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A PROSPECTIVE INTERVENTIONAL STUDY EVALUATING THE EFFICACY OF INDIVIDUALIZED HOMOEOPATHY ON AUTISM SPECTRUM DISORDER- STUDY PROTOCOL

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ABSTRACT:

BACKGROUND: Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by impairments in social communication and restricted and repetitive activities and interests. Symptoms usually manifest before the age of 5 years. Many mainstream interventions for autism focus on symptom management rather than holistic improvement. Evidence regarding the effectiveness of homoeopathic interventions in treatment of ASD to improve the quality of life of children is limited. This study aims to determine the effectiveness of individualized homoeopathic medicine in autism spectrum disorder to assess the improvement in the quality of life.

METHODS: This clinical trial enabled us to determine the extent of improvement in a child after receiving homoeopathic treatment. Here we compare each child's baseline and post- treatment status. We focus on children with autism aged 3 to 12 years. The subjects are taken into study for a period of 1.5 years, and followed up for a 6-month period. The scales used are INCLEN (International Clinical Epidemiology Network) tool to confirm their diagnosis and ADL (Activities of Daily life) scale to measure how much their daily life and independence have improved.

DISCUSSION: This study demonstrates that homoeopathic intervention may improve the quality of life of children with autism spectrum disorder. Unlike previous research that limited its scope to symptom management, this approach proves that individualized homoeopathic medicines, which are carefully selected based on a child's unique characteristics can achieve a holistic transformation. When integrated with appropriate therapies, homoeopathy empowers children to master essential daily activities.

KEYWORDS: Autism Spectrum Disorder, Individualized Homoeopathy, Clinical Trial, INCLEN, ADL

I. INTRODUCTION

Autism Spectrum disorder (ASD) is phenotypically a group of neurodevelopmental syndromes, characterized by impairments in social communication and restricted and repetitive behavioural patterns [(1)]. According to ICD-11, ASD is characterized by persistent deficits in the ability to initiate and to sustain reciprocal social interaction and social communication, and by a range of restricted, repetitive, and inflexible patterns of behaviour and interests [(2)]. The three areas of impairments in ASD are reduced to two: namely a social- communication domain and a behavioural domain including fixated interests and repetitive behaviour[(3)]. The onset is usually within the three years. Developmental regression in autism is a common

phenomenon of unknown origin. There is regression in language, social skills and play observed between the first and third years of life. [4] The prevalence of autism spectrum disorder has been increasing significantly affecting many individuals [3]. Recent studies show that the estimated prevalence of ASD has been increasing in the US, from 1.1% to 2.3% in 10 years, which is likely associated with changes in diagnostic criteria, improved performance of screening and diagnostic tools, and increased public awareness. [5] A study mentions that the male: female ratio is said to be 3-4:1 based on the descriptions on ASD observed by Leo Kanner and Hans Asperger. Although those were small clinic samples, this male bias was also seen in the early epidemiological studies of classic autism with concurrent intellectual disability. [6]

According to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), individuals with ASD tend to respond inappropriately in conversation and lack the ability to build relationships. They often engage in a series of abnormal routines and develop inappropriate obsessions on particular items. [7] Conventional treatments focus on behavioural therapies and medications. Many individuals with autism spectrum disorder and their families adopt alternative and complementary approaches for symptom management and improve their quality of life[1].

One of the most frequently studied conditions in the field of mental health today is autism spectrum disorder (ASD). The number of cases has risen dramatically, and various hypotheses have been proposed to explain this phenomenon [8]. Early intervention of ASD helps to access more intervention and to demonstrate better verbal and overall cognition at school. They are more likely to attend mainstream schools and require less ongoing support than children diagnosed later. Earlier diagnosis is important to promote more positive outcomes at school age. [9] Compared to people without ASD, individuals with ASD are said to have higher rates of depression, anxiety, sleep difficulties and epilepsy as co-morbidities. First-line therapy includes behavioural interventions and may be treated with specific behavioural therapy or medication [4] Although successful interventions have been developed that target specific skill deficits, often exhibited by children with autism, many of those interventions are exclusively behavioural in nature, and do not address the cognitive components of presenting problems. Cognitive-Behavioural Therapy (CBT) is used to address issues related to ASD nowadays. [10]

II. OBJECTIVES:

The objectives of the study are as follows:

- To evaluate the efficacy of individualized homeopathic treatment in children with autism spectrum disorder.
- To determine the quality of life of such individuals using ADL scoring

III. METHODS/DESIGN

This clinical trial is planned in OPD, IPD and rural centres of Sarada Krishna Homoeopathic Medical College, Kulasekharam, Tamil Nadu, India. The sample size of the study was calculated as 34. The finalized protocol was subjected to Institutional Ethics Committee for approval. Further review of the protocol and final approval from the university were obtained. The CTRI registration number is CTRI/2025/08/093036.

PARTICIPANTS:

- Age Group: 3-12 years
  Children between 3-12 years diagnosed with autism spectrum disorder based on DSM-5 and diagnosed using the INCLEN scale were included in the study.
- Both sexes are included.
- Children receiving concurrent conventional interventions during the study period will be excluded.

STUDY DESIGN:

- Cases presenting with autism spectrum disorder will be taken from OPD, IPD and rural centres of Sarada Krishna Homoeopathic Medical College.
- Diagnosed using INCLEN and quality of life assessed using ADL scoring
- After case taking, the case is analysed and individualized homoeopathic medicine is prescribed.

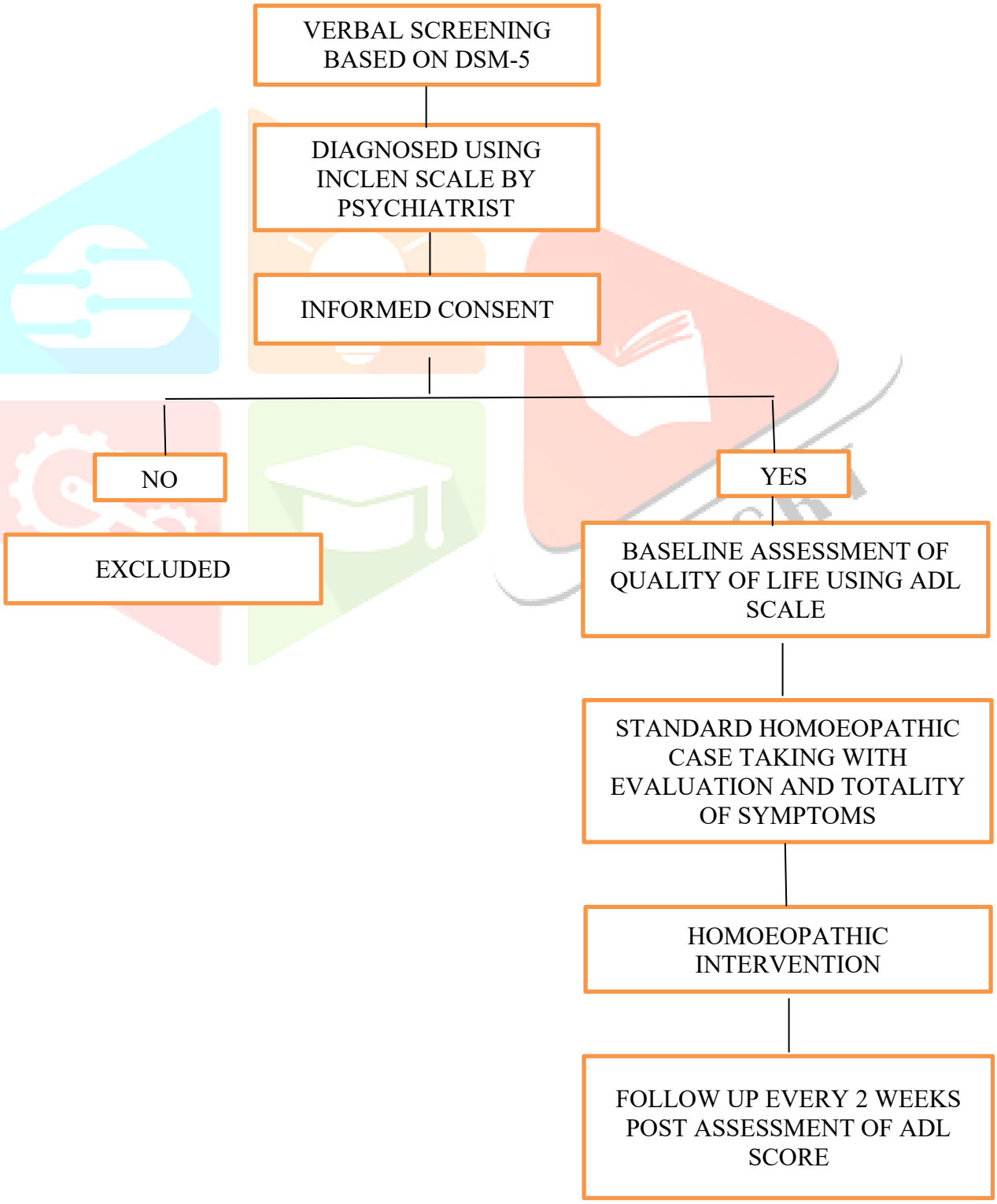
DATA COLLECTION:

The data will be collected using interview technique including case taking based Organon of medicine, in a pre-structured format. The diagnosis is made using the INCLEN scale, followed by baseline assessment using ADL. The data will be collected from the informant and through the physician's observation.

OUTCOME MEASURES:

The outcome of the treatment after individualized homoeopathic medicine will be assessed using the ADL score. The assessment will be performed pre- and post- treatment. The follow ups will be conducted at 2 weeks interval for a period of 6 months.

The flowchart of complete study (figure 1):



IV. STATISTICAL ANALYSIS:

Statistical evaluation of the results was performed using descriptive and inferential methods. Descriptive analysis provided an overview of the study population, while a paired t-test was used to measure the statistical significance of changes in ADL scores from baseline to the end of the treatment period. Data will be analyzed using SPSS software.

V. ETHICAL ISSUES:

The study protocol was approved by Institutional Ethics Committee of Sarada Krishna Homoeopathic Medical College, Kulasekharam, Tamil Nadu. Written informed assent/consent will be obtained from the participants/ participant's parents/guardians prior to study enrolment.

VI. DISCUSSION AND CONCLUSION:

This study aims to evaluate the efficacy of individualized homoeopathic medicines in treating ASD and to assess the improvement in the quality of life of children with ASD. Previous studies to understand the difficulties of parents of children with ASD observed certain difficulties in executing ADL in children by their parents, major finding was most parents reported that eating and toileting activities are the most affected areas in execution and difficult to manage. (11)

The main drawback of the study which can be observed in this study is that the 6-month time duration may not be sufficient for assessing the improvement in quality of life of individuals, especially for those diagnosed with moderate and severe ASD. In addition, no comparison groups are included in the study.

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