**Table F11. Risk of bias ratings for randomized clinical trials of fecal incontinence treatments**

| **Author, Year** | **Intervention** | **Risk of Bias** | **Rationale** |
| --- | --- | --- | --- |
| Bliss 2014[54](#_ENREF_54) | Dietary fiber | Low | Randomized study with allocation concealment; patients and outcome assessors blinded, likely providers too. Adjusted for multiple comparisons; ITT; all relevant outcomes reported; good description of treatments; diagram shows LTF information |
| Bliss 2001[20](#_ENREF_20) | Dietary fiber | Moderate | Randomization described, single blind study, unclear reporting (whether 42 or 39 patients were randomized, or if the 3 patients who discontinued did so before randomization); primary outcome not specified; ITT. Very limited baseline information on sample (in text). |
| Lauti, 2008[57](#_ENREF_57) | Dietary fiber and loperamide | Moderate | Low risk of selection bias. Patients and clinicians reportedly blinded but diet advice sheets regarding fiber were common public knowledge at that time (hence, diet unblinded but fiber supplement was deidentified). Non-standardized dietary intervention. Reported ITT but unclear how missing data from 16 was handled in analysis. |
| Park 2007[58](#_ENREF_58) | Topical phenylephrine | High | Excluded post-randomization data from 6 of 35 with poor compliance. Primary outcome NR. Randomization and allocation low risk. Blinding of pts not possible. Unclear if outcomes assessors were blinded (NR) |
| Carapeti 2000[64](#_ENREF_64) | Topical phenylephrine | Moderate | Low risk of selection bias. Patients and providers blinded; unclear if outcome assessors blinded. Co-intervention (loperamide) allowed in 42% of patients throughout study; attrition unclear (tables do not show number assessed and LTF NR ) |
| Carapeti 2000[62](#_ENREF_62) | Topical phenylephrine- ileoanal pouch | High | Limited baseline data (in text); patients and providers blinded; blinding of outcome assessors NR; primary outcome NR. Low risk of selection bias. Only period 1 data of crossover were analyzed (washout period may have been insufficient). Cointervention (loperamide) used by 2/3 of sample throughout study. |
| Sun 1997[27](#_ENREF_27) | Loperamide | High | No baseline data, not all outcomes reported and no justification for why FI counts NR; no details on blinding, allocation concealment, or blinding of outcome assessors |
| Hallgren 1994[14](#_ENREF_14) | Loperamide | Moderate | Limited baseline information (age, sex in text); no baseline values of outcomes, no details on allocation concealment, or blinding of outcome assessors |
| Read 1982[30](#_ENREF_30) | Loperamide | Moderate | Reported as double blind but no information on randomization mechanism; allocation concealment unclear. No baseline data on outcomes; primary outcome NR. |
| Palmer 1980[22](#_ENREF_22) | Mixed antidiarrheals | High | No baseline data except etiology; noncompleters excluded from analysis (17%); No information on randomization mechanism; blinding and allocation concealment NR; Primary outcome not specified. |
| Bharucha 2014[53](#_ENREF_53) | Clonidine | Low | Blinded study, random allocation, low attrition, ITT analysis with methods for missing data, validated outcome measures, all outcomes are reported at 4 weeks. |
| Pinedo 2012[39](#_ENREF_39) | Zinc-aluminum ointment | Moderate | Unclear risk of bias in several domains due to unclear reporting. Between and within group completer analysis. Needed 48, analyzed 44. |
| Pinedo 2009[42](#_ENREF_42) | Topical estrogen | Moderate | Double blind stated; NR if outcome assessors were blinded. Randomization method NR. Low attrition; excluded data from 1 placebo pt. who did not complete therapy. All outcomes reported |
| Kusunoki 1990[25](#_ENREF_25) | Sodium valproate | Moderate | Random order assignment but method not specified. No information on allocation concealment, or whether anyone was blinded. Limited sample, baseline information reported. Primary outcome not specified. |
| Damon 2014[37](#_ENREF_37) | PFMT-BF | High | Patients lost to followup were excluded from the analysis. Groups unbalanced at baseline for important prognostic factor (history of anorectal surgery). Inadequate randomization detail, allocation NR. Patient and provider blinding not possible. |
| Norton 2003[33](#_ENREF_33) | PFMT-BF | Moderate | Low risk of selection bias: randomization and allocation concealment acceptable. Blinding of patients and providers not possible. Attrition 18% overall and differed by group (some over 20%); reasons for withdrawal vague. Implications of LTF not discussed. ITT. |
| Heymen 2009[15](#_ENREF_15) | PFMT-BF | Moderate | No allocation concealment, providers not blinded. Run-in period followed randomization, then treatment failures at run-in commenced interventions with imbalance in group size; baseline considered end of run in and comparability at that point was NR. Attrition 23%. |
| Whitehead 1985[56](#_ENREF_56) | PFMT-BF | High | Unclear risk of selection bias (randomization and allocation not reported, group comparisons at baseline not reported); no blinding of patients, providers or outcomes assessors, intervention details not described; cointerventions NR, attrition NR. |
| Ilnyckyj 2005[55](#_ENREF_55) | PFMT-BF | High | Selection bias: unclear risk (randomization and allocation not reported, group comparisons at baseline NR). LTF 22% and no mention of implication of LTF or how missing data handled. No blinding of patients, providers or outcomes assessors. |
| Bols 2012[66](#_ENREF_66) | PFMT-BF | Moderate | Low risk of selection bias. Patients and providers not blinded; outcome assessors blinded. Multiple providers. High risk of detection bias (followup varied, very underpowered before attrition). ITT. |
| Solomon 2003[59](#_ENREF_59) | PFMT-BF | High | Provider and patients not blinded to treatment, cointerventions (patients on BF continued previous treatments); handling of missing data NR, analysis of completers likely. |
| Bartlett 2011[26](#_ENREF_26) | PFMT-BF exercise | High | Groups unbalanced at baseline for important prognostic factor (history of bowel surgery for cancer). Patients blinded but providers and outcomes assessors not blinded. Only 73% of participants analyzed at 2 yr. Randomization and allocation concealment acceptable. |
| Schwandner 2011[19](#_ENREF_19) | PFMT-BF electrostimulation | Moderate | Providers and patients not blinded; outcome assessors blinded. LTF 11% (reasons for withdrawal vague), select outcomes reported |
| Schwandner 2010[41](#_ENREF_41) | PFMT-BF electrostimulation | High | Patients who deteriorated were combined with drop outs and no change pts. in analysis; percent who deteriorated were not separately identified. Patients and providers not blinded; outcome assessors blinded. Attrition 61%. |
| Naimey 2007[45](#_ENREF_45) | PFMT-BF with electrostimulation | Moderate | No baseline characteristics table; no blinding of providers, patients or outcomes assessors. LTF 18%, no mention of how LTF or missing handled. Analysis not ITT. |
| Mahoney 2004[48](#_ENREF_48) | PFMT-BF with electrostimulation | Moderate | Completer analysis. Pts not blinded, providers blinded, outcomes assessors not blinded; adequate randomization and allocation concealment |
| Fynes 1999[61](#_ENREF_61) | PFMT-BF with electrostimulation | High | No baseline data, group comparisons at baseline NR, blinding not possible, multiple providers. |
| Norton 2006[63](#_ENREF_63) | Electrostimulation | Moderate | Poor treatment fidelity; patients, providers and outcomes assessors were unblinded; lacks baseline characteristics by group; attrition 23% |
| Healy 2006[46](#_ENREF_46) | Electrostimulation | High | Analyzed completers only. Aim was a care site comparison but treatments also differed by group (duration & protocol). Limited baseline characteristics reported. Attrition 17% |
| Christensen 2006[18](#_ENREF_18) | Transanal irrigation | Moderate | Randomization & allocation low risk; blinding of patients not possible. Weekly interviewer blinded. Cointerventions allowed as needed. ITT. LTF reported overall and by group. Handling of missing data acceptable. No correction for multiple testing. More pts in wheelchairs in control group. |
| Coggrave 2010[52](#_ENREF_52) | Stepwise bowel management intervention | High | Low risk of selection bias. Blinding not possible. High (35%) overall attrition and unequal by group (attrition higher in treatment group), poor treatment fidelity |
| Schnelle 2010[17](#_ENREF_17) | Exercise plus diet | High | FI outcome difficult to analyze: 45% of residents did not have a bowel movement during baseline or 10 days post-intervention. Difference between groups at baseline on some important factors. No blinding of patients or providers but validity checks done. Multi-component intervention and multi-center. |
| Schnelle 2002[16](#_ENREF_16) | Exercise plus incontinence care | High | Low risk of selection bias. Noncompleters dropped from analysis; impact of LTF discussed. High attrition, blinding of patients not possible. FI outcomes not presented for 2 months, only 8 months. Primary outcome not specified |
| Thin 2015[36](#_ENREF_36) | PTNS | Moderate | Low risk of selection bias. Adequate randomization, blinded (providers and assessors). Patient blinding not possible. Groups differed at baseline on important variables (prior/ongoing treatments including pad use, antidiarrheal drugs and biofeedback; evacuatory difficulties; FI etiology). No significance testing conducted; no between-group analyses. Small sample size; excluded post-randomization data on 23% of sample. |
| Dehli 2013[65](#_ENREF_65) | Dextranomer injections | Low  (to 6 mo) | Low attrition for 6 month analysis. Random allocation and blinded to the extent they were able. PFMT/BF intervention poorly described. ITT analysis with methods for missing data provided. Dismissed 44% of sample at 6 mo. for observational study. |
| Graf 2011[40](#_ENREF_40) | Dextranomer injections | Low  (to 6 mo) | Adequate randomization, blinded (patients and assessors) up to 6 mo, low attrition to 6 mo, sham group had nothing injected (unclear if pts could tell that nothing was injected); Multicenter and multiple providers |
| Morris 2013[38](#_ENREF_38) | Durasphere injections | Low | Adequate randomization, blinding, allocation concealment; low attrition, sufficient description of treatments, underpowered study (because trial stopped early), lacks demographic information |
| Tjandra 2009[43](#_ENREF_43) | Durasphere injections | Low | Adequate randomization, allocation concealment; no details on blinding of outcome assessors and not possible to blind surgeons; sufficient description of treatments. No attrition. |
| Davis 2004[47](#_ENREF_47) | Surgery | High | Blinding of patients not possible, limited sample information, unclear reporting (Fig. 1 participant flow does not account for all lost-to-follow-up; unclear if excluded adults differed on FI severity, etc.). Excluded post-randomization data on 18% of sample. |
| Hasegewa 2000[50](#_ENREF_50) | Surgery | High | Randomized but no details on method of randomization or allocation concealment. Unclear whether patients and outcome assessors were blinded; blinding not possible for surgeons. Followup varied (no defined assessment point). No baseline table, limited demographic information in text only; no information on co-interventions. |
| O’Brien 2004[49](#_ENREF_49) | Surgery | High | Blinding not possible; no information on outcome assessor blinding; sparse detail on comparator, no information on co-interventions. Excluded patient failed treatment and required colostomy from analysis. Limited demographic information. |
| Yoshioka 1999[21](#_ENREF_21) | Surgery | Moderate | No information on blinding of patients or outcomes assessors. Multiple descriptions of followup duration. Primary outcome not specified. Surgeons had limited experience with control surgery. No statistical comparison of between group differences at any time point for any outcome. |
| Osterberg 2004[29](#_ENREF_29) | Surgery | High | Non-completers excluded from analysis (16%). LTF differed by group (13% vs. 25% anal plug). Blinding of patients and providers not possible; blinding of outcomes assessors NR. No information on co-interventions, primary outcome not specified |
| van Tets 1998[34](#_ENREF_34) | Surgery | Moderate | Unclear if patients or outcome assessors were blinded. Primary outcome not specified. Multiple descriptions of followup duration (1.5-5 years) but outcomes reportedly assessed at 3 months. No statistical comparison of patient reported outcome measure, no information on allocation concealment, no information on co-interventions |
| Deen 1993[51](#_ENREF_51) | Surgery | High | No information on allocation concealment, no information on co-interventions, primary outcome not specified, FI frequency not reported at 6mo. and other data (FI severity) not usable. |
| Duelund-Jakobsen 2013[31](#_ENREF_31) | SNS | Moderate | Patients blinded; NR if outcomes assessors were blinded. Limited baseline sample information. No adjustment for multiple comparisons. LTF not clearly stated and sample size (denominators) not reported in results tables. Primary outcome NR. |
| Duelund-Jakobsen 2012[23](#_ENREF_23) | SNS | High | Randomization NR only allocation concealment; sparse demographic/sample baseline data (in text). Unclear if outcome assessors blinded. Cointerventions NR. Unblinded after 12 wks and followed only part of the sample. |
| Tjandra 2008[44](#_ENREF_44) | SNS | Moderate | Patient and provider blinding not possible, primary provider assessed outcomes. Outcomes only partially reported. Randomization and allocation concealment adequate. |
| Michelsen 2008[24](#_ENREF_24) | SNS | High | No baseline values reported for any measure; crossover RCT but no washout period; excluded data from drop-out. Blinding of outcome assessors NR; not possible to blind patients or providers. |
| Leroi 2005[28](#_ENREF_28) | SNS | High | Few details on randomization, primary outcome unclear. Patients blinded. Selective reporting: not all outcomes collected were reported; unclear what statistical comparisons being made, no adjustment for multiple comparisons. LTF dropped from analysis (13%) |

+/-=with or without; BF=biofeedback; FI=fecal incontinence; ITT=intention to treat analysis; LTF=lost to followup; mo=months; NR=not reported; PFMT=Pelvic floor muscle training; PTNS=percutaneous tibial nerve stimulation; Pts=patients; SNS=sacral neurostimulation