Appendix 1: Placebo-controlled randomized controlled trials of treatments of chronic constipation in older people

Study	Agent	Dose	*N*	Age, yr, mean	Setting	Duration, wk	Inclusion criteria	Results	Quality Score*	Sources of bias
Osmotic agents										
Sanders (1)	Lactulose	20g daily	55	86	Long-term care	12	≤ 3 BM per week and 1 or more of hard stools, tenesmus, griping, cramping, laxative, enema or suppository use	Stool frequency per day: 0.63 ± 0.31 stools with lactulose v. 0.58 ± 0.30 with placebo ($p < 0.02$); fewer episodes of fecal impaction with lactulose than with placebo (6 v. 66) ($p < 0.015$)	3	Randomization and blinding methods unknown
Vanderdonckt et al. (2)	Lactitol	20g daily	46	84	Long-term care	4	≤ 3 BM per week, straining, symptoms for 6 months, not bedridden	Stool frequency per week: 6 to 7 with lactitol v. 3 to 4 with placebo ($p < 0.001$)	3	Randomization and blinding methods unknown; point estimate of efficacy not reported
Wasselius-De Casparis et al. (3)	Lactulose	15ml daily, 50% lactulose syrup	103		Not reported	3	Regular laxative use	Success (defined as no additional laxative use) in 86% (47/54) taking lactulose v. 60% (30/49) taking placebo ($p < 0.02$)	2	Loss to follow-up not reported
Zangaglia et al. (4)	Polyethylene glycol	7.3g twice daily	57	71	Outpatient	8	Parkinson disease and Rome criteria for chronic constipation	Stool frequency per week: 6.6 ± 2.7 in treatment group v. 3.7 ± 1.9 in placebo group ($p < 0.002$)	4	
Bulk agents										
Cheskin et al. (5)	Psyllium	24g daily	10	77	Outpatient	4	< 3 BM per week and/or incomplete evacuation and/or hard stools with excessive straining on >25% of BM	Stool frequency per day: 1.3 with psyllium v. 0.8 with placebo ($p < 0.1$)	2	Small sample; not blinded
Ewerth et al. (6)	Psyllium	12g daily	10	68	Not reported	8	≤ 2 BM per week and painful defecation; diverticula on barium enema	Stool frequency per day: 0.98 with psyllium v. 1.02 with placebo (NS)	3	Small sample
Rajala et al. (7)	Wheat bran, lactitol in yoghurt	150 ml twice daily of 6.5% lactitol and 1.25% fibre mix (60% guar gum and 30% wheat bran)	51	76	Acute care, medical and surgical	2	< 1 BM per day with straining or regular laxative use	Stool frequency per week: 5.9 ± 3.8 with fibre v. 4.3 ± 1.8 with placebo ($p < 0.05$)	2	Not blinded; groups not balanced; mixture of laxatives
Sairanen et al. (8)	Galacto-oligosaccharides (GOS) in yoghurt	6g GOS - 6g prunes - 3g linseed daily	43	76	Long-term care or outpatient	3	< 5 BM per week without laxatives or straining; ambulatory	Stool frequency per week: 8.0 ± 0.6 with fibre v. 7.1 ± 0.5 with placebo ($p = 0.011$); straining score 1.3 with fibre v 1.5 with placebo ($p = 0.01$)	3	Very mild baseline constipation
Snustad et al. (9)	Fibre, not specified, in cookies	10g daily	80	77	Geriatric evaluation and rehabilitation unit	3	Receiving laxatives, admitted to unit	Difference in stool frequency not significant	2	Loss to follow-up not reported
Teuri et al. (10)	GOS in yoghurt	4.5g twice daily	18	80	Long-term care	2	< 3 BM per week, regular laxative use or hard feces most of the time	Stool frequency per week: 7.1 (95% CI 3 to 15) with fibre v 5.9 (95% CI 1 to 14) with placebo	3	Test for statistical significance not reported
Surakka et al. (11)	GOS in yoghurt	10g daily	42	68	Outpatient	3	< 5 BM per week or continuous difficulties in defecation, or both	Stool frequency (change in BM per 5 days) 0.5 with fibre (95% CI –0.4 to 1.4) v. –0.2 with placebo (95% CI –1.2 to 0.4) ($p = 0.084$);	3	Loss to follow-up not reported; groups not balanced

								change in straining score –3.5 (95% CI –4.7 to –2.0) with fibre v. –0.1 (95% CI –2.1 to 1.7) with placebo (p = 0.025)		
Stimulants										
Bub et al. (12)	Sennosides	20g sennosides A and B in 1 cup of Smooth Move tea daily	92		Long-term care	4	Laxative use ≥ 1 per week	4.14 more BM with stimulant than with placebo (p = 0.017)	4	Groups compared with their own run-in phase; laxatives used before study were continued during study period
Huang et al. (13)	CCH1 Chinese herbal formulation and magnesium oxide (MgO)	1.5g to 4.5g CCH1 powder daily; MgO titrated up to 750mg daily concurrently	90	73	Long-term care	8	< 3 BM per week or MgO ≥ 750mg daily or bisacodyl ≥ 5mg daily or 2 classes of laxatives or enema or suppository ≥ 1 per week	Stool frequency per week: 5.6 ± 2.0 with stimulant v. 4.6 ± 2.5 with placebo (p = 0.049)	3	Randomization and blinding methods unknown; mixture of laxatives
Stool softeners										
Hyland et al. (14)	Dioctyl sodium sulfosuccinate	100mg 3 times daily	40		Acute care	4	Chronic constipation not defined	Mean difference 1.0 ± 0.29 more stools per week with active treatment than with placebo (p < 0.01); 12/15 patients were less constipated with active treatment than when they received placebo	3	Randomization and blinding methods not reported; nonconstipated participants given placebo were excluded from analysis
Prokinetic agents										
Muller-Lissner et al. (15)	Prucalopride	1, 2 or 4mg once daily	300	76	Outpatient	4	≤ 2 BM per week, and 1 or more of straining, hard stool or incomplete emptying on at least 25% of motions	At week 1, 48.7% of patients receiving 4-mg dose had ≥ 3 BM per week with prucalopride v. 26.1% with placebo (p < 0.05)	5	Multiple statistical tests, with only 1 time point reaching significance
Biofeedback										
Simón et al. (16)	Electromyographic biofeedback	8 sessions	30	74	Outpatient	4	Rome criteria for chronic constipation	Stool frequency per week: F value 187.97 in biofeedback group v. 175.49 in educational control group (p < 0.01)	3	Not blinded; small sample

Note: BM = bowel movement, CI = confidence interval, NS = not significant.
*Quality score based on Jadad scale.(17)
‡Stool frequency.
§Straining.

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