



FOSHU-approved Fibersol[®]-2 product review

Stella Chen^{1,2}, Danik Martirosyan^{2*}

¹University of California, Berkeley, Berkeley, CA, USA; ²Functional Food Institute, San Diego, CA, USA

*Corresponding author: Dr. Danik Martirosyan, PhD, Functional Food Institute, San Diego, CA, USA

Submission Date: March 30th, 2021; **Acceptance Date:** May 14th, 2021; **Publication Date:** May 20th, 2021

Please cite this article as: Chen S., Martirosyan D. FOSHU-approved Fibersol[®]-2 product review. *Bioactive Compounds in Health and Disease*. 2021; 4(5): 79-89. DOI: <https://www.doi.org/10.31989/bchd.v4i5.797>

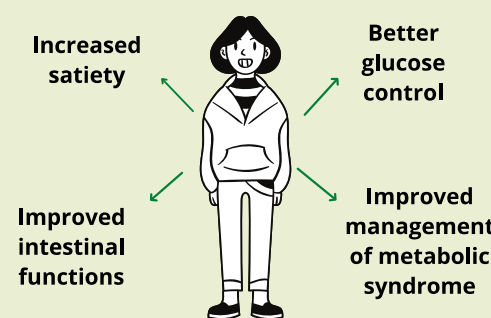
ABSTRACT

Fibersol[®]-2 is manufactured by Matsutani Chemical Industry Co., Ltd. and is sold as a tasteless powder or liquid to be added to foods or beverages. It is approved by the Japanese Ministry of Health, Labour, and Welfare as a “Standardized FOSHU (Food for Specified Health Uses)” ingredient that contains the bioactive compound, digestion-resistant maltodextrin. Its current designated functions under FOSHU are as a dietary fiber for improving intestinal regularity and for controlling postprandial blood glucose and triglyceride levels. Furthermore, clinical trials have been done in human and animal subjects to investigate other potential health benefits. This product review focuses on English-language publications of studies that tested Fibersol-2 on human subjects. From these studies, there is evidence that Fibersol-2 plays a role in controlling fasting blood glucose levels, improving intestinal function and metabolic syndrome, and increasing satiety in human subjects. However, more studies are needed to draw definite conclusions about the amounts of Fibersol-2 that are needed to observe each health benefit and to confirm the efficacy and significance of Fibersol-2’s benefits in the larger population, particularly the benefits that aren’t designated under FOSHU.


Keywords: Fibersol-2, FOSHU, glucose control, metabolic syndrome, intestinal benefit, microbiome, dietary fiber, satiety

Fibersol®-2 Potential Health Benefits

Tested in Human Subjects



Standardized FOSHU Ingredient



- 3-8 g as dietary fiber for intestinal regularity
- 4-6 g to control blood glucose

The formal FOSHU logo is shown at above right [1].

©FFC 2021. This is an Open Access article distributed under the terms of the Creative Commons Attribution 4.0 License (<http://creativecommons.org/licenses/by/4.0>)

INTRODUCTION

Fibersol®-2 is approved as a “Standardized FOSHU” ingredient [1]. FOSHU stands for “Foods for Specified Health Uses.” It is a designation used by the Japanese Ministry of Health, Labour, and Welfare to identify foods containing ingredients with officially proven health functions and physiological effects on the human body. To be approved by the Ministry as FOSHU, the food must be examined for efficacy, safety, use of nutritionally appropriate ingredients (i.e., no excessive use of salt or sugar etc.), “guarantee of compatibility with product specifications by the time of consumption,” and established quality control methods [2]. Fibersol-2 meets all these requirements.

Fibersol-2 contains the bioactive compound, digestion-resistant maltodextrin, and is produced by the Japanese company Matsutani Chemical Industry Co., Ltd. Its approved functions as a “Standardized FOSHU” ingredient are for improving intestinal regularity and moderating postprandial blood glucose levels and triglyceride levels. The FOSHU dosage recommendations are 3-8 g of Fibersol-2 as dietary fiber for improving intestinal regularity and 4-6 g for controlling blood glucose levels (no dosage

recommendations are available for controlling blood triglyceride levels). Fibersol-2 consists of a minimum of 90% dietary fiber and has also been on the list of the U.S.’s FDA-approved dietary fibers since 2018 [3]. So far, FOSHU and the FDA are the only governmental approvals that Fibersol-2 has.

Often referred to as “resistant maltodextrin,” “nondigestible dextrin,” or “indigestible dextrin,” Fibersol-2 is produced through a series of controlled enzymatic hydrolysis reactions of cornstarch molecules. This results in cornstarch molecules whose normal alpha-1,4-linkages are replaced with alpha and beta 1,2-, 1,3-, 1,4-, and 1,6- linkages, making it resistant to digestion. It is available as a tasteless, water-soluble, non-viscous powder or liquid that can be added to food and drinks without changing the taste or texture, and in Japan, there are at least 275 products that are FOSHU-approved because they contain Fibersol-2 [2].

As fiber is low in the modern Western diet and nutrition-related diseases are on the rise, Fibersol-2 has much promise in preventing and managing symptoms of conditions such as diabetes and obesity. This article will provide a review of several health

benefits of Fibersol-2 by reviewing scientific studies that have been done in human subjects to evaluate Fibersol-2 efficacy and dosage amounts. Studies for approved benefits (i.e. glucose control) will be evaluated and studies on potential health benefits

that have not been approved will be introduced. Fibersol-2's use as a functional food product will also be evaluated.

Table 1 shows a summary of the studies referenced in this article.

Table 1. Studies of Potential Health Benefits of Fibersol-2 in Human Subjects.

Reference	Function(s) Studied	Most Effective Fibersol-2 Dosage	Number of Subjects	Study Duration	Outcome	FOSHU-Approved Function(s)?	Trial Type
Livesey et al., 2009 [4]	Postprandial glucose control	3-10 g/meal	17-281	N/A	Fibersol-2 attenuates the glycemic response by 18% on average when added to carbohydrate foods and moderates postprandial glucose levels.	Yes	Meta-analysis
Hashizume et al., 2012 [5]	Control of fasting glucose and fasting insulin levels, insulin resistance, metabolic syndrome management	9 g/meal	30	12 weeks	Fibersol-2 decreased fasting glucose and fasting insulin levels, decreased insulin resistance, and improved metabolic syndrome management.	No	Clinical trial
Ruiz et al., 2015 [6]	Various Intestinal Benefits	15 g/day	66	3 weeks	Fibersol-2 reduced colon transit time, increased stool volume by 56% on average, improved stool consistency score by 21.4% on average, and exhibited other clinical intestinal functional benefits.	Expands on the current use of Fibersol-2 as dietary fiber for intestinal regularity	Clinical trial
Fastinger et al., 2008 [7]	Healthier microbiome	15 g	38	7 weeks total, 3 week treatment period	15 g of Fibersol-2 led to the highest increase in butyrate concentrations and the highest <i>Bifidobacterium</i> counts.	No	Clinical trial
Burns et al., 2019 [9]	Healthier microbiome	25 g	49	18 weeks total, 3 week treatment period	25 g of Fibersol-2 led to a 38% increase in <i>Bifidobacterium</i> levels. Stool wet weight also increased in the 25 g group.	No	Clinical Trial

Reference	Function(s) Studied	Most Effective Fibersol-2 Dosage	Number of Subjects	Study Duration	Outcome	FOSHU-Approved Function(s)?	Trial Type
Ye et al., 2015 [10]	Satiety	10 g/meal	19	N/A	Fibersol-2 improved both subjective and physiological satiety 3-4 hours post-meal.	No	Clinical trial
Fernández-Raudales et al., 2018 [11]	Satiety	11 g	24	4 days with 3-day washout periods in between	Drinks containing 11 g of Fibersol-2 significantly increased subjective satiety up to 3 hours post-drink. Fibersol-2 was not as effective as the protein drink though and failed to decrease appetite and hunger post-drink.	No	Clinical trial
Kishimoto et al., 2013 [12]	Maximum Dosage	N/A	10	N/A	The maximum dosage is 1.0 g/kg body weight for males and >1.1 g/kg body weight for females.	No maximum dosage recommendation in FOSHU guidelines	Clinical trial

REVIEW

FIBERSOL-2 AND GLUCOSE CONTROL: One of Fibersol-2's approved uses by FOSHU is for postprandial blood glucose control, a function that is particularly useful for diabetics. In a meta-analysis of 37 randomized-controlled trials, doses of 3-10 g (adjusted to 6 g in Table 1) of Fibersol-2 (RMD) were added to different carbohydrate foods [4]. Glycemic response was measured after the meal. Overall, there was a combined mean attenuation of the glycemic response by 18% ($p < 0.001$), and this attenuation was stronger when Fibersol-2 was added to drinks versus solid food. The attenuation was independent of the amount of carbohydrate ingested and was dose-dependent, as ingesting more Fibersol-2 leads to larger attenuation. Heterogeneity among the trials or I^2 had a value of 0.378 but was not significant ($p > 0.1$). The meta-analysis concluded that Fibersol-2 has an

attenuating effect on the glycemic response to carbohydrate foods at doses of 3-10 g/meal, and this attenuation was the most effective if Fibersol-2 was added to drinks.

Another study tested Fibersol-2's effects on patients with metabolic syndrome by adding 9 g of Fibersol-2 (RMD) to a 280-mL unsweetened, blended tea drink [5]. This drink was given to 15 subjects while the other 15 subjects received a placebo tea drink with 0 g of Fibersol-2. The nutritional content of the teas were the same except for the amount of Fibersol-2. Subjects consumed 3 cups of their assigned drink a day, once after each meal for 12 weeks. Subjects were told not to change their diet or lifestyle during the study. Among other improvements, fasting blood glucose, fasting insulin, and HOMA-R (index for fasting insulin resistance) showed improvement with lower levels of all three in

the RMD group. More specifically, fasting blood glucose dropped significantly compared to baseline in the RMD group during Week 8 and Week 12 ($p < 0.01$) from 5.44 ± 0.62 mmol/L to 5.18 ± 0.53 mmol/L. Fasting insulin in the RMD group did decrease from 60.1 ± 34.0 pmol/L to 50.7 ± 26.7 pmol/L but did not change significantly. HOMA-R decreased significantly compared to baseline in the RMD group between Week 8 and 12 ($p < 0.01$) from 2.1 ± 1.3 to 1.6 ± 0.9 .

It is necessary to point out that between Week 8 and Week 12 in the RMD group, the measured parameters either stayed constant at 1.6 ± 0.9 for HOMA-R or in the case of fasting blood glucose and fasting insulin, experienced a slight rebound to higher levels. This may suggest that Fibersol-2 need only be administered for 8 weeks to see the maximal effects and that administering Fibersol-2 for any longer won't lead to any significant changes in parameters. However, a longer and larger study would need to be done to confirm this hypothesis. Regardless, this study suggests additional uses of Fibersol-2 besides the FOSHU-approved function of postprandial control of blood glucose levels. Fibersol-2 may decrease fasting blood glucose and fasting insulin levels, as well as decrease insulin resistance in metabolic syndrome subjects.

This study also measured other metabolic syndrome risk factors and found that for the RMD group, metabolic syndrome risk factors decreased to 20 from 32. For 2 of those participants, they ended the study with no risk factors. The placebo group experienced a decrease as well from 32 to 25. This decrease may be that the interviews and assessments that were conducted as part of this study changed participant behavior and improved metabolic syndrome management.

Therefore, these 2 studies showed that Fibersol-2 in dosages of 3-10 g/meal may attenuate the

glycemic response in humans after ingesting carbohydrates, and the attenuation effect is stronger in drinks than in solid foods; this is a FOSHU-approved function. 9 g of Fibersol-2 per meal can moderate fasting glucose and insulin levels, decrease insulin resistance, and improve metabolic syndrome management; these functions are not yet FOSHU-approved.

Fibersol-2 and its intestinal benefits: Fibersol-2 has a myriad of potential intestinal benefits ranging from increased stool volume to a healthier microbiome [6-9]. This suggests Fibersol-2 possesses promise in improving intestinal functions and preventing and/or treating intestinal diseases.

In a 2016 study, Fibersol-2 was linked to improved intestinal function. 66 healthy adult volunteers ages 18-30 who did not have a daily defecation habit underwent a 21-day intervention [6]. 33 subjects received 15 g of Fibersol-2 (RMD) in powder-sachet form that was to be dissolved in water and 33 subjects received a placebo. Subjects were to consume their drinks during breakfast and maintain their usual diet throughout the study.

The RMD or Fibersol-2 group showed a decrease in total, left, and rectosigmoidal colon transit time and the decreases were significant compared to baseline ($p < 0.004$, $p < 0.008$, $p < 0.006$). Specifically, total colon transit time went from 53.0 ± 23.9 hr. to 39.7 ± 22.3 hr. Left colon transit time decreased from 14.9 ± 9.9 hr. to 10.2 ± 8.6 hr., and rectosigmoidal colon went from 25.9 ± 18.1 hr. to 17.2 ± 14.6 hr. Right colon transit time stayed relatively constant at 12.3 ± 8.0 hr. at baseline and 12.3 ± 8.7 hr at the end of 3 weeks. The placebo group had no significant changes in colon transit time.

Moreover, there was a significant increase in the RMD group for stool volume for each week over the

3-week timeline compared to baseline (31, 32, 56 %; $p < 0.006$, $p < 0.006$, $p < 0.0001$, respectively). Better stool consistency scores were observed in the RMD group over 3 weeks as well, with the score increasing by 21.4% ($p < 0.01$) on average compared to baseline. Stool consistency scores are self-reported and based off of the Bristol Scale with a higher score meaning better stool consistency. The placebo group showed no significant changes in stool volume or stool consistency.

This study suggests that 15 g of daily Fibersol-2 or RMD significantly reduces colon transit time and improves stool volume and consistency, signifying improved intestinal function. The study also found some evidence for clinical intestinal functions with significantly less RMD group subjects, compared to baseline, reporting sensations of straining (63.6 to 33.3 %, $p < 0.025$) and sensations of incomplete evacuation (51.5 to 27.3%, $p < 0.003$) in at least 25% of defecations after the treatment intervention. These functions go beyond the current FOSHU-approved use of Fibersol-2 as a dietary fiber for improving intestinal regularity.

It is not clear why this study was only conducted for 3 weeks. It would have been better if subjects had been followed for at least 12 weeks to keep a consistent timeline with Hashizume et al.'s paper on glucose control and metabolic syndrome management. It cannot be known whether intestinal parameters would have stayed constant or changed beyond 3 weeks, and further studies need to be done on Fibersol-2 and intestinal benefits before any definite conclusions can be drawn.

Additional studies have been done linking Fibersol-2 to a healthier microbiome, a function that is not FOSHU-approved. A 2008 study recruited 38 subjects for 7 weeks [7]. Subjects took either 15 g maltodextrin, 7.5 g maltodextrin + 7.5 g RMD

(Fibersol-2) or 15 g RMD. These treatments were taken between Weeks 3-5; Weeks 1-2 were baseline and Weeks 6-7 were a washout period. Subjects were to continue their typical diets. The results of the study found that butyrate levels increased with higher RMD dosages and the increase was significant ($p=0.05$) and continued to rise even during the 2-week washout period. This suggests Fibersol-2's positive effect on the microbiome because butyrate plays a role in maintaining the intestinal barrier and regulates homeostasis in colonocytes. Butyrate is the preferred energy substrate of colonocytes and is anti-inflammatory, anti-carcinogenic, and immunosuppressive. It may prevent ulcerative colitis and other inflammatory conditions.

Furthermore, during the treatment period, the 15 g RMD group had the highest *Bifidobacterium* concentrations, indicating a prebiotic effect of Fibersol-2. However, this prebiotic effect disappeared during the washout period. Bifidobacteria have been implicated in preventing and/or treating conditions such as colorectal cancer and inflammatory bowel disease and can improve intestinal regularity and competitively exclude pathogens [8]. The scientists concluded that further studies under more controlled conditions with more subjects and higher dosages of Fibersol-2 are needed to confirm Fibersol-2's positive effects on the microbiome.

A 2018 study also observed increased Bifidobacteria counts in subjects who consumed Fibersol-2 [9]. For 18 weeks, 49 subjects who typically consumed a fiber-insufficient diet were followed. Subjects took either 0, 15, or 25 g of RMD (Fibersol-2) for 3 of those weeks. The 25 g group experienced a 38% increase in *Bifidobacterium* levels ($p=0.08$). Moreover, stool wet weight increased by Week 3 of intervention in the 25 g RMD group only. Increased stool weight may improve bowel function. These

microbiome studies are still preliminary and again, further studies are needed on Fibersol-2 and its effects on the microbiome and intestinal functions before definitive conclusions can be drawn. There is also a need for more coordinated dosage and study lengths among these studies so that results can be compared.

Fibersol-2 and satiety: Fibersol-2 has been shown to increase satiety and promote levels of satiety-related hormones, a function that is not currently FOSHU-approved. Studies on Fibersol-2 and satiety are limited though.

19 healthy adult subjects were given 1 of 3 experimental teas with 0, 5, or 10 g of Fibersol-2, along with a standard meal that was eaten for 15 minutes [10]. The tea was 250 mL of peach flavored Nestea with Acesulfame K as the sole sweetener. The standard meal was an 8-inch Turkey sub sandwich (470 kcal) and potato chips (130 kcal). Subjective appetite measures and measurements of appetite-regulating hormones were taken. Subjects who consumed 10 g of Fibersol-2 reported improved satiety and less hunger 4 hours after eating compared to the 5 g Fibersol-2 group and control group ($p < 0.05$). The highest levels of self-reported satiety occurred 1.5 hours post-meal for the 10 g Fibersol-2 group.

PYY (peptide YY) and GLP-1 (glucagon-like peptide 1), which are appetite-regulating satiety hormones, showed significant increases in the 10 g Fibersol-2 group compared to the other two groups ($p < 0.05$). These hormone levels were measured at 0, 0.5, 1, 2, 3, and 4 hours after eating with the overall increase being most pronounced at 3 hours post-meal for the 10 g Fibersol-2 group. PYY suppresses food intake and appetite while GLP-1 promotes insulin release in response to glucose, and seeing increases

of these hormones after a meal is an indicator of increased satiety. The scientists in this study did acknowledge the timing discrepancy between the greatest subjective and physiological satiety experienced (1.5 vs 3 hours post-meal) and further studies are needed to clarify Fibersol-2's effects on satiety. Nevertheless, Fibersol-2 at a dosage of 10 g per meal may improve both subjective and physiological satiety in subjects, moderates appetite, and may be a promising ingredient for preventing and mitigating obesity and other feeding disorders [10].

Another study recruited 24 healthy male subjects to study the effects of Fibersol-2 and protein on satiety [11]. Each subject tried out all 4 treatment drinks with 3-day washout periods in between. These drinks were given to participants in the morning without breakfast. Control or blank drinks (B) contained 0 g of protein or fiber, the high-protein beverage (HP) contained 30 g of protein and 2 g of fiber, the high fiber beverage (HF) contained 11 g of fiber and 0 g of protein, and the high-protein, high-fiber beverage (HPHF) contained 30 g of protein and 11 g of fiber. Subjective satiety up to 4 hours post-drink was measured among other parameters. The fiber used was Fibersol-2.

2-3 hours post-drink, perceived satiety was significantly higher for HP, HF, and HPHF subjects ($p=0.02$). After 4 hours, satiety was significantly higher in the HP group only ($p=0.02$). The scientists did not identify any synergistic effects of fiber plus protein in the HPHF drink. This suggests that 11 g of Fibersol-2 does increase subjective satiety but is not as effective as protein. Fibersol-2 also did not significantly decrease appetite nor hunger post-consumption. Therefore, further studies are needed on the connection between Fibersol-2 and satiety.

Maximum dose determination: A study in 2013

tested different dosages of Fibersol-2 in 10 healthy male and female subjects and determined the maximum dose of Fibersol-2 that will not cause diarrhea [12]. The results showed that subjects who ingested 0.7, 0.8, 0.9, or 1.0 g Fibersol-2/kg body weight did not experience diarrhea. At the highest dose level of 1.1 g/kg body weight, 1 male subject developed diarrhea 2 hours after ingestion. Therefore, the study set 1.0 g/kg body weight as the maximum dose for men and >1.1 g/kg body weight as the maximum dose for women.

There were other gastrointestinal symptoms that were experienced by subjects, such as gurgling and flatus (gas in the stomach and intestines), but these symptoms were mild and transient and were not associated with dosage level. They were resolved without medical treatment.

Larger studies done in more diverse age groups are recommended for further determining maximum dosage levels. Once determined, it would be helpful to add maximum dosage guidelines to FOSHU recommendations to ensure that consumers do not ingest a harmful amount of Fibersol-2.

Evaluation of fibersol-2 as a functional food: As of 2020, the Functional Food Center defines “functional foods” as “natural or processed foods that contain biologically-active compounds; which, in defined, effective, non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers, for improving general health, for the prevention, management, or treatment of chronic disease or its symptoms,” [13]. Fibersol-2 fulfills this definition of functional food: it contains the “biologically-active compound” digestion-resistant maltodextrin. Under FOSHU, it is recommended in “defined, effective, non-toxic” dosages of 3-8 g and 4-6 g for improving intestinal regularity and controlling blood glucose respectively.

Improving intestinal regularity and moderating blood glucose and triglyceride levels are “clinically proven,” FOSHU-approved functions; therefore, Fibersol-2 can be used to prevent and manage diseases with problems in these hallmarks.

As a summary, from the trials mentioned in this review article, 3-10 g of Fibersol-2 can attenuate the glycemic response after ingestion of a carbohydrate meal [4]. 9 g of Fibersol-2 per meal can lower fasting blood glucose and insulin levels, decrease insulin resistance, and improve metabolic syndrome management in metabolic syndrome subjects [5]. 15 g of Fibersol-2 a day as a dietary fiber improves intestinal function as its consumption results in a shorter colon transit time, larger stool volume, better stool consistency score, and improved defecation (less straining and sensations of incomplete evacuation) [6]. 15-25 g of Fibersol-2 a day can increase butyrate levels and *Bifidobacterium* counts, which are indicators of a healthier microbiome [7-9]. 10-11 g of Fibersol-2 per meal increases subjective and physiological satiety up to 3-4 hours after a meal [10-11]. Maximum doses of Fibersol-2 stand at 1.0 g/kg body weight for males and >1.1 g/kg body weight for females [12].

These dosage amounts do tend to be higher than the FOSHU recommendations. For instance, the FOSHU recommendation for glucose control is 4-6 g, while the 2 papers examined went up to 10 g of Fibersol-2 for glucose control. Ruiz et al. suggested 15 g of Fibersol-2 as dietary fiber, but FOSHU recommends 3-8 g. This may be because the Japanese Ministry of Health, Labour, and Welfare (who approves products as FOSHU) examined many more papers (including Japanese publications) when setting these dosage requirements, and it is possible that the papers they examined tended to have lower average dosage amounts. It is also possible that the Ministry preferred to set more conservative, safer dosage amounts.

Most of the studies cited in this review, except the meta-analysis, had small sample sizes. There was also a lack of epidemiological studies and after-market research of Fibersol-2, so it is not clear how effective Fibersol-2 will be for the larger population and for different age and racial groups. Furthermore, the studies tended to test seemingly arbitrary amounts of Fibersol-2, with some trials only testing 1 dosage amount. There was no standard for how much Fibersol-2 to test for a certain health benefit among these papers, thus leading to the wide ranges of Fibersol-2 dosages and the differences from the FOSHU recommendations. Finally, the timelines for studies differed, which makes it difficult to determine exactly how Fibersol-2 can be used for its various benefits and whether effects are significant. Keeping a consistent study length is particularly important for health parameters that need to be observed for longer periods of time, such as intestinal benefits and fasting blood glucose and insulin levels. The intestinal benefits study by Ruiz et al. [6], for instance, should have been conducted for at least 12 weeks instead of 3 to match the timeline for the metabolic syndrome/glucose control study [5]. To sum up, even though Fibersol-2 is already FOSHU-approved, larger and coordinated trials with standardized doses that include epidemiological data and are conducted for longer periods of time are needed to further assess and draw definite conclusions on Fibersol-2 functions and effective dosage amounts before it can be widely used as a functional food by the public.

Safety: As mentioned in the Kishimoto et. al study, Fibersol-2 is safe at dosages of up to 1.0 g/kg of body weight for males and up to 1.1 g/kg body weight for females [12]. Reported gastrointestinal symptoms were limited to gurgling sounds and flatus. These symptoms were not associated with dosage level, were mild, and resolved without treatment.

Burns et al. found that 15-25 g of Fibersol-2 resulted in higher occurrences of “indigestion

syndrome” (rumbling, bloating, burping and gas symptoms) [9]. Reported indigestion symptoms were low with subjects reporting slight discomfort. Fasting et al. reported similar findings where subjects experienced some cramping, distention, and flatulence, with all symptoms being mild [7].

Overall, dosages tested in the studies were higher than FOSHU recommendations but were far below the maximum dosage recommendations set by Kishimoto et al.

CONCLUSION

This review does not contain a comprehensive review of all the potential health benefits of Fibersol-2. Rather, it focuses on blood glucose control, intestinal benefits, and satiety, which are 3 parameters that have been conducted in human populations and that have papers available in English. There are other potential benefits such as tumor suppression and mineral absorption that have only been done in animal trials or have papers in Japanese only [14-15]. As stated earlier, existing studies of Fibersol-2’s potential health benefits are limited and more research, particularly after-market research, on Fibersol-2’s various functions in the wider human population are needed. Future studies may help with:

1. Expanding the list of Fibersol-2’s currently approved uses.
2. Confirming efficacy in the wider population by including more age and racial groups.
3. Setting standardized dosage ranges of Fibersol-2 that are needed to observe each health benefit (i.e. glucose control) besides the current ones already listed in the FOSHU recommendations.

Matsutani Chemical Industries maintains a U.S. partnership with the Archer Daniels Midland Company to sell Fibersol-2 to a wider audience. This is a promising partnership because the U.S. diet tends

to be low in fiber and furthermore, metabolic syndrome and other lifestyle/nutrition-related diseases (i.e. Type 2 diabetes mellitus, obesity) are very prevalent in the U.S. population. Fibersol-2 can potentially be of great use to many people with these conditions or who are at risk, as a functional food product, to help prevent or manage symptoms for these conditions. It is my hope that this review article and future studies can improve Fibersol-2 access through educating the public and clarifying its various, scientifically proven uses. After-market research is especially needed as well to study Fibersol-2's effects on the larger, diverse population.

List of Abbreviations: Fibersol-2: Fibersol®-2; RMD: resistant maltodextrin, RCT: randomized controlled trial, CI: confidence interval, I²: among-studies

REFERENCES

1. TOKUHO, Food for Specified Health Use (FOSHU) [https://www.fibersol.com/wp-content/uploads/2012/04/FOSHU-2011_2.pdf] Retrieved March 22, 2021.
2. Ministry of Health, Labour and Welfare [www.mhlw.go.jp/english/topics/foodsafety/fhc/02.htm] Retrieved March 22, 2021.
3. U.S. Food and Drug Administration [<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-declaration-certain-isolated-or-synthetic-non-digestible-carbohydrates-dietary>] Retrieved March 22, 2021.
4. Livesey G, Hiroyuki T: Interventions to Lower the Glycemic Response to Carbohydrate Foods with a Low-Viscosity Fiber (Resistant Maltodextrin): Meta-Analysis of Randomized Controlled Trials. *The American Journal of Clinical Nutrition* 2009, 89:114-125.
5. Hashizume C, Kishimoto Y, Kanahori S, Yamamoto T, Okuma K, Yamamoto K: Improvement Effect of Resistant Maltodextrin in Humans with Metabolic Syndrome by Continuous Administration. *Journal of Nutritional Science and Vitaminology* 2012, 58:423-430.
6. Ruiz MSA, Espinosa MDB, Fernández CJC, Rubia AJL, Ayllón FS, García MA,
7. Santamaría CG, Román FJL: Digestion-Resistant Maltodextrin Effects on Colonic
8. Transit Time and Stool Weight: a Randomized Controlled Clinical Study. *European Journal of Nutrition* 2015, 55:2389-2397.
9. Fastinger ND, Karr-Lilienthal L, Spears JK, Swanson KS, Zinn KE, Nava GM, Ohkuma K, Kanahori S, Gordon DT, Fahey Jr. GC: A Novel Resistant Maltodextrin Alters Gastrointestinal Tolerance Factors, Fecal Characteristics, and Fecal Microbiota in Health Adult Humans. *Journal of the American College of Nutrition* 2008, 27:356-366.
10. O'Callaghan A, Sinderen DV: Bifidobacteria and Their Role as members of the Human Gut Microbiota. *Front Microbiol* 2016, 7:925.
11. Burns AM, Solch RJ, Dennis-Wall JC, Ukhanova M, Nieves J. C, Mai V, Christman MC, Gordon DT, Langkamp-Henken B: In healthy adults, resistant maltodextrin produces a greater change in fecal

variance, HOMA-R: index for insulin resistance, PYY: Peptide YY, GLP-1: Glucagon-like peptide 1, B: blank, HP: high-protein, HF: high-fiber, HFHP: high-fiber, high-protein.

Competing Interests: The authors have no financial interests or conflicts of interests.

Authors' contributions: Dr. Martirosyan conceived the topic of this review article while Stella Chen narrowed down the subject. Dr. Martirosyan provided detailed guidance and review of the writing and editing process while Stella Chen collected the data and wrote the review article.

Acknowledgements: No external funding was needed or given for this review article

- bifidobacterial counts and increases stool wet weight: a double-blind, randomized, controlled crossover study. *Nutrition research* 2018, 60:33-42.
12. Ye Z, Arumugam V, Haugabrooks E, Williamson P, Hendrich S: Soluble Dietary Fiber
 13. (Fibersol-2) Decreased Hunger and Increased Satiety Hormones in Humans When Ingested with a Meal. *Nutrition Research* 2015, 35:393-400.
 14. Fernández-Raudales D, Yor-Aguilar M, Andino-Segura J, Hernández A, Egbert R, López-Cintrón JR: Effects of High Plant Protein and High Soluble Fiber Beverages on Satiety, Appetite Control and Subsequent Food Intake in Healthy Men. *Food and Nutrition Sciences* 2018, 9.
 15. Kishimoto Y, Kanahori S, Sakano K, Ebihara S: The Maximum Single Dose of Resistant Maltodextrin That Does Not Cause Diarrhea in Humans. *Journal of Nutritional Science and Vitaminology* 2013, 59:352-357.
 16. Liufu J, Martirosyan D: FFC's Advancement of the Establishment of Functional Food Science. *Functional Foods in Health and Disease* 2020, 10:344-356.
 17. So E, Mutsuko O, Cuesta-Sancho S, Olson SL, Reif D, Shimomura K, Ouchi T: Tumor suppression by resistant maltodextrin, Fibersol-2. *Cancer Biology & Therapy* 2015, 16: 460-465.
 18. Miyazato S, Nakagawa C, Kishimoto Y, Tagami H, Hara H: Promotive effects of resistant maltodextrin on apparent absorption of calcium, magnesium, iron, and zinc in rats. *European Journal of Nutrition*, 49:165-171.
 19. Fibersol-2 [matsutani.co.th/our-product/functional-product/fibersol-2/.] Retrieved March 22, 2021.
 20. ADM Speciality Food Ingredients [www.foodprocessing.com/assets/Media/MediaManager/product_fibersol.pdf.] Retrieved March 22, 2021.