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A STUDY PROTOCOL TO KNOW THE IMPACT OF INDIVIDUALIZED HOMOEOPATHIC TREATMENT ON SOCIAL QUALITY OF LIFE AND SATISFACTION IN WORKING ADULTS WITH DEPRESSION

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ABSTRACT

Objective:

Depression is considered as a mood disorder in which patient experiences loss of energy and interest, guilt, difficult concentration, loss of appetite and thoughts of death or suicide. Changes in activity level, cognitive abilities, speech and vegetative functions (such as sleep pattern and sexual activity) are the other common symptoms. The interpersonal, social and occupational functioning of the patient also gets impaired.[1]Social Quality of Life is the perceived quality of a person's social relationships and support, which influences their physical health and overall well-being. Good social quality of life helps working people manage stress better, build healthy relationships at work, and stay mentally and physically healthy.[2] Individualized homeopathic treatment using potentised remedies may contribute to significant improvements in the social quality of life in people diagnosed with depression.

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 working population with depression. The quality of life and burnout will be assessed baseline and every 3rd month using Quality of Life Enjoyment and Satisfaction Questionnaire–Short Form[Q_LES_Q(sf)] and Copenhagen burnout inventory (CBI) scale respectively. The severity of depression symptoms will be assessed baseline

and every month using Patient health questionnaire-9 (PHQ-9) scale. The outcome will be measured by the difference of the score obtained in PHQ-9 scale every month and Q-LES-Q(sf) questionnaire and CBI scale every 3months.These scores shall be compared at the baseline and end of the 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 depression among working population 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 in depression among working population.

Keywords: Copenhagen burnout inventory scale, Depression, Homoeopathy, Patient health questionnaire-9 scale, Q-LES-Q (sf) questionnaire, Social quality of life, Working population.

INTRODUCTION:

1. BACKGROUND AND RATIONALE:

Depressive disorder is a common mental disorder. It involves a depressed mood or loss of pleasure or interest in activities for long periods of time. Depression is different from regular mood changes and feelings about everyday life. It can affect all aspects of life, including relationships with family, friends and community. It can result from or lead to problems at school and at work.

An estimated 3.8% of the population experience depression, including 5% of adults (4% among men and 6% among women), and 5.7% of adults older than 60 years. Approximately 280 million people in the world have depression *(1)*. Depression is about 50% more common among women than men. Worldwide, more than 10% of pregnant women and women who have just given birth experience depression *(2)*. More than 700 000 people die due to suicide every year. Suicide is the fourth leading cause of death in 15–29-year-olds.[2]

This World Mental Health Day 10 October 2024, WHO is uniting with partners to highlight the vital connection between mental health and work. Safe, healthy working environments can act as a protective factor for mental health. Unhealthy conditions including stigma, discrimination, and exposure to risks like harassment and other poor working conditions, can pose significant risks, affecting mental health, overall

quality of life and consequently participation or productivity at work. With 60% of the global population in work, urgent action is needed to ensure work prevents risks to mental health and protects and supports mental health at work.[3]

Depressive symptoms and functional impairments are closely linked to reduced quality of life in the working population. PHQ-9 helps assess the severity of depression, while the Copenhagen Burnout Inventory (CBI) evaluates work-related burnout. Q-LES-Q(sf) measures satisfaction and enjoyment in daily life and is widely used in clinical and occupational mental health studies.

Evidence from randomized trials suggests that individualized homeopathic Q-potencies produce similar improvements as fluoxetine in patients with moderate to severe depression.[4]In a large observational study of 3,709 patients receiving homeopathic care, individuals with depression reported significant long-term improvements in quality of life after 24 months.[5]A pragmatic cohort multiple RCT in UK primary care showed that an offer of adjunctive homeopathic treatment led to a significant 1.4-point greater reduction in PHQ-9 scores at 6 months (95% CI 0.2–2.5, p = 0.019) compared to usual care alone, with sustained effects at 12 months.[6] In a 2-year observational study of patients receiving homeopathy, those with depression reported significant improvements in health-related quality of life and symptom burden.[7] These studies highlights the supportive evidence of effect of homoeopathy in depression.

A cross-sectional study found that in clinically depressed outpatients, CBI scores were significantly correlated with depression severity as measured by QIDS-SR, with fatigue and sleep disturbances emerging as key predictors of burnout.[8] In the recent prospective observational study of adults with major depressive disorder found significant improvements in Q-LES-Q(sf) scores from baseline to week 8, which strongly correlated with reductions in MADRS depression scores.[9]

Even though various studies on homeopathy for depression have shown positive outcomes and encouraged for further research, there is no specific study focusing on depression in the working population and its impact on quality of life and satisfaction. Addressing this gap, it is essential to understand how homeopathy can help in improving mental well-being, productivity and overall quality of life in working individuals suffering with depression.

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. The homoeopathic intervention in this study will be administered by the Principal Investigator, while diagnosis of each case will be confirmed by a qualified consultant psychiatrist. The Principal Investigator will be responsible for participant follow-ups throughout the study period. This research has been developed in alignment with ethical principles outlined in the latest version of the Declaration of Helsinki and conforms to Good Clinical Practice standards applicable in India. All medicines used are approved formulations listed in recognized homoeopathic pharmacopoeias. Prior to initiation, the study received approval from the Institutional Ethics Committee and Scientific Advisory Board. Additionally, the clinical trial has been officially registered with the Clinical Trial Registry of India (CTRI/2025/06/089325).

Rating scales Used:

Patient Health Questionnaire-9 (PHQ-9): The Patient Health Questionnaire-9 (PHQ-9) is a validated tool for assessing depression, scoring nine key symptoms from 0 (not at all) to 3 (nearly every day) over the past two weeks. The total score ranges from (0-27). The score ranges are as follows: (0-4) – no or minimal depression, 5–9: Mild depression,10–14: Moderate depression,15–19: Moderately severe depression ,20–27: Severe depression. Patients with ≥5 will be considered in this study.[10]

The Quality-of-Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q – SF): The Short Form version of the Quality-of-Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF) was designed to measure patients' subjective experience of enjoyment and satisfaction. The scoring involves summing only the first 14 items to yield a raw total score. The last two items are not included in the total score but are standalone items. Each item is rated from 1(very poor) to 5(very good). The raw total score ranges from 14 to 70. Patients with ≥14 will be considered in this study.[11]

Copenhagen Burnout Inventory (CBI): The Copenhagen Burnout Inventory (CBI) is a 19-item questionnaire with three sub-dimensions: personal burnout, work-related burnout, and client-related burnout. According to Kristensen's criteria of burnoutlevels, scores of 50-74 are considered moderate, 75–99 high, and a score of

100 is considered severe burnout.[12]

SCREENING AND ENROLLMENT:

Individuals presenting with depressive symptoms from OPDs and other Peripheral units of NHRIMH, Kottayam, will be screened using the verbal screening form. On fulfilment 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:

Subjects presenting with symptoms of depression at the Outpatient Departments and peripheral units of the National Homoeopathy Research Institute in Mental Health, Kottayam, will be initially screened using a verbal screening questionnaire, the Patient Health Questionnaire-9 (PHQ-9), the Copenhagen Burnout Inventory (CBI), and the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF) at baseline. The screening data will be documented and maintained by the investigator. Following the initial screening, a consultant psychiatrist will conduct a diagnostic evaluation to confirm the diagnosis. Individuals meeting the eligibility criteria will be provided with detailed information about the study and invited to participate. Informed consent will be obtained from each participant before enrolment. Eligible subjects will undergo detailed case-taking using the standard case record format. Routine baseline investigations, along with condition-specific investigations as needed, will be conducted to exclude other serious medical conditions.

Patients are eligible if they are: Cases satisfying ICD 11 diagnostic criteria for Depression, Age between 18-60 years, Subjects of working population, Subjects of both the sexes, Score of Q-LES-Q(sf) ≥14, Score of PHQ-9 ≥ 5.

SAMPLE SIZE:

There were no previously published studies to ascertain the action of Individualized Homoeopathic Medicine in improving the social quality of life and satisfaction in Depression among working population, sample size was calculated by assuming moderate effect size 0.5. A minimum sample of 32 cases is needed for attaining 95% confidence level and 80% power. Considering 15% drop out, 38 cases will be enrolled in the study.

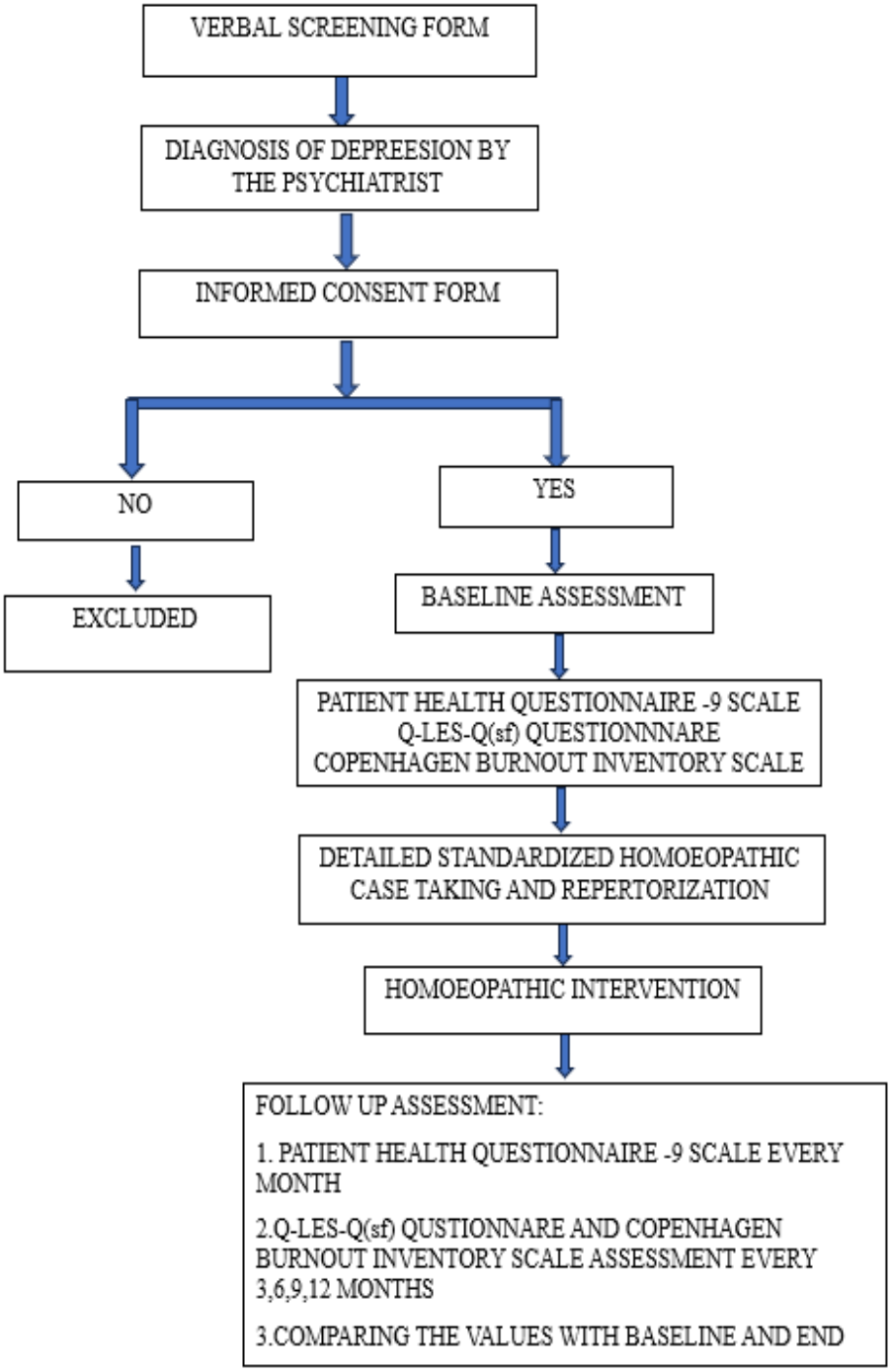

Fig: 01 FLOW CHART OF THE STUDY

INTERVENTION:

Homoeopathy

The investigator will carry out a thorough interview with both the patient and relevant informants to gather comprehensive case information. All findings will be documented using the Case Record Format (CRF). After a detailed evaluation, the totality of symptoms will be

determined. In continuation, repertorisation will be performed using suitable software and repertory tools. The most appropriate remedy will be selected with reference to the Homoeopathic Materia Medica. Treatment will begin with the selected medicine in 30C potency, and the potency may be adjusted according to the patient progress. If the patient's condition shows no further improvement after some time, the same remedy may be repeated, depending on the individual need. In the absence of any noticeable change, the case will be reassessed and a different remedy may be chosen. If any acute conditions develop during the study period, a suitable acute remedy will be prescribed based on the specific acute symptoms presented. Such cases will be recorded separately for further analysis.

OUTCOME MEASURES:

Primary outcome will be measured by the difference between the score obtained in Q-LES-Q(sf) questionnaire in the baseline and end of the treatment. Secondary outcome will be measured by the difference between the score obtained in Patients Health Questionnaire-9 scale and Copenhagen Burnout Inventory scale in the baseline and end of the treatment.

CRITERIA FOR BASELINE AND FOLLOW UP ASSESSMENT:

Assessment of study participants for symptoms of depression will be conducted using the Patient Health Questionnaire-9 (PHQ-9) at baseline and subsequently on a monthly basis. To evaluate social quality of life, Q-LES-Q(SF) will be used, while burnout levels will be assessed using the Copenhagen Burnout Inventory (CBI). Both Q-LES-Q(SF) and CBI will be administered at baseline, every three months, and at the end of the study period. Internal consistency for PHQ-9 = [Cronbach's α = 0.86 to 0.89]. Test-retest reliability (48 hours to 1 week): r = 0.84.[10] Internal consistency for Q-LES-Q(SF) [Cronbach's α = 0.90].Test-retest reliability (1-week interval): r = 0.86.[11] Internal consistency for CBI in each domain [Personal burnout: Cronbach's $\alpha \approx 0.87–0.90$ Work-related burnout: $\alpha \approx 0.85–0.87$ Client-related burnout: $\alpha \approx 0.80–0.85$]. Test-retest reliability (3–4 weeks): r = 0.73–0.83.[12]Laboratory investigations will be done as needed to rule out any serious medical conditions. Results from baseline and end of the study will be compared to assess improvements in quality of life with individualized homoeopathic treatment. 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**	
Informed consent	+	-	-	-	-	-	-
Intervention Homoeopathy	+	+	+	+	+	+	-
Assessment Verbal screening Form	+	-	-	-	-	-	-
Q-LES-Q (sf)questionnaire	+	+	+	+	+	-	+
Patient Health Questionnaire-9	+	+	+	+	+	+	+
Copenhagen Burnout Inventory scale	+	+	+	+	+	-	+

Diagnostic Criteria for Depression (ICD -11):

The concurrent presence of at least five of the following characteristic symptoms occurring for most of the day, nearly every day, during a period lasting at least 2 weeks is required for diagnosis of depression. At least one symptom from the affective cluster must be present. Assessment of the presence or absence of symptoms should be made relative to typical functioning of the individual.

Affective cluster

- Depressed mood as reported by the individual (e.g. feeling down, sad) or as observed (e.g. tearful, defeated appearance) (Note: in children and adolescents depressed mood can manifest as irritability.)
- Markedly diminished interest or pleasure in activities, especially those normally found to be enjoyable to the individual (Note: this may include a reduction in sexual desire.)

Cognitive-behavioural cluster

- Reduced ability to concentrate and sustain attention on tasks, or marked indecisiveness
- Beliefs of low self-worth or excessive and inappropriate guilt that may be manifestly delusional (Note: this item should not be considered present if guilt or self-reproach is exclusively about being depressed.)
- Hopelessness about the future
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation (with or without a specific plan), or evidence of attempted suicide.

Neurovegetative cluster

- Significantly disrupted sleep (delayed sleep onset, increased frequency of waking during the night, or early morning awakening) or excessive sleep
- Significant change in appetite (diminished or increased) or significant weight change (gain or loss)
- Psychomotor agitation or retardation (observable by others, not merely subjective feelings of restlessness or being slowed down)
- Reduced energy, fatigue or marked tiredness following the expenditure of only a minimum of effort

The symptoms are not better accounted for by bereavement.

The symptoms are not a manifestation of another medical condition (e.g. a brain tumour), and are not due to the effects of a substance or medication on the central nervous system (e.g. benzodiazepines), including withdrawal effects (e.g. from stimulants).

The clinical presentation does not fulfil the diagnostic requirements for a mixed episode.

The mood disturbance results in significant impairment in personal, family, social, educational, occupational or other important areas of functioning. If functioning is maintained, it is only through significant additional effort.

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 Patient Health Questionnaire-9, Q_LES_Q(sf)questionnaire and Copenhagen Burnout Inventory scale. 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:

Baseline characteristics will be represented using Graphs and tables. Changes in Q-LES-Q(sf) questionnaire, Patient Health Questionnaire-9 (PHQ-9) scale and Copenhagen Burnout Inventory (CBI) scale over a period of one year will be assessed using Friedman test. $P \leq 0.05$ will be considered as statistically significant**.**

2. DISCUSSION:

The core symptoms of depression are characterized by low mood, fatigue and loss of interest with significant impairment in social quality of life, which implies the association of depression with the social quality of an individual. Depression is associated with impairment

in Psychosocial functioning, role functioning, work productivity and quality of life. The proper evaluation and treatment for depression among working population are needed along with clinical management and assessment scales. The patients who have fulfilled the ICD- 11 diagnostic criteria and who are currently employed, possess the ability to understand English/Local language (Malayalam), and have provided the informed consent. The assigned sample size (38) expected to be enrolled in the study within the enrolment period of 6 months. After completion of the study, the data's obtained through standard rating scales will be recorded in the planned excel sheet. Many studies have shown better QOL with homoeopathic intervention in depression. Although several studies have reported positive outcomes of homeopathy in depression, there is a lack of specific research focusing on its impact on quality of life and satisfaction among the working population. Addressing this gap is crucial to explore how homeopathy can enhance mental well-being, productivity, and overall life quality in employed individuals.

3. CONCLUSION:

The present protocol aims to assess effect of individualised Homoeopathic similimum in improving the quality of life of individuals diagnosed with depression in working population. It focuses on evaluating overall improvements in their well-being through homeopathic treatment. The study will explore preliminary treatment outcomes, the feasibility, and the use of therapeutic approaches for managing depression effectively. Additionally, it aims to reduce the risk of publication bias and selective reporting, while encouraging further research in this area.

One of the anticipated limitations of this study is the reliance on self-reported data, which may affect the accuracy of the findings. Additionally, the absence of a comparison group and the small sample size may limit the generalizability of the results.

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5. COMPETING INTERESTS:

The authors declare that there are no competing interests.

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