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(RESEARCH ARTICLE)

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Clinical validation of de-stress and happy gut powder for stress reduction and gut health improvement

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Abstract

Introduction: Chronic stress and digestive disorders represent significant health challenges in modern society. This study investigates the potential of a novel herbal supplement, De-Stress & Happy Gut Powder, in addressing psychological stress and gastrointestinal symptoms through a comprehensive, natural approach.

Materials and Methods: A single-arm, open-label clinical study was conducted with 30 participants (18 males, 12 females) aged 20-40 years. Participants consumed one sachet of De-Stress & Happy Gut Powder daily for 30 days. Assessments included the Perceived Stress Scale (PSS), Gastrointestinal Symptom Rating Scale (GSRS), comprehensive blood tests, and vital sign measurements.

Results: The study demonstrated a statistically significant 57.54% reduction in perceived stress levels. Gastrointestinal symptom assessments revealed substantial improvements across multiple parameters, including upper abdominal pain, heartburn, acid reflux, and bowel-related symptoms. Hematological investigations showed statistically significant increases in white blood cell count, red blood cell count, and hematocrit, though these were not clinically significant. Adverse events were observed in 23.33% of participants and were not related to the investigational product.

Conclusion: De-Stress & Happy Gut Powder demonstrates promising potential in simultaneously addressing stress and gastrointestinal health through a natural, holistic approach. Further randomized, controlled trials are recommended to validate these preliminary findings.

Keywords: Stress; Gut health; Probiotics; Herbal supplement; Gastrointestinal symptoms

1. Introduction

One of the most important things generally not known about nutrition is what actually happens to food when it goes into the mouth. Surveyors must always need to consider stress as an inescapable part of modern life [1]. Stress and digestive health issues are interlinked, with chronic stress adversely affecting gut function through mechanisms such as altered gut motility, increased intestinal permeability, and changes in the gut microbiota [2].

Within the last decade, research regarding the human gut microbiome has exploded. While the gastrointestinal tract was once regarded simply as a digestive organ, new technologies have led the science world to wonder about the impact that the gut microbiota may have on human health and disease [3]. Through rigorous scientific examination, the clinical

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validation of De-Stress & Happy Gut Powder attempts to confirm its efficacy and safety. This product probably aims to improve digestive health as well as mental well-being, addressing the common relationship between stress and digestive problems in contemporary lifestyles. Such studies usually monitor basic safety measurements, such as complete blood count (CBC), liver function test (LFT), and renal function test (RFT) parameters, and concentrate on evaluating the product's effect on factors such as stress levels (using perceived stress ratings) and gastrointestinal symptoms (using GSRS scores). The significance of integrated health treatments that address both the psychological and physiological facets of wellness is highlighted by this holistic approach.

The gut microbiome is now becoming known for its role in metabolism, immune defenses, and behavior. From in utero variations to those that rapidly occur postpartum, our gut microbiome changes with age, environment, stress, diet, and health status as well as medication exposure [3]. This article reviews what is currently known regarding various influences on the gut microbiome and is meant to encourage the reader to further explore the unknown. Today's fast-paced society often creates psychological stress (hereinafter, "stress") in people that is beyond their adaptive capacity [4]. Although certain levels of stress help people to adapt and respond to threatening situations, excessive stress has a negative effect and not only increases the risk of mental illness but also induces physical diseases such as hypertension, cardiovascular disease, and digestive system disorders [5,6] functional gastrointestinal disorders, particularly dyspepsia overlap, are common in rural Indian population [7].

The application of natural supplements, like De-Stress & Happy Gut Powder, to mitigate stress and encourage gut health is growing more and more popular. This points to a growing trend in customer interest in all-encompassing methods of well-being.

There is a weak relationship between the symptoms of heartburn and the demonstrated degree of acid reflux. Up to 64% of the patients with stress and gastroesophageal reflux disease (GERD) reported aggravation of their symptoms by stress, and stress reduction measures often resulted in a subjective improvement [8].

2. Material and methods

2.1. Study Design

This study was an open-label, single-arm, safety study wherein each participant received De-Stress & Happy Gut Powder one sachet daily after a meal once a day.

30 participants were enrolled in the study. All thirty participants received De-Stress & Happy Gut Powder one sachet daily after a meal once a day and completed the study. The duration of treatment is considered from the enrollment to the day 30 visit of the participant.

A clinical validation of safety and effectiveness of De-Stress & Happy Gut Powder study conducted on male and female participants. Participants were recruited at the study center i.e. Lokmanya Medical Research Centre & Hospital, Pune, India. The study was approved by the Institutional Ethics Committee (IEC) Lokmanya Medical Research Centre. The trial was registered on the Clinical Trial Registry of India (CTRI) website (CTRI/2024/03/064117 [Registered on: 14/03/2024]).

The compositions of the investigational products i.e. De-Stress & Happy Gut Powder is a meticulously formulated blend comprising saffron extract for its antioxidant and anti-inflammatory properties, Gut Gard (licorice extract) for potential gastroprotective effects, Bael fruit powder for digestive wellness, Howaru Restore a proprietary probiotic blend of *Lactobacillus* and *Bifidobacterium* strains) to promote a healthy gut microbiome, sodium bicarbonate for pH balance, peppermint oil extract for its soothing and carminative effects, and inulin (a prebiotic fiber) to nourish beneficial gut bacteria. This comprehensive blend aims to offer a holistic approach to supporting digestive health and overall well-being.

2.2. Inclusion criteria

Male and Female participants between 20-40 years of age (both inclusive) were screened for eligibility criteria. Participants able to provide written informed consent approved by the ethics committee, and willing to complete the study intervention and follow-up were enrolled in the study.

2.3. Exclusion criteria

Exclusion criteria encompassed women of childbearing potential without adequate contraception, pregnant or lactating women, individuals with a substance abuse history, neurological conditions, recent surgical interventions, significant comorbidities, clinical insomnia, and those consuming ayurvedic or nutraceutical supplements within the preceding three months. The investigator retained discretion to exclude participants based on clinical judgment.

2.4. Methodology

This study was an open-label, single-arm, safety study wherein each subject received De-Stress & Happy Gut Powder one sachet daily after a meal once a day. The study included a total of 30 individuals. The trial lasted 30 days. On the screening visit, written informed consent was obtained from participants confirming participation in the study. Male and Female participants between 20-40 years of age (both inclusive) were screened. The consolidated standards of reporting trials (CONSORT) flow of the entire study are depicted in Figure 1.

The duration of treatment is considered from the enrollment to the day 30 visit of the subject.

After confirming their eligibility for the study, participants were enrolled in the study, and during the screening/baseline visit, the participant's demographic details were recorded. Medical history and demographic data including sex, age, body weight (kg), and height (cm), habits were recorded. Each participant underwent a complete general clinical and physical examination. After confirming their eligibility for the study, participants were enrolled in the study.

Assessment of changes in compliance, clinical, vital parameters, and tolerability of the investigational product, adverse events were evaluated from baseline to end of the study.

Assessment of changes in CBC, LFT, and RFT parameters, gut health using a GSRS score, and perceived stress by PSS score questionnaire was evaluated at screening and end of the study.

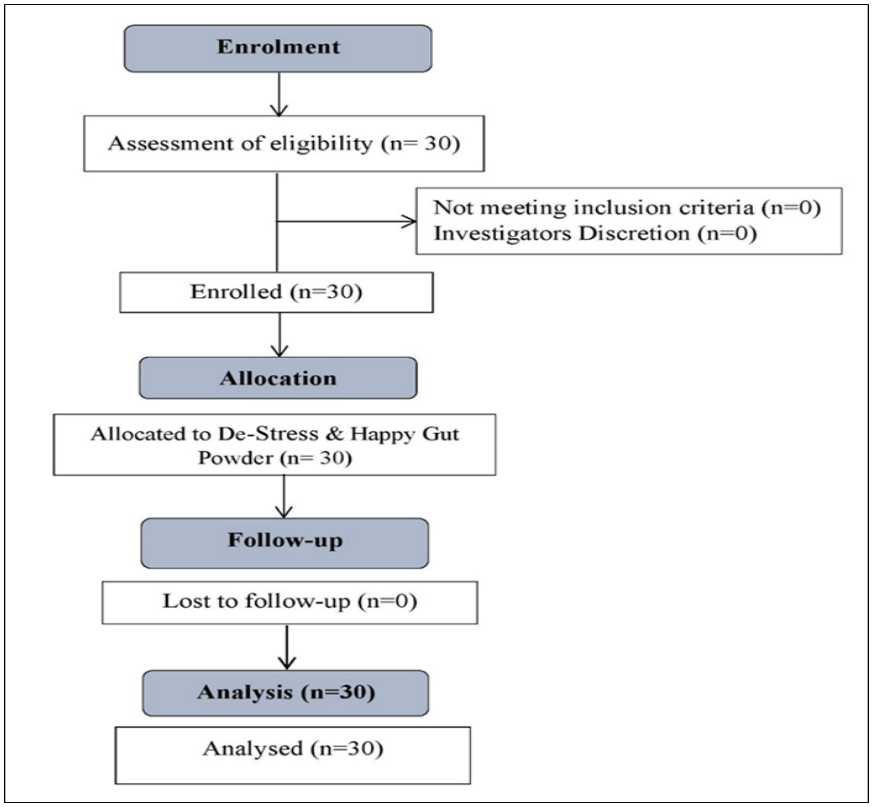

Figure 1 CONSORT flow diagram of the study

2.5. Statistical Analysis

The normality of the study data was calculated by the Kolmogorov-Smirnov Test. In this study, an analysis of demographic details was done using an Independent student t-test. Analysis of haematological and biochemical investigations and vital signs were done using a dependent student t-test (within a group) and Wilcoxon signed rank test (within a group). Analysis of perceived stress using the Perceived Stress Scale was done using a dependent student t-test (within a group).

3. Results

3.1. Demographic Characteristics

The study included 30 participants (18 males, 12 females) with a mean age of 31.00 ± 5.69 years. Significant differences were observed between males and females in height and weight. While age and BMI showed no statistically significant differences, anthropometric variations between sexes were evident in physical measurements. These demographic details are summarized in **Table 1**.

Table 1 Demographic Details

Parameter	Male Mean ± SD (n=18)	Female Mean ± SD (n=12)	P Value
Average Age (Years)	31.78 ± 5.44	29.83 ± 6.09	0.368
	31.00 ± 5.69		
Anthropometric Parameters			
Height (cm)	167.11 ± 9.96	157.08 ± 5.63	0.003*
Weight (kg)	67.83 ± 10.04	55.83 ± 8.16	0.018*
BMI (kg/m²)	24.31 ± 3.23	22.65 ± 3.32	0.182

Data is represented as Mean ± S.D. Analysis was done using the Independent student t-test. Significant at p< 0.05. * represent significant values.

3.2. Assessment of haematological and biochemical investigations

The statistically significant increases observed in white blood cell count, red blood cell count, haematocrit, mean corpuscular volume, neutrophils, alanine transaminase, and alkaline phosphatase, although not clinically significant suggesting that the investigational product was well-tolerated by the study participants.

No statistically or clinically significant changes were observed in other haematological and biochemical parameters, all of which remained within normal ranges before and after the use of the interventional product **Table 2**.

Table 2 Assessment of haematological and biochemical investigations

Blood Parameters				
Parameters	**Screening**	**Day 30**	**P value**	**Reference Range**
Hematological Parameters				
White Blood Cell Count	7770.67 ± 2137.22	8996.00 ± 2878.58	0.009*	4000 - 11000 cell/cu.mm
Red Blood Cell Count	4.93 ± 0.86	5.23 ± 0.58	0.093*	4.7 - 6.0 mil/cu.mm
Hemoglobin	12.97 ± 2.23	13.12 ± 1.87	0.281	Female: 11.6 - 15 gm/dL & Male: 13.2-16.6 gm/dL
Hematocrit (PCV)	40.31 ± 6.97	42.44 ± 4.78	0.009*	42 - 52 %
Mean Corpuscular Volume	82.64 ± 14.28	86.45 ± 10.07	0.002*	78 - 100 fL
Mean Corpuscular Hemoglobin	26.10 ± 5.37	27.04 ± 3.23	0.399	27 - 31 pg

Mean Corpuscular Hemoglobin Concentration	31.62 ± 1.55	31.58 ± 1.84	0.939	32-36 gm/dL
Platelet Count	313.17 ± 76.82	298.67 ± 58.64	0.434	150 - 450 10^3/u
Neutrophils	59.53 ± 7.38	63.30 ± 7.60	0.016*	40 - 75 %
Lymphocytes	32.33 ± 7.18	32.47 ± 5.84	0.914	20 - 40 %
Monocytes	5.10 ± 1.37	5.43 ± 0.90	0.218	2-10 %
Eosinophils	3.37 ± 0.72	3.47 ± 0.82	0.638	1-6 %
Basophils	0.00 ± 0.00	0.00 ± 0.00	1	0-1 %
Liver Function Test				
Protein Total	7.35 ± 0.76	7.58 ± 0.67	0.773	6.0 - 8.3 g/dL
Albumin	4.32 ± 0.37	4.41 ± 0.31	0.269	3.2 - 5.5 g/dL
Globulin	3.04 ± 0.78	3.17 ± 0.62	0.304	1.8 - 3.6 g/dL
A/G Ratio	1.53 ± 0.50	1.45 ± 0.33	0.381	1.2 - 2.2
Bilirubin Total	0.59 ± 0.34	0.59 ± 0.23	0.987	0.1-1.2 mg/dL
Bilirubin Direct	0.25 ± 0.13	0.26 ± 0.10	0.895	0-0.4 mg/dL
Bilirubin Indirect	0.34 ± 0.24	0.34 ± 0.21	0.946	0.1-0.8 mg/dL
Aspartate Transaminase	37.20 ± 11.92	36.08 ± 8.68	0.236	49 U/ L
Alanine Transaminase	31.66 ± 13.92	33.95 ± 11.51	0.008*	49 U/ L
Alkaline Phosphatase	142.29 ± 44.06	155.24 ± 49.25	0.018*	80 - 306 U/ L
Kidney Function Test				
Urea	21.40 ± 7.42	25.64 ± 10.40	0.002*	10-50 mg/dL
Creatinine	0.86 ± 0.19	0.83 ± 0.23	0.684	Female:0.6-1.4 & Male:0.7-1.4 mg/dL
Uric Acid	4.25 ± 0.91	4.07 ± 0.78	0.298	3.0 to 7.2 mg/dL

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at $p < 0.05$. * represent significant values

3.3. Assessment of vital signs

Table 3 Assessment of vital signs

Vitals Parameters			
Parameters	**Screening**	**Day 30**	**P value**
Systolic Blood Pressure (mmHg)	122.53 ± 6.04	121.40 ± 7.97	0.509
Diastolic Blood Pressure (mmHg)	80.80 ± 5.94	80.37 ± 6.71	0.801
Heart Rate (beats per minute)	75.17 ± 6.47	78.20 ± 9.00	0.186
Body Temperature (˚C)	35.83 ± 0.98	36.21 ± 0.52	0.027*
Respiratory Rate (breaths per minute)	17.90 ± 1.35	19.90 ± 9.74	0.234

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at $p < 0.05$. * represent significant values.

Body temperature showed a statistically significant increase from screening to day 30 (97.17 ± 0.94 with a p-value of 0.0279). However, other vital parameters including systolic blood pressure, diastolic blood pressure, heart rate, and respiratory rate did not show statistically significant changes from screening to day 30 as demonstrated in **Table 3**.

3.4. Assessment of adverse events

The adverse events observed during the study are presented in **Table 4**. Out of the 30 participants, a total of 7 participants (23.33%) experienced at least one adverse event. The most commonly reported adverse events were headache, nausea, fever, heartburn, body pain, sneezing, and acidity. For each adverse event, the number of participants affected and the corresponding rescue medication used are shown. AE's were not related to investigational product.

Table 4 Adverse Events Observed in the Study (N=30)

Adverse Events	No. of Participants (N=30)	Rescue Medication
Headache	1	Nicipplus
Nausea	1	Pantosec D SR
Fever	1	Crocin 500
Heartburn	1	Pan D
Body pain	1	Dolo 650
Sneezing	1	-
Acidity	1	Pantosec DSR
Total No. of Events	07	-
Total No. of participants (%)	07 (23.33%)	-

Adverse events are represented in the number of participants.

3.5. Assessment of perceived stress using the Perceived Stress Scale (PSS)

The Perceived Stress Scale (PSS) is a ten-question questionnaire with responses from 0 to 4, measuring an individual's stress perception. The total score is the sum of all responses, indicating the perceived stress level. Scores: 0-13 (low stress), 14-26 (moderate stress), 27-40 (high stress).

The assessment of perceived stress using the PSS demonstrated a statistically significant decrease from the screening visit to day 30 by 57.54% as presented in **Table 5**. The observed change in PSS score was statistically highly significant, suggesting a clinically meaningful improvement in the participant's subjective experience of stress.

Table 5 Assessment of perceived stress using the Perceived Stress Scale (PSS)

Duration	Screening	Day 30	P value
PSS Score	24.57 ± 1.59	10.43 ± 1.98	<0.001*

Data is represented as Mean ± S.D. Analysis was done using a dependent student t-test (within the group). Significant at $p< 0.05$.

3.6. Assessment of gut health using a Gastrointestinal Symptom Rating Scale (GSRS) score

The GSRS is a disease-specific instrument, developed, based on reviews of gastrointestinal symptoms and clinical experience, to evaluate common symptoms of gastrointestinal disorders.

It contains 15 items, each rated on a seven-point Likert scale as: 1- no discomfort at all; 2-minor discomfort, 3-mild discomfort; 4-moderate discomfort; 5-moderately severe discomfort; 6- severe discomfort; 7-very severe discomfort. At screening, participants reported varying levels of discomfort in different gastrointestinal symptoms, with most experiencing minor to moderate levels of distress. However, by day 30, a significant reduction in symptom severity was observed.

Specifically, symptoms such as upper abdominal pain showed a marked decrease, with 19 participants reporting minor discomfort at screening, which reduced to only 4 participants by day 30. Heartburn and acid reflux also demonstrated substantial improvement. At screening, participants reported moderate levels of discomfort, but by day 30, most indicated only minor or no discomfort.

Digestive issues like rumbling, bloating, and burping similarly exhibited significant reductions. Initially, participants experienced various levels of discomfort, but by the 30-day mark, the majority reported minimal to no symptoms. Notably, hunger pains were almost entirely eliminated, with 21 participants reporting minimal discomfort at screening, and all 30 participants showing no discomfort by day 30.

Bowel-related symptoms also showed remarkable improvement. Participants initially reported challenges with sensations of incomplete bowel emptying, diarrhea, loose stools, and constipation. However, by day 30, these symptoms were substantially mitigated. For instance, only 3 participants reported a sensation of incomplete bowel emptying compared to 23 at screening, and diarrhea and loose stools were significantly reduced.

The overall trend indicates a substantial enhancement in participants' gastrointestinal health over the 30-day period, with most symptoms moving from moderate discomfort to minimal or no discomfort. This suggests a potential positive intervention or natural improvement in the participants' gut health during the study period. Data is depicted in **Table 6.**

Table 6 Assessment of gut health using a Gastrointestinal Symptom Rating Scale (GSRS) score

SN	Questions	Score	No. of participants	
			Screening (n=30)	Day 30 (n=30)
1.	Have you been bothered by Pain or discomfort in your upper abdomen or the pit of your stomach during the past week?	1	00	07
		2	01	19
		3	14	04
		4	09	00
		5	06	00
		6	00	00
		7	00	00
2.	Have you been bothered by HEARTBURN during the past week? (By heartburn we mean an unpleasant stinging or burning sensation in the chest.)	1	02	07
		2	05	19
		3	11	04
		4	12	00
		5	00	00
		6	00	00
		7	00	00
	Have you been bothered by ACID REFLUX during the past week? (By acid reflux we mean the sensation of regurgitating small quantities of acid or flow of sour or bitter fluid from the stomach up to the throat)	1	04	16
		2	13	12
		3	02	02
		4	05	00
		5	06	00
		6	00	00
		7	00	00
3.	Have you been bothered by HUNGER PAINS in the stomach during the past week? (This hollow feeling in the stomach is associated with the need to eat between meals.)	1	21	30
		2	08	00
		3	01	00
		4	00	00

		5	00	00
		6	00	00
		7	00	00
4.	Have you been bothered by NAUSEA during the past week? (By nausea we mean a feeling of wanting to throw up or vomit.)	1	02	21
		2	12	09
		3	10	00
		4	04	00
		5	02	00
		6	00	00
		7	00	00
5.	Have you been bothered by RUMBLING in your stomach during the past week? (Rumbling refers to vibrations or noise in the stomach.)	1	04	19
		2	20	11
		3	05	00
		4	01	00
		5	00	00
		6	00	00
		7	00	00
6.	Has your stomach felt BLOATED during the past week? (Feeling bloated refers to swelling often associated with a sensation of gas or air in the stomach.)	1	11	17
		2	05	13
		3	10	00
		4	04	00
		5	00	00
		6	00	00
		7	00	00
7.	Have you been bothered by BURPING during the past week? (Burping refers to bringing up air or gas from the stomach via the mouth, often associated with easing a bloated feeling.)	1	11	15
		2	02	13
		3	05	02
		4	12	00
		5	00	00
		6	00	00
		7	00	00
8.	Have you been bothered by PASSING GAS OR FLATUS during the past week? (Passing gas or flatus refers to the need to release air or gas from the bowel, often associated with easing a bloated feeling.)	1	08	16
		2	08	14
		3	05	00
		4	09	00
		5	00	00
		6	00	00
		7	00	00

9.	Have you been bothered by HARD STOOLS during the past week? (If your stools (motions) have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being hard.	1	19	26
		2	06	04
		3	04	00
		4	01	00
		5	00	00
		6	00	00
		7	00	00
10.	When going to the toilet during the past week, have you had the SENSATION OF NOT COMPLETELY EMPTYING THE BOWELS? (This feeling of incomplete emptying means that you still feel a need to pass more stool despite having exerted yourself to do so.)	1	05	27
		2	18	03
		3	07	00
		4	00	00
		5	00	00
		6	00	00
		7	00	00
11.	Have you been bothered by DIARRHEA during the past week? (Diarrhea refers to a too frequent emptying of the bowels.)	1	14	18
		2	02	11
		3	11	01
		4	03	00
		5	00	00
		6	00	00
		7	00	00
12.	Have you been bothered by LOOSE STOOLS during the past week? (If your stools (motions) have been alternately hard and loose, this question only refers to the extent you have been bothered by the stools being loose.)	1	08	21
		2	14	08
		3	06	01
		4	02	00
		5	00	00
		6	00	00
		7	00	00
13.	Have you been bothered by an URGENT NEED TO HAVE A BOWEL MOVEMENT during the past week? (This urgent need to go to the toilet is often associated with a feeling that you are not in full control.)	1	09	26
		2	14	04
		3	07	00
		4	00	00
		5	00	00
		6	00	00
		7	00	00
14.	Have you been bothered by CONSTIPATION during the past week? (Constipation refers to a reduced ability to empty the bowels.)	1	23	26
		2	01	04
		3	06	00

		4	00	00
		5	00	00
		6	00	00
		7	00	00

Note: (1) No discomfort at all, (2) Minor discomfort, (3) Mild discomfort, (4) Moderate discomfort, (5) Moderately severe discomfort, (6) Severe discomfort, (7) Very severe discomfort.

4. Discussion

The current study provides valuable insights into the potential efficacy of De-Stress & Happy Gut Powder in managing stress and improving gastrointestinal health. The results demonstrated a remarkable 57.54% reduction in perceived stress levels, as measured by the Perceived Stress Scale (PSS), suggesting the product's potential in alleviating psychological strain [8]. This significant stress reduction aligns with the growing interest in natural, holistic approaches to mental well-being, particularly in today's fast-paced society where stress has become an inescapable aspect of modern life [1,4].

The study's findings are particularly noteworthy in the context of the emerging understanding of the gut-brain axis. While stress was once considered primarily a psychological phenomenon, recent research has highlighted its profound physiological implications, including its impact on digestive health [3,5]. The observed improvements in gastrointestinal symptoms, as assessed by the GSRS, provide compelling evidence of the product's potential to address the intricate relationship between stress and digestive disorders.

The formulation's unique blend of ingredients appears to contribute to its effectiveness. Saffron extract, a key component, demonstrated promising pharmacological effects, including anti-inflammatory, antioxidant, and potentially therapeutic properties [9]. Similarly, the inclusion of Bael fruit powder and a proprietary probiotic blend (*Howaru* restore) suggests a multi-faceted approach to gut health. The probiotic and prebiotic components (inulin) may play a crucial role in modulating the gut microbiome, which has been increasingly recognized for its significance in metabolism, immune defense, and even behavioral regulation [3,10-12].

The comprehensive approach of addressing both stress and gut health through a natural supplement reflects a growing trend in healthcare towards integrated, holistic treatment strategies. The study's results suggest that phytoconstituent-based products like De-Stress & Happy Gut Powder could offer a promising alternative to traditional pharmaceutical interventions for managing stress and digestive issues [12,13]. This is particularly relevant given the increasing consumer interest in natural, comprehensive approaches to wellness.

The substantial improvements observed in gastrointestinal symptoms are particularly compelling. Participants reported significant reductions in various digestive issues, including upper abdominal pain, heartburn, acid reflux, nausea, bloating, and bowel-related symptoms. The near-elimination of symptoms such as hunger pains and the marked reduction in other gastrointestinal discomforts suggest the potential of the product to provide meaningful relief for individuals struggling with digestive health challenges [14,15].

However, it is important to acknowledge the study's limitations. The open-label, single-arm design means that placebo effects cannot be entirely ruled out. Future research should consider randomized, double-blind, placebo-controlled trials to more rigorously validate these findings. Additionally, while the 30-day study period provided promising initial results, longer-term studies would be beneficial to assess the sustained efficacy and safety of the product.

5. Conclusion

This study provides preliminary evidence supporting the potential of De-Stress & Happy Gut Powder as a natural intervention for stress management and gut health improvement. The statistically significant reductions in perceived stress and improvements in gastrointestinal symptoms, coupled with the product's good safety profile, suggest a promising avenue for further research. As the scientific community continues to explore the complex interactions between stress, gut health, and overall well-being, such holistic approaches represent an exciting frontier in integrative health solutions.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

Dr. Kriti Soni and Dr. Sachin Mulik are part of Herbolab India Pvt. Ltd. Other author declares no conflict of interest.

Statement of informed consent

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

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