Recommendation 5.3 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 5.3: The expert panel suggests that health providers promote the option of using psyllium fibre supplements for persons living with fecal incontinence in the community.

Population: Adults (18 and older) living with fecal incontinence and/or constipation
Intervention: Adequate intake of fibre
Comparison: No adequate intake of fibre
Outcomes: Stool consistency, episodes of incontinence and QOL

Setting: Community (not recommended for persons in ICU and long term care settings)

Bibliography: 2114a, 2585

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Country	Intervention	Intervention	Control			
Stool consistency (measured using 4-level classification)													
1	RCT	Not serious	Not serious	Not serious	Serious [a]	Not serious	2585: USA	Participants were randomly assigned to 4 groups. All participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and exercise. One group received psyllium fiber supplements compared to the control. After randomization, fiber amounts were increased by 1/3 every 2 days during a 6-day incremental dosing period then maintained during a 32-day steady amount period **Group C**: 14.6g / day psyllium	**Psyllium Fiber Supplements** **Group C**: N= 54 Baseline = 0.25 (0.22) Supplement Period = 0.21 (0.20)	Participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and exercise. **Placebo**: N= 49 Baseline = 2.0 (0.15) Supplement Period = 2.0 (0.15)	The study reported an improvement in stool consistency in the group that received psyllium fibre supplements compared to the control group.	⊕⊕⊕◯ Moderate	2585: Bliss et al., 2014

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Country	Intervention	Intervention	Control			
Episodes of Incontinence (measured using bowel diaries)													
2	RCTs	Serious [b]	Not serious	Not serious	Serious [a]	Not serious	2114a: USA 2585: USA	2114a: Participants received either daily loperamide (plus placebo psyllium powder) or psyllium powder (plus loperamide placebo) for 4 weeks. For the first week of the intervention, participants were instructed to take 1 capsule (containing 2.0mg of loperamide or placebo) along with 5 ml of powder (3.4 mg of psyllium or placebo). After 2 week washout, participants crossed over 4 weeks of alternate treatment. 2585: Participants were randomly assigned to 4 groups. All participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and exercise. One group received psyllium fibre supplements compared to the control.	L1P2 - FI episodes/week - Baseline (N=43): 7.9±7.5 - End of first treatment (N=39): 4.1±5.1 - End of washout (N=37): 5.0±6.2 - End of second treatment (N=34): 4.7±5.7 P1L2 FI episodes/week - Baseline (N=37): 7.3±6.2 - End of first treatment (N=34): 4.8±4.8 - End of washout (N=30): 4.3+±4.2 - End of second treatment (N=29): 3.5±6.6 **FI incontinence episodes/week** **Psyllium (N = 54)** Baseline = 5.0 Post = 2.5	No true control Cross-over trial, therefore same participants as in intervention group Participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and	2114a: The study reported a trend towards reduction in FI episodes per week during the treatment crossover for the two groups. However, within each group, the study reported a reduction in FI episodes per week with 3.0% reduction in the psyllium group (p = 0.03). The study reported a decrease of 51% in FI frequency after psyllium fibre supplementation compared to 11% decrease in placebo group.	⊕⊕⊕◯ Moderate	2114a: Markland et al., 2015 2585: Bliss et al., 2014

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Country	Intervention	Intervention	Control			
								After randomization, fiber amounts were increased by 1/3 every 2 days during a 6-day incremental dosing period then maintained during a 32-day steady amount period **Group C**: 14.6g / day psyllium		exercise. **Placebo (N= 49)** Baseline = 6.2 Post = 5.5			
Quality of life (measured using FISI[1] and FIQL[2] questionnaires)													
2	RCTs	Serious [b]	Serious [c]	Not serious	Serious [a]	Not serious	2114a: USA	2114a: Participants received either daily loperamide (plus placebo psyllium powder) or psyllium powder (plus loperamide placebo) for 4 weeks. For the first week of the intervention, participants were instructed to take 1 capsule (containing 2.0mg of loperamide or placebo) along with 5 ml of powder (3.4 mg of psyllium or placebo). After 2 week washout, participants crossed over 4 weeks of alternate treatment.	2114a: L1P2 – condition specific QOL, MMHQ scores - Baseline: (N=43) 47.9 ±23.2 - End of first treatment: (N=40) 41.7±25.9 - End of second treatment: (N=34) 40.6±29.6 P1L2 - condition specific QOL, MMHQ scores - Baseline: (N=36) 41.9 ± 23.8 - End of first treatment: (N=32) 35.3 ± 24.2 - End of second treatment: (N=26) 31.2 ± 25.6	2114a: No true control Cross-over trial, therefore same participants as in intervention group	2114a: The study reported a trend towards improvement in QOL during the treatment crossover for the two groups.	⊕⊕◯◯ LOW	2114a: Markland et al., 2015 2585: Bliss et al., 2014

Evidence Profile 5.3: *A Proactive Approach to Bladder and Bowel Management in Adults*

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Country	Intervention	Intervention	Control			
							2585: USA	2585: Participants were randomly assigned to 4 groups. All participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and exercise. Three groups received three different fiber supplements and one group received a placebo. After randomization, fiber amounts were increased by 1/3 every 2 days during a 6-day incremental dosing period then maintained during a 32-day steady amount period **Group C**: 14.6g psyllium	**2585:** **Psyllium (N = 54)** QOL– no statistics provided in study	2585: **Placebo (N= 49)** Participants were instructed to drink minimum 840ml of fluid/day & maintain usual diet and exercise. QOL– no statistics provided in study	2585: The study did not report any statistics related to QOL. The study reported "no significant differences in FIQL, including lifestyle, coping, depression, and embarrassment scores, among the groups in the baseline or supplement periods".		

1. FISI: Fecal Incontinence Severity Index
2. FIQL: Fecal Incontinence Quality of Life

Explanations

a. Total number of participants in the study was less than the optimal 400 participants. We downgraded by 1.

b. Based on the Risk of Bias tool for Randomized Controlled Trials, a smaller study (2114a) had some concerns related to risk of bias due to limitations in how the study was conducted. Therefore, we downgraded by 0.5.

c. The data collection tools varied between studies; further, studies showed opposite results, therefore we downgraded by 1.