



ValidationInstitute

2023 Validation Report

Review for: Ayble Health

Validation Achieved: Outcomes

Valid through: October 2024



Company Profile



Category: Gastroenterology Disease Management

Website: www.ayblehealth.com

Public or Private: Private

Year Established: 2020

CEO: Sam Jactel, MBA

Company contact: sam@ayblehealth.com

Description:

Ayble Health is an all-in-one digital solution for gut health, providing a comprehensive ecosystem of support through GI-specialized behavioral and dietary programs, all with the human touch of a licensed care team. Ayble empowers patients with chronic GI conditions to manage their care beyond the pill, improve symptoms and reduce costs.

Ayble combines the largest GI behavioral health database in the world with proprietary machine learning algorithms to build personalized, predictive care pathways for every patient.

Through a mobile app on the patient's smartphone, **Ayble's** precision nutrition program helps guide people to identify - and then remove - their personal trigger foods. Patients can use **Ayble's** last-mile nutrition tools to put





Company Profile

their diet to practice: discover compatible foods among 120,000+ grocery products, experiment with 2.3M+ recipes, purchase products through retail partners (Walmart, Kroger, Instacart) and scan barcodes in store.

Ayble's precision psychology program helps patients address the mind-gut connection through customized, curated exercises, education and interactive content built on gold standard GI-specialized clinical psychology protocols.

In addition to **Ayble's** data-driven tools, every user gets access to 1:1 certified health coaches, dietitians and mental health professionals who offer motivation, guidance, and education throughout their journey. Finally, **Ayble's** integrated clinical referral tools allow users to book appointments with in-network physicians if needed to supplement their care.

Ayble's platform is built on 20 years of GI-specialized dietary and behavioral research, including primary publications in leading journals such as Gastroenterology, Inflammatory Bowel Diseases and Clinical & Translational Gastroenterology. Additional ongoing research is being conducted with partners at the Cleveland Clinic, Mayo Clinic, Northwestern University, Harvard, Massachusetts General Hospital and Brigham & Women's Hospital.

Ayble is accredited by the American Nutrition Association and partners with the Crohn's & Colitis Foundation and American Gastroenterology Association.





Claim Assertion for Validation

Crohn's Disease, Ulcerative Colitis, or Irritable Bowel Syndrome sufferers who use the Ayble app improve their clinical symptoms. The majority see significant symptom improvement after five weeks and maintain this improvement to 9 weeks. App users are also more successful in following dietary guidance than similar patients who are getting conventional care.

The Ayble app guides the user to identify, evaluate and remove foods that trigger gut symptoms, using diet and symptom tracking tools. Data from Ayble's GI database, 400+ published studies on the interaction between diet and symptoms and proprietary machine learning algorithms inform the guidance to users. The app adjusts guidance on a daily basis to maximize symptom relief for each patient.

By managing symptoms effectively, people who suffer these illnesses may also improve their work productivity and presenteeism. A 2019 study of 3,254 people with irritable bowel syndrome found that those who were employed or in school missed 1.5 days per month because of IBS and had 8.0 days per month where IBS affected their productivity. (Ballou S, 2019) Compared to people without these illnesses, people with IBS missed 3.9 more work days per year. (Buono JL, 2017)





Method / Calculation / Examples

Participants were recruited online to use a digitally delivered personalized elimination diet for Crohn's Disease (n=9), Ulcerative Colitis (n=12), and Irritable Bowel Syndrome (IBS) (n=16).

Each participant completed a survey to assess their symptoms before they began the program. IBS patients used the IBS Symptom Severity Score (IBS-SSS); Crohn's Disease patients took the Mobile Health Index (mHI-CD); and Ulcerative Colitis patients took the Patient Simple Clinical Colitis Activity Index (P-SCCAI). The same survey was used throughout the nine weeks to gauge progress. (Note: these surveys are valid clinical tools for measuring and monitoring symptoms.)

The symptom scores from pre-program were compared to the scores at five weeks (midpoint) and at nine weeks (endpoint). The change in scores was analyzed to determine whether it was mathematically significant. The change in scores was also compared to the smallest change that is enough to make a meaningful difference in the person's health status. The percentage of people with improved symptoms was calculated at five weeks and at nine weeks.

Participants reported their food intake, allowing the app to calculate how closely they were following dietary recommendations. How closely they were following the guidance (adherence) was measured as a ratio of their actual intake to the ideal intake. This was compared to published studies of patients' adherence to recommended diets.



Findings & Validation

Outcomes: Eighty-one percent of patients using Ayble's precision nutrition program significantly improved their IBS or IBD (Crohn's Disease or Ulcerative Colitis) clinical symptoms. Seventy eight percent of Ayble patients saw large enough symptom improvements to make a difference in health status.

Ayble's symptom improvement is much higher than other diet interventions achieve. For example, a 2019 study found that at six weeks, 46.5% of the participants on the Specific Carbohydrate Diet, and 43.5% of the participants on the Mediterranean Diet improved their symptoms. (Lewis, 2021)

Findings & Validation

Chart 1 summarizes the percentage of participants whose symptom scores improved significantly (a math function), and those whose symptoms improved enough to make a difference in their health status.

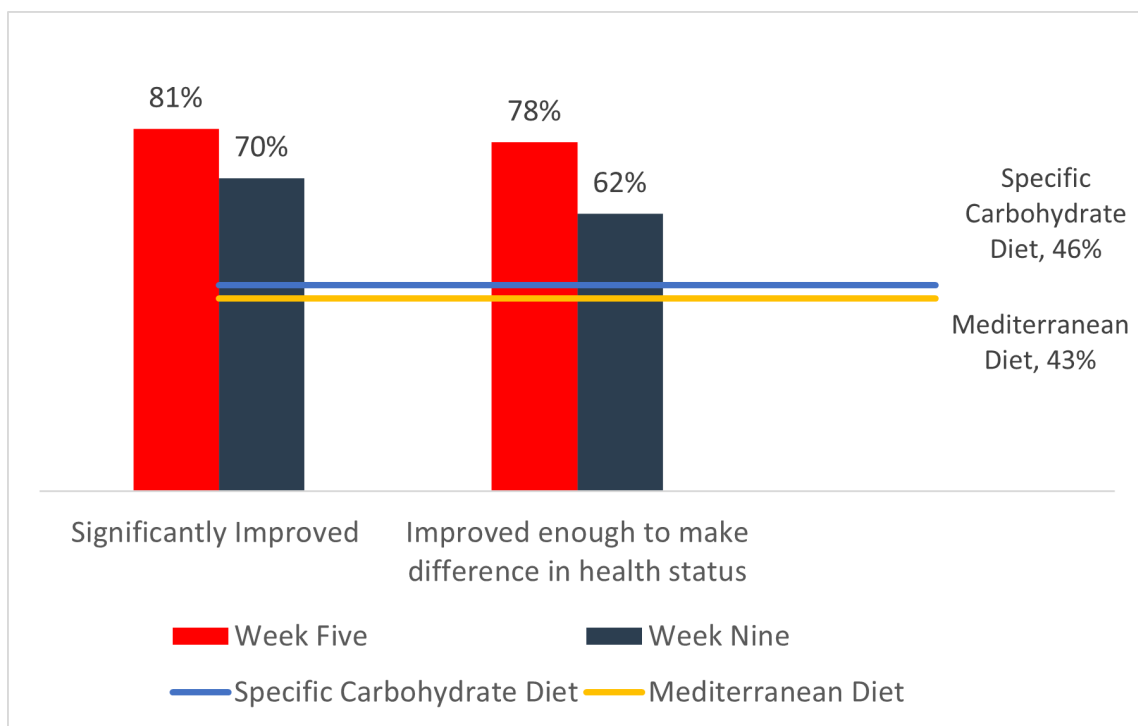


Chart 1: Summary of Participant Score Changes

Findings & Validation

In addition to clinical symptoms, 89% of participants reported significantly better quality of life. 92% of users reported they understood their gastrointestinal conditions better, 95% improved their ability to make healthy digestive choices and 89% felt more empowered and in control of their digestive health.

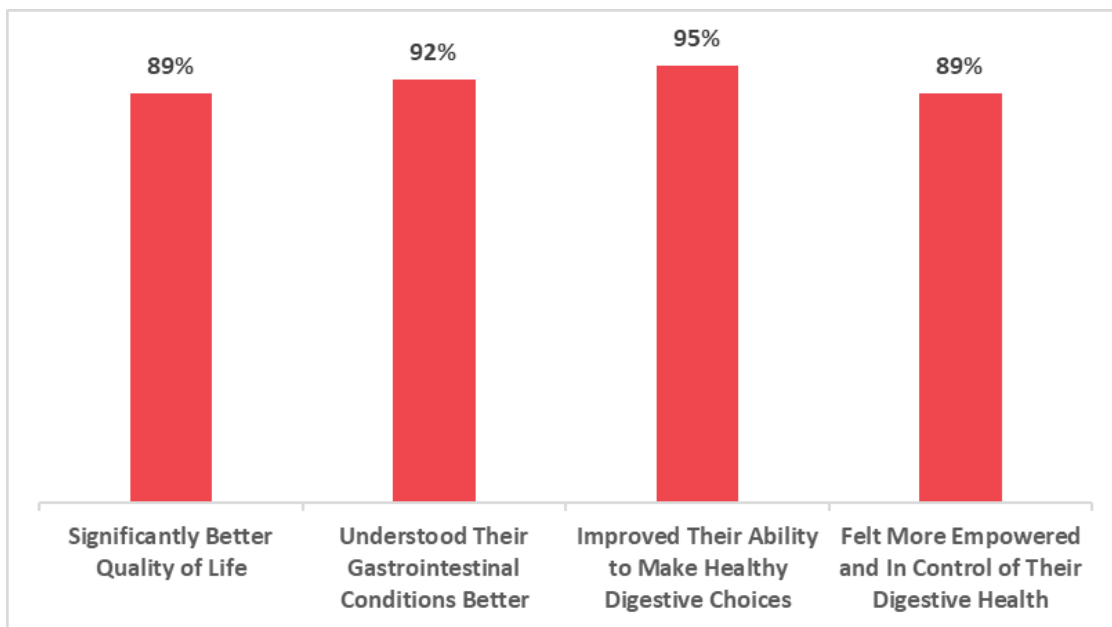


Chart 2: Summary of Participant Clinical Symptoms

Findings & Validation

Ayble users were on average 89% adherent to the program's dietary recommendations. All Ayble users had 50% or greater adherence to the guidance. Other studies count anyone at 50% adherence as compliant and show 40 to 60% of the people achieve that threshold. Using the 50% adherence standard, 100% of Ayble users were compliant.

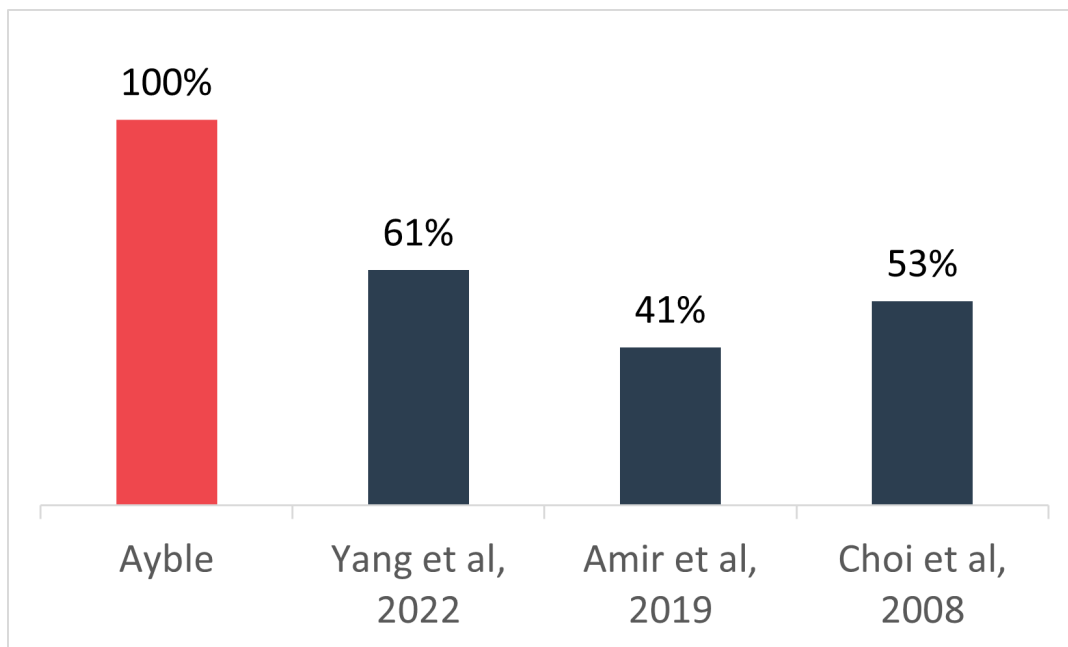


Chart 3: Users 50% or greater adherence to diet

Chart 3 shows the percentage of Ayble users' who had at least 50% compliance, and shows diet compliance from three published studies: (Yang, Ziruo Lin, Loh, & al, 2022) (Mari, et al., 2019) and (Choi YK, 2008).



Limitations

People joined and completed the program voluntarily. Their personal motivation may make them different from others who have the same illnesses; this, in turn, may make their results more favorable.

The number of people in the analysis is small, however results were statistically significant.



Works Cited

Ballou S, M. C. (2019). Effects of Irritable Bowel Syndrome on Daily Activities Vary Among Subtypes Based on Results From the IBS in America Survey. *Clin Gastroenterol Hepatol*, 2471-2478.

Buono JL, C. R. (2017). Health-related quality of life, work productivity, and indirect costs among patients with irritable bowel syndrome with diarrhea. . *Health Qual Life Outcomes*.

Choi YK, K. N. (2008). Fructose intolerance in IBS and utility of fructose-restricted diet. *J Clin Gastroenterol*.

Lewis, J. D. (2021). A Randomized Trial Comparing the Specific Carbohydrate Diet to a Mediterranean Diet in Adults With Crohn's Disease. *Gastroenterology*, 837–852.

Mari, A., Hosadurg, D., Martin, L., Zarate-Lopez, N., Passananti, V., & Emmanuel, A. (2019). Adherence with a low-FODMAP diet in irritable bowel syndrome: are eating disorders the missing link? *European Journal of Gastroenterology & Hepatology*, 178 - 182.

Yang, J., Ziruo Lin, G., Loh, Y. H., & al, e. (2022). Investigating the Role of Low-FODMAP Diet in Improving Gastrointestinal Symptoms in Irritable Bowel Syndrome. *Proceedings of Singapore Healthcare*.



Validation and Credibility Guarantee

Ayble Health's App achieved validation for Outcomes. Validation Institute is willing to provide up to a \$25,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit

<https://validationinstitute.com/credibility-guarantee/>

Savings

Can reduce health care spending per case/participant or for the plan/purchaser overall.

Outcomes

Product/solution has measurably improved an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Metrics

Credible sources and valid assumptions create a reasonable estimate of a program's impact.

Contractual Integrity

Vendor is willing to put a part of their fees "at risk" as a guarantee.





Validation Expiration: October 2024

CERTIFICATE OF VALIDATION

Applicant: Ayble Health
52 Appleton St. Boston, MA, 02116

Product: Ayble Health App

Claim: Crohn's disease, Ulcerative Colitis, or Irritable Bowel Syndrome sufferers who use the Ayble app improve their clinical symptoms.

Validation Achieved: Validated for Outcomes

Award Date: December 2022

Linda Riddell
VP, Population Health Scientist
Validation Institute

Benny DiCecca
Chief Executive Officer
Validation Institute



About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.

Validation Review Process

Validation Institute has a team of epidemiologists and statisticians who review each program. The team focuses on three components:

- Evidence from published literature that a similar intervention had similar results.
- The reliability and credibility of the data sources.
- The rigor of the approach to calculating results.

To achieve validation, the program has to satisfy each of these components. VI's team then summarizes the review into a report which is publicly available. Details of VI's review are available with the program's permission.