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A RANDOMIZED CONTROLLED STUDY TO ASSESS THE EFFICACY OF *ABHAYAM GHRITHA, VACAYASHTYAHWADI CHOORNA* AND SPEECH THERAPY IN CHILDREN WITH DELAYED LANGUAGE MILESTONES

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ABSTRACT

Background: Developmental disabilities are now a matter of global public health concern. With the increasing prevalence of developmental disabilities, benefits of early interventional services are inevitable to lessen the burden of associated behavioral problems. In India, Ayurveda significantly outstands among the complementary and alternative systems of medicine. Hence the study is proposed to determine the effectiveness of Ayurveda intervention in children with delayed language milestones.

Methods Ninety children with speech and global developmental delay will be enrolled in a randomized controlled trial to three groups. The primary outcome measure was the Receptive-Expressive Emergent Language scale (REELS) and secondary outcome measures include improvement in Social and communication skill, concentration and attention level with improvised school performance through Denver Development Scale. Interventions will be continued for three months and assessments were made on 30th day, 60th day, 90th day with a follow up assessment on 120th day after intervention. Intention to treat design was used to analyze the data collected.

Expected Outcome The anticipated outcome of the trial is to enhance the reversal of speech developmental delay through ayurveda interventions, with beneficial effects on behavioral, social and communication skills of the children.

Discussion The holistic approach of ayurveda through combined treatment module incorporating medicinal interventions like *Abhayam Ghritham, Vachayashtyahwadi Choornam* and speech therapy helps in improving the quality of life of the child along with treatment for the affected domain.

Keywords: *Abhayam Ghritham, Vachayashtyahwadi Choornam,* Speech Therapy, speech developmental delay

INTRODUCTION:

Developmental disabilities are now a matter of global health concern wherein the Indian pediatric population is at a higher risk of developmental disabilities as per the estimates of United Nations Children's Fund (UNICEF) profile of 2011 [1]. According to latest reports it is estimated that globally 52·9 million children (95% uncertainty interval [UI] 48·7–57·3; or 8·4% [7·7–9·1]) below 5 years of age are affected with developmental disabilities in 2016 [2]. The Global prevalence per 100 000 population of developmental disabilities among children younger than 5 years in 2016 is represented in figure 1. Studies have shown that developmentally delayed children with early diagnosis

obtain more optimization in their developmental trajectory than those diagnosed later in their life [3]. Early recognition of children with developmental problems is therefore important [4]. Developmental delay occurs when a child exhibits a significant delay in the acquisition of milestones or skills, in one or more domains of development (i.e., gross motor, fine motor, speech/language, cognitive, personal/social, or activities of daily living) [5]. A significant delay is defined as a difference of 25 percent or more from the rate expected, or a discrepancy of 1.5 to 2 standard deviations (SD) from the age expected norm [6]. Children with developmental disabilities are more vulnerable groups of the population [7].

Speech and language development is the widely used communicating tool. It is inevitable in adding to the overall development of children mainly in cognitive, social – emotional and adaptive development [8]. Early intervention to speech and development delay may reduce the severity of language delays and improves academic performance in school [9]. Delay in acquisition of developmental skills is often an early indicator of pervasive developmental problems and future learning disability [10]. The anticipated outcome of this trial is to enhance the reversal of speech developmental delay by administering *Abhayam Ghritham*, *Vachayashtyahwadi Choornam* and speech therapy in diagnosed children of 2-5 years of age.

OBJECTIVES:

To assess the comparative efficacy of *Abhayam Ghritham*, *Vachayashtyahwadi Choornam* and speech therapy as standalone treatments and in combination, in children with speech developmental delay assessed by global developmental delay criteria.

TRIAL DESIGN:

The current study is an open-label randomized controlled clinical trial (n=90) with random allocation (1:1:1) through random number table method. The total period of intervention will be for 90 days, wherein the assessment will be done at baseline (0^{th} day), 2 interim assessments (30^{th} day and 60^{th} day) followed by an end-line (90^{th} day) and a follow up assessment on 120^{th} day. The details of the study are described in table 1.

METHODOLOGY:

This protocol was written in accordance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) to improve the quality of reporting [11].

STUDY DESIGN:

The current study is a randomized controlled trial and children are enrolled to three groups through random number table method with random allocation 1:1:1. The study is conducted at the outpatient unit of department of Kaumarabhritya at VPSV Ayurveda College Hospital, Kottakkal are enrolled to the study.

INCLUSION CRITERIA:

The children of either gender, aged between two and five years, diagnosed having speech developmental delay assessed by global developmental delay criteria will be included in the study. The diagnosis and screening of the selected children will be done by pediatric psychologist and speech language pathologist.

EXCLUSION CRITERIA:

The Children diagnosed autism spectrum disorders, fragile x syndrome, mental

retardation, seizure disorders, down's syndrome, sensory loss, oro-facial abnormalities and children below the age of 2 years and above 5years will be excluded from the study.

INTERVENTION:

The participants in the trial will receive a multi-modular intervention comprising of poly-herbal Ayurveda formulations and speech therapy according to the group allocation. Patient adherence to the trial setting will be ensured through monthly follow up and interim phone calls. The description of intervention plan is shown in table 2.

Outcome (Primary and Secondary):

Baseline, two interim and end-line assessments followed by one month follow up data will be collected from the parents of recruited children during the time points. The expected primary outcome is the improvement in speech assessed through Receptive-Expressive Emergent Language scale (REELS). The secondary outcome expected is an improvement in the Social and communication skill, concentration level and scholastic performance of the child with increased attention level through Denver Development Scale.

Sample size:

Using Simon's randomized phase II design formula $f(i) = [B(i,p,n)]^{k-1} - [B(i-k,p,n)]^{k-1}$, the total sample size of the current study is randomly chosen to 90 participants. For statistical significance, considering p=20%, d=20% , power =0.9, $\alpha = 0.05$ and k = 3, sample size for each group was calculated as n=26. Taking drop outs into consideration, the sample size was taken as n=30 per group. After receiving the informed assent from parents of participants, they are allocated randomly through random number table method (1:1:1) into three groups - Group 1, Group 2 and Group 3 each constituting of 30 participants. The details of the participant flow are outlined in Figure 2

Recruitment:

The children attending the outpatient department of hospital will be screened for the inclusion and exclusion criteria and diagnosed children were randomly assigned to the trial by the research scholar of the study. The parents of the participants will be detailed regarding the purpose of the study, procedures to be followed throughout including the risks and benefits. Assents stating willingness of the participants to take part in the study were obtained from the parents after providing detailed clarifications to the parental queries regarding the study. The parents are also informed regarding the willful withdrawal from the study at any stage and the reason will be duly recorded.

Data Collection:

After screening participants, the research scholar will collect all the necessary data and recorded in a structured paper-based Case Report Form (CRF). The data collection and assessment relating to the developmental milestones and speech will be periodically recorded as baseline, two interim assessment, end-line analysis and after a follow up period of one month. The study instrument used for assessing the primary outcomes is REELS and for assessing the secondary outcome Denver Development Scale is used. Participant retention and follow up are ensured throughout the trial by the research scholar.

Data Management and Safety:

The collected data and the assessments entered in the CRF are also electronically

recorded and secured. Institutional Ethical Committee (IEC) is authorized to review and validate the data collected. No modifications in the trial were made after the start of study. The research scholar of the study is duly decisive to either proceed or terminate the trail of participants after evaluating the assessments. The institution also supports follow up of the discontinued or withdrawn participants after excluding from the study. The trial also abides by the Data Safety Management guidelines of Indian Council of Medical Research (ICMR).

Statistical method:

The Statistical methods employed for analyzing the primary and secondary outcomes were ANOVA, chi square, paired and unpaired t test. Comparison between groups will be done using one way ANOVA.

Data monitoring:

A Data Management Committee of IEC and an institutional doctoral committee group will review and monitor the data collected. The trial is also registered in the Clinical Trials Registry of India (CTRI). Periodic monitoring for any adverse events during the trial is done by the scholar. There were no chances of harm or unintended effects during the period of study. The triggering factors as of any means due after intervention will be subjected to stopping guidelines. Appropriate ancillary and post-trial care will be considered for the trial participants, if any. The effective results will be published according to the guidelines and data safety management policy.

Ethics and Dissemination

On drafting protocol, the submission to Institutional Ethics Committee is made. Amendments were made on outcome analysis and after furnishing required amendments, the protocol was finalized by the institutional ethics committee of Vaidyaratnam P S Varier Ayurveda College, Edarikode, Kottakkal with "Proceedings No: IEC/CI/28/17; dated 04-05-2017" has approved the research proposal. The trial was also registered with the Clinical Trials Registry of India, CTRI NO: CTRI/2019/11/021889 after getting ethical approval.

Consent

The assents stating the willingness of intervention were collected from parents after detailing every provision of the study. The confidentiality of the trial protocol was assured throughout. The study is conducted in accordance with the clinical trial protocol requirements and the ethical principles as per declaration of Helsinki, the International Conference on Harmonization Good Clinical Practice Guidelines (ICH GCP) and all applicable laws and regulations, including the Data Safety Management.

Dissemination

The study protocol and results will be presented at various conferences and the results will be published in a peer reviewed, open access International journal. Authorship on publishing the journal will follow the respective journal guidelines.

CONCLUSION:

There is an unprecedented global interest in children with developmental disabilities on achieving optimal health and well being during early childhood. The current protocol will provide an Information into the combined treatment module effectively adapted to manage and improve the affected domain of children thereby enhancing their quality of life. Results of

the current clinical trial will also provide new insights, capable of refining the existing treatment modalities especially in children with delayed language milestones. In summary, the described randomized controlled trial, if found effective will provide a significant contribution to potentially empower children with developmental disabilities.

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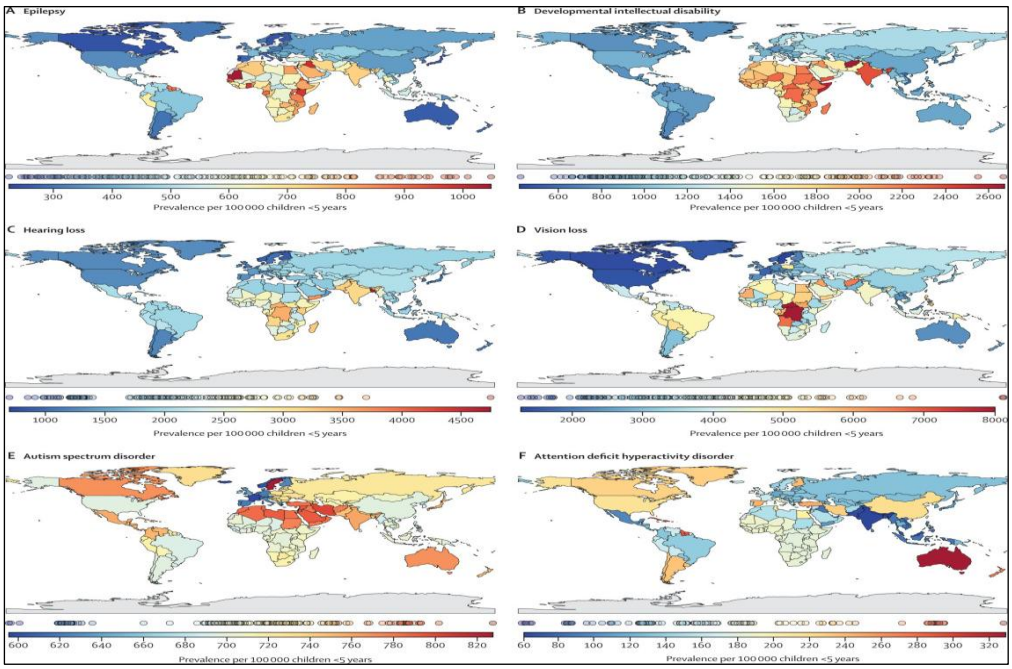
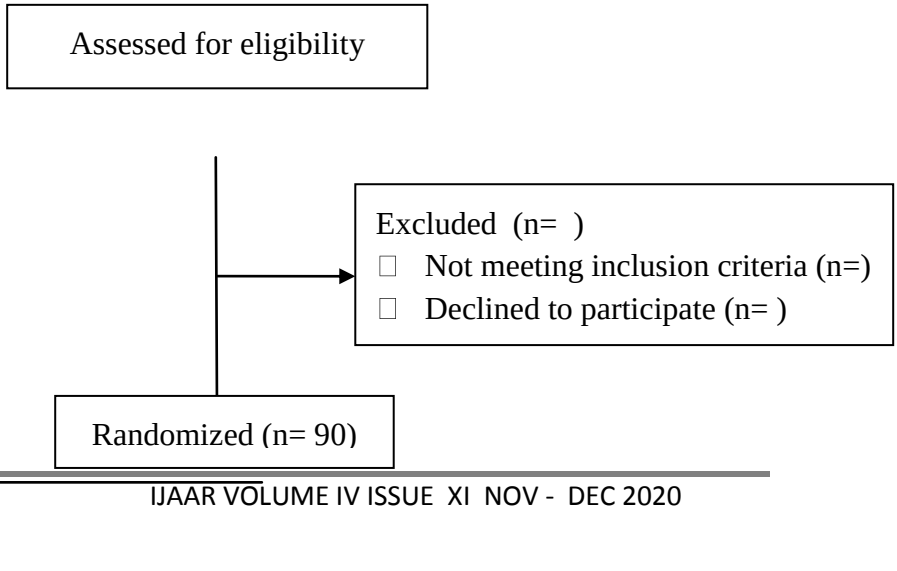


Figures

Figure 1: Global prevalence per 100 000 population of developmental disabilities among children younger than 5 years in 2016

Figure 2 : Participant Flow



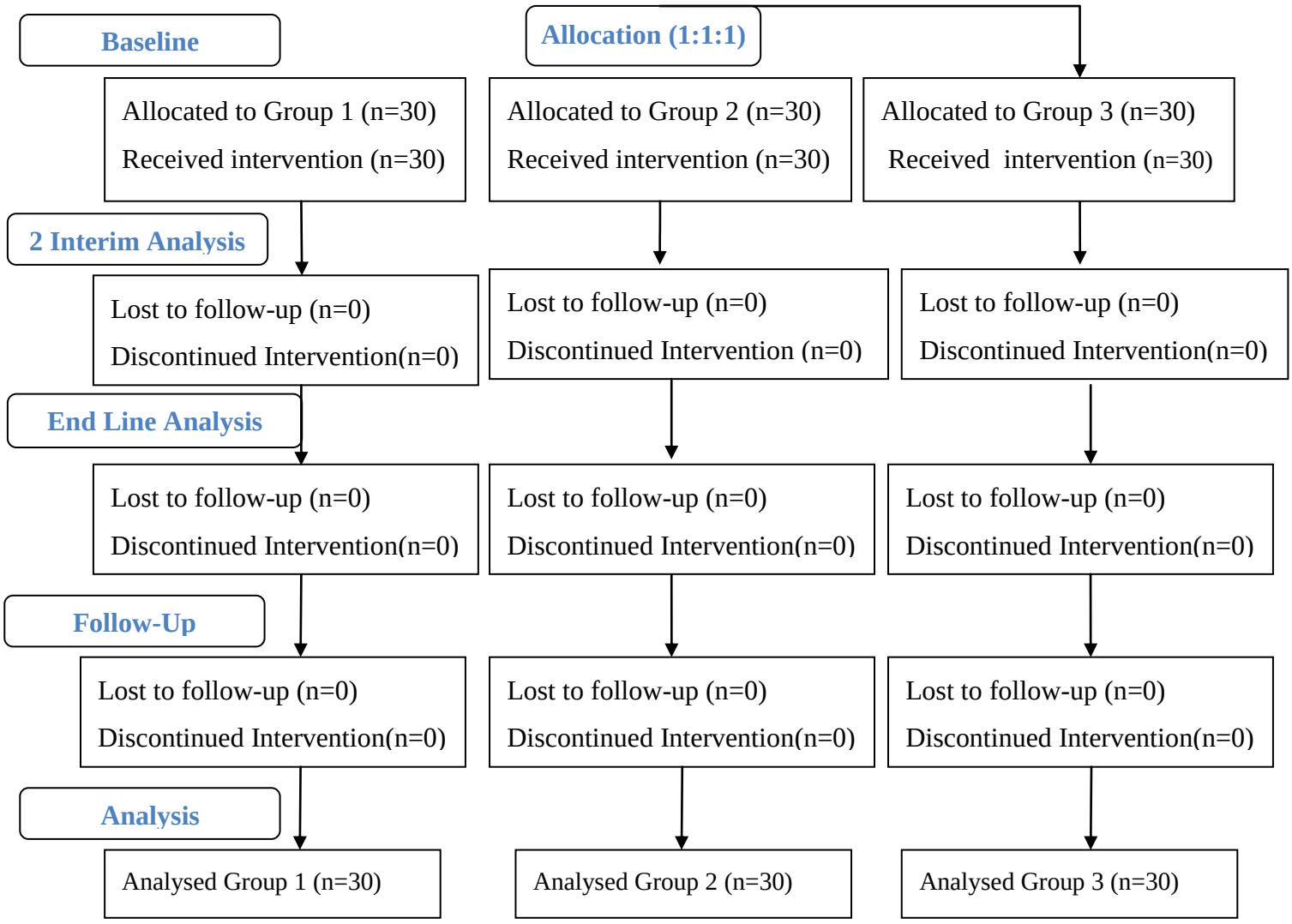


Table 1: Details of the study

STUDY PERIOD					
Time point	Base line t_1	Interim phase t_1	Interim phase t_2	End-line phase t_3	Followup phase t_4
Screening :					
Preliminary data	✓				
Physical examination	✓				
Eligibility screening	✓				
Assent	✓				
Allocation	✓				
Intervention					
Poly-herbal formulations (Group 1& 2)	✓	✓	✓	✓	

Speech Therapy (Group 2 & 3)	✓	✓	✓	✓	
Assessment					
REELS	✓	✓	✓	✓	✓
Denver Development Scale	✓	✓	✓	✓	✓

Table 2: Description on group wise intervention

Sl No	Particulars	Group 1	Group 2	Group 3
1	Sample Size	30	30	30
2	Internal Administration and duration	*Abhayam Ghritham* - 2.5 ml at morning (b/f) Duration – 90 days	*Abhayam Ghritham* - 2.5 ml at morning (b/f) Duration – 90 days	-
3	External Administration and duration	*Vachayashtyahwadi Choornam* – 2.5 gm with ghrita at night Duration – 90 days	*Vachayashtyahwadi Choornam* – 2.5 gm with ghrita at night Duration – 90 days	-
4	Other Interventions and duration	-	Speech Therapy Duration – 90 days	Speech Therapy Duration – 90 days