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Calming the surgical mind: A randomized Controlled Trial of Brahmi Ghana Vati versus Alprazolam for Preoperative Anxiety

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Abstract

Background

Preoperative anxiety is a common psychological response among patients awaiting surgery, characterized by fear, apprehension, and uncertainty regarding anaesthesia, surgical procedures, and postoperative outcomes. Elevated anxiety may adversely influence haemodynamic stability, anaesthetic requirements, pain perception, postoperative recovery, and patient satisfaction. Its effective management is therefore an important component of perioperative care. Brahmi Ghana Vati, an Ayurvedic formulation prepared from *Bacopa monnieri*, possesses potential anxiolytic properties; however, evidence regarding its use in the immediate preoperative period remains limited. This study compared the effects of Brahmi Ghana Vati and alprazolam on preoperative anxiety.

Methods

This single-centre, open-label, randomized comparative trial analysed 70 patients undergoing elective surgery, with 35 patients in each group. Group A received Brahmi Ghana Vati 1 g orally, while Group B received alprazolam 0.25 mg orally on the evening before surgery. Preoperative anxiety was assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) at baseline (A0), 12 hours after intervention (A1), and immediately before surgery (A2). Within-group changes were analysed using the Friedman test, while between-group differences were assessed using the Mann–Whitney U test. Additional post-hoc analyses evaluated the APAIS anxiety and information subscales.

Results

Both groups demonstrated statistically significant reductions in total APAIS scores across the assessment periods ($P < 0.001$). Mean (SD) reduction from A0 to A2 was 6.09 (1.88) in the Brahmi Ghana Vati group and 6.37 (1.99) in the alprazolam group. No statistically significant between-group difference was observed in overall APAIS reduction ($P = 0.986$), indicating comparable observed reductions. Exploratory analyses of the anxiety and information subscales similarly revealed no statistically significant between-group differences ($P = 0.731$ and $P = 0.421$, respectively). No adverse drug reactions or rescue-medication use were recorded.

Conclusions

Both Brahmi Ghana Vati and alprazolam were associated with statistically significant within-group reductions in preoperative anxiety. The interventions demonstrated comparable observed reductions in APAIS scores, with no statistically significant difference between groups. These findings suggest that

Brahmi Ghana Vati warrants further investigation as a potential Ayurvedic intervention for preoperative anxiety, although therapeutic equivalence cannot be established from this study.

Trial registration:

Clinical Trials Registry-India, CTRI/2024/12/077761; registered 6 December 2024, before enrolment. Self-funded; no institutional financial support.

Background

Preoperative anxiety is a patient-centred concern, not simply a physiological response to be suppressed before induction. Patients differ in whether they fear anaesthesia, surgery, pain, loss of control or the consequences of treatment; previous surgical experience, psychological characteristics and clinical circumstances also influence anxiety [1, 2]. For perioperative care, the relevant therapeutic goal is relief of distress while preserving the ability to communicate, participate in decisions and recover from anaesthesia. This creates a need to evaluate anxiolysis together with functional outcomes, rather than assuming that a lower anxiety score alone represents better care.

Alprazolam has demonstrated preoperative anxiolytic effects in randomized studies, providing a clinically relevant active comparator [3, 4]. Nevertheless, sedative premedication does not consistently improve patient-centred outcomes. In the PremedX trial, lorazepam did not improve the overall patient experience and was associated with slower early recovery; in I-PROMOTE, low-dose oral midazolam did not improve global perioperative satisfaction in older adults [5, 6]. These findings do not imply that all benzodiazepines or dosing regimens have the same effects. They do justify examining whether a non-benzodiazepine intervention could relieve preoperative distress without clinically important cognitive or recovery disadvantages.

Brahmi Ghana Vati is an aqueous concentrated preparation of *Bacopa monnieri*, a plant traditionally described in Ayurveda as a *Medhya Rasayana*. Its scientific rationale rests on more than traditional use: a standardized Bacopa extract showed anxiolytic activity without significant motor impairment in an animal experiment, and a longer-duration human trial reported selected cognitive and anxiety-related benefits [7, 8]. Such findings raise a testable possibility of anxiolysis with preserved function. These potential advantages require direct measurement in surgical patients.

The existing clinical evidence is heterogeneous. Acute healthy-volunteer studies of a standardized Bacopa extract reported differing effects on task-related stress and mood, whereas a Brahmi vati study in generalized anxiety disorder used a different formulation context, comparator and 45-day regimen [9, 10, 11]. A more recent 12-week trial found no advantage on primary cognitive outcomes, despite improvements in some secondary stress and fatigue outcomes [12]. Evidence from these settings cannot establish the efficacy of one evening dose of a locally prepared aqueous extract during the short

interval before surgery. The question is therefore formulation-, dose- and setting-specific, rather than whether Brahmi is generally superior to contemporary anxiolytics.

This trial compared single-dose Brahmi Ghana Vati with alprazolam in adults admitted for elective surgery. The principal comparison was baseline-to-immediate-preoperative reduction in the dissertation-defined six-item total Amsterdam Preoperative Anxiety and Information Scale (APAIS). Post-hoc anxiety and information-subscale analyses were undertaken to clarify the components of that change. The objective was comparative assessment, not demonstration of equivalence, non-inferiority or a sedation-sparing benefit.

Methods

Design, setting and participants

This prospective, single-centre, open-label, parallel-group randomized comparative trial was conducted in the inpatient Department of Shalyatantra, Dr. D. Y. Patil College of Ayurved, Hospital & Research Centre, Pimpri, Pune, India. The allocation list targeted 35 positions per group, with an intended 1:1 ratio. Reporting follows CONSORT 2025, with attention to the herbal-intervention and patient-reported-outcome extensions [13, 14, 15].

Recruitment occurred from 1 May to 28 December 2025, after completion of trial-drug characterization in April 2025. The overall dissertation study period was 18 months. Participant observation covered the preceding evening and the immediate preoperative period; efficacy follow-up ended just before surgery. The registered first-enrolment date of 3 February 2025 differs from the investigator-confirmed recruitment start.

Adults aged 18–70 years of either sex, scheduled for elective surgery and admitted at least one day beforehand, were eligible. Written exclusions were known neurological disease and current antidepressant or antipsychotic use. Written informed consent preceded enrolment. Withdrawal criteria included adverse effects, rescue-medication requirement, and surgery cancellation.

Randomization, replacement and masking

The randomization sequence was generated by a statistician in April 2025 using Research Randomizer [16]. A computer-generated allocation list assigned 70 positions equally between the two treatment groups. Eligible participants were enrolled by the principal investigator (first author), who also implemented treatment allocation according to the generated sequence and chronological order of enrolment. No allocation concealment was employed.

Interventions

Participants were assigned to two treatment groups. **Group A** received Brahmi Ghana Vati 1 g (two 500 mg tablets) orally with lukewarm water, while **Group B** received alprazolam 0.25 mg orally with water. Both interventions were administered as a single dose at approximately 8:00 PM on the evening before surgery.

Participants continued to receive routine preoperative care according to institutional practice. The study interventions were administered in addition to this care.

Brahmi Ghana Vati was prepared from authenticated *Bacopa monnieri* powder obtained from Sanchomee Herboveda Pvt. Ltd., Pune (batch SHPL/01/25). The powder (500 g) was boiled in 8 L of water and reduced to approximately 1 L. The decoction was filtered and further concentrated to obtain a semisolid Ghana, which was subsequently prepared into 500 mg tablets at the institutional pharmacy.

The formulation underwent physicochemical evaluation before clinical administration. Detailed findings of raw-drug and finished-product testing are presented in **Additional File 1 (Table S1)**. Quantitative estimation of bacosides was not performed.

Outcome assessment and analysis hierarchy

Preoperative anxiety was assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) at baseline (A0), 12 hours after intervention (A1), and immediately before surgery (A2). Participants completed the questionnaire themselves, with the investigator available for clarification when needed.

The primary outcome was the reduction in total APAIS score from A0 to A2, assessed within and between groups. Changes across all three time points were also examined. Additional post-hoc analyses of the anxiety and information subscales were performed to better understand the changes observed in total APAIS scores.

Harms

Adverse drug reactions and the need for rescue medication were monitored by the investigator from administration of the intervention until the patient was taken for surgery. Any adverse events were to be documented using the designated reporting forms. No adverse drug reactions or rescue-medication use were reported in either group during the observation period.

Sample-size determination

The sample size was calculated using the prevalence-based formula ($n = Z^2pq/d^2$\), where ($Z = 1.96$), ($p = 0.8971$), ($q = 0.1029$), and ($d = 0.10$). The calculated sample size was 35.46. Accordingly, a target of 35 patients per group was adopted, giving a total sample size of 70 patients.

Data management and analysis population

Data from the completed APAIS questionnaires were manually entered into Microsoft Excel and verified by the research supervisor after study completion. A total of 70 participants, with 35 in each group, received treatment and completed all three assessments.

Statistical analysis

Data were analysed using descriptive and inferential statistical methods. APAIS scores were expressed as mean and standard deviation (SD). As the scores were ordinal in nature, non-parametric tests were employed for statistical comparisons.

The **Friedman test** was used to assess changes in APAIS scores across the three assessment points (A0, A1 and A2) within each group. The **Wilcoxon signed-rank test** was applied for pairwise comparisons to determine changes between individual assessment points. Between-group differences in APAIS scores and their reduction from baseline were evaluated using the **Mann–Whitney U test**.

Additional post-hoc analyses examined changes in the APAIS anxiety and information subscales, along with differences in response patterns over time. Statistical significance was assessed at the **5% level ($p < 0.05$)**, and results were interpreted accordingly.

Results

Participant characteristics

Of the 108 patients assessed for eligibility, 38 were excluded before treatment. Seventy patients received the allocated interventions, with 35 participants in each group (Fig. 1). A total of 70 patients were included in the final analysis, with 35 in the Brahmi Ghana Vati group (Group A) and 35 in the alprazolam group (Group B). All analysed participants completed the three scheduled assessments: baseline (A0), 12 hours after intervention (A1), and immediately before surgery (A2).

The baseline demographic and clinical characteristics are presented in Table 1. Group A included 20 male patients (57.1%), while Group B included 23 (65.7%). Spinal anaesthesia was planned for 28 patients (80.0%) in Group A and 21 (60.0%) in Group B. The baseline mean total APAIS scores were 19.54 ± 2.38 and 19.91 ± 2.38, respectively.

Table 1
Baseline demographic and clinical characteristics by treatment group

Characteristic	Brahmi (n = 35)	Alprazolam (n = 35)
Age 21–30 years	4 (11.4)	8 (22.9)
Age 31–40 years	15 (42.9)	11 (31.4)
Age 41–50 years	3 (8.6)	6 (17.1)
Age 51–60 years	10 (28.6)	5 (14.3)
Age 61–70 years	3 (8.6)	5 (14.3)
Male	20 (57.1)	23 (65.7)
Female	15 (42.9)	12 (34.3)
Any recorded medical history	11 (31.4)	14 (40.0)
Previous stroke (subset of medical history)	0 (0.0)	1 (2.9)
Previous surgery	17 (48.6)	21 (60.0)
Any recorded substance-use history	6 (17.1)	12 (34.3)
Planned spinal anaesthesia	28 (80.0)	21 (60.0)
Planned general anaesthesia	1 (2.9)	4 (11.4)
Other planned regional anaesthesia	6 (17.1)	10 (28.6)

Values are n (%). Categories of anesthesia indicate the planned technique. Medical and substance-use categories are not mutually exclusive with other characteristics.

Changes in total APAIS scores

Both groups showed a progressive reduction in total APAIS scores during the preoperative period (Table 2). In Group A, the mean score decreased from 19.54 ± 2.38 at A0 to 16.06 ± 2.04 at A1 and 13.46 ± 2.63 at A2. A similar trend was observed in Group B, where the mean score decreased from 19.91 ± 2.38 at A0 to 15.77 ± 2.09 at A1 and 13.54 ± 1.96 at A2.

Table 2
Total APAIS scores at the three preoperative assessments

Visit	Brahmi Ghana Vati (n = 35), mean (SD)	Alprazolam (n = 35), mean (SD)
A0 (baseline)	19.54 (2.38)	19.91 (2.38)
A1 (12 hours)	16.06 (2.04)	15.77 (2.09)
A2 (before surgery)	13.46 (2.63)	13.54 (1.96)

Within-group Friedman tests: Brahmi chi-square(2) = 57.841, p < 0.001; alprazolam chi-square(2) = 67.778, p < 0.001. A0, before intervention; A1, 12 hours after intervention; A2, immediately before surgery.

The Friedman test demonstrated a statistically significant change in total APAIS scores across the three assessments in both groups (p < 0.001). Subsequent pairwise comparisons using the Wilcoxon signed-rank test also showed significant reductions between assessment points, indicating a consistent decline in scores throughout the observation period.

Between-group comparison

The mean reduction in total APAIS score from baseline (A0) to the final preoperative assessment (A2) was **6.09 ± 1.88 in Group A** and **6.37 ± 1.99 in Group B**. (Table 3)

The Mann–Whitney U test showed no statistically significant difference in the overall reduction between groups (U = 614.50, p = 0.986). The estimated mean difference in reduction was − 0.29 points (95% CI: −1.21 to 0.64).

At the final assessment (A2), the mean total APAIS scores were also similar between groups (13.46 ± 2.63 versus 13.54 ± 1.96; p = 0.643).

Table 3
Between-group comparisons of total APAIS scores

Comparison	Brahmi (n = 35)	Alprazolam (n = 35)	Mann–Whitney U	p-value
A0, mean (SD)	19.54 (2.38)	19.91 (2.38)	—	—
A2, mean (SD)	13.46 (2.63)	13.54 (1.96)	573.00	0.643
A0–A2 reduction, mean (SD)	6.09 (1.88)	6.37 (1.99)	614.50	0.986

Primary between-group comparison: A0-to-A2 reduction. Post-hoc mean difference (Brahmi minus alprazolam) in reduction: -0.29 points (95% CI -1.21 to 0.64). Baseline rank-test statistics are deliberately omitted because not given in the verified source excerpt.

Thus, both groups demonstrated significant reductions in total APAIS scores, without a statistically significant difference in the overall change between interventions.

Exploratory analysis of APAIS subscales

Additional post-hoc analyses examined the anxiety and information subscales separately to better understand the changes observed in total APAIS scores (Table 4).

Table 4
Exploratory APAIS anxiety and information subscale outcomes

Outcome	Brahmi: A0 to A2, mean (SD)	Alprazolam: A0 to A2, mean (SD)	A0–A2 reduction (Brahmi / alprazolam)	Between-group p
Anxiety	15.00 (1.70) to 10.91 (1.92)	15.23 (1.65) to 11.09 (1.36)	4.09 (1.56) / 4.14 (1.46)	0.731
Information	4.54 (0.89) to 2.54 (0.85)	4.69 (0.90) to 2.46 (0.82)	2.00 (0.77) / 2.23 (0.88)	0.421

Post-hoc subscale analyses (n = 35 per arm). Mann–Whitney U = 641.50 (anxiety) and 556.50 (information). Both within-group Friedman tests for each subscale: p < 0.001. Post-hoc mean differences in reductions (95% CI): anxiety − 0.06 (-0.78 to 0.66); information − 0.23 (-0.62 to 0.16).

Anxiety subscale

Mean anxiety scores decreased from 15.00 ± 1.70 at baseline to 10.91 ± 1.92 at A2 in Group A, and from 15.23 ± 1.65 to 11.09 ± 1.36 in Group B. The mean reductions were 4.09 ± 1.56 and 4.14 ± 1.46, respectively. Both groups showed statistically significant changes across the assessment periods ($p < 0.001$). However, the between-group difference in anxiety reduction was not statistically significant ($U = 641.50$, $p = 0.731$).

Information subscale

Mean information scores decreased from 4.54 ± 0.89 to 2.54 ± 0.85 in Group A and from 4.69 ± 0.90 to 2.46 ± 0.82 in Group B. The corresponding reductions were 2.00 ± 0.77 and 2.23 ± 0.88. Significant within-group changes were observed ($p < 0.001$), whereas the between-group comparison showed no statistically significant difference ($U = 556.50$, $p = 0.421$).

Changes in treatment response over time

Exploratory longitudinal analyses were performed to examine whether the pattern of change across the three assessments differed between the interventions.

No statistically significant group-by-time interaction was observed for total APAIS scores ($F = 1.612$, $p = 0.207$), anxiety scores ($F = 0.898$, $p = 0.412$), or information scores ($F = 1.063$, $p = 0.351$).

Although the initial reduction from A0 to A1 was numerically greater in Group B, the between-group difference did not remain statistically significant after adjustment for multiple comparisons (adjusted $p = 0.115$). These findings indicate that the available data did not demonstrate a consistent difference in the pattern of score reduction between the interventions.

Adverse events

No adverse drug reactions, rescue-medication use, or withdrawals attributable to adverse effects were recorded in either group during the documented preoperative observation period.

Discussion

The present study evaluated the effect of a single preoperative dose of Brahmi Ghana Vati in comparison with alprazolam on anxiety among patients undergoing elective surgery. Both interventions were associated with statistically significant reductions in APAIS scores from baseline to the immediate preoperative assessment. Although the magnitude of reduction varied slightly between groups, no statistically significant difference was observed in the overall change. These findings suggest that Brahmi Ghana Vati may have a potential role in the management of preoperative anxiety, warranting further investigation in adequately powered clinical trials.

Interpretation of the principal findings

Preoperative anxiety arises from several interacting concerns, including uncertainty about surgery, fear of anaesthesia, anticipated postoperative pain and concerns regarding recovery. Its management is therefore an important component of perioperative care, particularly because psychological distress can influence the patient's experience of surgery and recovery.

In the present study, the mean total APAIS score decreased from 19.54 to 13.46 in the Brahmi Ghana Vati group and from 19.91 to 13.54 in the alprazolam group. The reductions were statistically significant within both groups ($p < 0.001$), indicating a progressive decline in preoperative anxiety-related scores following administration of the interventions.

The mean reduction was 6.09 points with Brahmi Ghana Vati and 6.37 points with alprazolam. Despite these substantial within-group changes, the between-group difference was not statistically significant ($p = 0.986$). The observed reductions were therefore comparable in magnitude, although the absence of a statistically significant difference does not establish therapeutic equivalence. As emphasized by Altman and Bland, failure to demonstrate a difference should not be interpreted as proof that two interventions produce identical effects [19].

An important consideration is that the study employed an active comparator without an untreated or placebo-controlled group. Consequently, the observed reductions may reflect not only the pharmacological effects of the interventions but also reassurance, adaptation to the hospital environment, interactions with healthcare professionals and the natural progression of anxiety during the preoperative period.

Clinical relevance of Brahmi Ghana Vati in preoperative anxiety

The potential application of Brahmi Ghana Vati in the perioperative setting is supported by its traditional Ayurvedic use and emerging pharmacological evidence concerning *Bacopa monnieri*.

In Ayurveda, Brahmi is regarded as a *Medhya Rasayana*, traditionally associated with the promotion of mental clarity, cognitive function and psychological stability. From a contemporary pharmacological perspective, experimental investigations have demonstrated anxiolytic activity in preparations of *Bacopa monnieri*, providing a biological rationale for its clinical evaluation [7].

Previous research has predominantly investigated standardized Bacopa extracts over prolonged administration periods. Calabrese and colleagues reported improvements in selected cognitive and anxiety-related outcomes following 12 weeks of supplementation [8]. However, these observations cannot be directly extrapolated to the present study because the formulation, duration of administration and patient population differ considerably.

Preoperative anxiety presents a distinct therapeutic challenge. Unlike chronic anxiety disorders, it is generally transient and closely associated with an anticipated surgical event. Consequently, an intervention intended for perioperative use must demonstrate a clinically meaningful effect within a relatively short period.

The present study examined Brahmi Ghana Vati after a single evening dose, followed by reassessment approximately 12 hours later and immediately before surgery. This distinguishes it from investigations involving sustained Bacopa administration and contributes preliminary evidence concerning its use in the immediate perioperative setting.

Acute administration studies have yielded mixed findings. Downey and colleagues investigated the effects of a standardized Bacopa extract on cognitive performance, whereas Benson and colleagues examined its influence on mood and stress reactivity [9, 10]. Differences in their observations suggest that acute effects may depend on the formulation, dose and outcome being assessed.

Similarly, Khot and colleagues evaluated Brahmi Vati in generalized anxiety disorder using a longer treatment regimen [11]. Although that study contributes to the clinical literature on Brahmi, its findings cannot establish the effectiveness of a single dose in surgical patients.

These distinctions highlight the relevance of evaluating Brahmi Ghana Vati specifically for preoperative anxiety rather than assuming that findings from chronic anxiety conditions are directly transferable.

The present formulation underwent physicochemical evaluation before clinical administration. Nevertheless, quantitative estimation of bacosides was not performed. Although bacosides are among the major phytochemical constituents investigated in *Bacopa monnieri*, their concentration and contribution to the observed clinical response could not be established in this study. Experimental research has also suggested antioxidant effects of Bacopa preparations [20], but such mechanisms were not directly examined here.

Therefore, the observed changes should be interpreted as clinical findings associated with the administered formulation rather than evidence of a confirmed phytochemical or neuropharmacological mechanism.

Comparison with conventional anxiolytic premedication

Benzodiazepines remain an established pharmacological option for managing anxiety before surgery. Alprazolam was selected as the active comparator because of its documented anxiolytic effects in perioperative settings [3, 4].

Nevertheless, the clinical value of preoperative medication extends beyond reducing anxiety scores. Sedation, cognition, postoperative recovery and patient satisfaction are important considerations when selecting an anxiolytic intervention.

The PremedX trial reported that sedative premedication with lorazepam did not improve overall patient experience following general anaesthesia and was associated with delayed early recovery [5]. Similarly, the I-PROMOTE trial found no improvement in global perioperative satisfaction following low-dose midazolam in older patients [6].

These studies evaluated different benzodiazepines and patient populations and should not be interpreted as direct evidence against alprazolam. However, they demonstrate the importance of considering outcomes beyond immediate anxiety reduction.

Brahmi Ghana Vati may represent an intervention worth investigating within this broader framework. Its potential clinical relevance would be strengthened if future studies demonstrated meaningful anxiolysis while preserving alertness, cognitive performance and postoperative recovery.

The present study did not measure these functional outcomes. Consequently, although Brahmi Ghana Vati was associated with a reduction in preoperative APAIS scores, **no conclusion can be drawn regarding superiority over alprazolam in terms of sedation, recovery or overall safety**.

Anxiety and information requirements

The exploratory analysis of the APAIS subscales provides further insight into the observed changes.

The APAIS was developed to assess anxiety and the desire for information concerning anaesthesia and surgery as related but distinct dimensions of the preoperative experience [17]. Subsequent validation research has supported its utility in evaluating preoperative anxiety [18].

In the present study, both groups showed statistically significant reductions in anxiety-subscale scores. The mean reductions were 4.09 points with Brahmi Ghana Vati and 4.14 points with alprazolam, without a statistically significant between-group difference ($p = 0.731$).

This finding is consistent with the principal analysis and suggests that the observed decline in total APAIS scores was accompanied by a reduction in the anxiety component rather than arising solely from

changes in information requirements.

The information subscale also showed significant reductions within both groups, with no statistically significant between-group difference ($p = 0.421$).

However, a reduction in information-seeking scores should be interpreted cautiously. It may reflect increased reassurance, satisfaction with explanations already received or a reduced perceived need for further information. It does not necessarily indicate improved understanding or reduced psychological distress.

Furthermore, a substantial proportion of participants had reached the minimum possible information score at the final assessment, limiting the ability of the scale to distinguish additional changes between groups.

These observations reinforce the importance of evaluating the anxiety and information components separately in future studies. Since the subscale analyses were conducted after study completion, their findings should be regarded as exploratory.

Influence of the perioperative environment

The psychological experience of surgery is influenced by factors extending beyond medication. Patient counselling, previous surgical experiences, the anticipated type of anaesthesia and interactions with healthcare professionals may all affect anxiety levels.

In the present study, the proportion of patients scheduled for spinal anaesthesia differed between groups. Such differences in clinical characteristics may contribute to variation in anxiety-related responses, although their independent effects could not be established from the available data.

Evidence from other perioperative studies indicates that non-pharmacological interventions can also influence anxiety. Jlala and colleagues demonstrated reductions in perioperative anxiety following multimedia information provision among patients undergoing procedures under regional anaesthesia [21]. Bringman and colleagues similarly investigated relaxing music as a preoperative intervention and reported anxiolytic benefits [22].

These findings are relevant because participants in the present study received routine perioperative care in addition to their allocated medications. Reassurance and information provided during hospital admission may therefore have contributed to the reductions observed in both groups.

Future investigations would benefit from standardized preoperative counselling and documentation of concurrent interventions to better distinguish medication-related effects from those of the surrounding clinical environment.

Strengths and limitations

The present study contributes to the growing evidence on the potential role of *Bacopa monnieri* in anxiety management by examining Brahmi Ghana Vati specifically in the immediate preoperative setting. Unlike previous studies involving prolonged administration for chronic anxiety or cognitive outcomes, this trial evaluated a single-dose intervention during the short period preceding surgery. Its comparison with alprazolam, an established anxiolytic, provides clinically relevant preliminary evidence that both interventions were associated with significant reductions in preoperative anxiety scores, without a statistically significant difference in their observed effects.

The use of a validated assessment tool at three time points further strengthens the findings by demonstrating the pattern of anxiety reduction during the preoperative period. Nevertheless, the open-label design, modest sample size, and limited assessment of sedation and postoperative outcomes should be considered when interpreting the results. Although therapeutic equivalence cannot be established, the study addresses an important gap between existing research on Brahmi in chronic anxiety and its potential application in perioperative care, providing a foundation for larger clinical trials to establish its efficacy, safety, and practical utility.

Implications for future research

The findings provide a basis for further investigation of Brahmi Ghana Vati as a potential option for managing preoperative anxiety. However, confirmation requires larger, adequately powered randomized trials with concealed allocation, standardized formulations and prospectively defined clinical outcomes.

Future studies should prioritize the validated anxiety component of APAIS, establish a clinically meaningful between-group difference before recruitment and consider baseline-adjusted analyses where appropriate [24].

In addition to anxiety reduction, future investigations should evaluate sedation, cognitive performance, haemodynamic stability, postoperative recovery, patient satisfaction and adverse events. Such outcomes would help determine whether Brahmi Ghana Vati offers meaningful clinical advantages beyond the reduction of anxiety scores.

Conclusions

The present study provides new clinical evidence on the potential application of Brahmi Ghana Vati in the management of preoperative anxiety. Both Brahmi Ghana Vati and alprazolam produced statistically significant reductions in APAIS scores, with comparable observed improvements between groups and no statistically significant difference in their overall effects.

By investigating a single-dose administration of Brahmi Ghana Vati in the immediate preoperative period, this study extends the existing evidence on *Bacopa monnieri* beyond its established research context of chronic anxiety and cognitive function. The findings highlight its potential relevance in perioperative care and provide a clinical basis for further investigation of Ayurvedic anxiolytic interventions. This study

therefore contributes to the emerging evidence supporting the integration of traditional therapeutic approaches into contemporary perioperative research, while establishing a foundation for future trials to determine their clinical applicability.

Abbreviations

ADR
adverse drug reaction
APAIS
Amsterdam Preoperative Anxiety and Information Scale
CI
confidence interval
CONSORT
Consolidated Standards of Reporting Trials
CTRI
Clinical Trials Registry-India
SD
standard deviation.

Declarations

Ethics approval and consent to participate

The Institutional Ethics Committee of Dr. D. Y. Patil College of Ayurved & Research Centre, Pimpri, Pune approved the study (DYPCARC/IEC/864/2024; 5 July 2024). Written informed consent was obtained before enrolment. The trial was registered in the Clinical Trials Registry-India (CTRI/2024/12/077761) on 6 December 2024, before investigator-confirmed recruitment. Differences between the registry extract and final conduct are described in Methods.

Consent for publication

Written informed consent for participation and publication of study findings was obtained from all participants at the time of enrolment. Participants were informed that the study results could be published in scientific journals, with their identities and personal information kept confidential.

Availability of data and materials

De-identified data, the data dictionary, analysis code, the available study protocol and analysis documentation are available from the corresponding author on request, subject to institutional and ethical requirements.

Competing interests

The authors declare that they have no competing interests.

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Patient and public involvement

Patient or public involvement in trial design, analysis or dissemination was not documented.

Author Contribution

AK contributed to study conceptualization, methodology, investigation, data collection, data curation, and preparation of the original manuscript draft. SB and MJ contributed to study conceptualization. AP contributed to conceptualization, methodology, and manuscript review and revision. SB, MJ, AP, and PP provided research supervision and methodological guidance. MJ also contributed to manuscript review and revision.

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Figures

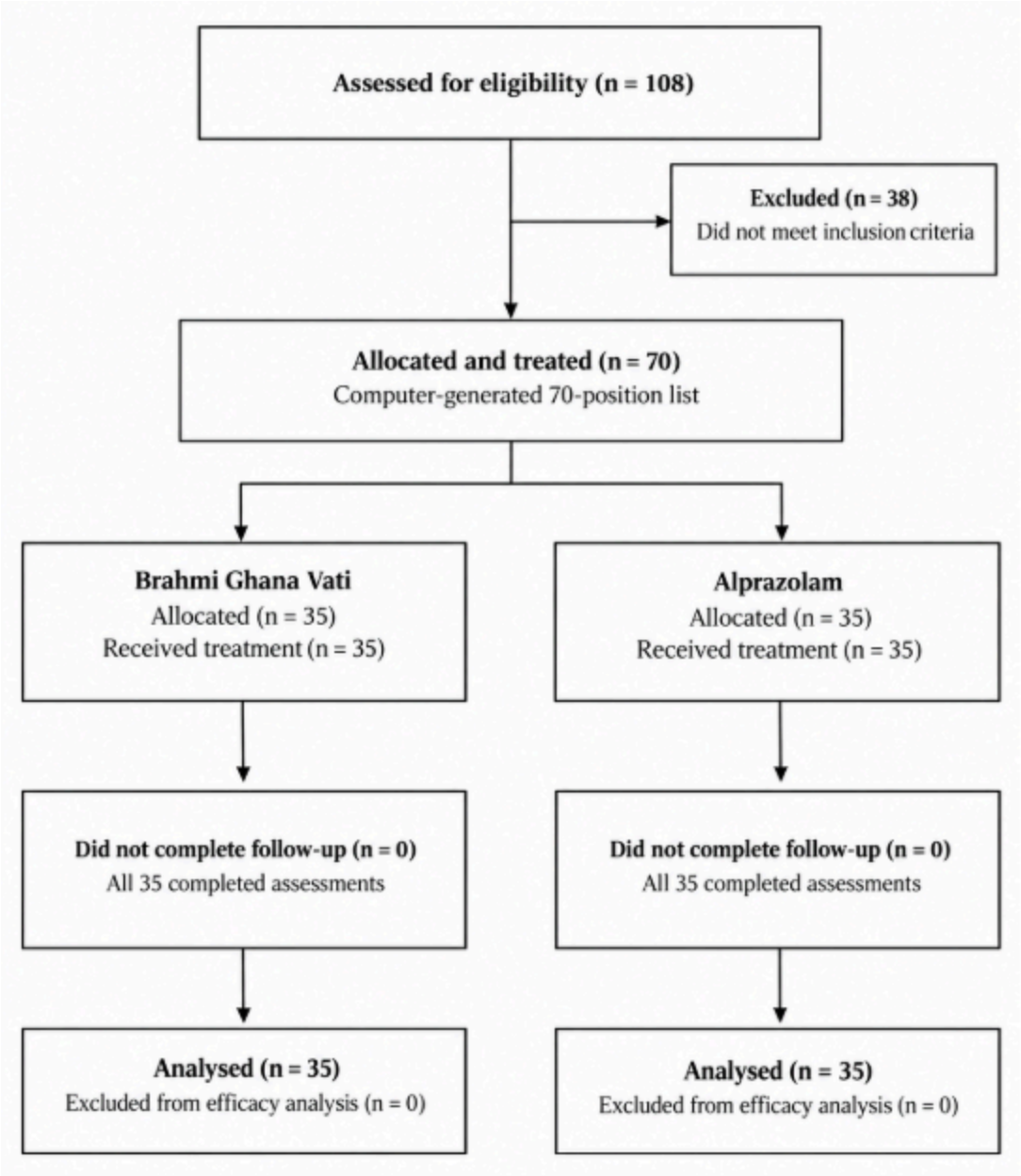


Figure 1

Participant flow through allocation, treatment and efficacy analysis

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