anxiety disorder. There were 8 cases (32%) patients suffering from moderate generalised anxiety disorder before treatment but there were no cases of moderate generalised anxiety disorder after treatment. Mild anxiety among 6 (24%) that after treatment generalised anxiety disorder came down to 3(12%). 22 cases (88%) normal limit after treatment. This study shows individualised homoeopathic treatment reduces anxiety in patients of Birsingh SHD OPD. Within 25 patients 8 (32%) are male patients and 17 (68%) are female patients in this study.

Discussion

This study shows the effectiveness of constitutional homoeopathic treatment in generalised anxiety disorder. The only possible way out is by judiciously selected first prescription and keen observation of the patient as a whole with past history, family history of the patients that bring a favourable result in G.A.D. with homoeopathy. The guidelines advised by our master Dr Samuel Hahnemann described how to treat mental disease in 1829 his 4th edition of Organon of medicine, aphorism 210-230 said that symptoms of previous corporeal disease with present symptoms of mind and disposition will give the complete picture of the disease and also

advised the psychotherapy and psychical remedies like friendly exhortations, consolatory arguments, serious representation and sensible advised with appropriate diet and regimen, which will rapidly change into health. He advised the physician to possess a thorough knowledge of the disease, knowledge of individual medicine, choice of remedy and proper dosage and repetition in aphorism 3 Organon of medicine. After proper treatment, patient feels greater the degree of comfort, increased calmness, freedom of mind, higher spirits that avoids other functional disturbances. We have to focus on environmental factors that triggers the latent psora in any individual [1-16].

Homoeopathic medicines are selected on the basis of totality of symptoms. 25 cases covered with homoeopathic medicines like Carcinosin, Nitric acid, Nux Vom, Thuja, Carbo veg. Zinc. Met, Lachesis, Aconite, Calc. Carb., Merc. Sol., Psorinum, Tuberculinum, Medorrhinum etc. on the basis of individualization. Guiding symptoms of the homoeopathic medicines are showing in the master chart.

The clinical outcome of the 25 cases was assessed with GAD-7 score, which showed marked reductions in the intensity of symptoms are showing in the master chart. Individualised homoeopathic medicine significantly reduces GAD-7 score.

Conclusion

In this study shows individualised homoeopathic treatment reduces anxiety in patients of Birsingh SHD, Ghatal, Paschim Medinipur, West Bengal, India. This study shows 11 cases severe GAD, 8 cases moderate GAD and 6 mild GAD cases are marked improvement and showing gradually decreasing GAD-7 score. Homoeopathy plays a major role in relieving patient's mind &body & restore the sick to health.

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