



FoodMed  
CERTIFIED

ayble

**Certification for:  
Tools to Manage Chronic Disease  
Expires August 31, 2024**



[www.foodmedcertified.com/](http://www.foodmedcertified.com/)

VALIDATION INSTITUTE, 250 First Avenue, Suite 301, Needham, MA 02494



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# Company Profile

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<b>Category:</b>	<b>Tools - Chronic Disease Management</b>
<b>Website:</b>	<a href="http://www.ayblehealth.com">www.ayblehealth.com</a>
<b>Public or Private:</b>	Private
<b>Year Established:</b>	2020
<b>CEO:</b>	Sam Jactel, MBA
<b>Company contact:</b>	sam@ayblehealth.com

## Description Provided by the Company:

**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

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their diet to practice: discover compatible foods among 200,000 grocery products, experiment with 2.5M+ recipes, purchase products through retail partners (Walmart, Kroger, Instacart) and scan barcodes in store.

Ayble's 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 1:1 access to board-certified health coaches who offer motivation, guidance, and education throughout the gut health journey. Finally, Ayble's integrated clinical referral tools allow users to connect 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.



# Overview of FoodMed Certification

## Review Components

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Validation Institute's independent review of medical nutrition and food programs guides purchasers on selecting effective, well-designed programs. Programs that earn the Food Med Certified designation will meet the standards shown below.

- **Program Foundation** – The output, such as guidance to consumers or care plans for medical professionals, is based upon reliable and credible data. Selection of this data is overseen by appropriately licensed and experienced people. In addition, the data must come from recognized, accredited sources; users' data can be used to refine the output over time. The program has systems and procedures managed by competent personnel to ensure this data is accurate and up to date. If the data sources and systems are handled by a contractor, the program must show that the contracts provide for all of the requirements.
- **Enrollment and Communications** – Prospective users are given accurate and reasonable descriptions of the program and its results. The program will report the following:
  - Size of eligible population, if possible.
  - Definition of enrolled (such as minimum number of visits or interactions)
  - Enrollment attrition and cause, such as lack of engagement or loss of eligibility



# Overview of FoodMed Certification

## Review Components

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- **Program Delivery** –The program will demonstrate how it addresses users’ barriers to optimal use. Barriers related to Social Determinants of Health and to cultural factors will be addressed. If the end user is a medical professional, then the program could integrate with existing record and workflow systems. If the end user is a consumer, the program needs to show how it accommodates different needs and preferences. The program also must show how it monitors program delivery success.
- **Health Outcomes** –If health outcomes are part of the program, the program will show how these are measured. Survey tools should generally be validated and be administered in the way they were validated. (Note: Food programs can separately have their health outcomes validated.) The program’s website and enrollment materials will show health outcomes based upon a minimum of 12 months of participant data; shorter time periods are allowed for health conditions whose treatment regimens are shorter. Where the outcome is weight loss, 24 months of participant data and post-program data are preferred.

Ayble Health submitted its program which helps people who have irritable bowel syndrome, and inflammatory bowel disease(Crohn’s Disease, and Ulcerative Colitis) to manage and reduce their symptoms. (For a complete description of the program and its validated outcomes, see Validation Reports





# Overview of FoodMed Certification Review Components

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- Validation institute.) Ayble Health submitted descriptions of the four components and other documentation to support their application.

The submitted materials need to meet the requirements and standards and have an executive officer's attestation of their accuracy. All materials, except those containing proprietary information, are available upon request.

Validation Institute reviewers, including staff and advisors, contributed to the evaluation.





# Applicant's Program Goal

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The Ayble Health program guides people who have irritable bowel syndrome (IBS), and inflammatory bowel disease (IBD, including Crohn's disease and Ulcerative Colitis) in determining what foods are causing symptoms and building sustainable dietary habits to improve those symptoms. Using an extensive research database, the program analyzes the person's diet and their symptoms and guides them through a personalized elimination diet protocol according to best practice clinical guidelines. The program applies the research data, supported by a machine learning algorithm and clinical team to help users more quickly and accurately identify the foods that are most likely the cause of their symptoms. The goal is for patients to build the least restrictive diet possible that most improves their digestive symptoms, compared to traditional trial-and-error methods.







# Program Foundation

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The data underlying Ayble Health's program guidance is compiled from efficacy studies, clinical guidelines, meta-analyses of common diets recommended for digestive health patients, and survey studies on irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD, including Crohn's Disease and Ulcerative Colitis) patients' daily dietary practices. From these studies, a list of trigger foods was mapped to the clinical and demographic characteristics of patients in each study. Ayble's database grows with every user who completes the Ayble program - anonymized, aggregated data from patients adds to clinical literature to improve trigger food recommendation algorithms. New research from scientific literature is also added monthly.

The program foundation incorporates and applies data reported by users. To establish a baseline and start the program, users report their symptoms and their regular diet for three weeks. Symptoms are self-reported using validated assessments: IBS patients use the IBS Symptom Severity Scale (IBS-SSS); Crohn's Disease patients complete the Mobile Health Index (mHI-CD); Ulcerative Colitis patients report symptoms using the Patient Simple Clinical Colitis Activity Index (P-SCCAI); patients with overlapping symptoms and diagnoses complete a combination of IBD and IBS questionnaires.

From the user's reported food and symptom baseline, the program then generates a list of foods shown in the literature (and prior Ayble users with similar characteristics) to be correlated with their symptoms. For the next two

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# Program Foundation

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weeks, the user eliminates these likely trigger foods and continues reporting symptoms. The user continues to report foods and symptoms each day, week, or month. After the elimination phase, the user can then reintroduce certain foods, one at a time, every three days, to test if foods are truly triggers. By the end of the program, Ayble users will have determined a) whether a food is a trigger, b) if a food is a trigger, how severe symptoms are expected to be, and c) how much food a user can tolerate before symptoms appear.

A PhD level data scientist oversees refining and improving the data and analysis framework.

To help users identify and purchase foods at the grocery store compatible with their diet, the program filters a groceries database of more than 200,000 grocery products from 40,000 store locations and 100 retail chains. Users can scan bar codes from products and look up produce or other items. The program reports whether the food fits or does not fit the user's recommended diet built on the Ayble platform, but also additional dietary criteria such as allergies, religious beliefs, and general preferences (veganism, vegetarianism, organic, fair-trade, etc). The program's contract with the independent database provider has service and accuracy standards, ensuring that users have up to date guidance. The database grows by 8,000-10,000 new items each month and store and brand coverage is constantly expanding. The independent provider has appropriately credentialed staff and advisors and is considered a reliable source.

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# Target Audience and Communication

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The Ayble Health program materials and website make reasonable promises, based upon the program's validated outcomes. Website visitors learn that 81% of users improved their symptoms, and 89% improved their quality of life during their participation in the Ayble program. These outcomes came from a clinical study that ran for 9 weeks; this is an accepted period for treating and monitoring symptom improvement. These measures are both included in Ayble Health's outcomes validation which Validation Institute conducted. (Ayble's outcomes validation report is available at Validation Institute's website or by request.)

This program has specific target users: people diagnosed with irritable bowel syndrome (IBS), or inflammatory bowel disease (IBD including Crohn's Disease and Ulcerative Colitis) who want to manage their symptoms by adjusting their diet. In addition, the program has specific measurable outcomes that mark a person's improvement. Thus, the target group and the program goals are simple and clear. There is little chance for non-target users to be enrolled or mis-informed about the goals.

Of the total number of people who download the app, 75% use it daily, another 10% use the program weekly and another 15% use the program monthly. Virtually all those who download the program use it for 16 weeks, well beyond the nine weeks needed to achieve measurable improvement. This real-world level of retention is similar to retention achieved in Ayble's

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# Target Audience and Communication

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published clinical studies. Users can learn what foods trigger their symptoms and make the suggested changes in a period of nine to sixteen weeks, but can work with Ayble's program, tools and coach indefinitely to build long-term sustainable dietary habits. Future analysis could address whether users continue to have symptom management success after they stop using the program.



# Program Delivery

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Users have access to the Ayble program on their smartphone. Thus, users can easily get guidance from the program in any setting at any time.

To give accurate guidance, the program requires the user to enter certain data during their participation. In the first three weeks, the user enters all food consumed and symptoms experienced; this data allows the program to link foods to the symptoms reported. After the initial phase, users need only report consumption of the foods that are triggering digestive symptoms. Users can also choose whether to report their consumption daily, weekly, or less often. This greatly reduces the burden on the user and increases the likelihood that a person will continue it.

The user can make sure the program's recommendations fit their diet preferences by entering these into the program. The program has more than 60 diet preferences available. For example, a vegan would receive recommendations that have no animal products. The program filters out foods containing nuts for an individual with that allergy, suggest organic or free-range products for a user interested in those criteria, or recommends low-sodium foods for people looking to reduce their salt intake. This feature ensures that the output is practical and valuable to the person.

Ayble has two service packages. The higher cost package includes unlimited access to a health coach and offers priority customer support. Pricing scales

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# Program Delivery

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with the service level and number of months in subscription. The service can be offered through an employer or a health plan with customized contracting terms.

The low rate of people dropping out (95% completion of the pilot program, according to published results) is evidence that the program delivery is accessible and valuable to users. Having employers offer the program as a benefit could make it available to users who could not afford the price.





# Claim Assertion for Validation

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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

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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

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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.

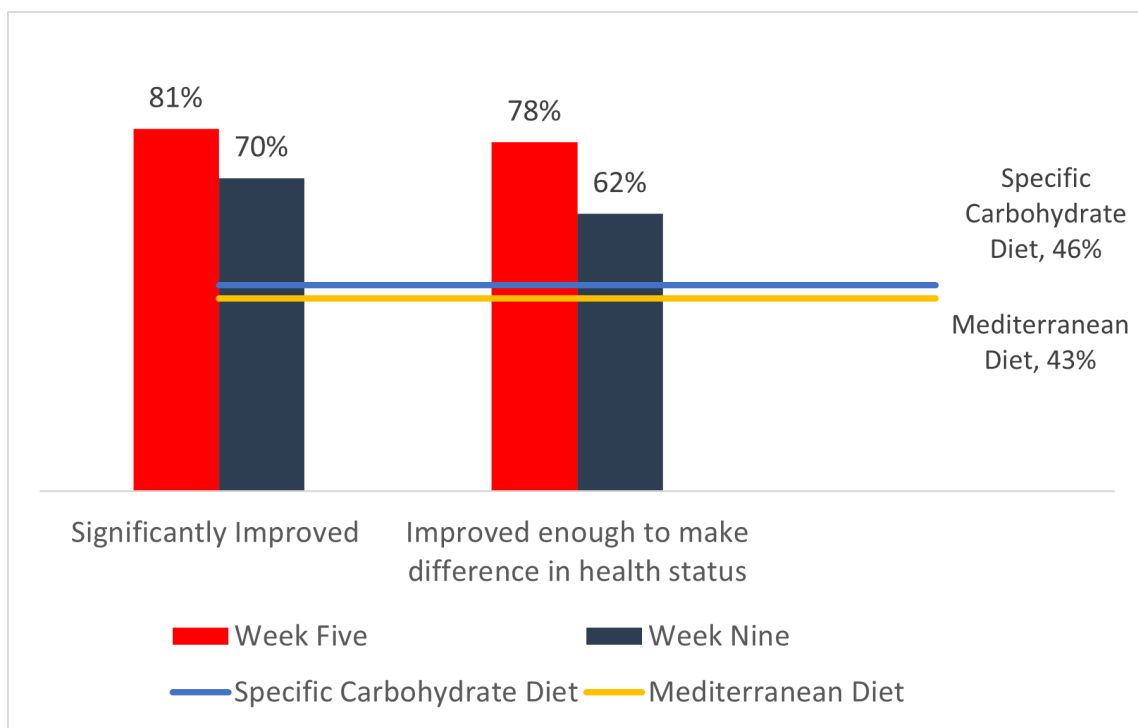


Chart 1: Summary of Participant Score Changes



# 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.

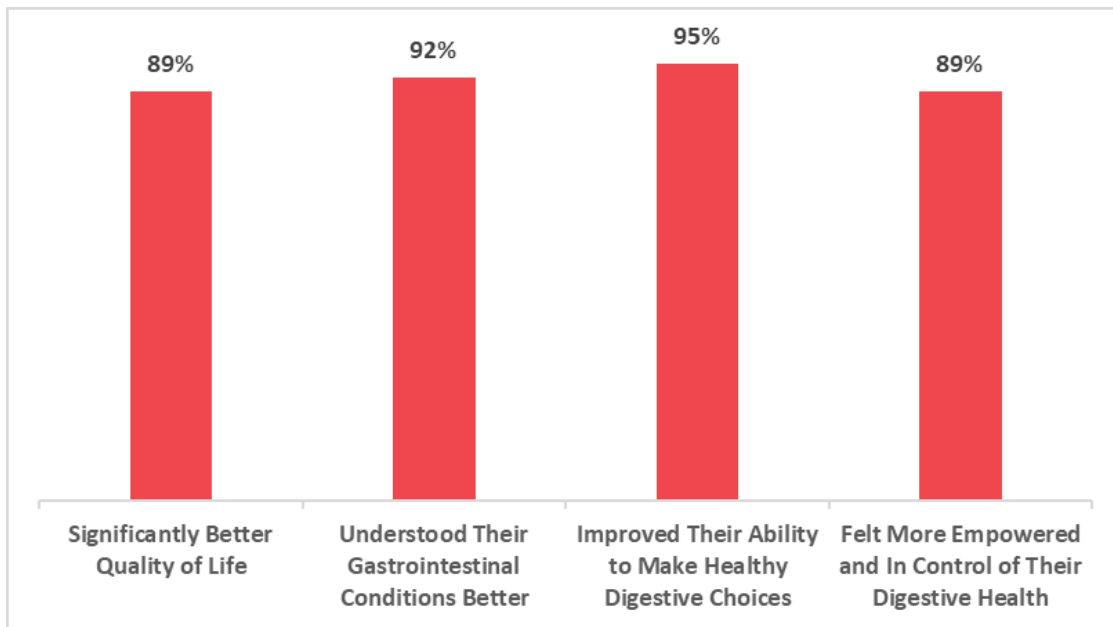


Chart 2: Summary of Participant Clinical Symptoms





# 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.

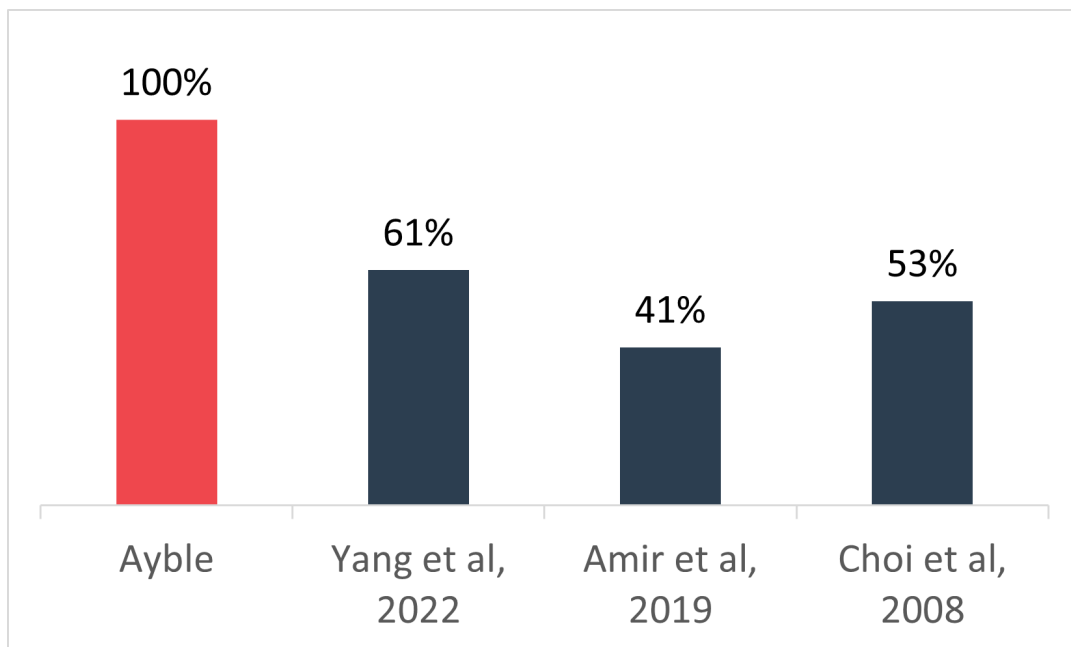


Chart 3: Users 50% or greater adherence to diet

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

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Analyzing how closely the Ayble Health program's recommendations (output) align with the data underlying it (foundation) is beyond the scope of this review.

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

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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

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**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.





# Certificate of Achievement

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## Ayble Health Program

Certified Program

## Ayble Health

52 Appleton St. Boston, MA, 02116

Company

## Certificate Achieved: Tools & Outcomes

Ayble Health submitted its program which helps people who have irritable bowel syndrome, Crohn's Disease, and Ulcerative Colitis to manage and reduce their symptoms.

## September 2023

Award Date

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**Linda Riddell**  
**Chief Data Scientist**  
**Validation Institute**

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**Benny DiCecca**  
**Chief Executive Officer**  
**Validation Institute**





# About FoodMed Certified & Validation Institute

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**FoodMed Certified**, a **Validation Institute (VI)** program, vets and verifies the effectiveness of nutritional programs and tools that enable individuals and employers to better manage their employee's health and wellbeing as well as decrease overall healthcare expenses. By leveraging VI's validation process for certifying Food is Medicine tools, platforms and nutritional programs, **FoodMed Certified** brings increased transparency to the rapidly expanding Food is Medicine movement.

**Validation Institute** is a membership organization comprising healthcare solution vendors, benefits advisors, and healthcare industry experts to offer unbiased, data-driven insights on healthcare solutions and services that drive increased transparency, improved healthcare outcomes and significant healthcare cost-savings.

This approach highlights the significant value from utilizing data-driven nutritional solutions that drive positive healthcare outcomes and encourage healthier habits.

