

Comparative Study on Efficacy of BrahmiGhrita as an Adjuvant with CBT(Cognitive Behavioral Therapy) in Management of Autism in Children-A Protocol

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Abstract

Background: Any abnormal and or impaired development that is developed before the age of 3 years identified by abnormally developed social skills, communication problems and a restricted of behaviour is defined as autism. In Ayurveda, the condition Autism may be understood on the lines of Unmad in a lesser degree and can be categorized as a minor psychological ailment of the child. Unmad is a clinical condition characterized by indecisiveness (DheeVibram) and unstable mind (Satwapariplawa), looking elsewhere usually by avoiding eye contact (Paryakuladrishti), lack of courage (Adheerata) incoherent and indistinct talk. (Abaddha Avaya) and lack of insight or imagination due to inability to process sensory information (HridayamchaShoonyam), when these symptoms exist in a minor form it could be considered as autistic behaviour. **Objectives:** To study the efficacy of BrahmiGhrita& CBT in patients of Autism by DSM-IV &V criteria & Amino acid levels plasma & urine in comparison to CBT alone on the same parameters **Methodology:** Patient of autism irrespective of sex, religion, from age group of 3 to 12 years shall be included in the study. Children with IQ >70 will be included in study. The treated group shall be administered the Ayurvedic treatment as follows: For group A- RajanyadiChurna 4.5-18

grams {depend upon age of patient} early in the morning daily for initial 7 days only, thereafter internal administration 9.6 —24 grams {depend upon age of patient} of BrahmiGhrita is given daily with a cup of hot milk or water or as per the choice of patient, early in the morning daily for period of 3 months {in Opd of hospital} along with CBT every 2 weeks for 3 months. For group B – CBT every 2 weeks for 3 months. **Results:** will be observed according to criteria of DSM-IV/V. **Conclusion:** BrahmiGhrita as an Adjuvant with CBT will be more effective than CBT alone in Management of Autism in Children.

Keywords: BrahmiGhrita, CBT, Autism.

INTRODUCTION:

Autism is a type of developmental disorder that occurs in the initial 3 years of life, and has affects on the normal brain development and also affects the social and communication skills.¹ Autism and its associated behaviour patterns have been estimated to occur in 2 to 6 in 1000 individuals. In India now the rate is 1 in 66 children in the age group of 2 -9 years.

The prevalence of autism is 4 times more in boys than girls. The term “autism” is derived from the Greek word autos (self) And ismos(action) and was used by Leo Kanner in his landmark paper in 1943 (4) and discussed the children with an extreme inability in order to relate to others. Autism spectrum disorders a general term used to cover a range of difficulties that occur in three main aspects of child development are communication skills, social skills and life skills. In unmadchitta gets disturbed which results in impairment in budhhi².

Unmad is a clinical condition characterized by indecisiveness (DheeVibram) and unstable mind (Satwapariplawa), looking elsewhere usually by avoiding eye contact (Paryakuladrishti), lack of courage (Adheerata) incoherent and indistinct talk. (Abaddha Avaya) and lack of insight or imagination due to inability to process sensory information (Hridayamcha

Shoonyam), when these symptoms exist in a minor form it could be considered as autistic behaviour.³

AUTISM SPECTRUM DISORDERS-

Autism spectrum disorder includes five types, Classic autism, Asperger's Syndrome, Childhood disintegrative disorder, Rett syndrome and Pervasive developmental Disorder.⁴

The Classic autism is a form of autism involves inability of interacting socially, communication issues and language usage. They develop language skills later in life than normal children, or sometimes, never.⁵

People having classic autism face obstacles in talking to other people. They do not have the feeling of love or a desire to interact with others. In Unmad, the child having Autism has a higher mental function and their perception towards reality is also quite distorted. There are various treatments designated for the treatment but majority of them are made of Ghrita (cow's ghee). Ghrita is known to treat the disease by infusing a single drug in combination

with other mood stabilizing types of drugs. Another well know Ayurvedic medicine is BrahmiGhrita. Ashtanga Hridhay the drug is also known to treat Unmad along with other conditions.⁶

Ingredients of BrahmiGhrita mainly works on improving mental stability, reduces anxiety, increases the concentration, improves memory and also antioxidant. Rajanyadichurna is another one that is selected in this study for the purpose of deepana, pachana karma in children⁷.

Objective of cognitive behavioural therapy (CBT) is to help children fully express their needs, worries and anxieties. CBT helps people identify and understand how do thoughts, emotions and certain behaviours are affected by each other.⁸

One of the advantages of CBT is that it gives you skills for life-it teaches you a new way of thinking and coping with your problems that you can use when times get tough. This is why The techniques are often called a toolkit.

High prevalence of disease and no specific treatment (simple, cost effective) in any science up till now is the main concern of today's era.

In view of the above lacunae in management, present study is planned to see the efficacy of BrahmiGhrita for any improvement in signs and symptoms of autism.

METHODOLOGY:

Study settings: Interventional study type [Comparative Single blind].

Randomized Single -blind Study on Efficacy of BrahmiGhritaAs an Adjuvant with CBT (Cognitive Behavioral Therapy) In Management of Autism in Children. (Superiority trial).

ELIGIBILITY CRITERIA:

Inclusion Criteria: -

Patient of autism irrespective of sex, religion, etc. from 3 to 12 years shall be included in the study. Children with IQ >70 will be included in study.

The diagnosis will be done with following features-

- a) Impairment of social relationships with people around.
- b) Impairment in communication and language skills.
- c) More attachment to some non-living objects.
- d) Unstable and indecisive mind.
- e) Having fear and lack of courage.

Exclusion Criteria: -

Patients suffering from other complications like cerebral palsy, mental retardation, seizures, ADHD and any other chronic disease with speech delay, and other 4 forms of autism shall be excluded from the study. Around 60 {30+30}, minimum 35 patients in each group will be enrolled with a drop out will be 20%.

Interventions:

Sampling: - Patients of Autism fulfilling the inclusion criteria shall be randomly divided into two groups at least 30 patients in each group with enrolled 35 patients in each group & total drop out will be 20%.

Randomization will be done according to computer generated random allocation software methods to avoid bias in the study.

Source of Data: - (Place)

Autism patients attending the outpatient department of Kaumarabhritya, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod, Wardha and from other sources i.e. Autistic society of children, Autism center at Nagpur, camps, shall be material for data.

Group A- Who will receive Brahmighrita orally daily for 3 months, Rajanyadichurna along with honey for first 7 days prior to ghrita in prescribed dose as proposed guide (age & /kg body weight).

Along with CBT (Cognitive Behavioral Therapy) every 2 weeks as proposed guideline till 3 months. (since the start of treatment every 2 weeks till end of treatment i.e., 90 days CBT will be given).

Group B - Who will receive CBT (Cognitive Behavioral Therapy), every 2 weeks during treatment for 3 months. (since the start of treatment every 2 weeks till end of treatment i.e., 90 days CBT will be given).

Withdrawal criteria: - If the symptoms get aggravated or any secondary conditions appear during study such subjects will be withdrawn from study and suitable alternative treatment will be provided free of cost till it becomes alright.

Study Duration: - 90 days.

Follow up period: - After completion of treatment period of 90 days, follow up will be done after the gap of one month {without treatment.}.

Outcome: Trial drug BrahmiGhrita as an adjuvant with CBT & CBT alone will be observed for outcome. Superiority effect is expected in a group where BrahmiGhrita as an adjuvant with CBT given.

- a) Improvement in social relationships with people around.
- b) Improvement in communication and language skills.
- c) more stable and focused mind.
- d) Having less fear and improvement in courage.

Sample Size and Sampling Method:

$$N = \frac{2(Z_{\alpha} + Z_{1-\beta})^2 \alpha^2}{\Delta^2}$$

WHERE-

Z_α - 1.96 (95% confidence level).

Z_β - 0.1 (where β type II error of rejecting null hypothesis).

α 2 - 18 (standard deviation).

N= sample size.

Δ^2 = Mean difference of interventions of previous study
& probable outcome of study.

(Considering study with CBT & BrahmiGhrita probably having 75% result / previous study having one intervention shows 59.7% result).

$$N = \frac{2(1.96 + 0.9)^2 \cdot 18^2}{(15.3)^2}$$

$$N = \frac{2(2.86)^2 \cdot 324}{234.09}$$

$$N = 22.61$$

$$N = 23$$

For better accuracy & higher validity of study 30 patients will be the size of the sample designated to each group. Total Number of Samples in both groups will be 60.

Randomization will be done according to computer generated random allocation software methods to avoid bias in the study.

DATA COLLECTION, MANAGEMENT AND ANALYSIS METHOD:

ASSESSMENT CRITERIA: -

I. SOCIAL RELATIONSHIP –

Scoring –

1. There is no evidence of problems or difficulty in relation to people.
2. Slight abnormalities in relationship. The child tends to avoid making eye contact with the adult.
3. Moderately abnormal relationship: continuous and forceful attempts are needed to receive the attention of the child.
4. Severity of abnormality in a relationship: The child is constantly unaware or uninterested in the activities of the adult.

II. IMPAIRMENT IN COMMUNICATION: -

1. Communicate verbally and normally, regarding to age and situation
2. Communicate with mild abnormality - speech shows overall retardation.
3. Communication moderately abnormal: Absence of speech in verbal communication or sometimes a mixture of abnormal or meaningful speech.

4. Communication severely abnormal: No signs of meaningful speech; child tends to make noise or shouts like an animal.

III. CONSISTENT ATTACHMENT TO SOME NON-LIVING OBJECTS.

1. Child is interested in toys or other objects normally.
2. Mildly interest in playing or using toys or other objects.
3. Moderately interested: the child shows some interest or may focus on an insignificant object around.
4. Severely inappropriate: The child may take part in the exact behaviour as in 3 above but at a higher level.

IV. UNSTABLE AND INDECISIVE MIND:

1. Visual response appropriate for age: Child's visual behaviour is normal and acceptable for his/her age.
2. Mildly abnormal visual response: Child is found to be more interested in looking at a mirror or may usually found staring in to random spaces.
3. Moderately abnormal visual response: Child may stare into space, avoid making eye contact.
4. Visual response severely abnormal: The mind flutters and the child constantly avoid eye contact or certain other things.

V. FEAR AND LACK OF COURAGE -

1. Normal scary or nervous feelings. The child's behaviour is according to his age/her age and situation both.
2. Mildly abnormal fear or nervousness. The child sometimes exhibits fearful or nervous behaviour.
3. Moderately abnormal fear or nervousness.
4. Severely abnormal fear or nervousness.

TOTAL SCORING WILL BE AS FOLLOWS –

Rating:

- 1) Score comes 5 - Child within normal limits.
- 2) Between 6 to 10 mild abnormalities.
- 3) Between 11 to 15 moderately abnormal.
- 4) Between 16 to 20 severe abnormalities.

DIAGNOSTIC TOOLS AND METHODS

CARS-Childhood Autism Rating Scale.

Indian Scale of Assessment in Autism.

The Autism Screening Questionnaire.

DSM-V.

NOTE - Indian Scale for Assessment of Autism. Scoring will be done as follows to diagnose the severity, <70- Normal, 70 to 106 – Mild Autism, 107 to 153 – Moderate Autism, >153-Severe Autism.

INVESTIGATIONS: -

- 1) CBC, Urine routine and microscopic. (if required)
- 2) EEG (if necessary).
- 3) Amino Acid Qualitative- Plasma & Urine.

DATA ANALYSIS [STATISTICAL METHODS]: -

The data will be analysed by using paired t-test & unpaired t-test for objective parameters and Wilcoxon signed rank test and Wilcoxon rank sum test, one/two ANOVA test for subjective parameters. Chi square test for qualitative with frequency of patients & unpaired t test for quantitative.

OBSERVATION AND RESULTS: -

Cases will be observed for a period of 3 months during treatment and for 1 month of follow up of study.

DISCUSSION AND CONCLUSION: -

Depending upon the observation, conclusion will be drawn for this study. Autistic children lack the feeling of affection or a desire to interact with others.⁹ In Unmad, the higher mental functionality altered and distorted reality perception.¹⁰ Ghrita is considered applicable for the treatment in combination with single drug and other nootropic drug and mood stabilizing drugs. The DHA, an omega 3 long chain polyunsaturated fatty acid is abundant in ghee which is seen in brain cells¹¹. The Ingredients of Brahmi ghrita^{12,13} which increased Mental Stability, increased Concentration. improves Intelligence, improves learning skills & speech, improves skin texture, increases cheerfulness, removes depression & stress in unmad¹⁴. Rajanyadichurna can be used for the purpose of deepana, pachana karma for children. CBT will be effective to deal with such complex behavioural disorders¹⁵ CBT gives you skills for life-it teaches you a new way of thinking and coping with your problems.^{16,17,18}

CONCLUSION:

Trial drug Brahmi Ghrita as an adjuvant with CBT & CBT alone will be observed for outcome. Superiority effect seen in a group where Brahmi Ghrita as an adjuvant with CBT is given.

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