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Evaluation of the clinical efficacy of Digestosap syrup in improving appetite: A single-arm, open-label pilot study

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Abstract

Background: Poor appetite can lead to nutritional deficiencies and compromised health. Digestosap syrup, a herbal formulation based on Ayurvedic principles, is designed to enhance appetite and support digestion. This study evaluates its clinical efficacy in improving hunger and related outcomes.

Methods: A single-arm, open-label pilot study was conducted with 30 participants aged 15–60 years with poor appetite. Participants received 10 ml of Digestosap syrup twice daily for 15 days. The primary outcome was the change in hunger assessed using a Numerical Rating Scale (NRS). Secondary outcomes included hunger patterns, satiety, bowel habits, sleep, and stool consistency (via Bristol Stool Chart). Data were analyzed using paired t-tests for primary outcomes and descriptive statistics for secondary outcomes.

Results: The mean hunger score increased significantly from 4.87 ± 0.86 to 7.67 ± 1.32 ($p < 0.001$), indicating improved appetite. Hunger patterns improved in 83.3% of participants, with regular meal-time hunger reported post-intervention. Bowel habits normalized in 60% of participants with irregular baseline habits, and stool consistency improved in 73.3% of participants.

Conclusion: Digestosap syrup significantly improved appetite and showed positive effects on hunger patterns, bowel habits, and stool consistency. These findings support its potential as a safe intervention for poor appetite, warranting further randomized controlled trials.

Keywords: Appetite; Digestosap Syrup; Ayurvedic Formulation; Hunger; Pilot Study; Digestive Health

1. Introduction

Poor appetite, or anorexia of non-malignant origin, is a widespread clinical concern that significantly impacts nutritional status and overall health. In India, the prevalence of poor appetite is notable, particularly among individuals with chronic illnesses, gastrointestinal disorders, and those experiencing psychological stress or aging-related changes. Studies estimate that approximately 20–30% of patients with chronic diseases such as tuberculosis, cancer, or liver disorders in India experience reduced appetite, contributing to malnutrition and diminished quality of life [1]. Additionally, community-based surveys indicate that up to 15% of the elderly population in India report appetite loss, exacerbating risks of sarcopenia and frailty [2]. This pervasive issue leads to inadequate nutritional intake, weight loss, and compromised immune function, underscoring the need for effective interventions to restore appetite and support digestive health.

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Herbal formulations, deeply rooted in traditional medicinal systems like Ayurveda, have emerged as promising solutions for addressing poor appetite due to their holistic approach to enhancing digestion and stimulating hunger. Ayurveda emphasizes the role of *Agni* (digestive fire) in maintaining health, and formulations containing *deepana dravyas* (digestive stimulants) are designed to kindle this fire, thereby improving appetite and nutrient assimilation. Digestosap syrup, a patented herbal product developed by Sitaram Ayurveda Pvt. Ltd., exemplifies this approach. It is a candy sugar-based formulation crafted using the Ayurvedic principle of *Rasakriya kalpana* (decoction-based syrup preparation). The syrup incorporates tamarind (*Tamarindus indica*), a time-tested ingredient known for its appetite-stimulating properties [3], alongside potent *deepana dravyas* such as Saindhava (*rock salt*), Jeeraka (*Cuminum cyminum*), Maricha (*Piper nigrum*), and Jatipatri (*Myristica fragrans* mace). These ingredients are selected for their synergistic effects in promoting digestion, alleviating bloating, and enhancing hunger.

While anecdotal evidence and traditional knowledge support the use of such herbal syrups, rigorous scientific validation is critical to establish their efficacy, safety, and underlying mechanisms of action. The absence of robust clinical data often limits the integration of traditional formulations into modern healthcare practices [4]. To address this gap, the present pilot study was designed to systematically evaluate the clinical efficacy of Digestosap syrup in improving hunger as the primary outcome. Secondary outcomes included its effects on hunger patterns, satiety, bowel habits, sleep quality, and stool consistency, all of which are integral to digestive and overall health.

2. Materials and methods

2.1. Study Design

This study was a single-arm, open-label pilot trial conducted at Sitaram Ayurveda Specialty Hospital, Thrissur, India, adhering to the Drugs and Cosmetics Rules, 1945, which govern the evaluation of patent and proprietary Ayurvedic formulations. The study was designed to assess the clinical efficacy of Digestosap syrup in individuals with poor appetite. The total duration of the study spanned approximately four months, encompassing participant recruitment, a 15-day intervention period per participant, and subsequent data compilation and analysis. The open-label, single-arm design was selected to provide preliminary evidence of efficacy, as permitted for pilot studies evaluating Ayurvedic drugs with established therapeutic ingredients listed in Schedule 1 of the Act. The study was approved by the Institutional Ethics Committee (IEC) and registered with the Clinical Trials Registry of India (CTRI) [5].

2.2. Participants

A total of 30 participants, aged 15–60 years and of either sex, were enrolled from the outpatient department of Sitaram Ayurveda Specialty Hospital. Participants were selected based on subjective reports of reduced hunger, indicative of poor appetite. To ensure a homogeneous study population and minimize confounding factors, stringent inclusion and exclusion criteria were applied. Inclusion criteria required participants to have a documented history of poor appetite. Exclusion criteria were designed to eliminate individuals with conditions or factors that could interfere with the study outcomes or pose safety risks, including:

- Diagnosed diabetes mellitus
- Pregnancy or lactation
- Known hypersensitivity to any ingredient in Digestosap syrup
- Use of other digestive or appetite-stimulating products within one week prior to enrollment
- Chronic gastrointestinal infections or inflammatory conditions
- Severe systemic illnesses or lifestyle-related diseases (e.g., uncontrolled hypertension)
- Dysphagia or inflammatory conditions of the oral cavity that impair food ingestion

Participants were withdrawn from the study if they experienced adverse events (AEs), laboratory abnormalities, or intercurrent illnesses that compromised their safety or study participation. All participants provided written informed consent, and the study.

2.3. Intervention

Participants received Digestosap syrup, a patented herbal formulation, at a dose of 10 ml twice daily after meals for 15 days. The formulation was based on the Ayurvedic principle of *Rasakriya kalpana*, a method involving the preparation of a concentrated decoction transformed into a candy sugar-based syrup. The composition of Digestosap syrup per 100 ml is detailed in Table 1.

Table 1 Digestosap syrup composition

Sl. No.	Sanskrit Name	Botanical Name	Quantity in 100 ml
1	Nirgundi	*Vitex negundo L.*	10 g
2	Haritaki	*Terminalia chebula Retz.*	4 g
3	Shunti	*Zingiber officinale Roscoe*	8 g
4	Pippali	*Piper longum L.*	6 g
5	Maricha	*Piper nigrum L.*	4 g
6	Dhanyaka	*Coriandrum sativum L.*	6 g
7	Hingu	*Ferula assa-foetida L.*	4 g
8	Ajmoda	*Trachyspermum ammi (L.) Sprague*	4 g
9	Chincha	*Tamarindus indica L.*	5.3 g
10	Sharkara	*Saccharum officinarum L. (Sugar)*	64 g
11	Saindhava	*Sodium chloride (Rock salt)*	3.2 g
12	Jeeraka	*Cuminum cyminum L.*	3.2 g
13	Maricha	*Piper nigrum L.*	1.6 g
14	Jatipatri	*Myristica fragrans Houtt. (Mace)*	0.36 g
15	Mishreya	*Foeniculum vulgare Mill.*	0.36 g
16	Pudina Arka	*Mentha piperita L. (Distillate)*	1.4 ml

2.4. Outcome Measures

The primary outcome was the change in hunger, measured using a Numerical Rating Scale (NRS) ranging from 1 (no hunger) to 10 (extreme hunger), assessed before treatment (baseline, Day 1) and after treatment (Day 15). Secondary outcomes encompassed a broader evaluation of digestive and related functions, including:

- **Hunger patterns**: Assessed *via* a subjective questionnaire evaluating hunger at meal times, hunger at non-meal times, and perceived adequacy of food intake (self-reported and family-reported).
- **Bowel habits**: Categorized as regular or irregular based on participant reports.
- **Sleep quality**: Classified as sound or disturbed through self-assessment.
- **Stool consistency**: Evaluated using the Bristol Stool Chart (Types 1–7, ranging from hard, constipated stools to watery stools).

Data were collected at baseline and post-intervention using a standardized Case Report Form to ensure comprehensive and consistent documentation.

2.5. Sample Size

A sample size of 30 participants was selected to provide sufficient data to establish proof of efficacy while maintaining feasibility for a pilot study [6]. This size was chosen to enhance statistical robustness compared to smaller pilot studies, allowing for meaningful preliminary insights into the syrup's efficacy and safety.

2.6. Statistical Analysis

The primary outcome (change in NRS hunger score) was analyzed using a paired t-test to compare pre- and post-intervention scores, assessing the statistical significance of the change. Secondary outcomes were summarized using descriptive statistics, including frequencies and percentages, to characterize changes in hunger patterns, bowel habits, sleep quality, and stool consistency. A p-value threshold of <0.05 was considered indicative of statistical significance. All analyses were performed using SPSS version 25 (IBM Corp., USA).

2.7. Safety Monitoring

Safety was a priority throughout the study. Adverse events, laboratory abnormalities, and concomitant medication use were meticulously recorded in the CRF. In the event of adverse reactions, rescue medications, such as *pittasamana* (soothing) or *virechana* (laxative) drugs, were available to manage symptoms and restore gastrointestinal balance. Participants were monitored closely to ensure their well-being and compliance with the intervention protocol.

3. Results

3.1. Participant Characteristics

The study enrolled 30 participants, comprising 16 males (53.3%) and 14 females (46.7%), with a mean age of 38.2 ± 12.4 years (range: 15–60 years). All participants completed the 15-day intervention period, resulting in a 100% completion rate with no withdrawals. Compliance with the prescribed regimen of Digestosap syrup (10 ml twice daily after meals) was also 100%, as confirmed through participant self-reports and follow-up assessments. This high adherence rate underscores the feasibility and acceptability of the intervention in the study population.

3.2. Primary Outcome: Hunger

The primary outcome, change in hunger, was assessed using a Numerical Rating Scale (NRS) ranging from 1 (no hunger) to 10 (extreme hunger). At baseline, the mean NRS hunger score was 4.87 ± 0.86, reflecting moderate to low appetite among participants. Post-intervention, the mean score significantly increased to 7.67 ± 1.32 ($p < 0.001$, paired t-test), indicating a substantial improvement in appetite. This 57.3% increase in hunger scores suggests that Digestosap syrup effectively enhanced appetite in the study cohort. Individual hunger scores, presented in Table 1, demonstrate consistent improvements across most participants, with 26 (86.7%) reporting a post-intervention score of 7 or higher.

Table 2 Hunger Scores (NRS, 1–10)

Participant	BT	AT
1	5	9
2	5	8
3	5	9
4	5	10
5	5	8
6	5	8
7	4	7
8	5	8
9	5	8
10	5	7
11	6	7
12	6	8
13	4	5
14	4	5
15	3	8
16	5	8
17	5	9
18	4	7
19	5	8

20	5	8
21	6	9
22	5	8
23	4	6
24	5	7
25	5	8
26	5	9
27	4	7
28	5	8
29	5	8
30	5	9

3.3. Secondary Outcomes

3.3.1. Hunger Patterns

Hunger patterns were evaluated using a subjective questionnaire addressing hunger at meal times, hunger at non-meal times, and perceived adequacy of food intake (self-reported and family-reported). At baseline, 23 participants (76.7%) reported an absence of hunger at meal times, which decreased markedly to 5 participants (16.7%) post-intervention. Conversely, hunger at non-meal times, which can indicate irregular appetite, reduced from 16 participants (53.3%) at baseline to 8 (26.7%) after treatment

Table 3 Hunger Pattern Questionnaire

Question	BT (YES)	AT (YES)
Hunger at meal times	7 (23.3%)	25 (83.3%)
Hunger at non-meal times	16 (53.3%)	8 (26.7%)
Family perceives adequate intake	5 (16.7%)	25 (83.3%)
Self-perceives adequate intake	6 (20%)	25 (83.3%)

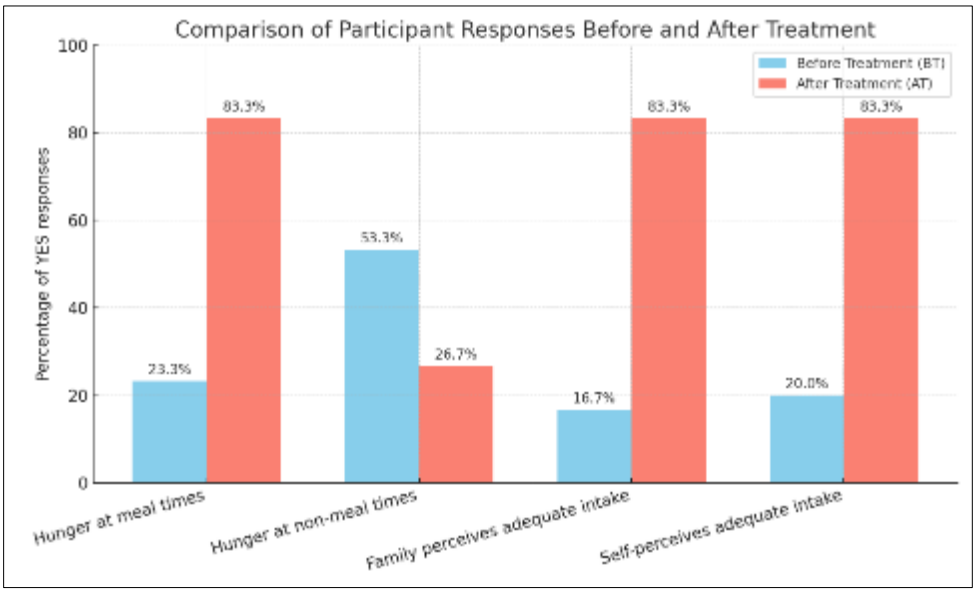

Figure 1 Comparison of Participant Responses BT & AT

. Family-reported perceptions of inadequate food intake improved significantly, with only 5 participants (16.7%) perceived as eating inadequately post-intervention compared to 25 (83.3%) at baseline. Similarly, self-reported perceptions of inadequate intake dropped from 24 participants (80%) to 5 (16.7%) post-intervention. These findings, summarized in Table 2 and Figure 1, indicate that Digestosap syrup not only enhanced hunger but also normalized hunger patterns, aligning appetite with meal times and improving perceived nutritional adequacy.

3.3.2. Bowel Habits

Bowel habits were assessed as regular or irregular based on participant reports. At baseline, 12 participants (40%) exhibited irregular bowel habits, characterized by inconsistent or infrequent bowel movements. Post-intervention, 7 of these participants (58.3%) achieved regular bowel habits, resulting in a total of 25 participants (83.3%) with regular bowel movements. This improvement suggests a positive effect of Digestosap syrup on gastrointestinal motility, likely attributable to its digestive-stimulant ingredients.

3.3.3. Sleep Quality

Sleep quality was evaluated as either sound or disturbed. At baseline, 14 participants (46.7%) reported disturbed sleep, which may be associated with digestive discomfort or poor nutritional status. Post-intervention, 7 of these participants (50%) reported sound sleep, increasing the total number of participants with sound sleep to 23 (76.7%). While this improvement is notable, the modest change suggests that sleep quality may be influenced by factors beyond the scope of this intervention, warranting further exploration. The study details of Bowel habits and Sleep quality are depicted in Figure 2.

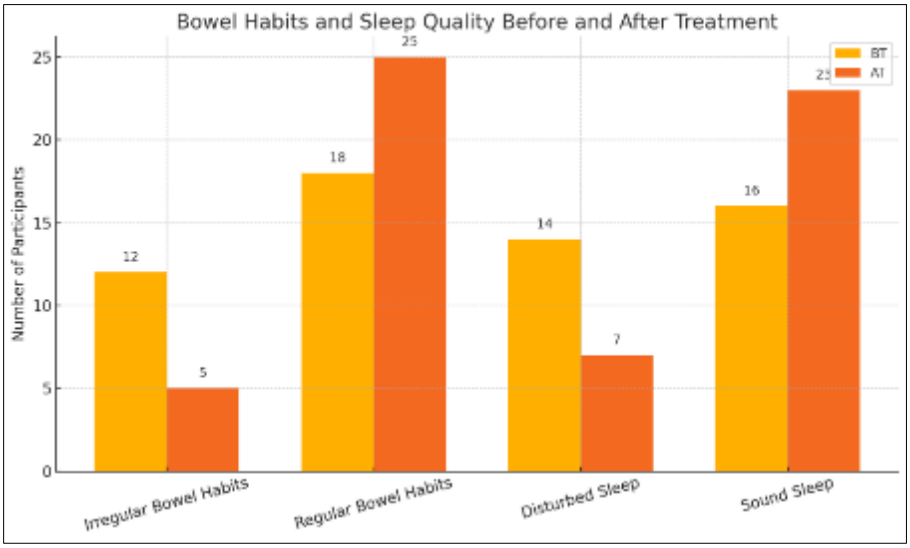

Figure 2 Pre & Post Intervention of Digestosap syrup w.r.t Bowel Habits and Sleep Quality

3.4. Stool Consistency

Stool consistency was assessed using the Bristol Stool Chart, which categorizes stools into Types 1–7 (Types 1–3: constipated; Types 4–5: normal; Types 6–7: loose). At baseline, 22 participants (73.3%) had constipated stools (Types 1–3), indicative of sluggish digestion. Post-intervention, this number decreased to 8 participants (26.7%), with 22 participants (73.3%) achieving normal stool consistency (Types 4–5). No participants reported loose stools (Types 6–7) at either time point. These results, presented in Table 3 and Figure 3, highlight the syrup's efficacy in improving digestive function and promoting optimal stool formation.

Table 4 Bristol Stool Chart

Type	BT	AT
1–3 (Constipated)	22 (73.3%)	8 (26.7%)
4–5 (Normal)	8 (26.7%)	22 (73.3%)
6–7 (Loose)	0 (0%)	0 (0%)

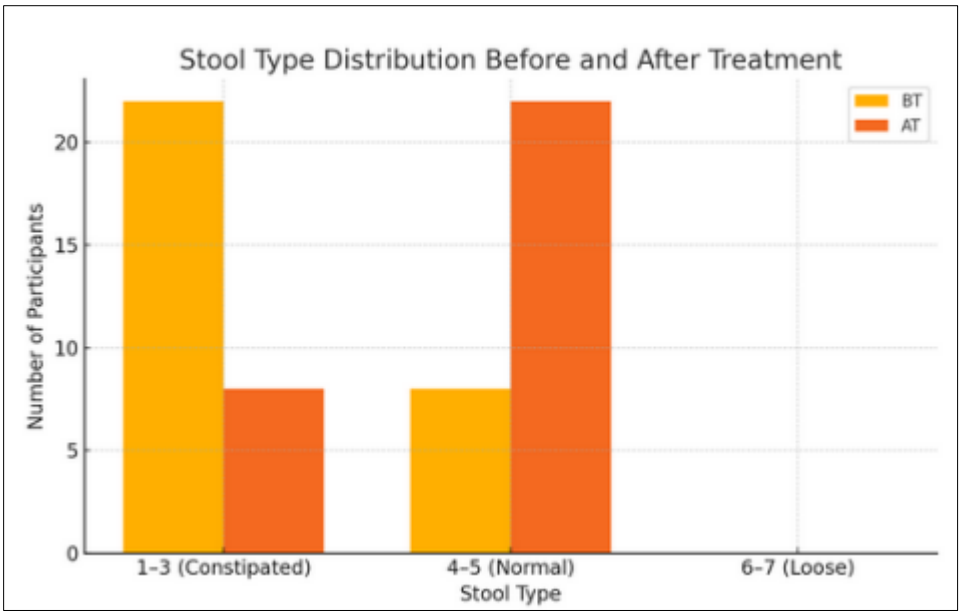

Figure 3 Bristol Stool Chart

3.4.1. Safety Outcomes

No adverse events, laboratory abnormalities, or intercurrent illnesses were reported during the study. The absence of safety concerns, coupled with the use of rescue medications (e.g., *pittasamana* or *virechana* drugs) being unnecessary, supports the safety and tolerability of Digestosap syrup in the study population.

4. Discussion

This pilot study provides compelling preliminary evidence that Digestosap syrup, an Ayurvedic herbal formulation, significantly enhances appetite in individuals with poor appetite. The primary outcome demonstrated a remarkable 57.3% increase in mean Numerical Rating Scale (NRS) hunger scores, from 4.87 ± 0.86 to 7.67 ± 1.32 ($p < 0.001$), underscoring the syrup's efficacy and consistent with Ayurvedic principles of stimulating Agni [7]. This improvement was mirrored in secondary outcomes related to hunger patterns, with 83.3% of participants reporting hunger at meal times post-intervention, compared to only 23.3% at baseline. These findings align with the traditional Ayurvedic use of tamarind (*Tamarindus indica*) and *deepana dravyas* (digestive stimulants) such as Saindhava (*rock salt*), Jeeraka (*Cuminum cyminum*), Maricha (*Piper nigrum*), and Jatipatri (*Myristica fragrans* mace), which are known to kindle *Agni* (digestive fire) and promote appetite. The synchronization of hunger with meal times suggests that Digestosap syrup not only enhances appetite but also regulates hunger patterns to meet nutritional demands, a critical factor in addressing malnutrition and related health challenges.

The secondary outcomes further highlight the syrup's broader impact on digestive health. Notably, 58.3% of participants with irregular bowel habits at baseline achieved regular bowel movements post-intervention, increasing the proportion of participants with regular habits to 83.3%. Similarly, stool consistency improved significantly, with 73.3% of participants achieving normal stool types (Bristol Stool Chart Types 4–5) compared to only 26.7% at baseline. These improvements are likely attributable to the synergistic effects of the syrup's ingredients, particularly tamarind, which is recognized for its mild laxative properties, and *deepana dravyas* like Pippali (*Piper longum*) and Shunti (*Zingiber officinale*), which enhance gastrointestinal motility and digestion [8]. Such findings suggest that Digestosap syrup may offer a holistic approach to digestive health, addressing not only appetite but also bowel regularity and stool quality, which are essential for nutrient absorption and overall well-being.

The effect on sleep quality was less definitive, with 50% of participants reporting disturbed sleep at baseline achieving sound sleep post-intervention [9]. This partial improvement may be indirectly linked to enhanced digestion, as gastrointestinal discomfort is a known contributor to sleep disturbances [10].

A key strength of this study is the absence of adverse events, supporting the safety and tolerability of Digestosap syrup across a diverse participant group (aged 15–60 years), including those with mild comorbidities not covered by the

exclusion criteria. The high compliance rate (100%) and lack of withdrawals reflect the intervention's acceptability and ease of administration, enhancing its potential for clinical use.

In conclusion, this pilot study establishes Digestosap syrup as a promising intervention for improving appetite and supporting digestive health, with significant effects on hunger, bowel habits, and stool consistency. These findings pave the way for more rigorous trials to validate and expand upon the current results, potentially positioning Digestosap syrup as a valuable tool in the management of poor appetite and related digestive disorders.

5. Conclusion

This pilot study provides robust preliminary evidence that Digestosap syrup, an Ayurvedic herbal formulation, significantly enhances appetite in individuals with poor appetite, as demonstrated by a 57.3% increase in mean Numerical Rating Scale (NRS) hunger scores ($p < 0.001$). Beyond its primary effect, the syrup exhibited promising secondary benefits, including the normalization of hunger patterns in 83.3% of participants, regularization of bowel habits in 58.3% of those with irregular baseline patterns, and improvement in stool consistency, with 73.3% achieving optimal stool types post-intervention. These findings suggest that Digestosap syrup offers a holistic approach to improving digestive health, addressing not only appetite but also related gastrointestinal functions critical to nutritional well-being.

The absence of adverse events throughout the study underscores the safety and tolerability of Digestosap syrup, even among a diverse participant group aged 15–60 years. Its ease of administration, evidenced by 100% compliance, further enhances its potential as a practical intervention for clinical use. Rooted in the time-tested Ayurvedic principles of Rasakriya kalpana and incorporating well-documented ingredients like tamarind and deepana dravyas, the syrup aligns traditional wisdom with modern therapeutic needs.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare no conflicts of interest. The funder had no role in study design, data collection, analysis, or manuscript preparation.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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