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Efficacy of Vijaya Ghrita in Comparision to Brahmi Ghrita on Specific Learning Disability in Children: An Open Labelled Randomized Controlled Clinical Trial

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ABSTRACT

INTRODUCTION: Specific Learning Disabilities (SLDs) are neurodevelopmental conditions, typically seen in school aged children, characterized by impairment in at least one of the three major areas; reading, written expression, and/or math. SLD can lead to have academic disadvantages and often act as a precursor to psychiatric comorbidities such as anxiety and depression. The cascading effects of Dyslexia can adversely affect the child's self-esteem, future goals, peer and family relationships and child's ability to progress through subsequent developmental stages. With the available references in the Ayurveda classics, learning or acquisition of knowledge *(jnanaotpatti*) is a result of successive and complex interaction and coordination of *indriya* (cognitive and motor organs), *indriyartha* (sense organs), *mana* (psyche), *atma* (soul) and *buddhi* (intellect). Above all, the function of these factors is bound by *tridosha* (fundamental body bio elements- *vata, pitta* and *kapha)* and *triguna* (Psychic constitution- *Satva, rajas* and *tamas*) in a specific coordination and balance. Any disturbance in these *tridosha* and *triguna* will cause disorder in functioning of *indriya*, *mana and buddhi* leading to impaired learning or SLD. Previous studies have shown that *Brahmi ghrita* was found to be effective in SLD in school going children. Thus, the present study evaluates the efficacy of *Vijaya ghrita*, mentioned in *Basavarajeeyam Vimsham Prakaranam* in SLD in children aged 8 to 15 years.

METHODS: This is an open labelled, randomised controlled clinical trial with 32 participants who have been diagnosed as a case of Specific Learning Disability (SLD) using NIMHANS SLD Battery. Trial

group will receive *Vijaya ghrita* at the dosage of 6g per day for age group 8 to 11 years and 10 g per day for 12 to 15 years with hot water as *anupana*. Control group will receive *Brahmi ghrita* in the same dosage with hot water as *anupana*.

DISCUSSION: The study is expected to show that the intervention of *Vijaya ghrita* is as effective as *Brahmi ghrita* in the Management of Specific Learning Disability in Children aged 8 to 15 years.

KEYWORDS: *Brahmi ghrita*, *Manas*, Specific Learning Disability, *Vijaya ghrita*.

1. INTRODUCTION

Specific Learning Disabilities (SLDs) are neurodevelopmental conditions, typically seen in school aged children, characterized by impairment in at least one of the three major areas; reading, written expression, and/or math.[1] SLD is one of the benchmark disabilities under the Rights of persons with Disability act, 2016 which ensures right to free education till 18 years.[2] DSM (Diagnostic and Statistical Manual Mental Disorders)- 5 estimates the prevalence of all learning disorders to be about 5% to 15% worldwide. Among children in USA, prevalence of SLD was found to be 9.7%. In India, the prevalence of SLD varies from 3% to 10%.[3] Specific Learning Disability can occur in 1.6-15% of Indian Children and have profound academic and psychological consequences. [1]

SLD can lead to have academic disadvantages and often act as a precursor to psychiatric comorbidities such as anxiety and depression. The cascading effects of Dyslexia can adversely affect the child's self-esteem, future goals, peer and family relationships and child's ability to progress through subsequent developmental stages.[4]

With the available references in the Ayurveda classics, learning or acquisition of knowledge (*jnanaotpatti*) is a result of successive and complex interaction and coordination of *indriya* (cognitive and motor organs), *indriyartha* (sense organs), mana (psyche), *atma* (soul) and *buddhi* (intellect).[5] *Indriya* and *Indriyartha sannikarsha* refers to the harmonious contact between sense organs and their respective objects, which is essential for proper perception and cognition. When this coordination is disturbed, it leads to impairment in any of the factors of *buddhi*. Sankhya shastra has narrated 4 functions of buddhi, they are- *aalochana* (Perception), *manana* (Contemplation), *abhimana* (Pride) and *avadharana* (Determination).[6] This impairment in *buddhi* causes defects in *jnanotpatti.* Above all, the function of these factors is bound by *tridosha* (fundamental body bio elements- *vata, pitta* and *kapha*) and *triguna* (Psychic constitution- *Satva, rajas* and *tamas*) in a specific coordination and balance. Any disturbance in these *tridosha* and *triguna* will cause disorder in functioning of *indriya*, *mana* and *buddhi* leading to impaired learning or SLD. [4]

Although SLD cannot be cured, there are interventions for SLD by which the children can adapt, accomplish academic achievement, and lead meaningful lives.[3] The intervention to Specific Learning Disability consists of remediation, accommodation and modification.[7] Remedial training is the main form of intervention. Furthermore, effective evidence-based interventions are needed to enrich the SLD children w.s.r to cognition. Ayurveda treatment principles can help in the management of learning disability by bringing back the impaired *dosha* (humors), *dushya* (that which vitiates) to normalcy, also enhances cognition. Considering the therapeutic effect of the ingredients present in *Vijaya Ghrita*[8], present clinical study intends to evaluate its effect on children with SLD.

2. OBJECTIVES

Primary objective

To evaluate the efficacy of *Vijaya Ghrita* in improving reading, writing, comprehension, visual-motor skills, arithmetic, memory and attention in children suffering with Specific learning disability compare its efficacy with *Brahmi Ghrita* and using NIMHANS SLD battery.

Secondary objective

To evaluate the efficacy of *Vijaya ghrita* in improving the overall School performance of children suffering with Specific Learning Disability and compare its efficacy with *Brahmi Ghrita* using NIMHANS SLD battery.

STUDY DESIGN

Minimum 32 children attending outpatient department and inpatient department of Kaumarabhritya of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH), Bengaluru who are fulfilling the inclusion criteria and willing to participate in the study under the parental assent or consent will be recruited for study for a period of 60 days. 32 children will be randomly divided into 2 groups namely Group A(16 children) and Group B (16 children). Group A (Study group) will be administered with *Vijaya ghrita* in a dose of 6g for 8-11 years and 10g for 12-15 years with hot water as *anupana* after food twice daily. Group B (Control group) will be administered with *Brahmi ghrita* in a dose of 6g for 8-11 years and 10g for 12-15 years with hot water as *anupana* after food twice daily. Assessment will be done using NIMHANS SLD battery by Clinical Psychologist. Statistical analysis will be done by considering the data of 0 (BT) and day 60 (AT) by using suitable test.

STUDY SETTING

Outpatient and Inpatient department of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.

STUDY DURATION

Total duration of the study is 60 days.

ELIGIBILITY CRITERIA

Eligibility Criteria: ICD-10-CM Diagnosis Code F81.0

Written Informed Consent shall be taken prior to participating in the study

INCLUSION CRITERIA

Children with Specific Learning Disability belonging to the age group of 8-11 years and 12-15 years screened using NIMHANS SLD battery for Learning Disabilities, with IQ>90, after getting consent from their parents.

EXCLUSION CRITERIA

1. Children having speech and hearing defects
2. Children having seizures Children having other systemic illness
3. Children having mental retardation
4. Children with IQ < 90
5. Children with Autism and ADHD Children with emotional and conduct disorder

INTERVENTION

The children in the study group will receive *Vijaya ghrita* in the dosage of 6 g per day for children aged 8 to 11 years and 10 g per day for children aged 12 to 15 years with hot water as *anupana* before food, twice daily for a period of 60 days.

The children in the control group will receive *Brahmi ghrita* in the dosage of 6 g per day for children aged 8 to 11 years and 10 g per day for children aged 12 to 15 years with hot water as *anupana* before food, twice daily for a period of 60 days.

Detailed study schedule is mentioned in table 1.

Table 1: STUDY SCHEDULE

Study event	Baseline	Day 0	Day 30	Day 60
IQ assessment, Autism and ADHD assessment and Emotional and behavioural assessment.	✓			

Informed consent	✓			
Demographic Data	✓			
Intervention	✓	✓	✓	✓
Follow up			✓	✓
Assessment by NIMHANS SLD Battery		✓	✓	✓
Assessment of Overall school performance by NIMHANS SLD Battery				✓
Drug Compliance	✓	✓	✓	✓
Rescue medication (if required)		✓	✓	✓
Assessment of Adverse events		✓	✓	✓

Discontinuation/Modification criteria:

To alleviate any emergency, the use of rescue medication is permitted as per the wisdom/discretion of the Principal Investigator. However, the same will be documented in appropriate Column in the Case Record Form.

Adherence monitoring strategy :

Patient is advised to keep track of symptoms and report via electronic media.

OUTCOMES

Primary outcome measure

Improvement in reading, writing and mathematical abilities in children suffering with Specific learning disability using NIMHANS SLD battery.

Secondary outcome measure

Improvement in overall school performance of children suffering from Specific Learning Disability using NIMHANS SLD battery.

SAMPLING SIZE

Sample size is calculated using Standard Deviation from previous study

N = 2(SD) 2 x (Z(1-α) +Zȝ)2 / d2

Standard Deviation = 2.7614

Zȝ = Power of the study = 0.84

Z(1-α) = Level of confidence = 1.96

d = 3%

N= 2(276)2*(1.96+0.84)2/ (300)2

=152352*7.84/90000 =13.27 =14

Sample size for the current study will be 14

Considering 10% dropout rate N=n/(1-d) i.e 2

Hence, For current study, sample size (N)= 16 for a single group; So, Total=32

Hence, for the current study sample size (N)= 32

16 samples in each group will be taken for the present study.

RECRUITMENT

Study group: 16 children between age group of 8-15 years of either sex, having signs and symptoms of Specific Learning Disability will be selected from OPD and IPD of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.

Control group: 16 children between age group of 8-15 years of either sex, having signs and symptoms of Specific Learning Disability will be selected from OPD and IPD of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.

ALLOCATION AND CONCEALMENT

Random allocation using computer generated random tickets which will be kept labelled in a sealed cover, to be opened in front of guide while starting intervention.

3. METHODS

Current research will be an Open label, interventional, prospective randomised controlled clinical trial.

Data Collection Method

Data collection will be carried out with a customised Case Report Form (CRF) and initial IQ Assessment, Autism and ADHD screening and emotional and behavioural screening. Children will be assessed for SLD using NIMHANS SLD Battery.

Data Management

Specific Case Report Form (CRF) will be used to collect detailed data and later it will be exported to MS Excel and statistical analysis will be done using IBM SPSS Version 26.

STATISTICAL ANALYSIS

For statistical analysis, the data will be obtained using Case Report Form (CRF) designed by incorporating all aspects for the study and will be compiled on to a MS Office Excel Sheet. Data will be tabulated and analyzed using SPSS (Statistical package for social sciences) version 26.

Descriptive Statistics:

Demographic data and other relevant descriptive statistics expressing in frequency (f), percentile (%), Range, Median In the present study assessment parameter considered for the study are ordinal which will

be expressed in mean, standard deviation, and standard error. The data generated is subjected to normality test with Shapiro Wilk test, if normality test is passed, parametric test would be employed otherwise non parametric test is employed.

Inferential Statistics:

The assessment parameters include qualitative and quantitative data. Level of significance: P<0.05 will be considered for the study. The study participants will be grouped into intend to treat and per protocol group. The data from the intend to treat group will be assessed for safety and data from per protocol group will be assessed for efficacy. The data would be subjected to normality test by Shapiro Wilk's method. If normality test is passed parametric analysis would be done if not non- parametric tests would be employed.

Non-parametric test:

Subjective data for within the group comparison

Friedman's test will be implied followed by post hoc Wilcoxon signed rank test. For between the group comparison

Mann Whitney U test will be employed.

Parametric tests: Numerical data will be assessed through:

Paired t test will be implied for within the group Unpaired t test for between the groups.

EFFECT SIZE

Magnitude of the test will be evaluated and calculated by Cohen's D effect size. The Parametric results of the two groups can be compared and magnitude of efficacy by calculating effect size (standardized mean difference of an effect) and expressed as Cohen's d (interpretation is to refer to effect sizes as small (d = 0.2), medium (d = 0.5), and large (d = 0.8))

Data Monitoring

The researcher and guide will monitor data, ensures adherence to the treatment protocol, tracking adverse effects, and managing participant enrolment.

Adverse effect Management and Safety measures

Although there are no anticipated serious side effects, any unexpected events that may come across during the study will be documented and notified to the concerned authority. Prior to the study, informant shall be asked to disclose any known allergies. All significant adverse events will be recorded in final report.

Ethical issues and Informed consent

Ethical approval for the trial was obtained from the Institutional Ethics Committee and SDMIAH on May 16th, 2024 (Ref: SDMIAH/IECI59/2024) and was registered in the Clinicals trial registry of India (CTRI) on 31st January 2025 (CTRI/2025/01/098629). The study will adhere to ethical principles outlined in the

Declaration of Helsinki. Written informed consent will be obtained prior to the trial. Participation will be entirely voluntary, with the option to withdraw at any point of time. Patient will be kept strictly confidential. In view of any adverse events, appropriate guidance will be provided.

Study Status

Open for recruitment

Dissemination

Upon completion of the trial, a research paper outlining the original findings will be published in an open access indexed journal for publication to facilitate wider scientific research.

4. DISCUSSION

Specific Learning Disability (SLD) is a prevalent problem in the society due to which the child is unable to cope up with regular academics. It is the need of the hour to recognise, identify and help in the management of students who exhibit symptoms of SLD. The current study with a standard control group will open new avenues for the management of students with SLD. Thus, it opens doors for new research and also helps in enhancing the quality of life of SLD children.

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