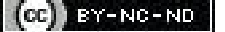


# Comparative Clinical Assessment of *Yastimadhu Rasayana* and *Ashwagandha Rasayana* in Young Adults with Easy Mental Fatigability: A Research Protocol

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## ABSTRACT

**Introduction:** In Ayurveda, the term “*Glāni*” refers to lassitude or exhaustion, including mental dejection, mental tiredness, languor, and overall fatigue and is indicative of various disorders. Mental fatigue is a growing concern in both clinical and occupational settings, often manifesting as reduced concentration, impaired cognitive performance, and diminished overall productivity. Traditional medicine has long sought remedies to counteract such fatigue, with several *Rasayana* (rejuvenative) formulations being highlighted for their neurocognitive benefits

**Need of the study:** Ashwagandha is well-known for its adaptogenic properties, particularly in reducing stress and mental exhaustion. Its role in alleviating fatigue highlights the potential of other *Rasayana* agents. *Yastimadhu* (*Glycyrrhiza glabra*), a *Medhya-rasayana*, is recognised in Ayurvedic pharmacology for enhancing mental clarity, energy, and cognitive resilience. While classical texts, such as those by Acharya Bhavprakash, discuss its benefits for mental fatigue, *Yastimadhu* remains underexplored in modern research. This study focuses on *Yastimadhu churna* as a potential treatment for mental fatigue, aiming to connect traditional Ayurvedic knowledge with contemporary scientific validation, thus supporting the integration of traditional medicine into modern clinical practice.

**Aim:** To evaluate and compare the clinical efficacy of *Yastimadhu Rasayana* versus *Ashwagandha Rasayana* in young adults exhibiting symptoms of easy mental fatigability.

**Materials and Methods:** The present randomised, single-blind, two-arm, parallel-group, controlled trial will be conducted at the Mahatma Gandhi Ayurveda College, Hospital, and Research Centre (H), Wardha, Maharashtra, from February 2025 to February 2026. The trial will involve two months of treatment administration followed by a four-week follow-up period. A total of 100 individuals who meet the specified inclusion and exclusion criteria will be recruited. At baseline, mid-intervention, and post-intervention, mental fatigability will be assessed using the Chalder Fatigue Scale (CFS), according to Ayurveda’s classic symptoms of *Glāni* and *Buddhi*, as well as the Modified Fatigue Impact Scale (MFIS) and the Psychomotor Vigilance Test (PVT-10). The Wilcoxon signed-rank test will be used for non-normally distributed data, while paired t-tests will be applied to normally distributed groups. Independent group-based t-tests will compare continuous normally distributed variables, and Mann-Whitney tests will be used for non-normal data. A significance level of  $p < 0.05$  will be applied.

**Keywords:** Chalder fatigue scale, Cognitive performance, Fatigue, *Glycyrrhiza glabra*

## INTRODUCTION

Mental fatigue is a complex condition that reduces cognitive performance and attentiveness and leads to feelings of exhaustion after prolonged mental effort. It affects a person’s ability to concentrate, process information, and perform daily tasks effectively [1]. Recent epidemiological studies show that the incidence of easy mental fatigue in young adults is rising, with reported rates ranging from 4-45%. This increase is largely attributed to busy and fast-paced lifestyles. Importantly, unexplained fatigue is more than three times as common as explained fatigue (7.6% versus 2.3%), with psychological problems accounting for a significant portion of cases [1,2]. Mental fatigue can manifest as physical tiredness, subjective feelings of exhaustion, and weariness and these symptoms may appear before, during, or after prolonged cognitive work [3].

In Ayurveda, fatigue is described through the term *Glani*, which means a lack of desire or motivation for physical work. *Glani* is considered a symptom in several diseases, such as *Pandu*, *Ras Kshaya*, *Ajeerna*, and *Murccha Purva Roop*. Even in healthy individuals, *Glani* can be seen as a preclinical symptom of conditions like *Akaaljararog* and *Ojokshaya* [4,5]. Ayurvedic texts explain that fatigue arises from abuse, misuse, or lack of use of the mind, emotions, or body. The mental faculties are described as *Dhi* (the power of grasping and learning), *Dhriti* (the ability to focus and concentrate), and *Smriti* (the

ability to recall information). These three functions together form the *Buddhi*, the psychological faculty responsible for reasoning and logic. Imbalances in *Dhi*, *Dhriti*, and *Smriti* reduce mental capacity [6]. Ayurveda further associates different types of fatigue with imbalances in the three *doshas*: mental fatigue with *Vata dosha*, emotional fatigue with *Pitta dosha*, and physical fatigue with *Kapha dosha* [7]. Herbal or plant preparations that help the body tolerate, resist, and adapt to stressors are collectively known as adaptogens. These substances have shown benefits such as reducing fatigue, alleviating depression, easing anxiety, lowering stress, and promoting healthy ageing. There are many examples of adaptogens, including *Withania somnifera* (*ashwagandha*), *Rhodiola rosea*, *Tribulus terrestris*, *Panax ginseng* (Korean ginseng), *Eleutherococcus senticosus* (Siberian ginseng), and *Bacopa monnieri*. Among these, *ashwagandha* is one of the most commonly used adaptogens in Ayurvedic medicine and one of the most extensively researched herbs [8]. It is also referred to as Indian ginseng or winter cherry. In addition to improving memory and cognition, *ashwagandha* possesses antistress, antioxidant, immunomodulatory, rejuvenating, anti-inflammatory, anti-arthritis, and anti-tumour effects [9].

*Yastimadhu* (*Glycyrrhiza glabra*), classified as a *Medhya-rasayana*, holds a special place in Ayurvedic pharmacology due to its reputed ability to enhance mental clarity, energy, and cognitive resilience

[10]. Classical texts, including the authoritative work of Acharya Bhavprakash, highlight its pharmacokinetic and pharmacodynamic properties in reducing mental fatigue and supporting sustained cognitive function [11]. Unlike ashwagandha, which has been widely validated in modern research, *Yastimadhu* remains relatively underexplored concerning mental fatigue, despite strong traditional support for its use.

## REVIEW OF LITERATURE

*Medhya Rasayana*, a subtype of *Kamya Rasayana*, are the nootropic herb that boosts intelligence, alertness, attention, and memory [10]. These drugs are recognised for their specific influence on mental performance, primarily through their neuro-nutrient effects and their ability to enhance cerebral metabolism. These formulations are traditionally understood to support the faculties of intellect (*Dhi*), retention (*Dhriti*), and memory (*Smriti*). The pharmacodynamic properties of *Medhya Rasayana*, characterised by *Shita Virya* (cool potency) and *Madhura Vipaka* (sweet post-digestive effect), are believed to promote *Kapha* and strengthen *Dharana Karma* (the cognitive function of retention). A classic example of such an agent is *Yastimadhu* [12]. The existing literature underscores the remarkable therapeutic potential of Ashwagandha and Yastimadhu, while also revealing significant limitations that underscore the necessity of this study. In a comprehensive randomised, double-blind, placebo-controlled trial, Smith SJ et al., (2023) highlighted the efficacy of a standardised Ashwagandha root extract (Witholytin®), demonstrating its ability to significantly alleviate perceived stress and fatigue in adults. This research not only confirms Ashwagandha's adaptogenic properties but also assures its safety for consumption [13]. Similarly, Bonilla DA et al., (2021), through a systematic review and Bayesian meta-analysis, affirmed that Ashwagandha plays a pivotal role in enhancing physical performance, showcasing notable improvements in strength,  $VO_2$  max, and recovery times. However, these promising results are primarily confined to middle-aged populations and heavily rely on subjective self-report measures, along with showing considerable variability in dosage and extract standardisation, which limits their generalisability across diverse age groups [14].

Conversely, *Yastimadhu (Glycyrrhiza glabra)* has gained research attention primarily for its potent anti-inflammatory and mucosal protective properties. Alhat DV et al., (2025) provided compelling evidence of its efficacy in alleviating pain associated with recurrent aphthous stomatitis, oral lichen planus, and radiation-induced oral mucositis. However, these findings are not directly related to mental fatigue or cognitive performance, emphasising a gap in the current understanding of its broader applications [15]. Meanwhile, Sheshagiri S et al., (2015) illustrated that *Yastimadhu* granules could enhance cognitive function in children, notably raising their Intelligence Quotient (IQ) scores. This aligns with its classification as a *Medhya-rasayana* in Ayurvedic tradition, which suggests benefits for intellect and cognitive clarity. Nevertheless, these findings are limited to paediatric samples, focusing mainly on IQ measures and lacking validation in adult populations experiencing mental fatigability [16].

The literature positions Ashwagandha as a well-recognised adaptogen with substantiated benefits in stress reduction and performance enhancement. In contrast, *Yastimadhu* remains largely underexplored in adult demographics, despite its strong traditional claims suggesting cognitive advantages. The limitations of previous studies, including reliance on subjective assessments, absence of standardised protocols, a predominant focus on paediatric populations regarding *Yastimadhu*, and the lack of direct comparative research, highlight the need for the current study. Therefore, this study aimed to evaluate and compare the efficacy of *Yastimadhu Rasayana* versus *Ashwagandha Rasayana* in young adults with symptoms of easy mental fatigue.

### Primary objectives:

1. To evaluate the efficacy of *Yastimadhu Rasayana* in the management of easy mental fatigue based on objective and subjective parameters.
2. To evaluate the efficacy of *Ashwagandha Rasayana* in the management of easy mental fatigue based on objective and subjective parameters.

### Secondary objective:

1. To compare the efficacy of *Yastimadhu Rasayana* and *Ashwagandha Rasayana* in the management of mental fatigue based on objective and subjective parameters.

**Null Hypothesis (H0):** There is no significant difference in the efficacy of *Yastimadhu Rasayana* and *Ashwagandha Rasayana* in the management of mental fatigue.

**Alternate Hypothesis (H1):** *Yastimadhu Rasayana* demonstrates significant efficacy in the management of mental fatigue when compared with *Ashwagandha Rasayana*.

## MATERIALS AND METHODS

The present single-centre randomised, participant-blind, double-arm, parallel-group, controlled trial will take place at the Mahatma Gandhi Ayurveda College, Hospital and Research Centre (H), Wardha, Maharashtra, from February 2025 to February 2026. This project has received approval from the Institutional Ethics Committee (Ref. No. MGACHRC/IEC/Aug-2024/875, Dated: 21/08/2024) and has been prospectively registered in the Clinical Trials Registry India (CTRI/2025/02/080533, Dated: 13/02/2025). Participants would be prepared to adhere to the treatment protocol parameters established by the study and would provide informed consent

### Inclusion criteria:

- Participants between the ages of 18 and 30 years.
- Individuals engaged in managerial roles, students, and academics often endure extended periods of cognitive demands.
- Participants who show symptoms of easy mental fatigability with a Checklist Individual Strength-Revised (CIS-R) score above 12 [17], demonstrating clinically significant levels of cognitive tiredness, concentration problems, and motivation loss, will be eligible for the study.
- Participants of both genders possess middle and upper-class socio-economic situations.
- Participants who are not utilising any tonics or multivitamins to enhance overall health.

### Exclusion criteria:

- Participants are unwilling to engage in the trial. The subjects who will exhibit haemoglobin levels below 13 g/dL.
- Individuals with acute and chronic metabolic, endocrine, and nutritional problems. Individuals afflicted with chronic severe illnesses and chronic fatigue syndrome.
- An individual with substance misuse issues related to alcohol and drugs.
- Patient exhibiting signs of delirium, confusion, and other alterations in awareness, as well as psychiatric disorders: currently utilising any psychotropic medications.

**Sample size calculation:** The mean CFS scores before intervention were  $16.81 \pm 4.49$  and after intervention  $11.55 \pm 5.42$  [13]. Standard error values reported in the referenced article were converted to standard deviations by multiplying SE by  $\sqrt{n}$ , where  $n = 60$ . The pooled variance was calculated as  $\sigma^2 = (4.49)^2 + (5.42)^2 = 49.56$ .

$$\sigma^2 = (4.49)^2 + (5.422)^2 = 20.1601 + 29.402084 = 49.562184$$

$$Z_{1-\beta} = Z_{1-\alpha/2} = 1.282, \quad \alpha Z_{1-\alpha/2} = Z_{1-\alpha/2} - \frac{0.05}{2} = Z_{1-0.025} = 1.960$$

Power=1-β=1-0.1=0.9,

d<sub>NI</sub>: Non-inferiority limit (10%), "Mean before (CFS Scores) =16.82±4.492 and after (CFS Scores) =11.75±5.422"

μ<sub>A</sub>=16.82", " μ<sub>B</sub>=11.75", " μ<sub>A</sub>-μ<sub>B</sub>=5.07

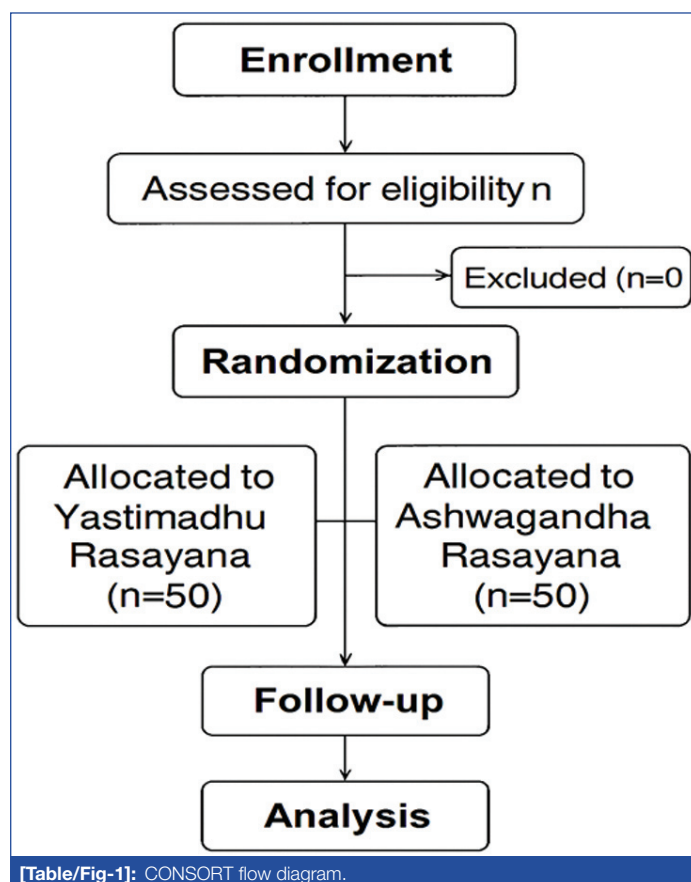
SD<sub>1</sub>=4.49, SD<sub>2</sub>=5.42: 10% (0.1), r: Allocation Ratio=1

$$n = \frac{(1+1)(1.282+1.960)^2 * (49.562184)}{1 * (5.07-0.1)^2} = 42 \text{ in each Arm}$$

Using an allocation ratio of 1:1, the required sample size was n=42 per arm. After adjusting for a 20% dropout rate, the final sample size was set at 50 participants in each arm.

## Study Procedure

Eligible participants will be randomised 1:1 to *Yastimadhu* (Group A) or *Ashwagandha* (Group B) following informed consent, in accordance with Good Clinical Practice and global ethical standards [Table/Fig-1]. Blinding will be achieved using identical packaging and labelling for both *Yastimadhu* and *Ashwagandha Rasayana*.



[Table/Fig-1]: CONSORT flow diagram.

Laboratory investigations will include Complete Blood Count (CBC), Thyroid Function Tests (T3, T4, TSH), and Glycated Haemoglobin (HbA1c) to exclude underlying diseases. Procurement of materials/ drugs - *Yastimadhu Churna* and *Ashwagandha Churna* shall be acquired from the certified pharmacy attached to the MGACH&RC, Salod (H), Wardha, Maharashtra, India, through the Procurement process. No conflicts of interest are disclosed. The study purchases API-compliant pharmaceuticals from GMP-certified *Dattatreya Rasashala* (License Number: NG/AYU/002/14) attached to the MGACH&RC, Salod (H), Wardha. Latine Name of drug – *Glycyrrhiza Glabra Linn*.

Name of the Drugs (Single)	Groups	Dose	Kaal (Time of administration)	Duration	Follow-up
<i>Yastimadhu Rasayana</i>	Group A (Intervention)	12 gm <i>Churna</i> OD orally with cow milk	<i>Apaan kaal</i> (empty stomach before breakfast)	2 months	0, 30 <sup>th</sup> , 61 <sup>th</sup> and 90 <sup>th</sup> day
<i>Ashwagandha Rasayana</i>	Group B (Compare group)	12 gm <i>Churna</i> OD Orally with cow milk	<i>Apaan kaal</i> (empty stomach before breakfast)	2 months	0,30 <sup>th</sup> , 61 <sup>th</sup> , and 90 <sup>th</sup> day

[Table/Fig-2]: Shows the study intervention details for both the experimental and control groups. The dose and administration Schedules followed the Guidelines provided in Classical Ayurvedic Literature [6,13]

Family- Fabaceae Ras - *Madhur Gun* - *Guru*, *Snigdha Virya* - *Sheet Vipaka* - *Madhur Doshnaghnata* - *vatahamk*; *pittashamak Sansthanik karm* - *medhya*, *nadi balya* Part used- roots. The treatment will last two months with a four-week follow-up.

Both the Intervention groups would first be given *Shodhan* (systemic bio-cleansing) for the first six days before starting administration of the intervention and comparing drugs. *Shodhan* would be done with 10 gm of *Haritaki* Powder once a day. Laboratory investigations will include a CBC, Thyroid Function Tests (T3, T4, TSH), and HbA1c to rule out any underlying diseases. The procurement of materials and drugs, specifically *Yastimadhu Churna* and *Ashwagandha Churna*, will take place at the certified pharmacy associated with MGACH&RC, Salod (H), Wardha, following the standard procurement process. There are no conflicts of interest to disclose. The study will purchase API-compliant pharmaceuticals from the GMP-certified *Dattatreya Rasashala* (License Number: NG/AYU/002/14), also linked to MGACH&RC, Salod (H), Wardha, Maharashtra, India.

The botanical information is as follows:

- Latin Name: *Glycyrrhiza glabra Linn*
- Family: Fabaceae
- Taste (Ras): Sweet (*Madhur*)
- Properties (Guna): Heavy (*Guru*), Oily (*Snigdha*)
- Potency (Virya): Cooling (*Sheet*)
- Post-Digestive Effect (*Vipaka*): Sweet (*Madhur*)
- Dosha Affinity: Beneficial for *Vata* and *Pitta*
- Therapeutic Action (Sansthanik Karm): Cognitive enhancer (*Medhya*) and nerve strengthener (*Nadi Balya*)
- Part used: Roots

The treatment duration will be two months, followed by a four-week follow-up.

Both intervention groups will undergo a *Shodhan* (systemic bio-cleansing) for the first six days before starting the administration of the interventions and comparison drugs. The *Shodhan* process will involve taking 10 grams of *Haritaki* Powder once daily at bedtime, mixed with lukewarm water. In this study, *Shodhana* therapy provides a theoretical basis for anticipating improvements in both objective and subjective assessments of neurocognitive function. The overall treatment will last for two months, with a follow-up four weeks thereafter, bedtime with lukewarm water. In this study, *Shodhana* therapy offers a theoretical basis for anticipating enhancements in both objective and subjective assessments of neurocognitive function. The treatment will last two months with a four-week follow-up [Table/Fig-2] [6,13]. Any adverse event, medication sensitivity, or other health concern or complication during the experiment will disqualify participants.

## Primary Outcome

**Chalder Fatigue Scale (CFS):** The primary outcome will be the difference in total CFS scores from baseline to the end of the intervention (Day 61). The CFS is an 11-item questionnaire designed to measure both physical and mental fatigue. Items 1-7 assess physical fatigue, while items 8-11 assess mental fatigue. Responses can be scored either bimodally (0-1; total score range 0-11) or on a Likert scale (0-3; total score range 0-33), with the Likert method offering greater sensitivity for intervention studies. The scale has demonstrated strong psychometric properties, including good

internal consistency (Cronbach's alpha >0.80) and construct validity across diverse populations [18,19].

**Psychomotor Vigilance Test (PVT-10):** Changes in reaction time, number of lapses, false starts, and overall performance decrement will be assessed at baseline and post-intervention to objectively quantify sustained attention and cognitive alertness associated with mental fatigue [20].

### Ayurvedic Symptom-based Outcomes

**Change in symptoms of *Glāni* (mental fatigability):** Assessed using predefined Ayurvedic parameters such as *Tandra*, *Bhrama*, *Hridayodvestana*, *Annam Na Rocate*, and *Vaktre Madhurta*, evaluated at baseline and post-intervention.

**Change in *Buddhi*-related functions (cognitive faculties):** Improvement in *Dhi* (*grasping*), *Dhriti* (*retention/concentration*), and *Smriti* (*memory recall*) assessed using a structured ordinal scoring system derived from classical Ayurvedic descriptions.

**Change in *Satva* (mental strength and resilience):** Assessment of emotional stability, coping capacity, and psychological endurance as indicators of mental resilience [11,21].

All these parameters will be assessed at baseline, 30<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup>.

## STATISTICAL ANALYSIS

All statistical analyses will be performed using Statistical Package for Social Sciences (SPSS) version 26.0 or KEEL version 3.0. Paired t-tests will be applied to compare groups when objective parameters are normally distributed, while the Wilcoxon signed-rank test will be used for non-normally distributed data. Between-group comparisons of continuous variables will be conducted using independent t-tests if the data follow a normal distribution and the Mann-Whitney U test if they do not. A p-value of less than 0.05 will be considered statistically significant.

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