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A CLINICAL STUDY TO ASSESS THE IMPROVEMENT OF SOCIAL QUALITY OF LIFE AND SATISFACTION IN PATIENTS DIAGNOSED WITH GENERALIZED ANXIETY DISORDER USING HOMOEOPATHIC REMEDIES

A STUDY PROTOCOL

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ABSTRACT

Objective:

Generalized Anxiety Disorder (GAD) is a common mental health disorder characterized by excessive and persistent worry or anxiety about a variety of everyday situations. This worry could be due to multifocal causes such as problems in finance, family, health etc., It is excessive, hard to manage, and frequently accompanied by a wide range of psychological and physical manifestations. This chronic condition can significantly impact a person's daily life, relationships, and overall well-being[10]. The Social Quality of life plays a vital role in individuals self satisfaction to achieve various targeted goals. Homoeopathic medicines in its minute potentised form are expected to bring a significant improvement in the social quality of life of persons diagnosed with GAD.

Materials and Methods:

This is a single-arm clinical trial to recognize the effectiveness of Individualized Homoeopathic Medicine in improving the social quality of life among patients with generalized anxiety disorders. The quality of life will be assessed every 3rd month using Quality of Life Enjoyment and Satisfaction Questionnaire–Short Form[Q_LES_Q(sf)] and the severity of anxiety symptoms will be assessed every month using Beck Anxiety Inventory scale.

The outcome shall be measured by the differences of scores obtained on the Beck Anxiety Inventory scale every month and the Q-LES-Q(sf) questionnaire every 3 months. These scores shall be compared at the baseline and end of treatment. Changes in the scales will be assessed using Friedman's test.

Discussion and conclusion:

The study shall help in finding out the influences of anxiety disorders on the social quality of life and also helps to prevent long-term complications. The further research on this topic adopting randomized controlled trial is recommended to refine the efficacy of homoeopathic medicines with strong evidence for improvement in social quality of life of individuals diagnosed with anxiety disorders.

Keywords: Anxiety disorders, social quality of life, Beck Anxiety Inventory scale, Q-LES-Q (sf) questionnaire, Homoeopathy.

INTRODUCTION:

1. BACKGROUND AND RATIONALE:

Anxiety disorders can have a profound impact on the social quality of an individual's life, affecting various aspects of their relationships, daily social interactions, and overall well-being. There are several ways in which anxiety disorders can influence the social quality of an individual. At early stages it will affect one person's confidence level which can be witnessed in their social performance. They may also develop lack of confidence in initiating or maintaining conversation with society, making friends, or participating in social activities which can manifest as a tendency to isolate oneself. Poor performance in social interaction brings them into a state of withdrawal from friends, family, and social events leading to social isolation. Anxiety disorders can strain relationships with family, friends, leisure time activities, romantic life and poor ability to perform in sexual activities. Excessive worry, irritability, and poor emotional understanding lead to misunderstandings among the couples, peers or in a family[1]. Individuals with anxiety disorders may develop avoidance behavior and misbelieve that they are unworthy. It can lead to limited social experiences, preventing the individual from fully participating in various aspects of competitive activities like academic excellence, work performance, group interactions and leadership skills. On long course of time it may lead to fear and negative impact of oneself resulting in poor social quality. Physical symptoms like sweating, trembling, dyspnoea, nausea, vomiting and palpitation may also contribute as a strong precipitating factor for anxiety symptoms leading to poor social quality of life. Chronic anxiety can contribute to low self-esteem. It's important

to note that the impact of anxiety disorders on social quality can vary widely among individuals and across different types of anxiety disorders. The severity of symptoms and the presence of co morbid conditions also contribute to the overall social impact. Treatment, including therapy and medication, can play a crucial role in addressing these social challenges and improving the individual's social quality of life.

The severity of symptoms and impairments in overall functioning were also significantly correlated with a low quality-of-life assessment score. A comprehensive understanding of the Beck Anxiety Inventory scale in patients with anxiety disorders is essential to provide information of the severity of anxiety symptoms. Q-LES-Q(sf) is designed to measure a patient's satisfaction and enjoyment in different areas of daily functioning. One potent psychosocial component best describes its factor structure. This is most frequently used in psychopharmacology and clinical trials.

This study aims to find out the severity of symptoms of anxiety disorders along with improvement in social quality of life score by using Individualized Homoeopathic Medicine. Observational studies suggest that Beck Anxiety Inventory (BAI) measures the somatic and cognitive symptoms of anxiety with high discriminant validity and helps in differentiating between those with and without an anxiety disorder. One Double-blind, randomized placebo-controlled, pilot trial mentioned the effectiveness of Individualized Homoeopathic Medicine in the treatment of GAD by using GAD-7 and HAM-A scale[1].A positive direction of anxiolytic effect was observed favoring homeopathy over placebo. Observational studies mentioned that individuals with GAD show less satisfaction with their quality of life than non-anxious adults in the community[2]. Recent literature, on QOL in anxiety disorders, with a focus on factors, mentions the relationship between anxiety and Quality of life[4]. Another study on Quality of life in anxiety disorders says about its relation to work and social functioning and dysfunction with regards to anxiety symptoms which reveals there is significant impairment of quality of life in patients with anxiety disorders [7].

The reliable studies supporting the efficacy of Homoeopathy for anxiety disorders are limited .The meta-analysis mention the impact of anxiety disorders on QOL by comparing anxiety disorder patients with nonclinical controls. Across multiple comparisons, with multiple measures of QOL, the results revealed a large effect size indicating poorer overall QOL among anxiety patients versus controls[13].The literature review findings also suggest that overall QOL impairment may be equivalent across the anxiety disorders, it has been

suggested that QOL in patients with anxiety disorders may be multidimensional.[12] In another literature review, the authority summarizes that the recent literature, published within the last 3 years, on QOL in anxiety disorders, with a focus on factors that may play a role in the relationship between anxiety and QOL[14].

MATERIALS AND METHODS

This study will be an open-label single-arm clinical trial planned to conduct at National Homoeopathy Research Institute in Mental Health, Kottayam, Kerala, India. Homoeopathy treatment will be given by the Principal Investigator and the case will be diagnosed by consultant psychiatrist. Supportive assistance in maintaining follow-ups shall be provided by the Principal Investigator. The study protocol is in accordance with the latest revision of the Helsinki Declaration on human experimentation and Good Clinical Practices in India. Although medicines proposed to be used during the study are known homoeopathic pharmacopoeia preparations. Necessary clearance of the Ethical Committee and Scientific Advisory Committee was obtained before undertaking the study. The trial is registered with the Clinical Trial Registry of India (CTRI/2023/12/060980). The protocol has been designed following guidance and approval by the Institutional Ethical Committee and Scientific Advisory board.

Rating scales Used:

The Beck Anxiety Inventory (BAI) is a 21-question multiple-choice self-report inventory that is used for measuring the severity of anxiety symptoms in adults over 17 years. The questionnaire includes the common symptoms of anxiety that the subject has experienced for the past few weeks such as numbness and tingling, sweating, and fear of the worst happening, anxiety regarding the future[10]. It is designed for individuals who are of 17 years of age or older and takes 5 to 10 minutes to complete. Several studies have found the Beck Anxiety Inventory to be an accurate measure of anxiety symptoms in children and adults.

The Q-LES-Q questionnaire, in both long and short form, is a widely used instrument for measuring QOL and satisfaction. Originally developed for using clinical trials and among trial participants with a wide variety of mental and medical disorders. It has been shown to offer high internal consistency, validity and reproducibility in non-psychiatric populations and in patients with a range of psychiatric illnesses. The Q_LES-Q total score was derived by summing scores from theirst 14Q_LES_Q(sf) items. Each score on a response scale ranging

from 1(very poor) to 5(very good). The raw total score which can range from 14-70 was expressed as a percentage of the maximum total score ranging from 0-100 for ease of interpretation, with a higher score indicating greater enjoyment or satisfaction[18].

SCREENING AND ENROLLMENT:

Individuals presenting with Anxiety symptoms from OPDs and other Peripheral units of NHRIMH, Kottayam, will be screened using the verbal screening form. On fulfillment of the necessary scoring the case will be referred to concern investigator and consultant psychiatrist for further confirmation of diagnosis and enrolment.

RECRUITMENT PROCESS AND INCLUSION CRITERIA:

The subjects who present with symptoms of GAD at Out Patient Departments and peripheral units of the National Homoeopathy Research Institute in Mental Health, Kottayam shall be screened with a verbal screening questionnaire, Beck Anxiety Inventory scale and (Q-LES-Q-(sf)) questionnaire at baseline. Since these scales are self-report measures, the subject should be able to understand the items and give their scoring in the given language (English). The screening format will be maintained by the investigator. After the screening, the consultant Psychiatrist will assess the case for diagnostic confirmation. Patients meeting the inclusion/eligibility criteria shall be given a detailed explanation of the project requirements and shall be invited to participate in the trial. A written informed consent will be taken from each subject and then, subjects qualified as per inclusion criteria will be enrolled. Detailed case-taking will be done in the case recording format. Basic routine investigations along with specific investigations will be done as per the need of the case to rule out other serious medical conditions.

Patients are eligible if they are: Aged between 18 to 65 years, Subjects of both sexes, Cases satisfying DSM-5 diagnostic criteria for GAD, Score of Q-LES-Q(sf)≥14. Subjects will be assessed at baseline with the Beck Anxiety Inventory scale, The Quality of life of the subjects will be assessed with Q-LES-Q (sf)

SAMPLE SIZE:

Assuming the recovery with Individualized Homoeopathic medicine mentioned in previous studies and due to lack of availability of data with similar studies the sample size of 30 is selected. Considering 20% drop out rate, 36 cases will be enrolled.

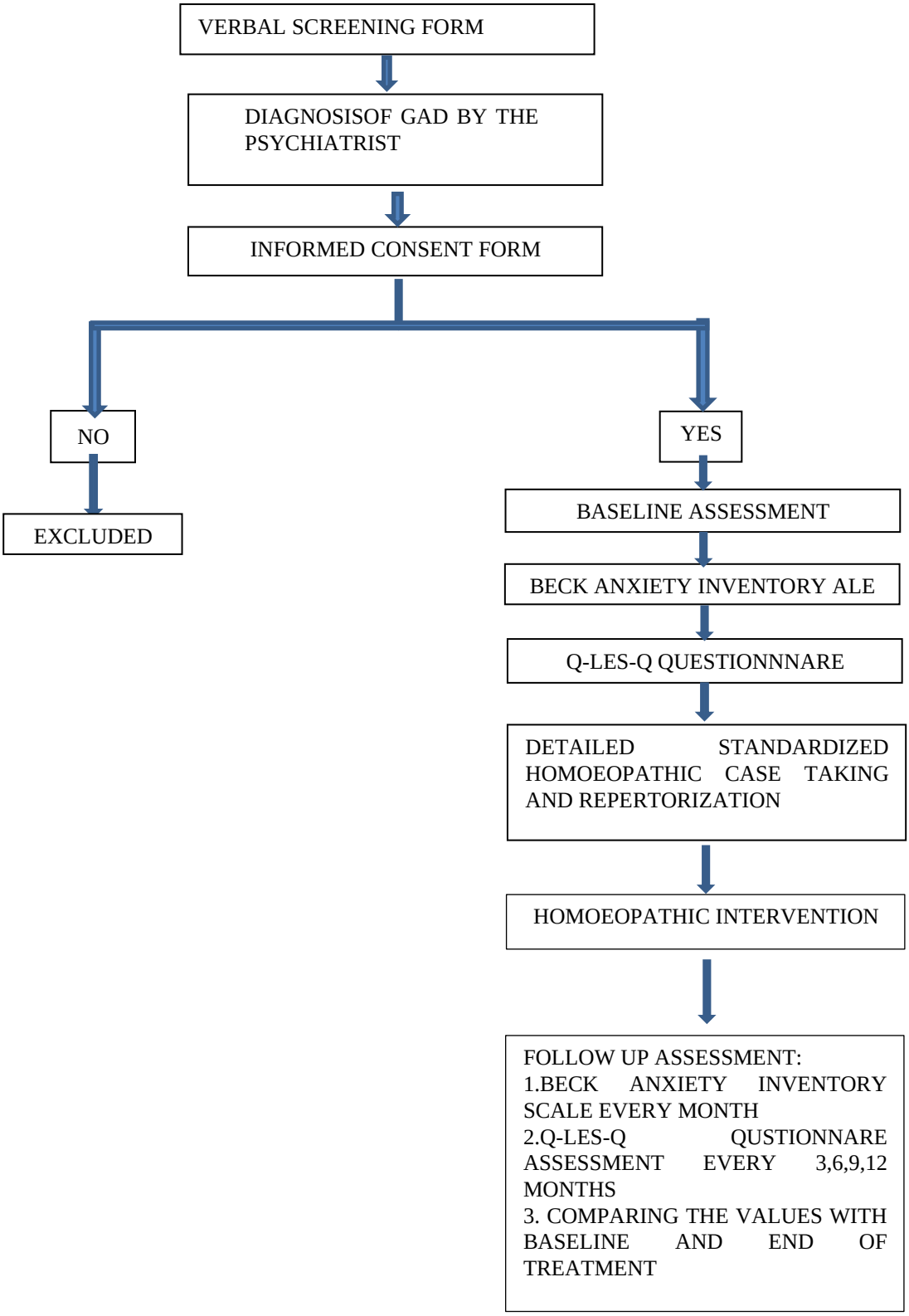

Fig – 01- FLOW CHART OF THE STUDY

INTERVENTION:

Homoeopathy

The investigator shall conduct an in-depth interview with the patient and bystanders. The case details will be interviewed in depth and recorded in the given Case Recording format (CRF), and based on further analysis and evaluation, totality will be erected. It will be followed by Repertorisation using the appropriate repertory and software. The final selection of remedy will be done after referring the Homoeopathic Materia Medica. Indicated medicine will be prescribed from 30C potency. The potency of the indicated medicine will be moderated as per the requirement. If improvement stops after a particular period, the next medicine will be repeated according to the needs of the patient. If no change takes place at all, the case will be retaken and a new remedy will be considered. In case of any acute ailments occurring during the course of the study, a acute remedy will be given based on acute totality and the data will be maintained separately for analysis

OUTCOME MEASURES:

The primary outcome will be improving the social quality of life and satisfaction in GAD using a Q-LES-Q(sf) questionnaire at the baseline following every 3 months and comparing the score at the end of the treatment. The secondary outcome is to understand the overall improvement in GAD symptoms using the Beck Anxiety Inventory scale**.**

CRITERIA FOR BASELINE AND FOLLOW UP ASSESSMENT:

Assessment of clinical trial study subjects for Generalized Anxiety Disorder will be done using Beck Anxiety Inventory scale at baseline and at every month. For assessment of social quality of life, Q-LES-Q(sf) questionnaire will be used at baseline and at every 3 months and at the end of the study. Internal consistency for the BAI = (Cronbach's α=0.92), Test-retest reliability (1 week) for the BAI = 0.75. In the Q-LES-Q questionnaire, the minimum raw score on the Q-LES-Q-SF is 14, and the maximum score is 70. Thus the formula for percentage maximum can also be written as (raw score -14)/56. Laboratory investigations shall be conducted as per the need of the case in order to exclude in any suspected serious medical conditions. The results at baseline and at the end of the study

would be compared and evaluated to determine how well a person's quality of life could be improved through individualized homoeopathic medicine. Details of the study timeline are given in the below Table.

TIMELINE OF THE STUDY:

Time	**Study period**						**Close out**
Eligibility screening	**Enrolment**	**Months**					
		3	**6**	**9**	**12**	**Every month**	
Eligibility screening	**+**	**-**	**-**	**-**	**-**	**-**	**-**
Informed consent	**+**	**-**	**-**	**-**	**-**	**-**	**-**
Intervention Homoeopathy	**+**	**+**	**+**	**+**	**+**	**+**	**-**
Assessment Verbal screening Form	**+**	**-**	**-**	**-**	**-**	**-**	**-**
Beck anxiety Inventory scale	**+**	**+**	**+**	**+**	**+**	**+**	**+**
Q-LES-Q (sf)questionnaire	**+**	**+**	**+**	**+**	**+**	**-**	**+**

Diagnostic Criteria for Generalized Anxiety Disorder (DSM-5)

A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months, about a number of events or activities (such as work or school performance).

B. The individual finds it difficult to control the worry.

C. The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms having been present for more days than not for the past 6 months)

D. The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

E. The disturbance is not attributable to the physiological effects of a substance(e.g., a drug of abuse, a medication) or another medical condition (e.g., hyperthyroidism).

F. The disturbance is not better explained by another mental disorder (eg.anxiety or worry about having panic attacks in panic disorder, negative evaluation in social anxiety disorder [social phobia], contamination or other obsessions in obsessive-compulsive disorder, separation from attachment figures in separation anxiety disorder, reminders of traumatic events in posttraumatic stress disorder, gaining weight in anorexia nervosa, physical complaints in somatic symptom disorder, perceived appearance flaws in body dysmorphic disorder, having a serious illness in illness anxiety disorder, or the content of delusional beliefs in schizophrenia or delusional disorder).

DATA COLLECTION:

Standard Case recorded format and Excel spread sheet shall be used for data capturing. Data recording shall be done through validated questionnaires/tools for outcome measures, such as Beck Anxiety Inventory scale-LES-Q questionnaire. Apart from these physical, psychological, clinical and demographic information of the patient shall also be noted.

Comparison of Q_LES_Q(sf)questionnaire score at baseline,3rd month,6th month,9th month,12 month.

symptoms	Baseline	3rd	6th	9th	12th	P value

STATISTICAL ANALYSIS:

Data obtained during the study would be verified and analyzed using STATCRAFT 2.0.3 software for outcome measurement. Beck Anxiety Inventory scale and Q-LES-Q will be assessed using Friedman's test. Changes in severity of disease according to Beck anxiety Inventory scale at baseline and end will be compared using marginal homogeneity test. P value ≤ 0.05 will be considered as statistically significant.

2. DISCUSSION:

The core symptoms of GAD are characterized by excessive worry and anxiety with significant impairment in social quality of life, which implies the association of GAD with the social quality of an individual. GAD is associated with impairment in Psychosocial functioning, role functioning, work productivity and quality of life.So the proper evaluation and treatment for GAD are needed along with clinical management and assessment scales. Studies mention that 92.1% of individuals with GAD have another lifetime comorbid Psychiatric disorder. The patients who have fulfilled the DSM-5 diagnostic criteria with age more than 16, with ability to speak and read English, and completion of informed consent. The assigned sample size (36) expected to be enrolled in the study for 6 months. After completion of the study, the data's obtained through standard rating scales will be recorded in the planned excel sheet for further study. Studies have shown better QOL with homoeopathic intervention in GAD. The GAD has poor quality of life and interventional studies need to consider QOL as one of the parameters for judging its effectiveness. Generalised anxiety disorder can be associated with substantial dysfunction[17].

3. CONCLUSION:

The present protocol also aims to assess and compare the quality of life of patients diagnosed with GAD. This study also emphasizes an overall improvement in quality of life of patients in Generalized Anxiety Disorder. The study aims to assess preliminary treatment outcomes in anxiety disorder, feasibility and safety of administering, and psychological and therapeutic measures for the management of anxiety disorders and improving the quality of life of person with anxiety disorders and also aims to reduce or minimize the risk of

publication bias and selective outcome reporting bias. This study also enables more explicit research in this particular topic.

The negative aspect which we expect from this study is the validity of the self-reporting data, no comparative group and limited sample size.

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5. COMPETING INTERESTS:

The authors declare that there are no competing interests.

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