Randomized Placebo-Controlled Double-Blind Clinical Trial on the Efficacy of AYUSHMANAS in the Management of Smritidaurbalya (Cognitive Deficit): A Study Protocol

GV Ramana¹, Renu Singh², Mukesh B Chincholikar³, Rakesh Rana⁴, BCS Rao⁵, Narayanam Srikanth⁶

ABSTRACT

Background: According to modern medicine, individuals whose general intellectual functioning is significantly below average and concurrently having deficits in adaptive behavior are considered to be having cognitive deficit. It may be congenital or caused by factors such as brain injuries, neurological disorders, or mental illness. In Ayurveda, the condition can be correlated with Manasasamandata. Various terms are used in the classics like Buddhimandyata, Jadata, Smritidaurbalya, etc., to denote impairment of intellectual functions. The current medications for cognitive deficit in modern medicine are not entirely satisfactory, so many patients seek alternative treatment for its management. Thus, there is a definite need to scientifically assess some of alternative treatment modalities.

Objective: To assess the efficacy and safety of a coded Ayurvedic drug—AYUSHMANAS—in children suffering from cognitive deficit.

Materials and methods: This is a prospective, randomized, double-blind, two-arm placebo-controlled clinical study. A total of 150 participants (75 in each arm) suffering with cognitive deficit will be included in line with inclusion and exclusion criteria. The participants of trial group will be administered with AYUSHMANAS (250 mg × 2 tablets) while in control group Placebo (250 mg × 2 tablets) will be administered twice daily after food for 180 days. A total of seven visits will be scheduled for each participant: first visit at screening day 0, 30th day, 60th day, 90th day, 120th day, 150th day, and 180th day. The outcomes intended from the study include observing changes in binet kamat test of intelligence (BKT) and mini-mental state examination (MMSE) and a modified MMSE (mMMSE) scores apart from assessing safety of the intervention. Observation of therapeutic and safety endpoint outcomes will be undertaken.

Discussion: This clinical protocol is designed for exploring a better clinical outcome with good safety profile in the management of cognitive deficit in children. If found effective, the selected drug can be listed in the management protocol of cognitive deficit at clinical practice level in terms of better efficacy, safety, and cost-effective intervention. The selected drug may also lead to better understanding and management of cognition related problems.

Trial registration: CTRI/2019/07/020324

Keywords: AYUSHMANAS, Binet Kamat test of intelligence, Cognitive deficit, Modified mini-mental state examination, Smritidaurbalya.

BACKGROUND

Cognition includes the processing of specific information pertaining to thinking, memory, perception, motivation, skilled movements, and language. Cognitive deficit or cognitive impairment is an inclusive term to describe any characteristic that acts as a barrier to the cognition process.¹ The term denotes deficits in global intellectual performance, such as mental retardation. It describes specific deficits in cognitive abilities (learning disorders, dyslexia), drug-induced cognitive/memory impairment that seen with intake of alcohol, glucocorticoids, and benzodiazepines.² ³

Individuals whose general intellectual functioning is significantly below average and concurrently having deficits in adaptive behavior are considered to be having cognitive deficit. This condition may be seen in children and also in some elderly people. It may be congenital or caused by factors such as brain injuries, neurological disorders, or mental illness.⁴ ⁵ It may be part of a syndrome, and there may be a family history of similar difficulties. It is often associated with history of delayed developmental milestones. In some children, mild cognitive deficit becomes more obvious when the child starts attending school. The child shows difficulty in learning slowly than other children, may also lag in speaking, walking, and difficulty in self care needs such as dressing or eating.

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Conflict of interest: None

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Standardized tests of intelligence and adaptive behavior are used to diagnose cognitive deficit. A medical classification listed by the World Health Organization (WHO); 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD–10) chapter ‘F’ classifies Psychiatric disorders as mental and behavioral disorders and codes them on an alphanumeric system from F00 to F99. In that series, F70–F79 classifies the mental retardation to cognitive deficit in to the following degrees.

<table>
<thead>
<tr>
<th>Average</th>
<th>90–109</th>
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<tbody>
<tr>
<td>Dull normal</td>
<td>80–90</td>
</tr>
<tr>
<td>Borderline</td>
<td>70–79</td>
</tr>
<tr>
<td>Mild MR</td>
<td>50–69</td>
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<tr>
<td>Moderate MR</td>
<td>35–49</td>
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<tr>
<td>Severe MR</td>
<td>21–34</td>
</tr>
<tr>
<td>Profound MR</td>
<td>&lt; 20</td>
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In Ayurveda, intellect is termed as Buddhi; hence, deficit in intellectual functioning can be termed as Budhimandya or Manasamandata. Numerous causative factors such as Mithyazaravihara (intake of incompatible and improper diet), Asatmyendriyarthamanasa (improper use of sensory organs), Beeja Dosha (congenital factors), Daushridkalina Apacharata (non-fulfillment of desires of pregnant women), emotional and behavioral factors of the mother during pregnancy, Vega Dharana (suppression of natural urges), and gynecological disorders are said to cause this condition.

Long-term intervention with modern medicines may have adverse effects on the body, and the potential toxicity of these drugs in children cannot be overlooked. Hence, there is a great need to find a safe and effective Ayurvedic medicine for long-term intervention in children.

Medhya Rasayana (intellect enhancer) represents herbal therapeutics that boosts memory, restore cognitive deficits, and improve mental function. As per the available research evidence, it is clear that Ayurvedic formulations or medicinal plants used in the memory loss/memory-related ailments, possess neuro-protective, and nootropic activity. In this study, an effort will be made to find out a suitable long-term intervention in the treatment of cognitive deficit in children.

In this study, it is assumed that AYUSHMANAS may be safe and efficacious in alleviation of the signs and symptoms of cognitive deficit and improve intelligence quotient (IQ) levels in children. If successful, the study may provide an evidence-based complementary therapeutic approach to slow or prevent the clinical progression of cognitive deficit. The protocol is incorporated with details of the overall study design and approach of the trial.

**Materials and Methods**

**Study Objective**
The study is planned to test the hypothesis that AYUSHMANAS is a safe and effective intervention in cognitive deficit in children.

**Design Overview**
This clinical trial is designed as a randomized, placebo-controlled, double-blind, parallel-group study. The study design will assimilate rigorous existing clinical research methodology in accordance with the principles set out in the good clinical practice (GCP) guidelines according to the theory that guides the appropriate use of traditional medicines in clinical practice.

A total 150 child participants (75 in each group) will be recruited at Advanced Center for Ayurveda in Mental Health and Neurosciences, (ACAMH&NS), Bengaluru, India. The children and their parents will be given the information brochure of the trial, and informed written consent will be obtained from them before enrolment in the study. This trial is supported by the Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi (an autonomous body under Ministry of AYUSH, Govt. of India) under Intra Mural Research (IMR) projects, and it is also registered with the Clinical Trials Registry - India (CTRI) (CTRI/2019/07/020324; registered on 23/07/2019).

Out of the total 36 months study period, 3-month period is designated for pre-study preparations such as staff recruitment, purchase of equipment, procurement of the trial drugs, and Institutional Ethics Committee (IEC) clearance, etc. The period that will be needed for execution of works like screening, enrollment of patients, laboratory investigations, etc., will be for 30 months. The data will be analyzed at the end of follow-up of all trial cases after meeting the sample size. The details of various stages of the study are enlisted in the Flowchart 1.

**Inclusion Criteria**
- Children of either sex aged between 8 years and 13 years
- Children with IQ between 63 and 80 per Binet Kamat Test of Intelligence (BKT)
- Willing and able to participate for 180 days

**Exclusion Criteria**
- The children with a history of peptic ulcer disease, any gastric or duodenal surgery, gastrointestinal (GI) bleeding or other GI disorders.
- Severe infection and/or clinically significant hepatic, respiratory, renal, cardiac, or hematological disorders.
- Abnormal laboratory values at enrollment into the study: serum creatinine 1.2 > mg/dL, serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT) > 3 times upper limit of normal; serum bilirubin or alkaline phosphatase (ALP) >1.5 times upper limit of normal.
- Patient’s guardian who cannot be relied upon to comply with the test procedures or are unwilling to give informed consent.
- The children who has any intramuscular, intra-articular, or intravenous corticosteroids within 4 weeks prior to study entry.
- History of recent and clinically significant drug abuse.
- Pre-existing blood dyscrasias, e.g., bone marrow hypoplasia, leukopenia, thrombocytopenia etc.
- Children are unlikely to comply with protocol, e.g., non-cooperative attitude, inability to return for follow-up visits, and unlikelihood of complete study.
- Children in whom another investigational drug was used within 3 months prior to entry in this study.
- Children with poorly controlled epilepsy (history of attack in last 3 months).
- Children to whom BKT cannot be administered for any reason.

**Conditions and Procedures for Withdrawal of Study Subjects**
- If the patient develops any serious adverse effect (necessitating hospitalization) OR
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There is noncompliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

**The decision to withdraw a participant from the trial would be taken only by the Principal Investigator who will then have to set out a detailed justification and also indicate the line of further management if needed. The same needs to be informed to the Sponsor and the Ethics Committee within two working days.**

**Researcher’s Decision**

The investigator may decide to remove subjects from the study for any of the following reasons:

- Any major ailment or progressive cognitive decline, necessitating the institution of new modalities of treatment.
- In case of poor compliance (<80%)
- At subject’s/guardian’s request

**Participants’ Voluntary Withdrawal**

As stipulated in their informed consent forms, the participant/participant’s guardians have the right to withdraw from the study at any time. Participants who do not formally withdraw from the study but cease to accept medication and undergo testing or who become impossible to contact are also considered withdrawn. The researcher should realize and record the reasons for participants’ withdrawal to the greatest extent possible, noting whether the treatment is obviously ineffective, difficult to tolerate owing toad-verse reactions, or whether the patient cannot continue to participate in clinical research for some other reason, such as economic or personal factors. Whatever the reason, the case record should be retained; the last test results will be carried forward to the final result; and a full data set will be analyzed for the treatment’s efficacy and adverse effects.

**Intervention Measures**

The recruited participants would be provided with either oral coded drug AYUSHMANAS (250 mg) twice daily after food with water as Anupana for 180 days or matching placebo, depending upon the randomized allocation process. Both the investigator and participant would be blinded as the study design is a double blind model. Posology details are provided in the Table 1.
**Drug Management**

The trial medicines will be prepared and supplied by Regional Ayurveda Research Institute for Skin disorders (RARISD), Vijayawada. The package, drug name, function and indication, usage and dosage, storage condition, valid period, and name of the manufacturer will be marked, and a tag indicating “trial use” will be attached. Drugs will be kept in the appropriate temperature in a dry, shady, and cool place. Drug administrators would return unused drugs to estimate participant compliance and note these in the CRFs. Each intervention will be prepared according to the standards of Good Manufacturing Practice (GMP).

**Data Collection and Monitoring**

All data will be recorded by clinical investigators in a standardized case report form (CRF) and instantly recorded in the database. All information regarding clinical trial will be properly documented, carefully handled, and meticulously stored in order to ensure its accurate interpretation and verification. Original CRFs will be kept at the participating center for 5 years after completion of the study.

All the selected cases for the study will be advised to have followed up visits at 30-day interval (i.e., on day 30, day 60, day 90, day 120, day 150 and day 180). Statistical Unit of CCRAS, Head Quarters, New Delhi, and the Research Officers who are directly involved in this project will monitor the progress of the trial through regular site visits.

**Participant Information Sheet and Consent Form**

Prior to any trial-related activity, the Principal Investigator will give the patient verbal and written information about the trial in a form the participant can read and understand. The investigator would ensure that the participant is fully informed about the aims, procedures, discomforts and expected benefits of the trial. It must be emphasized that participation is voluntary, and participants have the right to opt out of the trial at any time without any prejudice. A voluntary, signed witnessed informed consent should be obtained from the parents of the participant prior to any clinical trial related procedure.

**Study Procedures**

During the treatment, the following information will be collected and recorded: basic medical history, diagnosis and screening, general physical and systemic examination and observation of effectiveness, laboratory investigations such as hemoglobin (Hb%), total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), random blood sugar (RBS), liver and kidney function tests, i.e., SGOT, SGPT, ALP, total bilirubin, total protein, albumin, globulin, A/G ratio, serum alkaline phosphate, serum creatinine, blood urea, uric acid, and urine sugar, albumin, ketone bodies, etc will be carried out at screening (0 day) and at the end of treatment period (180th day) in all participants to assess the safety of the drug.

Periodic assessment of the subjects will be done at Baseline (0 day), 30th day, 60th day, 90th day, 120th day, 150th day, and at the end of 180th day.

Assessment of IQ by BKT will be done at screening and at the end of 180th day. Regular assessment of mini-mental state examination (MMSE) and a modified MMSE (mMMSE) on baseline and at the end of 30th day, 60th day, 90th day, 120th day, and 150th day will be done. Parental perception evaluation will be done at the end of 180th day. All information related to the treatment/study schedule is provided in Figure 1.

**Ethical Aspects**

The trial will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and Indian Council of Medical Research (ICMR) ethical guidelines involving human participants (2006) and that are consistent with Indian/International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. Prior to commencement of the trial, the protocol, the participant information sheet and the consent form will be submitted to the Institutional Ethics Committee and written approval will be obtained from the IEC. Protocol amendments if any will also be approved by the IEC according to the usual procedure. This study has been approved by the IEC of ACAMH&NS, Bengaluru, CCRAS vide letter no F.4-70/ACAMHNS/2017-18/Tech/IEC. All eligible participants, willing to provide signed written informed consent shall only be included in the trial.

**Deviation From the Protocol**

The trial should be conducted in compliance with the protocol. Deviations from the protocol should not be made except when necessary to alleviate an immediate hazard to trial patients. All the deviations from the protocol, including unplanned changes to interventions, examinations, data collection and method of analysis should always be reported to sponsors and IEC at the earliest along with the exact reason for that deviation.

**Sample Size**

Assuming a reduction in the BKT score in group I (AYUSHMANAS) by 8 points and a change of 3 points in group II (Placebo) with a standard deviation of 10 points based on the results of the previous studies, with 95% confidence Level (α = 0.05) and 80% power. Expecting a dropout rate of 20% the number of patients to be enrolled in the study is 150 (75 per group).

**Method of Randomization and Blinding**

A randomization chart will be generated with the help of computer generated random numbers. Participants will be randomized in the ratio of 1:1 to either receive AYUSHMANAS or matching placebo. Trial drugs will be packed according to the randomization chart and will be delivered at the trial site. The randomization schedule will be strictly controlled. The blinding of the trial drugs will be done by following the method of sequential number order. The medicine box will be serially numbered according to participant’s enrollment number and will be dispensed accordingly. Unblinding during the trial will only be undertaken in case of any Serious Adverse Events (SAE).

**Drug Compliance**

If there is more than or equal to 80% compliance, the participant will be continued in the trial. The compliance needs to be assessed at each visit during the follow-up (1-month interval) by assessing the approximate quantity of drug consumed by the patient.

**Concomitant Medication**

Participants registered under the trial will be instructed to avoid the use of any other drugs on their own for any ailment and will be clearly instructed to consult the treating investigators for any...
symptom or complaint, or if they feel anything unusual. The investigator will record any medication(s) he/she may prescribe to alleviate their ailments.

**Rescue Medication**

To alleviate any emergency, the use of any Ayurveda rescue medication is permitted as per the wisdom/discretion of the investigator. However, the same need to be documented in appropriate column in the Case report form.

**Outcomes Measures**

**Primary Outcome Measure**

- Changes in BKT

**Secondary Outcome Measure**

- Change in mMMSM
- Parental perception evaluation

**Safety Assessment and Adverse Event (AE)/Adverse Drug Reaction (ADR)**

Safety will be monitored by laboratory investigations at the end of the trial period and also by recording the onset of any untoward AE/ADR during the 180 days, while monitoring the physical and general assessment parameters including vital signs.

In addition, we will make at least one on-site monitoring visit during the study to ensure that participating center complies with the study protocol and GCP principles. Any adverse event or adverse drug reaction, if observed during treatment period or during follow-up visits, will be clearly documented, and its appropriate and timely management will be done and the same will be reported to the Ethics committee and the sponsor(s) at the earliest.

AEs, such as signs and symptoms and other ailments, will be documented at every study visit. Each AE will be classified as a mild, moderate, or severe AE, and its correlation with the intervention drugs will be assessed. Severe AEs will be reported to the principal investigator and the ethics committee within 24 hours. The data and AEs will be accurately and appropriately recorded on the CRF. All of the AEs will be recorded, monitored, and treated until properly resolved.

**Statistical Analysis**

Clinical symptoms, subjective parameters, and laboratory parameters will be subjected to univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS 15.0) version with appropriate statistical methods. An interim analysis, if required, can be done when at least 25% participants have completed their trial period. All information regarding clinical trial will be properly documented and stored in order to ensure its accurate interpretation and verification.

**Discussion**

Cognitive deficit is a disorder of children with major impact on their learning ability. Children with learning disabilities pay less...
attention than normal, and this cannot be attributed to IQ alone. Learning process is generally influenced by intelligence, memory, and conducive environment. For becoming a good learner, a child must have less fluctuation of attention, increased power of concentration, spontaneity in word recognition, and capacity to memorize things quickly and correctly.  

All the ingredients of the coded drug are supposed to exert Medhya effect. It is interpreted that Medhya drugs acts by clearing the obstructions in channels of Manovahasrotas by which they may be helping in reducing the symptoms of Manovikara (mental disorders). Vata is considered as the controller of the mind and Pacification of the Vata also plays an important role in the resultant action of these drugs.

AYUSHMANAS is a poly herbal coded formulation developed by CCRAS for effective management of diseases affecting Manovaha Srotas. Ingredients of this formulation possess neuroprotective, nootropic, and pharmacological properties to enhance memory, mental function and development of immunity.

In the present study, it is proposed to establish the effect of AYUSHMANAS in the management of cognitive deficit. Further, the intervention aims to establish and to appropriately validate the effect of the medicine in destabilizing the pathogenesis. The clinical trial protocol plays a vital role in study conduction, reporting, and appraisal. To facilitate appropriate high-quality methodology and quality control, this protocol has been developed according to the SPIRIT 2013 explanation and elaboration method of recruitment, allocation, concealment, and data collection processes. The results of this study may generate scientific and rigorous evidence for the study of cognitive deficit with Ayurveda intervention.

Trial Status

Recruitment of participants has commenced on 04/01/2020. At the time of this manuscript submission, 19 participants have been recruited, and the study is in progress.

Acknowledgments

Authors thank the Director General, CCRAS. Author gives special thanks to all the participants who are participating in this study.

References

हिंदी सारांश

स्मृतिदौर्बल्य (कोमर्निटिव डेफिसिट) के प्रबंधन में आयुष्मानस की प्रभावकारिता पर रेन्डरमाइजेड प्लेसबो नियंत्रित डबल ब्लाइन्ड चिकित्सिय परीक्षण - एक अध्ययन प्रोटोकॉल

जी वी रमण, रेनु सिंह, मुकेश बी चिन्होलिकर, राकेश राणा, बी सी एस राव, नारायण श्रीकान्त

पृष्ठभूमि: आधुनिक चिकित्सा के अनुसार, जिन व्यक्तियों की सामान्य बौद्धिक कार्यपद्धति औपलब्य से काफी नीचे है और अनुकूल व्यवहार में समय की रूप से कमी है, उन्हें स्मृतिदौर्बल्य (कोमर्निटिव डेफिसिट) माना जाता है। यह स्मृति दौर्बल्य जन्मजात हो सकता है या विशिष्टकृत की चोटों, न्यूरोलोजिकल विकारों या मानसिक बीमारी जैसे कारकों के कारण हो सकते हैं। आयुर्वेद में इस अवस्था को मानसिद्धान्तिक साहित्य में स्वाभाविक रूप से जोड़ा जा सकता है। बौद्धिक कार्य में हानि को सुधार करने के लिए विभिन्न शब्दों का उपयोग शास्त्रों में किया जाता है जैसे कि बुद्धिमानाधिकार, जाजता, स्मृति दौर्बल्य, आदि। इस के लिए प्रेक्षक कारकों में मिथ्याहार-विहार, असाध्यविदितार्थ संपत्ति, बीजज्ञानी और दौड़ीकालिन अपराधार्थ, इत्यादि सम्मिलित हैं जो शरीरिक और मानसिक दोषों का प्रकार करते हैं। आधुनिक चिकित्सा में स्मृतिदौर्बल्य (कोमर्निटिव डेफिसिट) के लिए वर्तमान औषधियों पूर्व तक से संबंधित नहीं हैं; अधिकांश रोगी इसके प्रभाव के लिए वैज्ञानिक उपचार के कुछ तरीकों का वैज्ञानिक रूप से आकलन करने की एक निश्चित आवश्यकता है। वर्तमान शरीर अध्ययन का उद्देश्य कोडेड आयुर्विदिक औषधि आयुष्मानस की प्रभावकारिता और सुरक्षितता का आकलन करना है और स्मृतिदौर्बल्य (कोमर्निटिव डेफिसिट) से पीड़ित बच्चों में इस दवा के प्रभाव का वैज्ञानिक रूप से अध्ययन और विचारधारा करना है।

सामग्री एवं विधि: यह एक प्रोटोकॉल, डबल ब्लाइन्ड, दो आरंभ, प्लेसबो नियंत्रित चिकित्सिय अध्ययन है। स्मृति दौर्बल्य से पीड़ित कुल 150 बच्चों (प्रयोक्ता वर्ग में 75) को अपर्याप्त उपचार को यथार्थ में रखते हुए सम्मिलित किया जाएगा। प्रतिभागियों का चयन दो वर्गों में किया जाएगा। परीक्षण औषधि वर्ग के प्रति भागिदारों को मात्रिकार रूप से आयुर्वेद चिकित्सा (एक कोडेड औषधि) यानी आयुष्मानस टैबलेट तथा मिशेंजर वर्ग के प्रति भागिदारों को प्लेसबो टैबलेट, 250 मिलीग्राम, 2 गोलियां, बुजुर्ग के सादे, आयुष्मान पानी के साथ दिन में दो बार, 180 दिनों के लिए दी जाएगी। प्रयोक्ता प्रतिभागियों के लिए साथ विजिट का समय निर्धारित किया जाएगा: प्रथम विजिट 0 दिन, 30वें दिन, 60वें दिन, 90वें दिन, 120वें दिन, 150वें दिन और 180वें दिन। अध्ययन के उद्देश्य से किया गया परीक्षण में सुरक्षा का आकलन करने के अलावा बीकॉटी और एमएमएसई स्कोर में परिवर्तन समीक्षित है। चिकित्सिय और सुरक्षा समस्याओं की उपलब्धि और प्रभावण हो सकता है।

चर्चा: यह चिकित्सिय प्रोटोकॉल बच्चों में स्मृतिदौर्बल्य के प्रबंधन में एक उत्तम चिकित्सिय परीक्षण और सुरक्षितता के लिए बनाया गया है। यदि प्रभावी गया जाए, तो चिकित्सिय औषधि को उत्तम प्रभावकारिता, सुरक्षा और प्रभावी लाभ के संदर्भ में विचित्सिय अभ्यंस स्तर पर स्मृति दौर्बल्य के प्रबंधन प्रोटोकॉल में सुरक्षित रूप से जा सकता है। चिकित्सिय औषधि से स्मृतिदौर्बल्य संबंधित समस्याओं की उत्तम समझ और प्रभावण हो सकता है।

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