

Evidence Profile 5.1: A Proactive Approach to Bladder and Bowel Management in Adults

Recommendation 5.1 Evidence Profile (Quantitative)

Recommendation question 5: Should adequate intake of fibre and/or fluids be recommended to improve outcomes in persons living with fecal incontinence and/or constipation?

Recommendation 5.1: The expert panel suggests that health providers counsel persons on adequate fibre intake to prevent and manage constipation.

Population: Adults (18 and over) living with constipation or fecal incontinence

Intervention: Adequate intake of fibre

Comparison: No fibre

Outcomes: Frequency of bowel movements, stool consistency, laxative use, quality of life

Setting: All health settings except ICUs

Bibliography: 503, 3138, 3158, 9690, 1115, 1297, 1079, 1062, 1301, 2242

Note: All studies included persons with chronic or functional constipation except for studies 1301, 1297 & 9690 which included healthy adults.

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Country	Intervention	Intervention	Control			
Frequency of bowel movements (measured with bowel movement diary)													
5	RCT	Serious ^a	Not serious ^b	Not serious	Serious ^c	Not serious	503: Germany 9690: Belgium 1297: US 3138: Netherlands 152: UK	503: four weeks daily intake of 12g inulin vs. placebo (maltodextrin) 9690: intake of wheat bran extract (WBE) (15g/day in week one and 30g/day in week two) and intake of oligofructose (15g/day in week one and 30g/day in week two) vs. placebo (soft drink)	503: (N=44) Baseline = 2.5 [IQR 2.5–3.0] stools/week Post intervention = 4.0 [IQR 2.5–4.5] stools/week 9690: (N=19) 30 g/d WBE treatment period mean = 1.1, sd = 0.3 30 g/d oligofructose mean = 1.2, sd = 0.4 Bristol composite measure 30 g/d WBE treatment period mean = 4.2, sd = 1.2	503: (N=44) Baseline = 2.9 [IQR 2.3–3.0] stools/week Post placebo = 3.0 [IQR 2.5–4.0] stools/week 9690: (N=19) placebo mean = 1.2, sd = 0.3 Bristol composite measure placebo mean = 3.7, sd =	503: There was an increase in stool frequency in the inulin group compared to the placebo group (p = 0.038). 9690: Bowel frequency was not modulated by the intake of WBE or oligofructose. However Bristol composite measure (defecation freq and stool consistency) was higher after WBE treatment compared to placebo (p=0.038)	⊕⊕○○ LOW	503: Micka et al., 2017 9690: Francois et al., 2014 1297: Timm et al., 2014 3138: Duncan et al., 2018 152: Lever et al., 2019

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								<p><u>1297</u>: 20g/day of polydextrose (PDX) or soluble corn fibre (SCF) for 10 days vs. low fibre control (LFC)</p> <p><u>3138</u>: polydextrose 6g/serving or 4g/serving consumed twice daily vs. placebo (maltodextrin)</p> <p>152: three groups: control (no prunes plus 300 ml/d water); 80 g/d</p>	<p>30 g/d oligofructose mean = 4.1, sd= 0.9</p> <p><u>1297</u>: (N=36) Stools in 5-day collection (Mean ± SD) PDX = 5.5 ± 2.3 SCF =5.3 ± 2.1</p> <p><u>3138</u>: (N=34) 4g: mean ± SD = 1.0 ±2.0 (N= 34) 6g: mean ± SD = -0.2 ±-2.3</p> <p>152: stool frequency (BM/week):</p>	<p>0.7</p> <p><u>1297</u>: (N=36) Stools in 5-day collection (Mean ± SD) LFC = 4.4 ± 2.1</p> <p><u>3138</u>: (N=36) mean ± SD = 0.6 ±1.2</p> <p>152: stool frequency</p>	<p>1297: The number of stools passed by participants during the PDX and SCF periods was higher than during the LFC period (P ≤ 0.0005).</p> <p>3138: There was a slight decrease in the frequency of bowel movement after 28 days from baseline when taking polydextrose 12g compared to the placebo [mean difference=-0.5(-1.5, 0.5).</p> <p>152: The prune groups had more frequent BMs than the control (p = 0.023)</p> <p>Overall, most studies demonstrated an increase in frequency of bowel movements with the intake of fibre.</p>		

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								prunes (plus 300 ml/d water); 120 g/d prunes (plus 300 ml/ d water)	80g/d prunes (Mean[SD]) Baseline = 5.1 (2.1) After 4 weeks = 6.8 (3.8)	(BM/week): Baseline = 5.4 (1.4) After 4 weeks = 5.4 (2.1)			
1	Quasi-experimental	Serious ^d	Not serious	Not serious	Serious ^c	Not serious	1062: Greece	5mg of partially hydrolyzed guar gum daily for 4 weeks. Results examined pre and post-intervention.	(N=39) Pretreatment: complete spontaneous bowel movement (CSBM) per/week= 0 (0-0) (median[IQR]) Post-treatment: CSBM per week = 1.25(0.25-3) (median[IQR])	No true control	Overall, there was an increase in the median number of CSBM after intake of partially hydrolyzed guar gum (p < 0.001).	⊕○○○ VERY LOW	1062: Polymeros et al., 2014
1	Systematic Review (of RCTs)	Serious ^d	Not serious	Not serious	Serious ^c	Not serious	1079: Various countries	Food containing inulin vs. various placebo in 4 RCTs.	Total number of people receiving intervention across 4 studies = 124	Total number of people receiving placebo across 4 studies = 84	There was an overall effect of inulin on stool frequency (mean difference=1.60, 95% CI: 1.07, 2.14).	⊕⊕○○ LOW	1079: Yurrita et al., 2014

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Stool consistency (measured with Bristol stool form, frequency of abnormal stool)													
7	RCT	Serious ^d	Not serious	Not serious	Not serious	Not serious	<p><u>3158</u>: Iran</p> <p><u>1297</u>: US</p> <p><u>9690</u>: Belgium</p> <p><u>503</u>: Germany</p> <p><u>3138</u>: Netherlands</p> <p>10: Iran</p> <p>152: UK</p>	<p><u>3158</u>: Either 10g flaxseed or psyllium daily for 12 weeks vs. placebo (maltodextrin)</p> <p><u>1297</u>: 20g/day of polydextrose (PDX) or soluble corn fibre (SCF) for 10 days vs. low fibre control (LFC)</p> <p><u>9690</u>: intake of wheat bran extract (WBE) (15g/day in week one and 30g/day in week two) and intake of oligofructose (15g/day in week one and 30g/day in week two) vs. placebo(soft drink)</p>	<p><u>3158</u>: flaxseed group (N=26) ave. change from baseline =1.96±0.8</p> <p>Psyllium group (N=24): ave. change from baseline= 0.29 ±1.1</p> <p><u>1297</u>: (N=36) PDX ave. score =4.64 ± 1.31</p> <p>SCF ave. score = 3.89 ± 1.47</p> <p><u>9690</u>: (N=19) WBE ave. score = 4.2±1.2</p> <p>Oligofructose ave. score =4.2±1.0</p> <p>Bristol composite measure</p> <p>30 g/d WBE treatment period mean = 4.2, sd = 1.2</p> <p>30 g/d oligofructose</p>	<p><u>3158</u>: placebo (N=27) ave. change from baseline =0.59 ±1.6</p> <p><u>1297</u>: (N=36) LFC ave score= 3.86 ± 1.38</p> <p><u>9690</u>: (N=19) Placebo ave score = 3.8±0.9</p> <p>Bristol composite measure</p> <p>placebo mean = 3.7, sd = 0.7</p>	<p><u>3158</u>: There was an improvement in stool consistency (P<0.001) in both flaxseed and psyllium groups compared to the placebo group</p> <p><u>1297</u>: PDX consumption resulted in softer stools (P = 0.002) compared with soluble corn fibre and the control</p> <p><u>9690</u>: Bristol composite measure (defecation freq and stool consistency) was higher after WBE treatment compared to placebo (p=0.038)</p>	⊕⊕⊕○ MODERATE	<p>3158: Soltanian & Janghorbani, 2018</p> <p>1297: Timm et al., 2013</p> <p>9690: Francois et al., 2014</p> <p>503: Micka et al., 2017</p> <p>3138: Duncan et al., 2018</p> <p>10: Soltanian & Janghorbani, 2018</p> <p>152: Lever et al., 2019</p>

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								<p>503: four weeks daily intake of 12g inulin vs. placebo (maltodextrin)</p> <p>3138: polydextrose 6g/serving or 4g/serving consumed twice daily vs. placebo (maltodextrin)</p> <p>10: intervention group received 10 g flaxseed pre-mixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks. Control group received sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks as placebo.</p> <p>152: : three groups: control (no prunes plus 300 ml/d water); 80 g/d prunes (plus 300 ml/d water); 120 g/d prunes (plus 300 ml/ d water)</p>	<p>mean = 4.1, sd= 0.9</p> <p>503: (N=44) median score = 3.0 [IQR 3.0-4.0]</p> <p>3138: (N=34) polydextrose 4g ave. score =0.3±1.1</p> <p>(N=34) polydextrose 6g ave. score = 0.3±1.2</p> <p>10: stool consistency in flaxseed group improved (values are provided in mean (SD))</p> <p>Baseline = 1.35 (0.5)</p> <p>After 4 week therapy = 2.38 (0.6)</p> <p>After 8 week therapy = 2.96 (0.6)</p> <p>After 12 week therapy = 3.31 (0.7)</p>	<p>503: (N=44) median score = 3.0 [IQR 2.1-4.0]</p> <p>3138: (N=36) ave. score =0.1±1.2</p> <p>10: stool consistency did not improve in placebo group</p> <p>Baseline = 1.26 (0.5)</p> <p>After 4 week therapy = 1.59 (1.2)</p> <p>After 8 week therapy = 1.33 (0.6)</p> <p>After 12 week therapy = 1.85</p>	<p>503: 63.6% persons in the placebo group had scores <3, compared to 77.3% in the inulin group. In other words, more people had harder stools in the placebo group.</p> <p>3138: Slight improvement</p> <p>10: There was in improvement in stool consistency in the intervention group</p>		

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										(1.6)	152: Slight improvement in 80g/day group, but no major differences between groups in BSFS score at the end of 4 weeks (p =0.259)		
									152: Bristol Stool Form Scale 80g/d prunes [Median (IQR)] Baseline = 3.5 (1.3) After 4 weeks = 3.8 (1.9)	152: Bristol Stool Form Scale Baseline = 4.0 (1.4) After 4 weeks = 4.1 (1.7)	Overall, all studies demonstrated an improvement in stool consistency.		
3	Quasi-experimental (before and after)	Serious ^e	Not serious	Not serious	Not serious	Not serious	1062: Greece 1301: UK 2242: China	*all studies below examined results on the same people, pre and post-intervention. 1062: 5mg of partially hydrolyzed guar gum daily for 4 weeks 1301: at least 5.4g fibre/day for 2 weeks 2242: persons with functional constipation and with IBS constipation received high specific	1062: (N=39) pretreatment median score =1.8 [IQR 1.8-2.5] Post-treatment median score = 3.7 [IQR 3.4-4.5] 1301: (N=153) baseline period ave. score= 3.49 ± 1.28 Fibre intervention period ave. score = 3.80 ± 1.14 2242: (N=205) functional constipation group = frequency of	1062, 1301 & 2242: no true control	1062: Guar gum treatment improved the median stool form score by approximately two Bristol scale units from 1.8 (1.8–2.5) to 3.7 (3.4–4.5) overall during treatment period. 1301: Consumption of fibre led to improvements in stool type. 2242: consumption of high specific volume polysaccharide led to improvements in stool	⊕⊕○○ LOW	1062: Polymeros et al., 2014 1301: Lawton et al., 2013 2242: Cong et al., 2015

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								volume polysaccharide 3x/day for 14 days	abnormal stool form declined from 2.26 ± 0.81 to 0.04 ± 0.26 (p<0.05) (N=60) IBS constipation group = frequency of abnormal stool form declined from 2.27 ± 0.73 to 0.35±0.48		form. Across all three studies, there was a improvement in stool form.		
1	Systematic review	Serious ^d	Not serious	Not serious	Serious ^c	Not serious	1079: Various countries	Food containing inulin vs. various placebo in 3 RCTs.	Total number of people receiving intervention across 3 studies = 96	Total number of people receiving placebo across 3 studies = 52	There was a overall effect of inulin on stool consistency (mean difference=1.07, 95% CI: 0.7, 1.45).	⊕○○○ VERY LOW	1079: Yurrita et al., 2014
Laxative use (measured with daily diary)													
1	Quasi-experimental	Serious ^d	Not serious	Not serious	Serious ^c	Not serious	1062: Greece	5mg of partially hydrolyzed guar gum daily for 4 weeks. Results were examined on the same people, pre and post-intervention.	1062: (N=39) Pre-treatment days per week with laxative intake: median = 3(0-3) & post-treatment: median =0 (0-1.25) (p<0.001)	1062: No true control	There was a decrease in the days per week with laxative use after the intervention.	⊕○○○ VERY LOW	1062: Polymeros et al., 2014
Quality of Life (measured with inflammatory bowel disease questionnaire [IBD-Q], patient assessment of constipation quality of life [PAC-QoL], digestive wellbeing questionnaire [DWQ])													

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3	RCT	Serious ^d	Serious ^a	Not serious	Serious ^c	Not serious	503: Germany 3138: Netherlands 1115: US	503: four weeks daily intake of 12g chicory inulin in healthy adults vs. placebo (maltodextrin) (QOL measured with satisfaction and physical discomfort; lower number indicated higher satisfaction) 3138: polydextrose 6g/serving or 4g/serving consumed twice daily in constipated adults (QOL measured with global and satisfaction scores) 1115: education re: specific instructions for persons with Crohn's disease to consume high-fibre and low refined carbohydrate diet including consumption of whole wheat bran cereal for 4 weeks vs. control group that received more general dietary information	503: (N=44) satisfaction median =1.5 [IQR 0.8–2.3] Physical discomfort median = 1.3 [IQR 0.5–1.8] 3138: refer to table ^f 1115: (N=4) scores increased by 44 points	503: (N=44) satisfaction median = 2.0 [IQR 1.0–2.8] Physical discomfort median = 1.3 [IQR 0.8–2.0] 3138: refer to table ^f 1115: (N=3) scores increased by 19 points	503: Satisfaction subscale improved with inulin intake. There were no differences in physical discomfort between groups. 3138: improvement was detected in group that received 6g polydextrose, 2x/day in global and satisfaction domains 1115: Wheat bran group had improvements in quality of life scores compared to control group. Across all three studies, there was an improvement in quality of life (to varying degrees) after taking fibre.	⊕⊕○○ LOW	503: Micka et al., 2017 3138: Duncan et al., 2018 1115: Brotherton et al., 2014
1	Quasi-experimental (before and after)	Serious ^d	Not serious	Not serious	Serious ^c	Not serious	1301: UK	At least 5.4g fibre/day for 2 weeks. Results were examined on the same people, pre and post-intervention.	Refer to Table 2 in the article: general wellbeing scores for 10 domains in study (pg. 1443)	No true control	Consuming high wheat bran fibre containing cereals led to improvements in all general well being parameters.	⊕○○○ VERY LOW	1301: Lawton et al., 2013

Explanations

a. Based on the Risk of Bias 2.0 tool for RCTs, the studies had some concern related to how they were conducted. We downgraded by 0.5.

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- b. Most studies had positive results. Therefore, we downgraded by 0.5.
- c. Total sample size was less than the optimal 400 participants, therefore we downgraded by 1.
- d. Based on the ROBINS-I tool for quasi-experimental studies, the studies had serious concerns in how studies were conducted. We downgraded by 1.
- e. Based on the ROBINS-I tool for quasi-experimental studies, the studies had very serious concerns in how they were conducted. We downgraded by 1.5.
- f.

Fibre intake	Number of participants	Change in PAC-QOL Global Scale (mean±SD)	Change in PAC-QOL Satisfaction Scale (mean±SD)
Polydextrose 4g	34	-0.4±0.6	-0.6±0.9
Polydextrose 6g	34	-0.3±0.7	-0.3±1.2
Placebo	36	-0.1±0.5	-0.1±0.9

- g. Studies used different tools to measure outcome. As a result, we downgraded by 0.5.

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