**Appendix Table E4. Included studies for FMT nonstandard treatments**

| **Author, Year, Country, Design,**  **Funding Source** | **Population, Age, % Women, Race/ethnicity** | **Sample Size, Intervention(s),**  **Control(s), Study Duration** | **Outcomes** | **Harms** |
| --- | --- | --- | --- | --- |
| ***Newly identified studies*** |  |  |  |  |
| Cammarota, 2015[44](#_ENREF_44)  Italy  Open-label RCT  University | Adults with recurrent CDI (diarrhea [≥3 loose or watery stools per day ≥2 consecutive days, or ≥8 loose stools in 48 hours] and positive CD toxin stool test within 10 weeks of antibiotic treatment), mean age 73, 59% women, race/ethnicity NR | 39 FMT:  20 FMT (14 with one infusion of FMT, 6 with >1 infusion) and vancomycin (125 mg four times a day for 3 days); 19 vancomycin only (125 mg four times daily for 10 days, followed by 125–500 mg/day every 2–3 days for ≥3 weeks)  Followup: 10 weeks after the end of treatments | Resolution of diarrhea, adverse events | No significant adverse events in either group |
| Satokari, 2015[45](#_ENREF_45)  Finland  Retrospective review  University, foundation | Adults with recurrent CDI (laboratory-confirmed CDI [positive culture and toxin] despite antimicrobial treatment), mean age 56 (range 20-88), 69% women, race/ethnicity NR | 49 FMT (n=23 freeze-stored, n=26 fresh)  Followup: 12 weeks (n=49) or 1 year (n=42) | Resolution of diarrhea or symptoms, recurrence, death, adverse events | No serious adverse events, mild transient fever (n=2) after freeze-stored FMT |
| Zainah, 2015[46](#_ENREF_46)  United States  Retrospective review  Funding NR | Adults hospitalized with severe refractory CDI (severe: endoscopic evidence of pseudomembranous colitis, treatment in the ICU for CDI, or ≥2 of: age >60 years, serum albumin <2.5 mg/dL, temperature >38.3C, WBC count >15,000 cell/mL within 48 hours of CDI diagnosis; refractory: non-resolution of CDI despite 7 days of therapy with oral vancomycin with or without IV metronidazole), mean age 73, 64% women, race/ethnicity NR | 14 FMT  Followup: 100 days | Resolution of diarrhea, recurrence, death | NR |
| Dutta, 2014[47](#_ENREF_47)  United States  Prospective  Health organization, University | Adults aged 18-90 with recurrent CDI (≥2 laboratory-confirmed relapses of CDI after antimicrobial treatment), mean age 65 (range 18-89), 82% women, 74% white, 22% black, 4% Asian | 27 FMT  Followup: mean 21 months (range 10–34) | Resolution of diarrhea or symptoms, CDI, adverse events | Low-grade fever (n=5, 19%), bloating (n=3, 11%), both of which resolved spontaneously within 12–24 hours |
| Khan, 2014[48](#_ENREF_48)  United States  Retrospective review  Funding NR | Adults with recurrent CDI (1-3 courses of metronidazole and/or vancomycin before FMT), mean age 65, 89% women, race/ethnicity NR | 20 FMT  Followup: 6 months | Resolution of diarrhea, recurrence, adverse events, patient satisfaction | None |
| Lee, 2014[49](#_ENREF_49)  Canada  Retrospective review  University | Adults with refractory or recurrent CDI (refractory: ongoing diarrhea despite ≥5 days oral vancomycin ≥125 mg 4 times/d; recurrent: symptom resolution ≥2 days after treatment discontinuation with recurrence of diarrhea), mean age 72, 56% women, race/ethnicity NR, 74.5% hospitalized | 94 FMT  Followup: 6-24 months | Resolution of diarrhea, recurrence, death, adverse events | Transient constipation and excess flatulence (10%) |
| Ray, 2014[50](#_ENREF_50)  Retrospective review  Funding NR | Adults with recurrent or severe CDI (≥2 recurrences [>3 loose stools a day or positive CD stool sample after antibiotics] or life-threatening illness from CDI requiring hospitalization and/or ICU admission), mean age 62 (range 27-89), 80% women, race/ethnicity NR | 20 FMT:  16 recurrent  3 severe/complicated  1 severe  Followup: mean 3 months (range 0-10) | Resolution of diarrhea or symptoms, recurrence, adverse events | Abdominal cramping, bloating, flatulence, nausea that resolved (n=5, 25%) |
| Seekatz, 2014[51](#_ENREF_51)  United States  Prospective  Government, foundation | Adults with recurrent CDI (≥2 laboratory-confirmed relapses and failure of standard antibiotics), mean age NR, gender NR, race/ethnicity NR | 14 FMT  Followup: 6 months | Resolution of diarrhea or symptoms, CDI recurrence, adverse events | NR |
| Weingarden, 2014[52](#_ENREF_52)  United States  Case series  Government, university | Adults with recurrent CDI (3-9 episodes of CDI and failure of multiple rounds of antibiotics), median age 62 (range 29-87), 83% women, race/ethnicity NR | 12 FMT  Followup: 1 year+ | Resolution of diarrhea or symptoms, CDI, recurrence | NR |
| Youngster 2014[53](#_ENREF_53)  United Sates  Open-label feasibility study  Health organization | Adults with recurrent CDI (≥3 mild to moderate episodes and failure of a 6- to 8-week taper with vancomycin with or without an alternative antibiotic, or ≥2 severe episodes resulting in hospitalization and associated with significant morbidity), median age 65, 45% women, race/ethnicity NR | 20 FMT (capsules):  16 recurrent  4 refractory  Followup: 6 months | Resolution of diarrhea or symptoms, adverse events | No serious adverse events deemed treatment-related; abdominal cramping and bloating (n=4, 20%) |
| Youngster 2014[54](#_ENREF_54)  United States  Open-label RCT  Government, university | People aged 7-90 with recurrent or refractory CDI (≥3 mild to moderate episodes and failure of a 6- to 8-week taper with vancomycin with or without an alternative antibiotic, or ≥2 severe episodes resulting in hospitalization and associated with significant morbidity), mean age 54 (range 7-90; 3 children), 55% women, race/ethnicity NR | 20 FMT:  10 colonoscopic,  10 nasogastric  Followup: 8 weeks (n=20), 6 months (n=15) | Resolution of diarrhea without relapse within 8 weeks, adverse events | No serious adverse events; abdominal cramping and bloating (n=6, 30%), which resolved within 72 hours |
| Emanuelsson, 2014[55](#_ENREF_55)  Sweden  Retrospective review  No funding | Adults with recurrent CDI (failure of repeated courses of antibiotics), median age 69, 61% female, race/ethnicity NR | 23 FMT  Followup: median 18 months (range 0-201) | Resolution of diarrhea and symptoms, adverse events | No significant adverse events on the day of microbiota infusion |
| Patel, 2013[56](#_ENREF_56)  United States  Retrospective review  Funding NR | Adults with recurrent CDI (≥2 documented episodes of CDI, failure of antibiotics and ongoing diarrhea [≥3 unformed stools per day] in the absence of antibiotics), mean age 61, 55% women, race/ethnicity NR | 31 FMT  Followup: 1 week and 1 month (n=30), 3 months (n=23), 1 year (n=6) | Resolution of diarrhea or symptoms, recurrence, death, adverse events | No serious adverse events; microperforation caused by a biopsy during the FMT procedure (n=1) |
| Pathak, 2014[57](#_ENREF_57)  United States  Retrospective review  Funding NR | Adults with recurrent CDI (≥3 episodes and failure of vancomycin with or without an additional antibiotic; some cases severe but details NR), age range 37-92, 67% women, race/ethnicity NR | 12 FMT followed by 2 months of *S. boulardii*  Followup: range 2-30 months | Resolution of diarrhea or symptoms | NR |
| Rubin, 2013[58](#_ENREF_58)  United States  Retrospective review  Health organization | Adults with recurrent CDI (initial laboratory-confirmed diagnosis of CDI and ≥2 laboratory-confirmed recurrences following standard antibiotics), mean age 63, 65% women, race/ethnicity NR | 74 FMT  Followup: 60 days | Resolution of diarrhea, recurrence, adverse events | None |
| van Nood, 2013[59](#_ENREF_59)  The Netherlands  Open-label randomized trial  Government | Adults with recurrent CDI (recurrence with positive stool test for CD toxin following at least one adequate course of treatment), mean age 70, 43% women, race/ethnicity NR | 43 randomized  17 vancomycin (500 mg 4 times/day for 4 days), bowel lavage, FMT  13 vancomycin, bowel lavage  13 vancomycin  Followup: 10 weeks | Resolution of diarrhea, CDI, adverse events | No serious adverse events; immediately after procedure, resolved within 3 hours: diarrhea (94%), cramping (31%), belching (19%); during followup: constipation (19%) |
| Hamilton, 2012[60](#_ENREF_60)  United States  Case series  Foundation, government | Adults with recurrent CDI (history of toxin-positive CDI and ≥2 documented recurrences despite standard antibiotics), mean age 59, 72% women, race/ethnicity NR | 43 FMT  Followup: NR | Resolution of diarrhea, CDI (not tested if asymptomatic), recurrence, adverse events | No serious adverse events; irregularity of bowel movements and excessive flatulence (approximately one third of patients), which resolved |
| Jorup-Ronstrom, 2012[61](#_ENREF_61)  Sweden  Case series  Funding NR | Adults with recurrent CDI (≥3 relapses and failure of multiple courses of antibiotics) median age 75 (range 27-94), 62.5% women, race/ethnicity NR | 32 FMT (cultured for 10 years)  Followup: median 26 months (range 1-68) | Cure (“if no relapse occurred”), improvement, recurrence, adverse events | None |
| Kelly, 2012[62](#_ENREF_62)  United States  Case series  Funding NR | Adults with recurrent CDI (≥3 relapses and failure of multiple courses of antibiotics), mean age 59 (range 19-86) 92% women, 100% white | 26 FMT  Followup: mean 11 months (range 2-30) | Resolution of diarrhea, CDI, recurrence | NR |
| Mattila, 2012[63](#_ENREF_63)  Finland  Retrospective review  Foundation | Adults with recurrent CDI (laboratory-confirmed recurrence [positive culture and toxin] despite antimicrobial treatment), mean age 73 (range 22-90), 60% women, race/ethnicity NR | 70 FMT  Followup: 12 weeks and 1 year | Resolution of symptoms, recurrence, death, adverse events | No serious adverse events |
| Mellow, 2011[64](#_ENREF_64)  United States Case Series  Funding NR | Adults with recurrent (≥3 episodes, n=12) or refractory (not defined, n=1) CDI, mean age 67 (range 32-87), 46% women, race/ethnicity NR | 13 FMT  Followup: mean 5 months (range 3-24) | Resolution of diarrhea, recurrence, stool test for CDI (n=10), death | NR |
| Garborg, 2010[65](#_ENREF_65)  Norway  Retrospective review  Funding NR | Adults with recurrent CDI (failure of ≥2 courses of antibiotics; n=37 laboratory-confirmed, n=3 toxin negative), mean age 75 (range 53-94), 53% women, race/ethnicity NR | 40 FMT  Followup: 80 days (no systematic followup) | Resolution of diarrhea, adverse events | None |
| Aas, 2003[66](#_ENREF_66)  United States  Retrospective review  Health organization | Adults with recurrent CDI (≥2 laboratory-confirmed relapses following antibiotics), mean age 73 (range 51–88), 72% women, race/ethnicity NR | 18 FMT  Followup: 90 days | Resolution of diarrhea, stool test for CDI (n=14), recurrence, death, adverse events | None |
| ***Previously identified studies*** |  |  |  |  |
| Rohlke, 2010[67](#_ENREF_67)  United States  Retrospective review  No funding | Adults with recurrent CDI (CD toxin positivity and consistently recurring symptoms over ≥6 months, despite ≥3 courses of traditional treatments, including pulsed and tapered vancomycin), mean age 49, 89% women, race/ethnicity NR | 19 FMT  Followup: mean 27 months (range 6-65) | Resolution of symptoms, recurrence | NR |
| Yoon, 2010[68](#_ENREF_68)  United States  Case series  No funding | Adults with recurrent CDI (documented CD toxin-positive diarrhea and documented recurrence despite standard antibiotics), mean age 66 (range 30-86), 75% women, race/ethnicity NR | 12 FMT  Followup: range 3 weeks to 8 years | Resolution of symptoms, adverse events | None |
| MacConnachie, 2009[69](#_ENREF_69)  United Kingdom  Retrospective review  Funding NR | Adults with recurrent CDI (recurrence of loose stool following antibiotic treatment for toxin positive CDI), mean age 82 (range 68-95), 93% women, race/ethnicity NR | 15 FMT  Followup: median 16 weeks (range 4-24) | Resolution of symptoms, adverse events | No adverse events related to FMT |

CD=*C. difficile*; CDI=*C. difficile* infection; FMT=fecal microbiota transplant; ICU=intensive care unit; NR=not reported; WBC=white blood cell