Journal of Ayurveda & Holistic Medicine

https://jahm.co.in

eISSN-2321-1563

Study Protocol

Efficacy of Hingvastaka Churna Arka with Vilvadi Gutika in the Management of Functional Gastrointestinal Disorders in Children with Autism Spectrum Disorder: A Randomized Controlled Trial

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ABSTRACT:

Background: Autism Spectrum Disorders (ASD) presents in early childhood, affecting sensory processing, communication and cognition. Functional Gastrointestinal Disorders (FGIDs) are the most prevalent comorbidities in ASD. The symptoms of FGIDs include altered stool patterns, bloating, flatulence and frequent abdominal discomfort. These may affect the learning capacity, behavioral stability, and quality of life. Gut-microbial dysbiosis resulting from the gut- brain axis dysregulation plays a pivotal role in the development of FGIDs in ASD. *Mandagni* (poor digestion) is primarily the root cause of FGIDs. Additionally, *Amavisha* (metabolic toxin) can also impact neurocognitive functioning. While prebiotics and probiotics are currently in vogue, the effective management of FGIDs is yet to be established. *Hingvastaka Churna*, *Rajanyadi Churna* and *Vilvadi Gutika* have already been researched in Neurocognitive disorders; however, showed limitations of poor palatability. Oral sensory issues and gut irritation pose limitations to the use of preservatives in medicines for ASD. *Arka* (liquid distillate), owing to its extended shelf- life and absence of preservatives, can be advantageous in gastrointestinal disturbances. Thus, *Hingvastaka Churna Arka* and *Vilvadi Gutika* were aimed at managing FGIDs in children with ASD. **Materials and Methods:** The current study is a prospective, open-label, randomized controlled, efficacy, superiority trial involving 60 ASD children with FGIDs. The trial group will receive *Hingvastaka Churna Arka* with *Takra* (buttermilk) before food and *Vilvadi Gutika* after food, thrice daily, for 30 days, with age- specific dosing. The control group will receive *Rajanyadi Churna Arka* and *Vilvadi Gutika* similarly. The Primary outcome measure is the reduction in symptoms of FGIDs based on the 6- Item Gastrointestinal Severity Index (6-GSI) and Gastrointestinal Symptom Rating Scale (GSRS). Secondary outcomes will be evaluated by changes in ASD- related symptoms using ATEC based on parental feedback. **Conclusion:** The findings of the study may potentially demonstrate the safety and efficacy of *Hingvastaka Churna Arka* and *Vilvadi Gutika* in managing FGIDs in children with ASD.

KEYWORDS: Functional Gastrointestinal Disorders, Autism Spectrum Disorders, *Hingvastaka Churna Arka*, *Rajanyadi Churna Arka*, *Vilvadi Gutika*, 6- Item Gastrointestinal Severity Index, Gastrointestinal Symptom Rating Scale, Autism Treatment Evaluation Checklist.

TRIAL REGISTRATION: CTRI/2026/01/102631

RECEIVED ON: 05-03-2026

REVISED ON: 10-03-2026

ACCEPTED ON: 14-03-2026

Access This Article Online:

Quick Response Code:

Website Link: https://jahm.co.in

DOI Link: https://doi.org/10.70066/jahm.v14i2.2633

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CITE THIS ARTICLE AS

K Smruthi, Reena K. Efficacy of Hingvastaka Churna Arka with Vilvadi Gutika in the Management of Functional Gastrointestinal Disorders in Children with Autism Spectrum Disorder: A Randomized Controlled Trial. Journal of Ayurveda and Holistic Medicine (JAHM) 2026; 14(2):17-27.

1. INTRODUCTION

Autism Spectrum Disorders (ASD) encompass a diverse group of neurodevelopmental conditions characterized by varying levels of impairment in social communication and reciprocal interaction, accompanied by persistent patterns of restricted, repetitive, and inflexible behaviors, interests or activities. [1] The frequently associated comorbid conditions include intellectual disabilities, psychiatric disorders, and, notably, Functional Gastrointestinal Disorders (FGIDs). Among these, FGIDs are particularly prevalent, with incidences ranging from 30% to 70%. [2] A study from South India done on the "Gastrointestinal Manifestations and Associated Comorbidities in ASD Children" identified constipation and dietary issues as the most common symptoms (82.29%), followed by pica (36.46%), abdominal pain (26.04%), diarrhea (14.58%), and dyspepsia (4.79%). [3] These comorbidities further contribute to sensory issues, metabolic disturbances, and intellectual impairments, thereby reducing the quality of life in affected children and causing significant distress to their parents. [4]

The clinical features of ASD show notable resemblance to *Unmada* (insanity), involving *Ashta Vibhrama* (disruption of eight mental faculties), such as, *Mano Vibhrama* (impaired thoughts), *Buddhi Vibhrama* (impaired perception or cognition), *Samjna Vibhrama* (impaired sensory perceptions), *Smriti Vibhrama* (impaired memory), *Bhakti Vibhrama* (impaired preference or attachment), *Sheela Vibhrama* (impaired emotion or habit), *Chesta Vibhrama* (abnormal gestural activity) and *Achara Vibhrama* (impaired social conduct and behavior), with a predominant effect on the *Manas* (mind). [5] In Ayurvedic pathology, *Manasika Vikara* (mental disorders) are known to impair *Agni* (digestive fire), leading to *Agnimandya* (weak digestion) and accumulation of *Ama* (metabolic toxins), which subsequently results in *Koshtajanya Roga* (gastrointestinal disorders). [6] The presence of *Ama* (metabolic toxins) contributes to gut inflammation and increased intestinal permeability, presenting as altered bowel habits, anorexia, nausea, and abdominal discomfort. [7] Other Ayurvedic references state that the *Manovaha srotas* (pathways of mental functions) and *Rasavaha srotas* (channels carrying nutritive fluid) intricately operate together and any abnormality in these disrupts the nutritive absorption and alters the sensorium. This further results in improper digestive functioning, invariably affecting neurocognition. [8]

A complex neuro-enteric axis links gastrointestinal symptoms with sensory processing abnormalities in ASD. This is primarily mediated by the autonomic nervous system and modulated by neurohormonal dysregulation, particularly involving GABA and serotonin, alongside stress response mechanisms and immune- microbiota interactions. [9- 10] These fundamental factors are implicated in core ASD behaviors such as stereotypy, social withdrawal, ritualistic tendencies, and, in some cases, self- injurious behavior, highlighting gastrointestinal symptom management as a potentially valuable therapeutic target. [11]

Management of FGIDs seen in children with ASD remains largely unexplored owing to the complex pathologies involved, hitherto, effective interventions are yet to be established for the same. While prebiotics and probiotics have demonstrated some efficacy, the application of conventional therapies falls short, necessitating integrative approaches. [12] Ayurveda offers a holistic perspective, linking *Manasika Vikara* (psychological disturbances) with *Koshtajanya vikara* (gastrointestinal disorders) through concepts like *Agnidushti* (impaired digestion), *Ama* (metabolic toxins), and *Amavisha* (metabolic toxin). The findings of a case study on a child who received *panchakarma* and oral medications such as *Ajamoda Arka* and *Vilvadi Gutika*, focusing on gut health, showed improvements in the Children's Global Assessment Scale (CGAS) and Parent- Rated 10-item Likert Scale (PRILS-10) after ninety days. [13] Another

study reported the effectiveness of *Rajanyadi Churna* and *Vilvadi Gutika* in managing gut dysbiosis in children with ASD. [14] *Rajanyadi Churna*, is indicated to be used in *balasya sarvarogeshu* (all disorders of children), especially in gastrointestinal disorders, as it is *grahani deepaka* (enhancing digestive fire) and *vatanulomaka* (regulating *vata*). As the *churna* (powder formulation) possesses poor palatability, *Rajanyadi Churna Arka* was chosen as the comparator. *Hingvastaka Churna*, traditionally indicated for *Agnimandya* (reduced appetite), *Shula* (Abdominal pain), and *Gulma* (Abdominal tumour), possesses *Ama pachaka* (metabolizing toxins), *Agnideepaka* (enhancing digestive fire), and *Vatanulomaka* (regulating *vata*) properties. [15] *Takra* (Buttermilk), recognized as a natural probiotic and predominantly used in treatment of *Grahani roga* (celiac disease), enhances *Agnideepana* (enhancing digestive fire) when administered with *Hingvastaka Churna*. [16] No serious harm or adverse reactions were noted based on the previous studies done on *Rajanyadi churna* and *Hingvastaka churna*.

The need to address issues of palatability, acceptability, and addition of preservatives in various dosage forms is cardinal to prevent oral sensory issues and risk of gut irritation in children with ASD. The gut is prone to irritants such as preservatives in medicines, which in turn act as a major barrier that hinders a promising intervention in these cases. *Arka* (liquid distillate) is proven to be better absorbed and less irritable to the sensitive gut. To improve acceptability among children with ASD, *Hingvastaka Churna Arka*, a liquid distillate, has been developed. [17] Clinical trials on *Ajamoda Arka*, *Shatapushpa Arka* and *Hingvastaka Arka* for infantile colic showed their safety and effectiveness, supporting the utility of modifying the classical *Churna* into *Arka* form. *Vilvadi Gutika* also offers *Deepana* (appetite stimulant), *Pachana* (improves digestion), and *Vishahara* (removes toxins) actions, aiding in the elimination of *Amavisha* (metabolic toxin). [18] This study is therefore designed to evaluate the combined efficacy of *Hingvastaka Churna Arka* and *Vilvadi Gutika* in enhancing gastrointestinal function, alleviating FGIDs symptoms, and improving overall clinical features in children with ASD.

2. OBJECTIVES:

Primary objective:

To evaluate the efficacy of *Hingvastaka Churna Arka* in combination with *Vilvadi Gutika* in managing FGIDs in children aged 3- 10 years with ASD, by specific assessment of clinical features such as constipation, diarrhea, stool consistency, stool odor, flatulence, and abdominal pain using the 6- Item Gastrointestinal Severity Index (6- GSI).

Secondary objectives:

i. To compare the combined efficacy of *Hingvastaka Churna Arka* and *Vilvadi Gutika* with *Rajanyadi Churna Arka* and *Vilvadi Gutika* in the management of FGIDs in children with ASD.
ii. To document the reduction in ASD related manifestations in the Autism Treatment Evaluation Checklist (ATEC).
iii. To review the Gut-Brain Axis relationship in FGIDs and ASD, and to evaluate the safety and efficacy of *Arka Kalpana* (liquid distillate formulation) in FGIDs based on parental reports.
iv. To obtain data on any potential side effects of Adverse Drug reactions of any of the study drugs.

3. METHODS:

Trial Design: This is a prospective, open-label, parallel group, randomized controlled, efficacy, superiority trial involving children aged 3-10 years diagnosed with ASD and FGIDs. Participants shall be assigned to two groups parallelly to receive oral medications for 30 days.

Trial Setting: Outpatient and Inpatient Department of Kaumarabhritya, SDMIAH, Bengaluru.

Trial Duration: 30 days.

The Participant Timeline is elaborated in Figure 1.

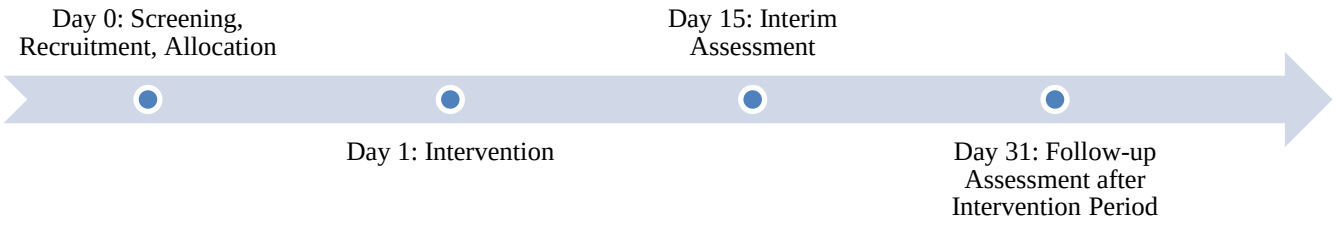

Figure 1: Participant Timeline

Eligibility Criteria:

ICD CODES: Autism Spectrum Disorder: ICD-11-6A02, Functional Gastrointestinal Disorders: ICD- 11- DD9Z. [19- 20]

NAMC CODES: *Unmada*: EM- 2, *Grahani*: EB-7 [21]

Parents or legal guardians who provide informed consent/ assent and demonstrate willingness to ensure full compliance with the study protocol.

Inclusion Criteria:

1. Children of either gender, aged between 3 and 10 years, fulfill DSM-5 TR criteria for ASD and screening positive on the M-CHAT-R tool.
2. Children with ASD presenting with 2 or more items on the 6- GSI Scale and the ROME IV Criteria for the diagnosis of FGIDs.

Exclusion Criteria:

1. History of prebiotic or probiotic use within the past three months, use of laxatives, or adherence to special diets or food restrictions.
2. Presence of any acute infections and is receiving any pharmacological treatments for the same.
3. ASD children presenting with other co-morbid systemic illnesses, or any other chronic neurological or metabolic disorders.

Assessment Criteria:

1. 6 Item Gastrointestinal Severity Index- 6 GSI [22]
2. Gastrointestinal Symptom Rating Scale- GSRS (based on Ayurveda) [23]
3. Autism Treatment Evaluation Checklist- ATEC [24]

Intervention and Comparator:

The medicines for both the intervention and comparator groups will be procured from a GMP certified pharmacy that complies with the standards of manufacturing as mentioned in the Ayurveda Pharmacopoeia of India (API) and World Health Organization (WHO). [25] The method of drug preparation will be based on the Ayurvedic Formulary of India (AFI). The medicines prepared will undergo proper quality control and drug standardizations, with the final product mentioning the manufacturer's name and batch number before giving to the participants. The trial group participants will receive *Hingvastaka Churna Arka* and *Vilvadi Gutika* for a 30- day duration. Control group participants will receive *Rajanyadi Churna Arka* and *Vilvadi Gutika* for a duration of 30 days as outlined in Table 1.

Table 1: Intervention and Comparator

S. No.	Age	Dose of Control/ Trial drug	Dose of *Anupana- Takra*	Dose of *Vilvadi Gutika*	Time of administration	Assessment
1.	3 to 6 years	2.5 ml	5 ml	½ tablet 380 mg	Thrice daily before food	0-day: Before treatment 15-day: Interim 31-day: After treatment
2.	7 to 10 years	5 ml	10 ml	1 tablet 760 mg	Thrice daily before food	

Discontinuation/ Modification Criteria:

Participants will be monitored from Day 0 to Day 31, with an Interim assessment on Day 15 for clinical improvement, compliance, and adverse drug reactions. Dose modifications or rescue medicines will be provided based on the gradings of severity of the need, at the discretion of the Principal Investigator, in cases of worsening or improvement of the conditions, or on request of the participant. A specially designed Case Report Form (CRF) will be used to document all changes in the study.

Adherence Monitoring Strategy and Retention Plan:

To ensure proper administration of medicines and maintenance of adherence throughout the study, all participants shall be contacted through digital or telecommunication means to clarify doubts and provide support. Adherence will be measured by pills count method and return of empty bottles and strips when the participant comes for the interim assessment. The compliance percentage will be calculated based on the proportion of quantity of medicines actually taken by the quantity of medicines prescribed.

Concomitant Care:

The specially designed CRF will be used to record all concurrent illnesses and medications. All medications taken by the participant should be acknowledged by the Principal Investigator. Any prescribed medications will be duly documented. Any essential medications and long-term medications which do not interfere with the intervention shall be continued and other medications will be strictly prohibited.

Outcomes:

All outcomes of changes in the appetite, bowel patterns, stool consistency, sleep adequacy, and overall behavioral symptoms will be compared before and after the intervention period, on Day 0 and Day 31.

Primary Outcome Measure: Reduction in the symptoms of FGIDs based on the changes noted in the 6- GSI and the GSRS as an endpoint assessment.

Secondary Outcome Measure: Reduction in ASD related manifestations based on parental feedback in the ATEC.

The comprehensive study plan is presented in Table 2. The participant timeline is elaborated in Figure 2.

Table 2: Comprehensive Study Plan

Study Event	Day 0	Day 15	Day 31
Baseline assessment- DSM 5 T R Criteria, ROME IV criteria	✔		
Informed consent	✔		
Recruitment	✔		
Demographic profile	✔		
Intervention (30 days)	✔	✔	
Follow-up		✔	✔
Assessment by clinical evaluation- M-CHAT R, 6- GSI Scale, GSRS Scale, ATEC	✔		✔
Evaluation using the assessment parameters- 6- GSI Scale, GSRS Scale, ATEC	✔		✔
Drug compliance		✔	✔
Rescue medication (If required)		✔	✔
Assessment of adverse events		✔	✔

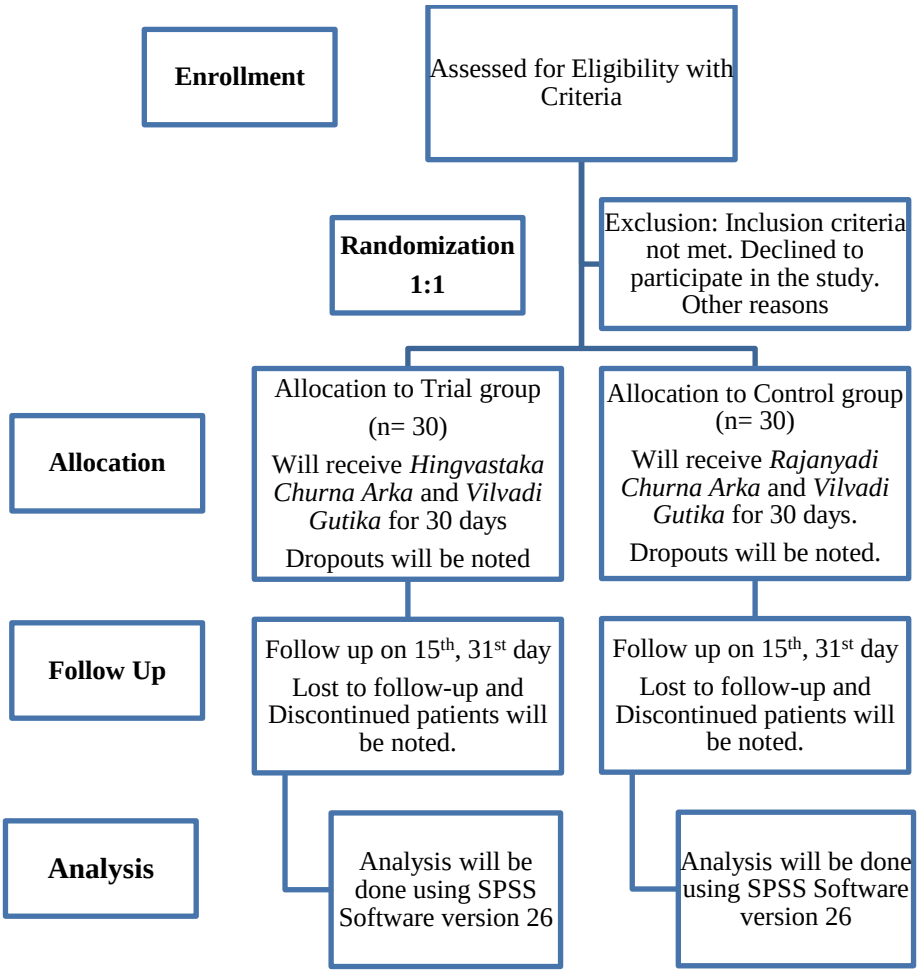

Figure 2: Participant Flow Diagram

Sample Size:

The current study's sample size has been calculated using a standard formula based on the Standard deviation of a relevant previous clinical study. [15]

Assumptions taken regarding sample size calculation:

Mean Difference: Approximately 12% (trial > control)

Standard Deviation: Approximately 15% based on the graphical data

Significance level α = 0.05 for a Two- tailed test

Power (1−β) = 0,80 (80%)

$$n = \frac{2\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \sigma^2}{d^2}$$

$$n = \frac{2\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{2(1.96 + 0.80)^2\ (15)^2}{(12)^2}$$

$$n = \frac{2\ \times 7.61\ \times\ 225}{144}$$

$$n = \frac{3427}{144}$$

n = 23.8 ≈ 25

Considering a 10% dropout rate, $n = \frac{n}{(1-d)}$

$n = \frac{25}{(1-0.10)}$

n = 27.78 ≈ 30

Considering feasibility of the study, an arbitrary of 30 participants will be included in each group, with a total sample size of 60 participants.

Recruitment Strategy:

Participants will be recruited from the Outpatient and Inpatient Department of Kaumarabhritya, SDMIAH, Bengaluru. Children aged 3- 10 years who meet the DSM- 5 TR Criteria for ASD and screen positive on the 6- GSI will be identified by the investigators. Prior to the enrollment, the parents will be explained the details of the study and their willingness to participate in the study. Interested participants will be enrolled in the study after taking written informed consent. Assent will also be taken from the parent due to age consideration and subnormal levels of mental status of the child. Only those willing to adhere to the study protocol for a 30- day intervention period will be included. Parents or legal guardians will be approached during routine visits, and the study objectives, procedures, benefits, and risks will be explained. Recruitment will continue until the target sample size of 60 participants is reached.

Randomization: Simple Random Sampling with 1:1 allocation.

Sequence Generation: Computer- generated Random sequences will be used to allocate and assign participants to either group.

Allocation and Concealment: Random tickets will be placed in Sequentially Numbered Opaque Sealed Envelopes (SNOSE) and opened in the presence of the guide at the initiation of the trial.

Implementation: The Supervisor will produce a random allocation sequence based on randomization software that will be accessed by the Principal Investigator.

Blinding: Open- Labeled Trial. The outcome assessor and Data analyst will be blinded at the time of Statistical analysis.

Data Collection Method:

A customized CRF will be developed based on the Inclusion and Diagnostic criteria and used to collect all data, such as demographic details, medical history, and key features of FGIDs and ASD. Internationally accepted and validated scales on FGIDs namely 6- GSI and GSRS, and ATEC on ASD will be adapted to collect data and assess outcomes, and the Principal Investigator will be trained for the same prior to the collection of data. [22- 24] The Data will be collected by direct interaction with parents/ participants.

Data Management:

All study data will be digitalized into a secure electronic database. Database access will be restricted to authorize study personnel only. Data management will be done using SPSS software version 26 to ensure effective data backup. A unique ID will be assigned to each participant's data to avoid double data entry. Investigators will review the data for completeness, consistency, and accuracy, and any discrepancies will be cross- verified with source documents. Across the study, the personal details will be kept confidential by allotting unique participant identifiers in the dataset.

Statistical Methods:

Primary Analysis: Statistical analysis will be done using MS Office Excel, and analyzed using IBM SPSS Version 26. The study participants will be grouped and categorized into the intention-to-treat and per-protocol groups. The data from the intention-to-treat group will be assessed for safety, and data from the per-protocol group will be assessed for efficacy. The data would be subjected to a normality test by Shapiro-Wilk's method. If the normality test is passed, parametric analysis would be done; if not, non-parametric tests would be employed. Missing data more than 10% will be considered as dropouts and will not be considered for statistical analysis.

Descriptive Statistics: Baseline data will be analyzed in terms of "Mean", "Median", "Frequency", "Standard Deviation", "Standard Error", and "Percentile" for nominal, ordinal and continuous data.

Inferential Statistics: It will be done using Parametric and Non- Parametric tests.

Level of Significance: A p- value of < 0.05 at a Confidence Interval of 95% will be considered statistically significant.

Non-Parametric Tests: Subjective data assessed with:

1. Friedman test for < 2 sets within the same group.

2. Wilcoxon signed-rank test for differences within groups, before and after treatment.

3. Mann-Whitney U test for between the trial and control groups.

Parametric Tests: Objective data assessed with:

1. Unpaired t-test or objective data, assessed between groups

2. Paired t-test will be assessed within the group before and after treatment.

Chi-square test will be used for Categorical data.

Effect Size: Cohen's d (standardized mean difference) interpreted as small (0.2), medium (0.5), or large (0.8) effect sizes will be used to compare parametric outcomes between the two groups for eliciting treatment efficacy.

Data and Trial Monitoring:

The Data Monitoring Committee, consisting of the designated members of the Institutional Research Committee (IRC) and the Departmental Research Committee (DRC), will be responsible for periodical monitoring and auditing of data. The Principal Investigator and the Supervisor will be responsible for supervising the trial, and ensuring proper participant enrollment, treatment protocol adherence, follow-up and adverse events documentation. Interim Analysis will not be done considering small study duration. Study progress and data quality will be periodically reviewed and reported to the Institutional Research and Data Monitoring Committee, if necessary. Any protocol amendments or adverse events shall be promptly reported to the Institutional Ethics Committee (IEC).

Adverse Event Management and Safety Measures:

Before enrollment, a history of any potential allergies will be collected. Though no serious adverse events are anticipated, any reactions noted during the interventional period will be documented using the ADR (Ayush Suraksha) form and will be graded as mild, moderate and severe based on symptomatic presentations and managed with appropriate treatment. In severe cases, the participant will be withdrawn from the study and will be provided with appropriate management. The same will be reported to the institutional Pharmacovigilance unit within 24 hours and documented in the final report.

Ancillary Care: Participants presenting with any associated illnesses will be provided appropriate management without intervening in the trial protocol.

ETHICS:

Ethical Issues and Informed Consent:

Ethical approval for the current study was obtained from the "IEC of SDMIAH" on July 7, 2025 (Ref: SDMIAH/IEC/15/2025). The Prospective registration of the study with the "Clinical Trials Registry of India (CTRI)" on January 30, 2026 (Ref: CTRI/2026/01/102631). The protocol will adhere to the Declaration of Helsinki, and written informed consent/ assent will be obtained before commencement. Participation will be entirely voluntary, with the right to withdraw at any stage of the trial. The Principal Investigator, designated data auditors, and the study supervisor will have access to the anonymized final dataset, ensuring strict confidentiality of patient data. The outcomes of the study will be shared via open-access publications and presented at conferences whenever necessary.

Protocol Amendments: Any factors affecting the safety and scientific quality of the trial will be reported to the IEC within 24 hours, and if required, amendments will be made to ensure that research remains ethical, valid and in compliance with guidelines.

Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable: Not Applicable.

Declaration of interests: There are no conflicts of interest.

Study Status: The study has commenced, with 10 participants enrolled so far. Recruitment is ongoing.

Dissemination:

The results will be published in an open-access, peer-reviewed, indexed journal, on completion of the trial, to ensure wide dissemination among the scientific community and support future research. In addition, a seminar will be held to share the results with relevant stakeholders. A structured community awareness program will also be conducted to share relevant outcomes with the general public.

4. DISCUSSION:

FGIDs are increasingly prevalent in children with ASD, emphasizing the impact of gastrointestinal disturbances on Neurodevelopment and Neurocognitive abilities. Children experiencing gut disturbances habitually show increased irritability, social isolation, hyperactivity and sleep disturbances compared to their peers without any gastrointestinal manifestations. Further, dietary challenges, restricted preferences, and difficulty managing cravings add to the burden on parents, significantly affecting quality of life.

The concept of the gut- brain axis, which relates to the *Koshtajanya* and *Manasika Vikara* (gastrointestinal and psychological disorders), is still largely underexplored. Nonetheless, there are inadequate clinical studies illustrating the advantages of Ayurvedic therapies in these conditions. It is essential to re- evaluate the fundamentals of balancing the *Koshta* (gut), *agni* (digestive fire) and eliminating the *Amavisha* (metabolic toxin) to enhance results in such conditions.

In pediatric care, palatability is a significant issue, especially in ASD children who frequently experience oral sensory issues and struggle with dosage forms like *Churna* (powder) and *lehya* (electuary). Despite the advantages of oral medications in addressing gut disturbances, proper modifications in the formulations are essential to enhance acceptability and adherence. Clinical experiences indicate that *Hingvastaka Churna Arka* given with *Takra* (buttermilk) as an *Anupana* (adjuvant) improves both flavor and therapeutic effectiveness. Thus, this research intends to assess Ayurvedic formulation in a suitable dosage to treat FGIDs in ASD children, with wider application potential if proven effective.

Abbreviations:

ASD: Autism Spectrum Disorders

FGIDs: Functional Gastrointestinal Disorders

GABA: Gamma-aminobutyric acid

CGAS: Children's Global Assessment Scale

PRILS-10: Parent- Rated 10-item Likert Scale

6- GSI: 6- Item Gastrointestinal Severity Index

ATEC: Autism Treatment Evaluation Checklist

ICD: International Classification of Diseases

NAMC: National Ayurveda Morbidity Codes

DSM-5 TR: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision

M-CHAT-R: Modified Checklist for Autism in Toddlers, Revised

GSRS: Gastrointestinal Symptom Rating Scale

GMP: Good Manufacturing Practice

API: Ayurvedic Pharmacopoeia of India

WHO: World Health Organization

AFI: Ayurvedic Formulary of India

CRF: Case Report Form

SNOSE: Sequentially Numbered Opaque Sealed Envelopes

IRC: Institutional Research Committee

DRC: Departmental Research Committee

IEC: Institutional Ethics Committee

CTRI: Clinical Trials Registry of India

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Data collection and Literature search: KS, RK

Writing- Original draft: KS, RK

Reviewing & Editing: RK, KS

Approval of Final manuscript: RK, KS

Acknowledgements: Authors acknowledge constant support and guidance from Dr Jagdeesh Kunjal, Principal, SDM Institute of Ayurveda and Hospital, Bengaluru; Dr Ravishankar B, Research advisor, Sri Sri Institute of Ayurveda; fellow researchers and faculty members of Department of Kaumarabhritya for constructive suggestions and encouragement.

Declaration of Generative AI

The authors declare this manuscript was written without the use of generative artificial intelligence tools. All the content, including text generation, data analysis and references was developed and reviewed by the author without assistance from AI technologies.

Data Availability: The custodian, Research Co-Ordinator and the Head of the Institute, SDM Institute of Ayurveda and Hospital, and Rajiv Gandhi University of Health Sciences, Bengaluru. will have access to the data.

Conflict of Interest – The authors declare no conflicts of interest.

Source of Support – The authors declare no source of support.

Additional Information:

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