

Table 1. Evidence Supporting “PHGG Fiber Contributes to Normal Bowel Movements” (Main Claim and Sub-Claims)

Green = positive, supportive results		Yellow = neutral results (no effect shown)		Red = negative results (opposite effect shown)				
<p>●● indicates key supportive data. *indicates Japanese-language article; included in the Kapoor et al (2017) meta-analysis (reference #1 below); summarized information extracted from the Kapoor et al paper. Abbreviations: BM, bowel movement; PHGG, partially hydrolyzed guar gum; IBS, irritable bowel syndrome; IBS-C, constipation-predominant IBS; IBS-D, diarrhea-predominant IBS; RCT, randomized controlled trial</p>								
Reference	Study Design	Intervention(s)	Study Population	“PHGG fiber contributes to normal bowel movements”				
				“Promotes regularity”	“Can help soften and bulk stools”	“Helps manage constipation, increasing the frequency of BMs”	“Helps improve BMs in patients with constipation w/out leading to diarrhea”	“Helps manage diarrhea w/out leading to constipation”
Studies Conducted in Adult Populations (Note: the meta-analysis by Kapoor et al includes 1 RCT conducted in children in the estimates for “elderly/children”)								
1. Kapoor et al, 2017 ●●	Meta-analysis	PHGG (dosage & formulation varies by study; range of dosage: 5 - 36 g/day; all but 1 study were ≤15 g/day)	Meta-analyses in healthy adults included 7 studies: 4 RCTs, 3 observational studies; n=325	See results summarized for “Helps manage constipation, increasing the frequency of BMs”	Significant pooled effect on fecal volume (pre- to post-PHGG: 0.23; 95% CI, 0.14–0.32) in 4 RCTs; similar significant effect on fecal volume vs placebo in 2 placebo-controlled trials Significant effect on fecal weight (pre- to post-PHGG: 42.63 g/day; 95% CI, 27.39–57.88). Significant pooled effect on fecal moisture (pre- to post-PHGG: 2.64%; 95% CI, 1.09–4.19)	Pooled estimates for significant change in # of BMs/day (pre- to post-PHGG): +0.58 BMs/day (95% CI, 0.43–0.74) in healthy subjects +0.63 BMs/day (95% CI, 0.46-0.81) in subjects receiving <10 g PHGG/day	No evidence of diarrhea after initiation of PHGG in any of the studies	
		PHGG (dosage & formulation varies by study; range of dosage: 4 – 10.5 g/day)	Meta-analysis in elderly/children included 3 studies: 1 RCT; 2 observational studies; n=66	See results summarized for “Helps manage constipation, increasing the frequency of BMs”		Pooled estimate for significant change in # of BMs/day (pre- to post-PHGG): +0.85 BMs/day (95% CI, 0.43–0.74) in elderly/ children	No evidence of PHGG intervention leading to diarrhea in any of the studies	
2. Niv et al, 2016	Randomized, double-blind,	PHGG (3 g/day for 7 days; 6 g/day for next 11 weeks) or	Adults diagnosed with IBS according	No difference between PHGG and control in change		[Authors report there were not enough patients in the IBS-C	[Authors report there were not enough patients in the IBS-D	[Authors report there were not enough patients in the IBS-D

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	placebo-controlled study	maltodextrin (control)	to Rome III criteria; n=108	from baseline for BMs/week: -0.8 ± 5.1 (PHGG); -0.4 ± 4.1 (control). Note that mean baseline # of BMs/week was relatively high (13.4 in PHGG; 13.7 in control), with little room to increase (or desire for increase) from an intervention. This baseline value is consistent with the majority of patients having either IBS-mixed or IBS-D, rather than IBS-C.		sub-group to do sub-group analyses]	sub-group to do sub-group analyses]	sub-group to do sub-group analyses]
3. Russo et al, 2015	Open-label, single-arm study	PHGG; patients instructed to take PHGG after breakfast every day in a glass of water (dosage info not provided by authors) for 4 weeks	Adults with IBS-C; n=68	See results summarized for “Helps manage constipation, increasing the frequency of BMs”	Mean Bristol scores improved after PHGG (vs run-in period; from 1.97 ± 0.96 to 2.8 ± 0.6 , $p<0.05$); also improved in all subgroups analyzed by gender, age, and BMI ($P<0.05$).	Mean # of BMs/day increased after PHGG (vs run-in period; from 0.38 ± 0.22 to 0.51 ± 0.20 , $p<0.05$); reduction in mean colonic transit time after PHGG ($p<0.05$); reduction in use of laxatives/enemas ($p<0.05$)	No evidence that PHGG intervention resulted in diarrhea	
4. Polymeros et al, 2014	Open-label, single-arm study	PHGG 5 g/day for 4 weeks	Adults with IBS-C (per Rome III); n=39 completers	See results summarized for “Helps manage constipation, increasing the frequency of BMs” and “Helps improve BMs in patients with constipation w/out leading to diarrhea”	After 4 weeks of PHGG, median (IQR) Bristol score was increased from baseline by almost 2 units: pre-treatment: 1.8 (1.8-2.5) vs post-treatment: 3.7 (3.4-4.5), $P<0.001$	Increase in median (IQR) # of complete spontaneous BMs from 0 (0-0)/week pretreatment to 1.25 (0.25-3)/week post-treatment ($p<0.001$); increase in median (IQR) # of spontaneous BMs from 1.5 (0-2.5) pre-treatment to 4.75	Bristol scores indicated normal stool consistency after PHGG intervention; no episodes of diarrhea reported (no serious adverse events reported and only 6 adverse events [none diarrhea] reported)	

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						(2.25–6.75) post-treatment (p<0.001)		
5. Tanaka, 2013 *	Open-label, single-arm study	PHGG 12 g/day for 1 week	Hospitalized elderly adults using laxatives; n=14	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>		Fecal defecation frequency improved (p < 0.05), even as consumption of laxative aids declined		
6. Ishihara et al, 2012 *	Open-label, single-arm study	PHGG 10.5 g/day for 24 weeks	Elderly adults with senility; n=21	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>		Fecal defecation frequency improved to 5.3 times/week during PHGG ingestion; decreased to 4.8 times/week when PHGG was discontinued		
7. Maeda et al, 2012	Open-label, single-arm study	PHGG 10 g/day for 6 weeks	Maintenance dialysis patients with constipation; mean age 70 years; n=35	Constipation scores decreased after PHGG (from 7.9 to 5.0; p<0.01); post-PHGG score indicates amelioration of constipation				
8. Inoue & Kato, 2009 *	Open-label, single-arm study	PHGG 7 g/day for 4 weeks	Frail elderly with constipation; n=14	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>		Fecal defecation frequency increased significantly		
9. Nakagawa et al, 2008 *	Randomized, placebo-controlled crossover study	PHGG 5.2 g/day for 2 weeks	Healthy adults; n=50	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>	PHGG increased fecal volume (p < 0.05)	PHGG increased (p<0.01) fecal defecation frequency from 3.88 ± 0.17 at baseline to 4.66 ± 0.23 times/week after the 1st week and 5.34 ± 0.26 after the 2nd week	No evidence that PHGG intervention resulted in diarrhea	
10. Alam et al, 2008	Randomized controlled trial	ORS + 25 g PHGG; ORS + 50 g PHGG, or ORS alone (control)	Adults males with cholera, ages 18-55 years, with watery diarrhea					No significant differences in diarrhea duration and mean stool weight during

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			<24 hours, severe dehydration; n=195					the first and second 24 hours. In subgroup analysis excluding very high purging patients, stool weight was significantly reduced in the first 24 hours in both groups receiving PHGG (PHGG 25 g, 136 ± 68 vs PHGG 50 g, 144 ± 49 vs control, 176 ± 43, p=0.01)
11. Belo et al, 2008	Randomized, blind study with active control group consuming a high-fiber diet	High fiber diet (30 g/day) alone and with additional PHGG 10 g/day for 15 days	Hospitalized patients with functional constipation; n=64	No additional effect beyond the effect of the high fiber diet alone (See results summarized for "Helps manage constipation, increasing the frequency of BMs")	No additional effect beyond the effect of the high fiber diet alone (See results summarized for "Helps manage constipation, increasing the frequency of BMs")	High fiber diet alone reduced functional constipation by 78%; no additional effect of PHGG on BM frequency, stool consistency, laxative use; PHGG group did have a reduction in bowel complaints		
12. Nakamura et al, 2007	Single-arm dose-escalating study	PHGG 5 or 10 g/day	Healthy females (mean age 21 years) with transitory diarrhea induced by the investigators using maltitol or lactitol	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				5 g/day of PHGG suppressed transitory diarrhea in ~36% of subjects; after increasing the PHGG dose to 10 g/day in the maltitol-induced diarrhea group, 82% (23/28) of subjects experienced suppression of diarrhea
13. Sakata & Shimbo 2006 *	Open-label, single-arm study	Strict diet for a 2-week session in the spring; then the same strict diet plus PHGG 12.5 g/day for a 2-week session in the fall	Healthy women; n=9		PHGG: increased fecal bulk in 4 subjects, and decreased bulk in 2; softened stools in 3 subjects, and made stools harder in 4; increased fecal			

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					moisture in 5 subjects and decreased moisture in 2.			
14. Rushdi et al, 2004 ●●	Randomized controlled trial	Fiber-free enteral formula alone or with PHGG 22 g/L for 4 days	Adult patients on enteral nutrition with persistent diarrhea; n=20	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				Number of liquid stools in the PHGG group on day 4 was significantly lower vs control (1.0 ± 0.7 vs 2.1 ± 0.8 ; $p < 0.01$); no cases of constipation reported in PHGG group (1 case in control)
15. Homann et al, 2004 ●●	Randomized, double-blind, controlled study	Enteral nutrition without additional fiber or with PHGG added @ 20 g/L	Patients with diarrhea following surgery/medical illness, on total enteral nutrition (n=30) or supplemental enteral nutrition (n=70, 1000 mL/d)	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				Lower rate of diarrhea events in PHGG vs control (12% vs 30%); fewer days with diarrhea in PHGG group vs controls (10.2 days vs 40.6 days); discharge of enteral nutrition secondary to GI-side effects was significantly less common in PHGG vs control
16. Nakao et al, 2002	Open-label, single-arm study	PHGG started at 7 g/day; increased at 1-week intervals to 28 g/day. After 4 weeks, PHGG discontinued for 2 weeks to confirm PHGG effect	Patients (mean age 79 years) with diarrhea during long-term nutrition management; n=20	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				Fecal water content and frequency of daily BMs decreased ($p < 0.01$ and $p < 0.05$, respectively) after 4 weeks of PHGG
17. Spapen et al, 2001 ●●	Randomized, double-blind, controlled study	Enteral formula without added fiber or with PHGG added @ 22 g/L; feeding provided for a minimum of 6 days (mean	Septic patients receiving total enteral nutrition (mean age 68 years); n=25	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				Significantly lower frequency of diarrhea days in PHGG group vs control ($8.8\% \pm 10.0\%$ vs $32.0\% \pm 15.3\%$; $P = 0.001$); PHGG also had (vs control) fewer

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		duration was 148 days for PHGG group; 146 days for control group)						days with diarrhea per total feeding days (16/148 days [10.8%] vs 46/146 days [31.5%]; P<0.001) and lower mean diarrhea score (4.8 ± 6.4 vs 9.4 ± 10.2; P<0.001)
18. Giaccari et al, 2001	Open-label, single-arm study	PHGG 5 g/day for 24 weeks	Patients with IBS, 14-71 yr old (n=133 from weeks 1-4; increasing dropout rate over remainder of study)	BM regularity (as shown by the standard deviation for number of BMs/week) improved from week 3 onward (vs. baseline); also, maximum number of BMs/week declined progressively from 35 at baseline to 20 at week 4, continuing downward thereafter		BMs/week were significantly (P<0.05) increased at weeks 3 and 12 (no statistical analysis after week 12 due to high dropout rate); mean (SD) at baseline: 5.62 (4.29), at week 3: 6.23 (2.37), and at week 12: 6.66 (1.6).		
19. Tanaka et al, 2000 *	Randomized, placebo-controlled, crossover study	Test diet without and with PHGG 7 g/day for 2 weeks (PHGG fiber was delivered via rice gruel; all subjects received the test diet for 2 weeks and the placebo diet without dietary fiber for 2 weeks)	Healthy women (mean age 27.7 years); n=46	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>	Fecal volume was significantly (p<0.05) increased after 2 weeks vs pre-treatment period; similar trend for increased fecal volume vs placebo control	In subjects with >4.5 BMs/week during placebo (n=30), fecal defecation frequency increased during PHGG from 6.5 ± 2.2 to 7.3 ± 2.4 times/week; among subjects with <4 BMs/week during placebo (n=16), fecal defecation frequency increased during PHGG from 3.2 ± 0.7 to 4.0 ± 0.9 times/week		
20. Okazaki et al, 1999 *	2 randomized, placebo-controlled trials	Study 1: PHGG 10 g/day for 2 weeks Study 2: PHGG 5 g/day for 2 weeks	Study 1: Healthy adults; n=14 (all but 1 were women)	See results summarized for <i>"Helps manage constipation,</i>	Study 1: PHGG increased fecal volume significantly (p<0.01)	Study 1: PHGG increased BMs/week from 5.29 ± 2.61 to 6.86 ± 2.11 after the first week and to		

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			Study 2: Healthy women; n=15	<i>increasing the frequency of BMs</i>	Study 2: PHGG increased fecal volume significantly (p<0.01)	7.14 ± 3.59 after 2 weeks (p<0.01) Study 2: PHGG increased BMs/week from 3.67 ± 1.45 to 5.53 ± 2.23 after the first week and to 5.21 ± 1.76 after 2 weeks (p<0.05)		
21. Patrick et al, 1998	Open-label, single-arm study	PHGG started at 4 g/day and gradually increased to 12 g/day, while concurrently decreasing laxative dosing	Elderly residents who regularly consumed laxatives; n=16	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>	Stool consistency maintained as PHGG gradually replaced regular laxative use	Similar BM frequency in the laxative (1.1 ± 1.0 times/day) and PHGG (1.0 ± 0.6 times/day) phases	"Ease of BMs" maintained as PHGG gradually replaced regular laxative use	
22. Yamatoya et al, 1995	Randomized, parallel group study	PHGG 5 g/day or 15 g/day for 2 weeks	Healthy women; n=65	See results summarized for <i>"Helps manage constipation, increasing the frequency of BMs"</i>	Trending increase in fecal volume observed in both groups	Significant (p<0.05) increase in BM frequency in both groups		
23. Homann et al, 1994	Randomized, double-blind, controlled trial	Standard enteral formula without and with PHGG @ 20 g/L	Post-operative patients receiving either total enteral nutrition (n=30) or partial enteral nutrition (n=70)	See results summarized for <i>"Helps manage diarrhea, w/out leading to constipation"</i>				Use of PHGG resulted in significantly fewer patients with diarrhea (12% vs. 30% on the fiber-free formula, p<0.05) and a significant reduction in the number of days patients suffered from diarrhea (10.2 vs. 40.6 days, p<0.05). Enteral nutrition was discontinued due to GI side effects in 4 patients on the control diet, and 0 patients on the PHGG-supplemented diet (p<0.05).

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24. Takahashi et al, 1994	Open-label, single-arm study	PHGG 11 g/day for 3 weeks	Women with constipation (abdominal pain and discomfort and BM frequency typically <3x/week; volunteers were employed or family members of the study sponsor), ages 18-48 years (mean 28.7); n=15	See results summarized for " <i>Helps manage constipation, increasing the frequency of BMs</i> "	Fecal moisture increased significantly from 69.1% to 73.8% (pre- vs post-PHGG); average fecal weight also increased from 88.9 ± 8.2 to 104 ± 10.3 g per day; no significant difference was observed in the fecal wet or dry weight (pre- to post-PHGG)	Significant increase in mean BMs/day from 0.46 ± 0.03 to 0.66 ± 0.05 with PHGG consumption. Three weeks after PHGG was stopped, daily frequency of BMs decreased significantly to 0.52 ± 0.04		
25. Takahashi et al, 1993	Open-label, single-arm study	PHGG 36 g/day (3 servings/day for 4 weeks) (Control diet for 4 weeks, then free diet for 4 weeks, then control diet + PHGG for 4 weeks)	Healthy men; n=8	See results summarized for " <i>Helps manage constipation, increasing the frequency of BMs</i> "	Significant (p<0.05) increase in fecal weight (122.6 ± 11.7 to 195.2 ± 17.7 g per day) pre- vs post-PHGG	Mean BMs/day increased significantly at weeks 3 and 4 of PHGG administration (vs both control and free diet periods); control diet period = 0.89 ± 0.15; free diet period = 0.93 ± 0.14; PHGG week 3 = 1.09 ± 0.16; PHGG week 4 = 1.13 ± 0.13		
26. Meier et al, 1993	Randomized, crossover study	Self-selected diet vs standard enteral formula (fiber-free) vs standard enteral formula plus PHGG @ 21 g/L; each diet was consumed for 7 days	Healthy males; n=12	Not clear that the experimental conditions in this study (in which PHGG was added to a total liquid diet in healthy volunteers without constipation or diarrhea) have external validity (generalizability) to a healthy population using PHGG to support regularity or to a population with	Stool consistency did not differ among the diet periods	No significant difference in BMs/day across the 3 diet interventions (1.0 ± 0.03 for self-selected diet; 1.15 ± 0.16 for fiber-free liquid diet; 0.95 ± 0.08 for liquid diet+PHGG). The sum of all BMs was not significantly different during the period of liquid diet without fiber (n=83) and the		

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				a tendency towards constipation or diarrhea using PHGG to normalize BMs		period of liquid diet with fiber (n=69).		
27. Lampe et al, 1992	Randomized, double-blind, crossover study	3 enteral formula diets: fiber-free formula with Maltrin 21 g/day or PHGG 21 g/day or soy polysaccharide 21 g/day in random order; data also collected during a period of self-selected diet at baseline	Healthy males; n=11	Not clear that the experimental conditions in this study (in which PHGG was added to a total liquid diet in healthy volunteers without constipation or diarrhea) have external validity (generalizability) to a healthy population using PHGG to support regularity or to a population with a tendency towards constipation or diarrhea using PHGG to normalize BMs	Fecal consistency was similar on all diets; fecal weight and fecal moisture did not differ significantly on the PHGG-enriched liquid diet and the fiber-free liquid diet	Stool frequency (BMs/day) did not differ significantly on the PHGG-enriched liquid diet and the fiber-free liquid diet		
Studies Conducted in Children								
28. Alam et al, 2015	Randomized controlled trial	WHO oral rehydration solution alone or with PHGG 15 g/L	Children ages 6-36 months with acute watery diarrhea of <7 days duration, some or severe dehydration, and low (<-3) weight-for-length/weight-for-age z-score; n=126					Duration (hours) of diarrhea was shorter in PHGG vs control (57 ± 31 vs 75 ± 39; p=0.01); Kaplan Meier survival analysis also showed reduced duration of diarrhea in PHGG group (p=0.045)
29. Romano et al, 2013	Randomized, placebo-controlled study	5 g/day of PHGG in 50 mL of fruit-juice or 50 mL of juice only, for 4 weeks	Children ages 8-16 years with chronic abdominal pain (CAP) or IBS (per Rome III); n=60	40% of children in the PHGG group had normalized bowel habits (ie, Bristol ratings of 3 or 4) at 4 and 8 weeks, vs 13.3% in the control group (p=0.025).			Bristol scores in the IBS-C subgroup trended toward greater improvement (ie, were increased) vs placebo but did not reach statistical significance.	Bristol scores in the IBS-D subgroup trended toward greater improvement (ie, were decreased) vs placebo but did not reach statistical significance.

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30. Paul et al, 2011	Open-label, single-arm study	PHGG for a minimum of 6-8 weeks; no dosage information provided	Children, ages 1-18 years, with IBS symptoms; 72% were >5 years of age; n=46	Pre- to post-PHGG improvement of: - alternating diarrhea and constipation in 82% (23/28); - diarrhea in 58% (11/18)			See results summarized for "Supports regularity"	See results summarized for "Supports regularity"
31. Üstündağ et al, 2010 ●●	Randomized design with active control	PHGG (3, 4, or 5 g/day for ages 4-6, 6-12, and 12-16 years, respectively) or lactulose syrup (1 ml/kg/day) for 4 weeks	Children, ages 4-16 years with constipation (per Rome III); n=61	See results summarized for "Helps manage constipation, increasing the frequency of BMs"	Stool softness improved in both groups (PHGG: 2.1 to 3.9; Lactulose: 2.8 to 4.3; p<0.05); the difference between groups was not statistically significant	Mean weekly BMs increased (p<0.05) from 4 ± 0.7 to 6 ± 1.06 in the lactulose group and from 4 ± 0.7 to 5 ± 1.7 in the PHGG group. Although the increase in the lactulose group was larger (vs PHGG; p<0.05), the authors noted that parents and children were satisfied with the increased defecation frequency, and decreased abdominal pain and stool withholding obtained with PHGG	Results showed an increase in mean weekly defecation frequency with PHGG of 1 BM/week; the mean increase with laxative use was 2 BMs/week. No evidence of diarrhea resulting from PHGG treatment. Parents expressed more frequent complaints about adverse side effects in the lactulose group, especially regarding flatulence	
32. Alam et al, 2005 ●●	Randomized controlled trial	Comminuted chicken diet with or without 20 g/L PHGG	Male children, ages 5-24 months, with history of watery diarrhea lasting for >14 days; n=116	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				PHGG improved % of children with diarrhea resolved within 7 days (84% vs. 62%; p=0.02); survival analysis also showed reduced duration of diarrhea with PHGG (p=0.0017)
33. Alam et al, 2000 ●●	Randomized, double-blind, controlled study	WHO ORS without or with 20 g/L PHGG	Male children, ages 4-18 months, with watery diarrhea <48 hours duration; n=150	See results summarized for "Helps manage diarrhea, w/out leading to constipation"				PHGG reduced the duration of diarrhea vs control (mean ± SD, 74 ± 37 vs. 90 ± 50 hours, P=0.03). Survival analysis for duration of

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								diarrhea also showed a reduction for the group receiving PHGG (P=0.025). The PHGG group had less daily stool output from days 2-7 vs control; the reduction was significant on day 7 only.