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Research Article

A Clinical Validation Of Efficacy And Safety Of Polyherbal Formulation For Symptomatic Relief Of Acute Non-Productive Cough And Throat Irritation.

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Abstract

Introduction: Acute nonproductive cough, often caused by upper respiratory tract infections, is a very common and disturbing symptom. Conventional treatments often cause undesirable side effects, and existing herbal formulations lack sufficient efficacy data, highlighting the need for safer approaches. A randomized, controlled clinical study that compared efficacy of polyherbal syrup (GP/PROD/2021/004) versus marketed syrup for relief of acute nonproductive cough and throat irritation.

Method: A randomized, parallel-group, multicentric, active-controlled clinical trial enrolled 65 participants aged 18-65 years with acute nonproductive cough. Participants were randomized to receive either the polyherbal syrup (test group) or marketed syrup (control group) for five days. Outcomes included changes in day/night cough frequency, throat irritation, symptom relief duration, and drowsiness using various Likert scales.

Results: After five days of treatment with the polyherbal syrup (GP/PROD/2021/004), 83.3% of participants experienced relief from daytime cough, while 90% reported relief from nighttime cough. More than 90% of participants showed improvement in throat irritation, chest pain, wheezing, and shortness of breath. Notably, all participants reported complete resolution of throat clearing and sore throat, and 95% experienced relief from cough and throat irritation after their first morning dose. No adverse events were reported, and no recurrence of cough symptoms was observed following treatment discontinuation.

Conclusion: The polyherbal syrup demonstrated significant efficacy in alleviating acute nonproductive cough and associated symptoms, providing rapid and sustained relief without inducing drowsiness or symptom recurrence. These findings support the potential role of polyherbal syrup in offering effective, well-tolerated alternatives for cough management.

Keywords : *Endocannabinoid system; Immune system; Ramos cell line; Daudi cell line; Raji cell line; Jurkat cell line; Molt-4 cell line.*

INTRODUCTION

Acute cough is the most prevalent acute condition encountered in outpatient clinical settings [1]. While cough serves a critical protective mechanism for airways and lungs under normal physiological conditions, it can become excessively troublesome and potentially detrimental to airway mucosa when nonproductive. Acute cough is clinically defined as a cough lasting less than three weeks [2]. Upper respiratory tract infections, allergic triggers, and environmental pollutants represent the most common etiological factors for acute cough. Conventional self-medication approaches typically involve cough and cold remedies comprising antihistamines and decongestants. Although these combinations aim to achieve antitussive activity, they frequently produce undesirable side effects, including sedation, constipation, and oral dryness. Analgesics such as acetaminophen and ibuprofen are commonly

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recommended for symptomatic management of associated symptoms like headache and muscle aches [3,4].

Randomized controlled trials have demonstrated limited efficacy of traditional antitussive interventions. Notably, studies have shown no significant advantage of antitussives (e.g., codeine) over placebo in reducing cough urge during common cold episodes, though they may potentially improve nocturnal sleep patterns [5]. Expectorants, frequently prescribed for productive cough, lack robust clinical evidence supporting their effectiveness in acute cough management. Existing research gaps persist, with no high-quality observational studies or RCTs definitively establishing their clinical utility [6].

Current pharmacological interventions present substantial limitations. Decongestant nose drops and nasal sprays offer only short-term symptomatic relief, with prolonged usage beyond seven days demonstrating no sustained benefits and potential risks of atrophic rhinitis [7]. These clinical challenges underscore the critical need for a reliable, long-acting therapeutic intervention that can consistently and safely provide extended cough relief, particularly during nighttime. Traditional medical systems, specifically Ayurveda, have extensively documented cough management strategies under the classical chapter 'Kasa'. Ayurvedic Materia Medica comprehensively describes numerous plant-based interventions potentially beneficial in alleviating cough symptoms without the adverse effects associated with conventional allopathic formulations.

Nonproductive cough predominantly manifests seasonally or in conjunction with chronic conditions such as asthma or chronic obstructive pulmonary disease (COPD). As the most frequent acute medical presentation, there exists an emerging imperative for an intervention delivering rapid symptomatic relief without significant side effects. Existing herbal cough formulations demonstrate substantial clinical research limitations, with insufficient data substantiating their efficacy and safety. A marketed cough syrup was selected as the comparator instead of a placebo to ensure a clinically relevant evaluation against an existing standard of care. Given the ethical considerations of withholding treatment in symptomatic participants and the widespread use of herbal cough formulations, comparing GP/PROD/2021/004 with an established marketed preparation allows for a more pragmatic assessment of its therapeutic benefits and safety profile. The proposed plant-based syrup GP/PROD/2021/004 comprises ingredients scientifically validated for cough and related symptom management. This research comprehensively evaluated the effectiveness of GP/PROD/2021/004 in management of nonproductive cough, addressing current therapeutic gaps in cough management.

MATERIALS AND METHODS

Study Design

The study was a randomized, parallel-group, multicentric, active-controlled clinical trial aimed at evaluating the efficacy and safety of a polyherbal formulation for the symptomatic relief of acute non-productive cough and throat irritation. The study was conducted at two sites: Lokmanya Medical Research Centre and Hospital, Pune, and Atharv Multispeciality Research Centre, Pune. Both sites were approved by the Institutional Ethics Committee (IEC) of Lokmanya Medical Research Centre, Chinchwad, Pune (ECR/175/Inst/MH/2013/RR-19). The study was registered with the Clinical Trials Registry of India on 05/01/2022, under registration number CTRI/2022/01/039180.

The research adhered strictly to Ayush/ICH-Good Clinical Practices guidelines, prioritizing participant safety and well-being throughout the study. The study was conducted as per the approved protocol, declaration of Helsinki and Good Clinical Practices guidelines. Clinical trial data were collected between January 2022 and March 2022.

Inclusion and Exclusion Criteria

The study targeted male and female patients aged 18-65 years experiencing acute non-productive cough and throat irritation for less than one week. Participants were carefully selected based on specific inclusion and exclusion criteria. Eligible subjects had a daytime cough score of 0-2 on a 6-point Linkert scale, were willing to attend follow-up visits, and agreed to abstain from other cough medications. Participants were excluded if they had existing respiratory conditions, underlying lung pathologies, recent myocardial infarction, or pre-existing life-threatening diseases.

Sample Size

Sample size calculation was methodically determined based on a hypothesis that 90% of subjects in the test group would experience throat irritation relief by day 5, compared to approximately 54% in the marketed syrup group. The researchers applied a 90% power with a 5% confidence interval, requiring 31 subjects per group to achieve statistically significant results [4]. Initially screening 68 participants, the study successfully enrolled 65 participants through randomization, ultimately achieving 60 participants completed the study (**Figure 1**).

METHODOLOGY

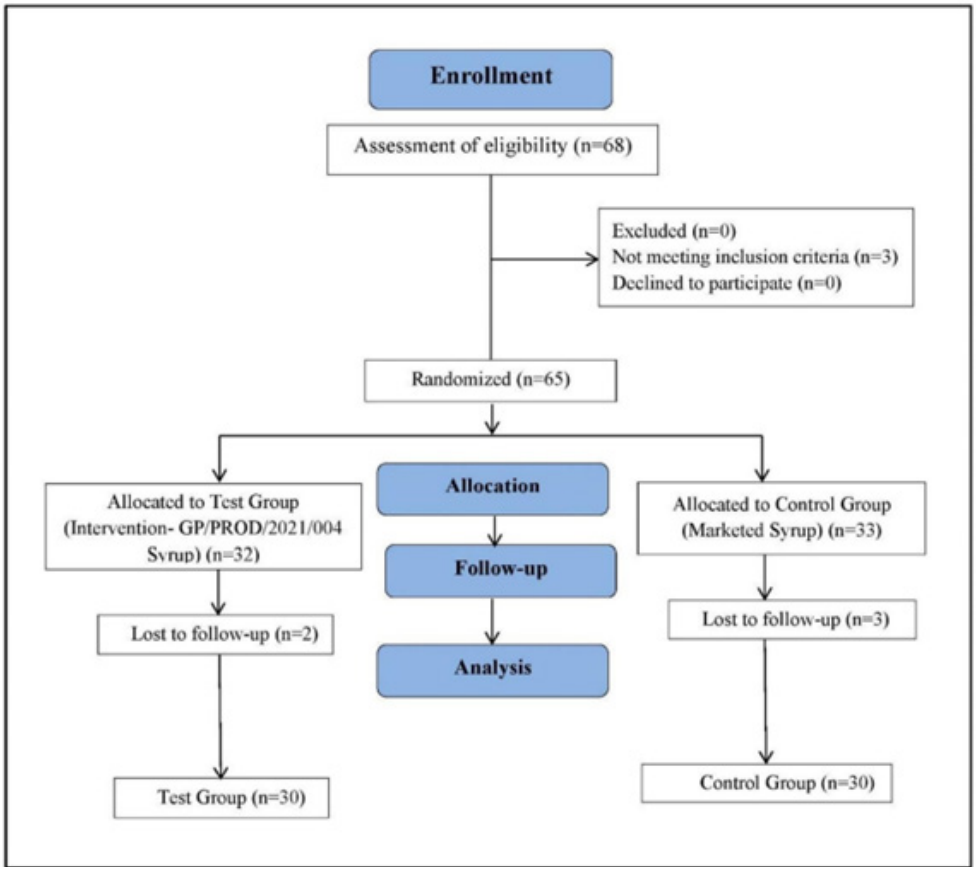
In this study total of 65 participants were enrolled in this study, with 32 in the test group and 33 in the control group. 5 participants dropped out from both groups, and 60 participants completed the study and were analyzed (**Figure 1**). Screening

began with a comprehensive assessment, including medical history, demographic details, and laboratory examinations. After obtaining written informed consent, participants underwent baseline evaluations measuring cough frequency, throat irritation, and other symptoms using Linkert scales. The study employed a computer-generated randomization list prepared by biostatistician, to allocate participants equally between two treatment groups: a polyherbal syrup (test group) and a marketed syrup (control group).

Participants received their assigned intervention, 10 ml of the investigational product taken thrice daily for a five-day treatment period. The polyherbal syrup contained standardized extracts of Trachyspermum ammi (Ajowain), Glycyrrhiza glabra (Jethimadha), Ocimum sanctum (Tulsi), Piper longum (Lindipipar), etc. Marketed syrup contained Diphenylhydramine Hydrochloride, Ammonium Chloride, Sodium Citrate, Ethanol (95%). Follow-up visits on days 2, 3, 4, and 5 involved detailed symptom assessments using multiple Linkert scales to track cough frequency, throat irritation, relief from clinical symptoms, drowsiness and recurrence of cough.

The primary objective was to evaluate the efficacy of the Polyherbal syrup in providing symptomatic relief for acute nonproductive cough and throat irritation. Secondary objectives focused on assessing safety and tolerability by monitoring various symptoms, including chest pain, wheezing, shortness of breath, and potential cough recurrence. A comprehensive post-treatment telephonic follow-up was conducted 15 days after the study to track any symptom recurrence and ensure participant safety.

Figure 1: Consort diagram for the study



Statistical Analysis

Statistical analysis was performed using SPSS software (10.0 Chicago, SPSS Inc.) Continuous variable i.e. age was summarized by overall using summary statistics i.e. the number of observations, mean and standard deviation with 95% CI (among normal distribution) analyzed by student t test. Changes in day and night cough frequencies, throat irritation, time to symptom relief, and duration of relief were analyzed using Mann-Whitney U test and Fisher-Freeman-Halton Exact test. Drowsiness was evaluated using chi-square test and Mann-Whitney U test. Adverse events were reported as frequency distributions between groups, while vital signs were assessed using chi-square test.

RESULTS

Demographic Characteristic

Total 60 participants completed the study (30 in each group). The mean age was 37.03 ± 11.62 years in the test group and 36.03 ± 11.68 years in the control group, showing no statistically significant difference (p=0.741). Both groups were comparable in their gender distribution as well.

Changes in Frequencies of Cough During Day

The study evaluated daytime cough frequency using a 6-point Likert scale, with higher scores indicating reduced coughing. According to this scale; 0 = Distressing coughs most of the day, 1 = Frequent coughing, which interferes/ interrupts with usual day time activities, 2 = Frequent coughing, which did not interfere with usual daytime activities, 3 = Cough for more than two short periods, 4 = Cough for one or two short periods, 5 = No cough during the day

At baseline, both test and control groups had comparable mean cough scores of 1.73 and 1.80, respectively. Progressive improvement was observed across subsequent visits, with significant differences noted at Visit 1 (p=0.027).

The percentage of participants relieved from daytime cough was 16.7% (n=5) by visit 3 and reached 83% (n=25) by visit 4 in the test group, compared to 6.7% (n=2) and 80% (n=24) in the control group, demonstrating the formulation's effectiveness in managing daytime cough frequency (**Table 1 & Figure 2**).

Changes in Frequencies of Cough during Night

The study evaluated nighttime cough frequency using a 6-point Likert scale, with higher scores indicating reduced coughing. According to this scale; (0 = Distressing coughs preventing sleep, 1 = Frequent coughs most of the night, 2 = Frequent waking due to cough activities, 3 = Waking once or early due to cough, 4 = Cough on waking only, 5 = No cough during the night)

At baseline participants who were having frequent coughs most of the night and waking frequently due to cough initially, showed improvement toward the end of study, with cough on waking only or no cough during night time in both the treatment arms.

After visit 1, mean cough score during night was 2.73 in test group which was significantly more as compared to 2.23 among control group (Marketed syrup). This score again improved in subsequent visits indicating betterment of cough frequency during night.

On visit 4, the around 90% (n=27) participants of test group (GP/PROD/2021/004) and 83% (n=25) participants of control group (Marketed syrup) showed no symptoms of cough during night. Thus indicating better potential of polyherbal syrup in decreasing the night time cough frequency as compared to marketed syrup. (**Table 1 & Figure 2**)

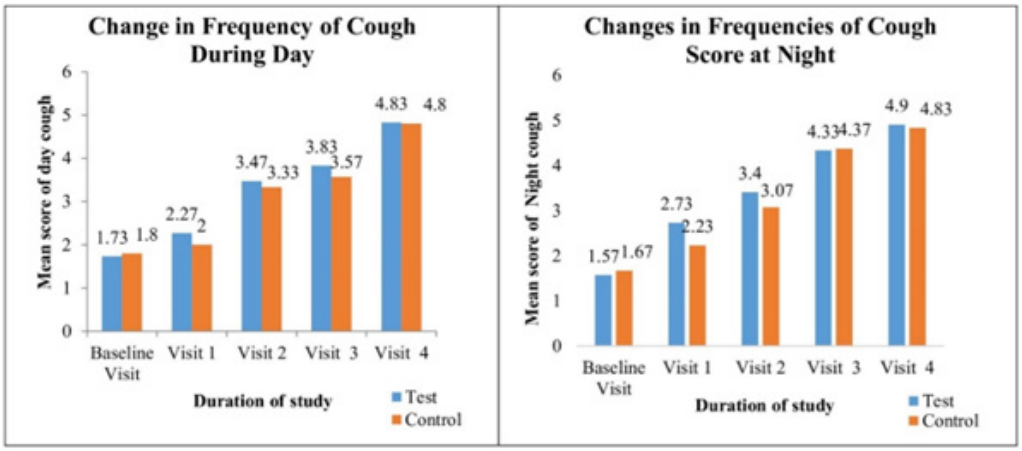
Table 1: Changes in Frequencies of Cough During Day and Night

Score	Baseline		Visit 1		Visit 2		Visit 3		Visit 4	
	Test No. (%)	Control No. (%)	Test No. (%)	Control No. (%)	Test No. (%)	Control No. (%)	Test No. (%)	Control No. (%)	Test No. (%)	Control No. (%)
Cough scoring during daytime Mean ± SD (percentage improvement)										
0	-	-	-	-	-	-	-	-	-	-
1	08 (26.7)	06 (20.0)	02 (06.7)	06 (20.0)	-	-	-	-	-	-
2	22 (73.3)	24 (80.0)	18 (60.0)	18 (60.0)	-	-	-	-	-	-
3	-	-	10 (33.3)	06 (20.0)	16 (53.3)	20 (66.7)	10 (33.3)	15 (50.0)	-	-
4	-	-	-	-	14 (46.7)	10 (33.3)	15 (50.0)	13 (43.3)	13 (43.3)	06 (20.0)
5	-	-	-	-	-	-	05 (16.7)	02 (06.7)	25 (83.3)	24 (80.0)

Mean ± SD	1.73 ± 0.45	1.80 ± 0.41	2.27 ± 0.58	2.00 ± 0.64	3.47 ± 0.51	3.33 ± 0.48	3.83 ± 0.70	3.57 ± 0.63	4.83 ± 0.38	4.80 ± 0.41
P value	-	0.659	-	*0.027	-	0.186	-	0.128	-	0.568
Cough scoring during nighttime Mean ± SD (percentage improvement)										
0	-	-	-	-	-	-	-	-	-	-
1	13 (43.3)	10 (33.3)	-	10 (33.3)	-	-	-	-	-	-
2	17 (56.7)	20 (66.7)	14 (46.7)	17 (56.7)	-	10 (33.3)	-	-	-	-
3	-	-	10 (33.3)	10 (33.3)	10 (33.3)	08 (26.7)	08 (26.7)	05 (16.7)	-	-
4	-	-	06 (20.0)	-	12 (40.0)	12 (40.0)	10 (33.3)	10 (33.3)	10 (33.3)	05 (16.7)
5	-	-	-	-	-	-	15 (50.0)	15 (50.0)	27 (90.0)	25 (83.3)
Mean ± SD	1.57± 0.50	1.67± 0.48	2.73± 0.78	2.23± 0.63	3.40± 0.50	3.07± 0.87	4.33± 0.76	4.37± 0.76	4.90± 0.31	4.83± 0.38
P value	-	0.509	-	*0.007	-	0.096	-	0.794	-	0.357

(Data was analyzed by Mann Whitney U Test. *Significant at p< 0.05. (SD= Standard Deviation)

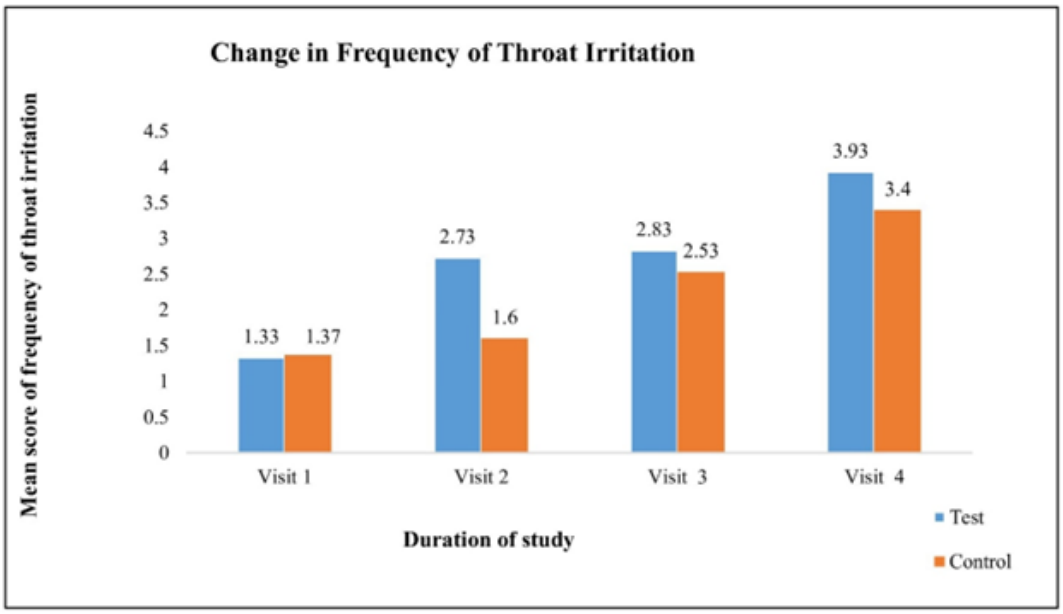
Figure 2: Changes in Frequencies of Cough During Day and Night



Changes in Frequency of Throat Irritation

Changes in throat irritation were evaluated on the basis of changes in throat irritation score where it was scored as follows: 4 = 76%-100% decrease, 3 = 51%-75% decrease, 2=26%-50% decrease, 1 = 0%-25% decrease, and 0 = 0% decrease. At Visit 4, among Test group score was increased to 3.93 and it was significantly more as compared to 3.40 in the control group indicating decrease in throat irritation after 5 days of treatment (**Figure 3**).

Figure 3: Changes in frequency of throat irritation



Change in Frequencies of Symptoms Score

Change in frequency of symptoms (chest pain, wheezing & shortness of breath and frequent throat clearing and sore throat) assessed based on following score: 0 = No symptom, 1 = Mild symptom, not affecting daily activities, 2 = Mild symptom, affecting daily activities, 3 = Moderate symptom, not affecting daily activities, 4 = Moderate symptom, affecting daily activities.

- ***Chest Pain***

Around 35% of participants from both the groups were experiencing chest pain associated with cough at the baseline visit. This chest pain was seen to be subsided from visit 1 in both the groups, indicating that the plant based syrup (GP/PROD/2021/004) given to the test group has comparable efficacy in mitigating chest pain to that of marketed cough syrup given to control group (**Figure 4**).

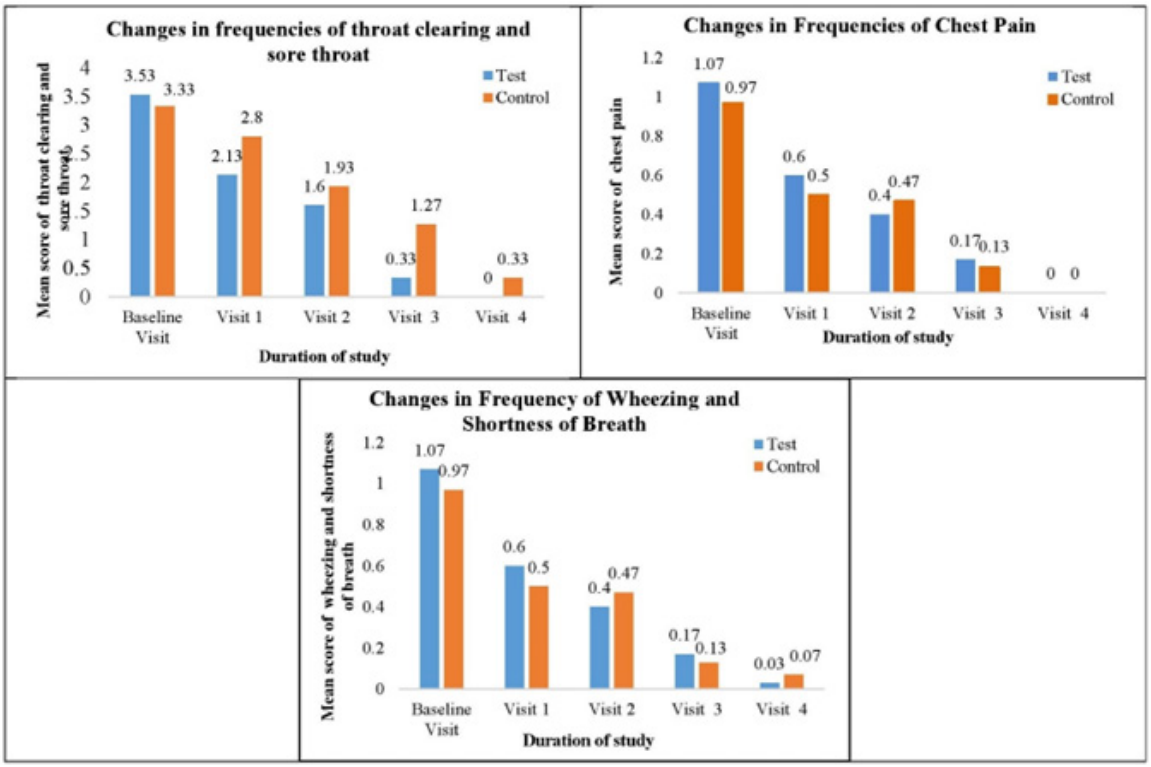
- ***Wheezing & Shortness of Breath***

Mean score of wheezing & shortness of breath were comparable at baseline, after treatment in both the groups this score showed a trend of decrease from Visit 1 till Visit 4. when compared, changes were comparable and difference was not significant (Figure 4).

- ***Frequent Throat Clearing and Sore Throat***

After Visit 4, all of the participants among test group (GP/PROD/2021/004) showed no symptoms of frequent throat clearing and sore throat which was more as compared to the cases among control group (Marketed syrup). Thus indicating slightly better effect of the polyherbal syrup (GP/PROD/2021/004) given to the test group as compared to Marketed syrup given to control group in terms of alleviating throat clearing and sore throat (**Figure 4**).

Figure 4: Changes in Frequencies of Chest Pain, Shortness of Breath, and Throat clearing and sore throat.



Changes in Frequencies of Time to Relief from Cough and Throat Irritation

GP/PROD/2021/004 demonstrated a progressively faster onset of cough and throat irritation relief compared to the marketed syrup. By Visit 1, relief within 31–60 minutes was reported by 73.3% of the Test group versus 66.7% of the Control group. By Visit 3, 66.7% of the Test group achieved relief within 0–15 minutes, compared to 40.0% of the Control group. By Visit 4, all participants in the Test group experienced relief within 0–15 minutes, whereas only 83.3% in the Control group did. While the differences were not statistically significant, the trend suggests slightly rapid relief with GP/PROD/2021/004, particularly for morning symptoms (**Table 2**).

Table 2: Changes in Frequencies of Time to Relief from Cough and Throat Irritation

Score	Time to relief from cough and throat irritation Mean ± SD (percentage improvement)							
	Visit 1		Visit 2		Visit 3		Visit 4	
	Test No. (%)	Control No. (%)	Test No. (%)	Control No.(%)	Test No. (%)	Control No. (%)	Test No. (%)	Control No.(%)
0 (No relief)	-	-	-	-	-	-	-	-
1 (Relief >61min)	-	-	-	-	-	-	-	-
2 (Relief within 31 - 60 min)	22 (73.3)	20 (66.7)	12 (40.0)	18 (60.0)	-	-	-	-
3 (Relief within 16 - 30 min)	08 (26.7)	10 (33.3)	18 (60.0)	12 (40.0)	10 (33.3)	18 (60.0)	-	5 (16.7)
4 (Relief within 0 - 15 min)	-	-	-	-	20 (66.7)	12 (40.0)	30 (100.0)	25 (83.3)
P value	-	0.588	-	0.196	-	0.069	-	1.000
Mean ± SD	2.27 ± 0.45	2.33 ± 0.48	2.60± 0.50	2.40± 0.50	3.67± 0.48	3.40 ± 0.50	4.00 ± 0.00	3.83 ± 0.38
P value	-	0.659	-	0.186	-	0.076	-	0.992

(Data was analyzed by Fisher -Freeman-Halton Exact Test; By Mann Whitney U Test. (SD= Standard Deviation).

Changes in Frequencies of Duration of Relief from Symptoms

Change in frequencies of duration of relief from symptoms assessed based on following score: 0 = No effect, 1 = Up to 1 hour, 2 = Up to 2 hours, 3 = Up to 3 hours, and 4 = Relief up to 4 hours.

The duration of symptom relief improved progressively across visits in both groups. At Visit 1, both groups showed similar relief patterns (2-3 hours) with no significant difference (p=0.833). A significant difference emerged at Visit 2 (p=0.001), with the test group showing better relief duration. By Visit 3, 66.7% of the test group experienced 4-hour relief versus 40% in the control group. At Visit 4, all test group participants reported 4-hour relief compared to 83.3% in the control group (4.00 vs 3.83). The test group demonstrated more consistent improvement in symptom relief duration throughout treatment.

Changes in Frequencies of Measure of Drowsiness and Alertness

All participants in the Test group (GP/PROD/2021/004) maintained alertness throughout the study, with no reports of drowsiness. In contrast, the Control group (marketed syrup) experienced persistent drowsiness, with the percentage of alert participants decreasing from 83.3% at baseline to 50% by the end of the study. Overall, GP/PROD/2021/004 provided effective relief from acute nonproductive cough without drowsiness, demonstrating a superior safety profile in maintaining alertness.

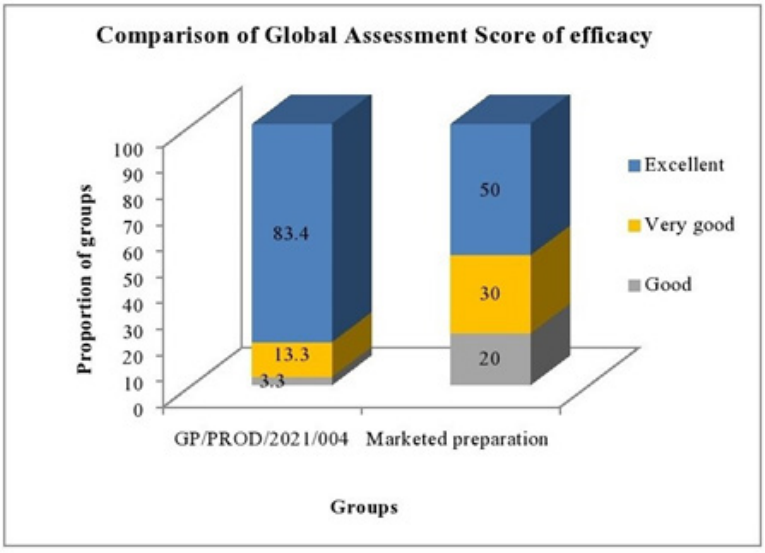
Recurrence of Cough after Discontinuation of Intervention

A telephonic follow-up on Day 15 post-treatment discontinuation revealed no recurrence of cough in either group. This indicates that the polyherbal formulation (GP/PROD/2021/004) demonstrated comparable efficacy to the marketed syrup in preventing cough recurrence.

Comparison of Global Assessment Score of Efficacy

Physician's Global Assessment of efficacy, evaluated using the Global Assessment Scale, showed that 83.4% of participants in the Test group (GP/PROD/2021/004) achieved an "excellent" efficacy rating compared to 50.0% in the Control group (marketed syrup). The polyherbal syrup demonstrated significantly superior efficacy in providing symptomatic relief from acute nonproductive cough and throat irritation (**Figure 5**).

Figure 5: Comparison of global assessment score of efficacy



Hematological Parameters

There were no clinically as well as statistically significant changes observed in hematological parameters of test and control group after treatment with polyherbal syrup (GP/PROD/2021/004) and marketed syrup, respectively.

Vitals assessment

The participant's vitals (radial pulse, blood pressure, respiratory rate, and body temperature) were analyzed from baseline to the end of study. It was observed that there were no significant alterations in the vitals throughout the study.

Adverse event profile

There were no reported adverse events in the study pertaining to both groups.

DISCUSSION

The current study provides compelling evidence supporting the efficacy of the plant based polyherbal syrup (GP/PROD/2021/004) in managing various respiratory symptoms associated with cough [8-10]. The findings reveal significant improvements across multiple clinical parameters, demonstrating the formulation's potential as a promising approach to conventional cough medications. The polyherbal preparation, composed of herbs including Trachyspermum ammi (Ajowain), Glycyrrhiza glabra (Jethimadha), Ocimum sanctum (Tulsi), and Piper longum, exhibited a synergistic antitussive, bronchodilator, antibacterial, and anti-inflammatory action [11-13]. Notably, the study revealed remarkable efficacy in alleviating throat irritation, with GP/PROD/2021/004 showing 93.3% activity in curing throat irritation within 5 days, compared to only 40% in the control marketed syrup [14,15]. The polyherbal syrup demonstrated superior performance in reducing daytime and night-time cough frequencies, with the percentage relief being 3% greater for daytime cough and 6.7% greater for night-time cough compared to the marketed syrup.

A critical differentiating factor was the minimal side effect profile. Unlike conventional cough medications that often lead to side effects such as drowsiness and potential habituation, the plant based formulation showed no incidence of drowsiness [9]. In fact, while about 50% of participants in the marketed syrup group experienced drowsiness due to its alcohol-based solvent, the test group remained entirely alert. The global assessment of efficacy was particularly promising, with 83.4% of participants in the test group reporting very good efficacy after just 5 days of treatment, compared to only 50% in the control group [16-18]. Remarkably, all participants in the test group obtained relief from cough within 15 minutes and other symptoms within 4 hours after the first morning dose, compared to 83.3% in the control group. The study's most significant finding was the long-term efficacy of the formulation. After 15 days, there was no recurrence of cough in the test group, indicating the polyherbal formulation's potential for sustained respiratory symptom management. The unique combination of ingredients provides not just symptomatic relief but also addresses the root cause of respiratory infections while potentially increasing participant immunity.

Clinical evidence further supports the formulation's efficacy. A randomized trial with Glycyrrhiza glabra showed significant improvement in chronic cough severity [19], while Ocimum sanctum demonstrated notable immunomodulatory effects [20]. Cinnamomum zeylanicum demonstrated anti-oxidative stress potential in human studies, adding to the comprehensive therapeutic approach [21]. The synergistic effects of ingredients like Syzygium aromaticum, which showed significant antibacterial and antioxidant activities, and Piper species with their anti-quorum sensing properties, contribute to its holistic approach to respiratory health [22, 23].

The phytoconstituents' comprehensive action including antibacterial, anti-allergic, and anti-inflammatory properties sets this formulation apart from traditional cough medications that typically focus solely on symptom suppression. The demulcent and carminative activities of ingredients like cinnamon, vasaka, liquorice, and piper contribute to its effectiveness in providing complete relief from throat-related symptoms [24]. While the results are promising, the researchers suggest the need for further investigation to fully understand the precise mechanisms of the plant based polyherbal formulation. The study represents a significant step towards integrating traditional herbal knowledge with modern medical research, offering a potential approach to conventional cough treatments with reduced side effects and comprehensive symptom management.

The plant based polyherbal formulation (GP/PROD/2021/004) demonstrates considerable potential as an effective, safe, and holistic approach to managing acute cough and associated respiratory symptoms.

CONCLUSION

The plant-based polyherbal formulation (GP/PROD/2021/004) is an effective remedy for managing respiratory symptoms. It showed 93.3% effectiveness in treating throat irritation and significantly reduced daytime cough frequency by 83.3% and nighttime cough frequency by 90%. The study reported 100% relief from throat clearing and sore throat. Additionally, 95% of participants experienced relief after their first morning dose. By the final visit, all participants achieved symptom relief within 0–15 minutes.

Unlike traditional medications, this formulation provided rapid relief without causing drowsiness. It was rated "excellent" by 83.4% of participants in the global assessment. No recurrence of symptoms was observed during the 15-day follow-up. The formulation also demonstrated 100% improvement in symptom relief duration up to 4 hours and maintained alertness in all participants. The study highlights the potential of integrated herbal medicine in developing more holistic, patient-friendly treatment options. Further research could explore its long-term implications and precise mechanism of action in respiratory health management.

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Author Contribution

All authors have significantly contributed to this work, including its conception, design, and data acquisition. They were actively involved in analyzing and interpreting the data, as well as drafting, revising, and critically reviewing the manuscript. Each author has approved the final version for publication, agreed on the chosen journal, and takes full responsibility for the accuracy and integrity of the work in all aspects.

Inform Consent

Written informed consent was obtained, ensuring confidentiality and the right to withdraw. Data was used solely for research, adhering to the Declaration of Helsinki's ethical principles.

Conflict Of Interest

Dr. Shridhar J. Pandya, and Dr. Chetan H. Savaliya, Dr. Vaishnavi B. Shiravale are part of Gplife Healthcare Pvt Ltd. Other author declares no conflict of interest.

Ethical Approval

The study was approved by Institutional Ethics Committee of Lokmanya Medical Research Centre, Chinchwad, Pune (ECR/175/Inst/MH/2013/RR-19) and was registered with the Clinical Trial Registry of India (CTRI/2022/01/039180).

Fundings

The research was conducted without any external funding that could lead to bias in the study outcomes.

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