A prospective, open labeled, 8-week clinical study evaluating the effects of P84 on gut and health outcomes

Objective: To evaluate subjective and objective changes in gut and digestive health parameters following 8 weeks of daily use of P84.

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Introduction

Gut and digestive health are fundamental to overall human health and are closely linked to immune regulation, nutrient absorption, metabolic function, and systemic stress. The gastrointestinal tract hosts a complex microbial ecosystem that plays a critical role in maintaining intestinal homeostasis, supporting digestion, synthesizing bioactive metabolites, and modulating immune responses. (Lin and Medeiros 2025) Alterations in gut microbiota composition and function have been associated with gastrointestinal symptoms, metabolic disturbances, and immune dysregulation. (Shabani *et al.* 2025)

Several factors, including poor dietary habits, chronic stress, antibiotic exposure, lifestyle behaviors, and environmental influences, can disrupt gut microbial balance and digestive function. (Pandit *et al.* 2025) Reduced microbial diversity and impaired intestinal barrier integrity may result in increased intestinal permeability ("leaky gut"), allowing microbial products to enter systemic circulation and trigger an immune response. These changes have been associated with digestive discomfort, bloating, altered bowel habits, and increased susceptibility to illness. (Di Vincenzo *et al.* 2024)

Objective biomarkers have emerged as valuable tools for evaluating gut and digestive health. Stool-based markers such as calprotectin, secretory IgA, beta-defensin, short-chain fatty acids, bile acids, zonulin, and lipopolysaccharide-associated markers provide insight into systemic intestinal stress, immune activity, digestive efficiency, microbial metabolism, and barrier integrity. Comprehensive stool analyses allow for a non-invasive and integrated assessment of gut health parameters. (Duvoisin *et al.* 2017)

Dietary supplements containing plant-based nutrients, prebiotic fibers, probiotics, digestive enzymes, and bioactive compounds are increasingly used to support gut microbial diversity, digestive processes, immune balance, and intestinal barrier function. (Mafe *et al.* 2025) Clinical and mechanistic evidence suggests that such formulations may favorably influence gut microbiota composition, reduce systemic intestinal stress, enhance mucosal immunity, and improve gastrointestinal symptoms. (Sun *et al.* 2025)

P84 is a dietary supplement consisting of two proprietary herbal powder formulations, PhytoPower 1 and PhytoPower 2. They contain a wide range of red-, blue-, purple-, green-, and yellow-colored fruit and vegetable powders together with digestive enzymes, probiotics, and prebiotic fibers. In an earlier in vitro study, P84 activated 14 key gut peptides and proteins associated with gut process regulation, gut repair, and gut restoration mechanisms. This provided compelling mechanistic evidence for how P84 was working on the cellular level. This further prompted more research to identify measurable outcomes in human health.*

To further expand this exploratory work, a human clinical study to further investigate changes in gut and digestive health parameters following daily use of P84 over an 8-week period was developed. Objective stool-based biomarkers were used to assess microbial diversity, systemic intestinal stress, immune response, digestive function, and intestinal barrier integrity, alongside validated gastrointestinal symptom questionnaires to capture participant-reported outcomes.

STUDY DESIGN

A prospective, open-label, single-arm, 8-week clinical study design was used to evaluate the effects of daily supplementation with P84 on gut and digestive health outcomes. The study was conducted at a single clinical site under controlled outpatient conditions.

No placebo or active control group was included in the study. As a single-arm study, each subject served as his or her own control, with post-treatment assessments compared to baseline measurements. This design was considered appropriate for the exploratory evaluation of the effects of P84 on gut and digestive health.*

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SELECTION OF STUDY PARTICIPANTS

Inclusion Criteria

1. Male or female adults aged 18 to 80 years (with approximately 50% men and 50% women, an even distribution across the age groups 18–30, 31–60, and 61–80 years, and 12–15% African American participants) were enrolled at the time of screening.

2. Participants were willing and able to provide written informed consent before undergoing any study-related procedures.

3. Participants were willing and able to comply with all study procedures, including clinic visits, completion of questionnaires, and stool sample collection at predetermined time points.

4. Participants were willing to collect and provide stool samples, either in-clinic or at home, as instructed.

5. Participants were willing to abstain from alcohol consumption (including beer, wine, and spirits) for the duration of the study.

6. Participants were proficient in written and spoken English.

7. Participants were willing to provide a valid email address and mobile phone number and were able to complete electronic forms and questionnaires using a smartphone.

8. Participants were able and willing to travel to the Research Institute for scheduled in-clinic visits and stool sample collection.

9. Participants reported no known food allergies based on self-report.

10. Participants were willing to maintain their usual diet and lifestyle habits, except as required by the study protocol.

11. Participants had self-reported gastrointestinal symptoms, defined as a baseline Gastrointestinal Symptom Rating Scale (GSRS) score of ≥8 (35 subjects) or a score of ≤3 (5 subjects).

Exclusion Criteria

1. Participants had a known allergy or hypersensitivity to any ingredient(s) of the study product or other herbal products.

2 Participants had the presence or history of any medical condition that could have interfered with study participation or outcome interpretation, including but not limited to:

a. Malabsorption disorders
b. Chronic gastrointestinal diseases
c. Severe depression
d. Clinically significant cardiovascular disease within the past 3 months

3. Participants were pregnant, breastfeeding, or planning to become pregnant during the study period, based on self-report.

4. Participants had a pregnant partner or a partner who was planning to become pregnant during the study period and who was unwilling or unable to use an acceptable method of contraception.

5. Participants had a history of any cancer within the past 5 years.

6. Participants were active or occasional smokers.

7. Participants were currently using probiotics and were unwilling to discontinue their use at least 4 weeks prior to study enrollment.

8. Participants had a history of weight loss surgery or any type of bowel surgery, including resection or colectomy.

9. Participants had an active infection within the past 3 months that required antibiotics, antiviral medication, or hospitalization.

10. Participants had used immunosuppressive medications within the past 12 months, including systemic corticosteroids or biologic agents.

11. Participants had a history of seizure disorder or had used seizure medication within the past 4 weeks.

12. Participants had a history of HIV infection or solid organ transplantation.

13. Participants had used medications for chronic gastrointestinal or digestive conditions, including but not limited to:

    a. Proton pump inhibitors or antacids (e.g., omeprazole, Prilosec®)
    b. Laxatives or gastrointestinal motility agents
    c. Medications for irritable bowel syndrome (IBS), Crohn's disease, or had a history of hospitalized diverticulitis

14. Participants had any other condition that, in the opinion of the Principal Investigator, made them unsuitable for participation or could have compromised subject safety or study integrity.

TREATMENT

The dosage regimen for all participants was one stick pack each of PhytoPower 1 and PhytoPower 2 daily. Participants were instructed to mix the contents of both stick packs together into 16 fl. oz. (480ml) of water and consume the preparation once every morning within 30 minutes, with or without food, for a duration of 8 weeks.

Adult male and female subjects aged 18 to 80 years who met all eligibility criteria were enrolled into a single treatment group. Each subject serves as their own control for the assessment of study outcomes.

After providing written informed consent, subjects were assigned to a unique screening number. Following confirmation of eligibility based on the inclusion and exclusion criteria, subjects were enrolled and assigned a unique subject identification number.

Each participant had to fill out 2 questionnaires at baseline, week 2, week 4, week 6, and week 8 timepoints and also provide a stool sample at baseline and week 8 to be analyzed using the Gut Zoomer test (see below).

QUESTIONNAIRES

a. *Gastrointestinal Symptom Rating Scale (GSRS)*

The Gastrointestinal Symptom Rating Scale (GSRS) was a validated, patient-reported questionnaire used to assess the digestive symptoms including abdominal pain or discomfort, heartburn, reflux, hunger pains, nausea, stomach rumbling, feeling bloated, burping, feeling gassy, constipation, diarrhea, loose/hard stool, urge to have a bowel movement, and sensation of not completely emptying the bowels over the previous week using a 1-to-7 scale (1 = no discomfort, 7 = very severe). (Svedlund *et al.* 1988)

GSRS assessments were performed at Baseline, Week 2, Week 4, Week 6, and Week 8.

b. *Subjective Digestive Health and Well-Being Questionnaire*

A customized Subjective Health Questionnaire was used to capture participant-reported perceptions related to overall well-being, digestive comfort, product tolerability, and user experience during the study.

The questionnaire assessed dietary habits and supplement use, sleep quality, energy levels, mood, skin health, mental clarity, focus and brain fog, susceptibility to feeling "under the weather," product tolerability, ease of use, flavor/taste acceptability, mixability, perceived health improvements, and likelihood of recommending the product.

Responses were captured using 5-point Likert scales, 7-point Likert scales, and open-ended responses where applicable.

The first questionnaire was administered at baseline and captured current supplement use, dietary habits, and baseline health perceptions. Interim questionnaires were administered at Week 2, Week 4, Week 6 to evaluate perceived changes in health parameters, product tolerability, side effects, and product experience. The end-of-study questionnaire was administered at the end of the study at Week 8 and captured overall perceived health improvements, time to onset of benefits, final product tolerability, satisfaction, and likelihood of recommending the product.

GUT ZOOMER

The Gut Zoomer test provided by Vibrant Wellness (Santa Clara, CA, USA) is a health analytics tool based on the gut microbiome. It measures the potential for intestinal permeability, cardiovascular, metabolic, neurological, intestinal, autoimmune, liver, hormonal, and nutritional health concerns. Additionally, it has panels for detection of gut pathogens and digestive markers.

This test is split into several sections:

1. Gut diversity – This is an indicator for the amount of individual bacteria from each of the bacterial species present in your gut microbiome. There are two indices calculated including Shannon's Index (scale 0-3) and Simpson's Index (scale 0-1). For both calculations, higher index values represent increased diversity of species. While Shannon's is a better indicator of "richness" of diversity, Simpson's is a better indicator of "evenness." The calculated Index values are surrounded with a risk indicator (green – high diversity, yellow – moderate diversity, and red –low diversity).

2. Gut phyla – Distribution is displayed in a pie chart with each pie representing the percentage of individual phyla tested. Key Ratios are calculated and displayed comprising F/B (Firmicutes to Bacteroidetes ratio) and P/B (Prevotella to Bacteroides ratio) along with the corresponding risk indicator.

3. Gut commensal – This section represents a relative bacterial abundance value. Relative abundance is the percent composition of an organism of a particular kind relative to the total number of organisms in your gut microbiome. The abundance of individual bacterial phylum/family/genus/species is calculated by comparing the relative abundance to the healthy reference range. Reference ranges have been established using results from 200 healthy individuals. The abundance is always mentioned in the report along with the potential associated risks; however, it is applicable only when indicated in RED. Associated probiotic tests are displayed in each panel with suggestions based on potential associated risks.

Table 1 shows the risk categories associated with an imbalance in gut commensals.

Table 1. Gut commensal and their associated health outcomes.

Intestinal Permeability
Occasional Intestinal Gas
SIBO
Autoimmune Health
Metabolic Health
Liver Health
Hormones
Nutrition
Cardiovascular Health
Neurological Health
Probiotic Health
Keystone Health

4. Gut pathogens –This section includes pathogenic bacteria, parasites, viruses, and fungi, and they are indicated as DETECTED or NOT DETECTED along with the levels in respective units. Worm and antibiotic resistance gene testing are displayed as DETECTED or NOT DETECTED based on the test result.

5. Digestion and immune balance – Markers are displayed along with a risk indicator and the corresponding reference range for each test calculated using results from 200 healthy individuals (Table 2). All test results are displayed with a risk indicator and abundance direction, as applicable (red = high risk, yellow = moderate risk, and green =low risk).

Table 2. Stool analysis and associated markers for digestion and immune imbalance.

Pancreatic Elastase 1
Fecal Immunochemical Test (FIT)
Fecal Zonulin
pH
secretory IgA (sIgA)

6. Systemic intestinal stress – Markers are displayed along with a risk indicator and the corresponding reference range for each test calculated using results from 200 healthy individuals (Table 3). All test results are displayed with a risk indicator and abundance direction, as applicable (red = high risk, yellow = moderate risk, and green = low risk).

Table 3. Stool analysis and 7 systemic stress markers analyzed.

Beta-defensin 2
Lysozyme
MMP 9
S100A12
Calprotectin
Fecal Lactoferrin
Fecal Eosinophile Protein X

7. Gut antibodies – Markers are displayed along with a risk indicator and the corresponding reference range for each test calculated using results from 200 healthy individuals (Table 4). All test results are displayed with a risk indicator and abundance direction, as applicable (red = high risk, yellow = moderate risk, and green = low risk).

Table 4. Stool analysis and the gut antibody attributes analyzed.

Lipopolysaccharide Antibody
Anti-Saccharomyces cerevisiae
Tissue Transglutaminase
Deaminated Gliadin
Fecal Anti-Gliadin
Actin Antibody

8. Gut metabolites – Markers are displayed along with a risk indicator and the corresponding reference range for each test calculated using results from 200 healthy individuals. All test results are displayed with a risk indicator and abundance direction, as applicable(red = high risk, yellow = moderate risk, and green = low risk).

A range of metabolites were analyzed for bile metabolites, short chain fatty acid metabolites, as well as fat malabsorption metabolites.

RESULTS

1. Gut Zoomer results

   a. Gut diversity results showed that 77% of subjects showed an improvement in the Shannon's Index and 61% of subjects showed an improvement in the Simpson's Index.
   b. The improvements resulted in the gut phyla ratios of Firmicutes/Bacteroidetes and Prevotella/Bacteroides improving 100% or staying the same in the participating subjects.
   c. The results for gut commensals and their associated risk categories are shown in Table 5.

Table 5. Results for associated risk categories associated with an imbalance in gut commensals

Risk Category	**Results**
Intestinal Permeability	56% of subjects showed an improvement in microorganisms supporting a strong gut barrier*
Systemic Intestinal Stress	100% of subjects showed an improvement in microorganisms supporting a healthy gut stress response*
Cardiovascular Health	95% of subjects showed an improvement in microorganisms supporting a healthy cardiovascular system*

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d. The digestion and immune markers pancreatic elastase 1, FIT, fecal zonulin, and secretory IgA showed that 93%, 98%, 70%, and 74% of subjects showed improvements in those markers. pH stayed within the normal range in all subjects throughout the study (Table 6).

Table 6. Results for digestion and immune markers.

Market	Results
Pancreatic Elastase 1	93% of subjects showed an improvement*
Fecal Immunochemical Test (FIT)	98% of subjects showed an improvement*
Fecal Zonulin	70% of subjects showed an improvement*
sIgA	74% of subjects showed an improvement*
pH	100% of subjects stayed in normal range*

e. Seven systemic intestinal stress markers were analyzed and showed that 81% of all subjects saw an improvement in all 7 markers associated with heightened stress in the gut. A total of 86%, 95%, 100%, 81%, 88%, 95%, and 88% of subjects saw an improvement in beta-defensin 2, lysozyme, MMP9, S100A12, calprotectin, fecal lactoferrin, and fecal eosinophile protein X, respectively (Table 7).*

Table 7. Results for intestinal stress markers.

Market	Results
Beta-defensin 2	86% of subjects showed an improvement*
Lysozyme	95% of subjects showed an improvement*
MMP9	100% of subjects showed an improvement*
S100A12	81% of subjects showed an improvement*
Calprotectin	88% of subjects showed an improvement*
Fecal Lactoferrin	95% of subjects showed an improvement*
Fecal Eosinophile Protein X	88% of subjects showed an improvement*

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f. A total of 6 gut antibody markers were analyzed and at least 95% of subjects saw an improvement in all 6 markers associated with an over-reactive immune response in the gut. A total of 95% of subjects showed an improvement in the lipopolysaccharide antibody marker. All subjects saw an improvement in anti-Saccharomyces cerevisiae, tissue transglutaminase, deaminated gliadin, fecal anti-gliadin, and actin antibody, respectively (Table 8).*

Table 8. Results for gut antibody markers.

Market	Results
Lipopolysaccharide Antibody	95% of subjects showed an improvement*
Anti-Saccharomyces cerevisiae	100% of subjects showed an improvement*
Tissue Transglutaminase	100% of subjects showed an improvement*
Deaminated Gliadin	100% of subjects showed an improvement*
Fecal Anti-Gliadin	100% of subjects showed an improvement*
Actin Antibody	100% of subjects showed an improvement*

g. A total of 5 bile acid metabolites, 5 short-chain fatty acid (SCFA) metabolites, and 1 estrogen metabolite were analyzed. A total of 64% of subjects showed an improvement in all 11 gut metabolites that indicate a healthier and more metabolically active gut ecosystem, and a total of 74% of subjects showed an improvement in fat malabsorption markers (Table 9).*

Table 9. Results for gut antibody markers.

Market	Results
Cholic Acid	100% of subjects stayed in the healthy normal range*
Chenodeoxycholic Acid	100% of subjects stayed in the healthy normal range*
Deoxycholic Acid (DCA)	70% of subjects improved or stayed in the healthy, normal range*
Lithocholic Acid (LCA)	84% of subjects improved or stayed in the healthy, normal range*
LCA/DCA Ratio	74% of subjects improved or stayed in the healthy, normal range*
Acetate	100% of subjects improved or stayed in the healthy, normal range*
Propionate	93% of subjects improved or stayed in the healthy, normal range*
Butyrate	64% of subjects improved or stayed in the healthy, normal range*
Valerate	79% of subjects improved or stayed in the healthy, normal range*
Total SCFA	60% of subjects improved or stayed in the healthy, normal range*
Beta-glucuronidase	95% of subjects improved or stayed in the healthy, normal range*
Total Fecal Fat	74% of subjects improved or stayed in the healthy, normal range*
Total Fecal Triglycerides	93% of subjects improved or stayed in the healthy, normal range*
Long-chain FA	88% of subjects improved or stayed in the healthy, normal range*
Total Cholesterol	86% of subjects improved or stayed in the healthy, normal range*
Total Phospholipids	95% of subjects improved or stayed in the healthy, normal range*

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RESULTS CONTINUED

2. Subjective Questionnaire results

   a. The GSRS questionnaire showed that P84 was safe and well tolerated throughout the 8-week study period. At the beginning of the study and before consuming P84, there were a variety of GI symptoms, such as occasional abdominal discomfort, hunger pains, nausea, stomach rumbling, feeling bloated, feeling gassy, and constipation rated as “moderate discomfort” in about 4% of the subjects. At the end of the study, 100% of these subjects improved in all these parameters.*

A summary of results from the subjective questionnaire is seen in Table 10.

Table 10. Results of subjective questionnaire at the end of the study.

91% of subjects noticed a positive change in overall sleep quality*
90% of subjects noticed a significant (p=0.007) positive change in energy levels throughout the day*
73% of subjects noticed a significant (p=0.011) positive change in overall mood quality*
85% of subjects noticed a positive change in mental clarity*
49% of subjects noticed a positive change in focus*
77% of subjects noticed a significant (p=0.016) positive change in their susceptibility to being under the weather*
77% of subjects liked the flavor and taste experience

Conclusion

Stool analysis is considered an effective measure of health, because it assesses multiple interconnected systems at once: digestion, nutrient absorption, the gut microbiome, immune function, systemic intestinal stress, intestinal barrier integrity, and microbial metabolism. Improvements in stool biomarkers often indicate broader improvements in overall physiological health, particularly when combined with clinical improvements in symptoms and other health measures, since the gut influences metabolism, immune health, and even brain function.

This 8-week study of daily use of P84 in 42 subjects evaluated changes in gut and digestive parameters using a stool-based biomarker test kit called Gut Zoomer from Vibrant Wellness. There was a significant improvement in gut microbial diversity and various metabolites.

A total of 77% of subjects showed an improvement in gut microbiome diversity, and 61% showed a more even distribution of the microorganisms in the gut microbiome. 70% of subjects showed an improvement in the zonulin marker, a peptide involved in supporting a strong gut barrier. This was exciting because it verified the observation in our earlier in vitro study where we saw a 19% decrease in zonulin (HP2) secretion.*

Subjects improved in several stool markers associated with heightened stress parameters (81%), overreactive immune responses (95%), and gut metabolites (64%), indicating a healthier and more metabolically active gut ecosystem. Results also showed that 74% of subjects showed an improvement in nutrient absorption. This was also meaningful because it verified the results from the earlier in vitro study that demonstrated improvements in peptides involved in regulating, restoring, and repairing gut function and microbial balance.*

The improvements in the gut microbiome composition and metabolite profiles mirrored the answers obtained from the two subjective questionnaires, which were also used to evaluate the safety of the product.

This study showed that P84 was well liked, safe, well tolerated, and associated with high compliance and acceptability, supporting its role in promoting gut health and overall wellness in adults.*

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