

Future developments and new technologies in the field of faecal incontinence – scanning the horizon

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Appendix 1: Search terms for pipeline trials on faecal incontinence

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Appendix 1: Search terms for pipeline trials on faecal incontinence

The following search terms were used in NIHR Innovation Observatory's 'ScanMedicine' database (<https://www.scanmedicine.io/>). The search was conducted in August 2020.

(fecal incontinence) OR (defecation disorder) OR (encopresis) OR (soiling) OR (stool incontinence) OR (incontinent of stools) OR (leaking faeces) OR (faecal leakage) OR (stool leakage) OR (leakage of motions) OR (faecal soiling) OR (faecal urgency) OR (stool urgency) OR (faecal frequency) OR (hypotonic sphincter) OR (hypotonic anal sphincter) OR (pelvic dyssynergia) OR (faecal leakage) OR (faecal seepage) OR (faecal loss) OR (stool seepage) OR (leaking stools) OR (seepage of motions) OR (leaking of motions) OR (urgent defaecation) OR (frequent defaecation) OR (neurogenic bowel) OR (faecal continence) OR (stool continence) OR (anal continence) OR (anus continence) OR (bowel continence) OR (alvi continence) OR (alvi incontinence) OR (defecation urgency) OR (incontinence of wind) OR (incontinence of flatus)

Note on search terms: the interface works with natural language terms. Alternative spellings, for example, 'faecal' or 'fecal' were not needed as the interface allowed for alternative spellings. The interface did not work with truncation or adjacency and instead mapped alternative endings and word orders.

The following search limits were applied:

Enrolment year \geq 2015

Registries limited to: Brazil, Peru, USA, EU, AUSNZ, UK, India, Japan, South Korea, Thailand, and Sri Lanka

Trial recruitment status: excluding trials that were Suspended, Terminated, Withdrawn, or had an Unknown trial status

Appendix 2: Inclusion/exclusion criteria

Articles were excluded as ‘wrong outcome’ if they contained outcomes that didn’t relate to FI.

Articles were excluded as ‘out of CI scope’ if they related to FI but were within the remit of another Cochrane group (e.g., Pregnancy and Childbirth).

| Include | Exclude | Reason for exclusion |
|--|---|---|
| Constipation in elderly, children or neurogenic conditions, or any other population that cycles between constipation and FI | Constipation in adults, (without reference to cycling between constipation and FI), broad reviews, laxative prescribing or general reviews, during pregnancy | Constipation during pregnancy falls under the remit of Cochrane Pregnancy and Childbirth |
| LARS – with mention of treating the FI aspect of the syndrome that happens after LAR (keep as special batch) (LAR is covered by another group – they do not currently cover LARS but check with that Cochrane group?) | LARS – reconstruction techniques (anastomosis) or other surgeries and other alternative resection or re-joining of bowel. | Covered by other Cochrane group(s) |
| Dermatitis - Incontinence associated | Dermatitis - diaper wearing of infants or neonates | Falls in the remit of another Cochrane Skin group |
| Episiotomies – treatment of long-term consequence if covers FI | Episiotomies – techniques and whether or not to do them | Falls in the remit of another Cochrane group |
| Repair of anal tears in the postpartum period is not included but treatment of long-term consequences as regards FI are included | Repair of anal tears postpartum | Falls under the remit of a different Cochrane group unless it is treatment of long-term consequences or repair beyond the postpartum period |
| Obesity – weight loss to prevent/treat FI | Obesity | This should be included if looking at weight loss to prevent or treat FI – if looking at other aspects of obesity not included |
| Diagnosis – RCTs or diagnostic test accuracy | Aetiology of FI | Not within the scope of this project |

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|---|---|---|
| Guidelines (NICE) - If they include systematic review | Economics | Outside the scope of this priority setting exercise |
| Recommendations - If they include systematic review | Commentary type papers | Not relevant |
| | Epidemiology – prevalence/incidence/burden of disease | Not within the scope of this project |
| | Comparative reviews looking at something else where FI is an outcome (e.g. surgery A vs Surgery B for rectal anal cancer or Radiotherapy) | The topics are covered by other Cochrane groups |
| | QoL where looking at measuring or development of the scales | Not directly relevant |
| Autism Spectrum Disorder (ASD) if related to prevention/treatment of FI in this population | | |
| Stroke - Include if looking at prevention or treatment of FI in stroke patients – if looking at other aspects of stroke then it is not included | | |
| Neurological conditions where the main focus seemed to be FI or related issues (spinal cord injury, multiple sclerosis) | | |
| Neurogenic bowel | | |
| Spinal cord injury - if looking at FI | | |
| Multiple sclerosis - if looking at FI | | |
| Cauda equine/tethered cord – if FI was one of the main topics | | |
| Cancer - If looking at longer term consequences of cancer treatment once cancer has resolved | Bowel prep surgery (e.g. for cancer treatment) | Covered by other Cochrane groups |

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|--|---|---|
| | Screening for cancers – most commonly bowel cancer | Covered by other Cochrane groups |
| | Ovarian cancer | Covered by other Cochrane groups |
| | Prostate cancer | Covered by other Cochrane groups |
| | Anal or Rectal or bowel or colorectal cancer | Covered by other Cochrane groups |
| Pregnancy / Postpartum Complications that include FI or FI affecting sexual function | Comparing obstetric practices | Covered by Cochrane Pregnancy and Childbirth group (we do cover prevention and treatment of FI using physical therapies pre/postpartum) |
| Rectovaginal fistula | Obstetric anal sphincter injury (OASIS) | Falls under the remit of Cochrane Pregnancy and Childbirth |
| | Crohn's disease, Diverticulitis, IBS/IBD, Ulcerative colitis, Diarrhoea | Covered by Cochrane Incontinence but different topic area or covered by Cochrane group(s) |
| | Haemorrhoids | Covered by another Cochrane group |
| | Fistula in ano / anal fissure | Covered by another Cochrane group |
| | Pouches, colostomies, stomas or anastomoses | Covered by other Cochrane groups |
| | Rectal prolapse/rectocele | A different part of our scope |
| | Anastomotic leakage or leakage related to stomas or colostomies, | Covered by other Cochrane groups |
| | Bladder surgery/neobladders/cystoplasty/Urinary diversion | Not within the scope of this project – partly covered by another of our reviews |
| | Urinary incontinence (with no mention of FI or 'double incontinence') | Covered by a different part of our group's scope |
| | Pelvic organ prolapse | Covered by a different part of our group's scope (includes posterior vaginal wall prolapse) |
| Frail elderly syndrome | Congenital malformations | Not within the scope of Cochrane Incontinence |

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|--|--|-----------------------------------|
| Lifestyle interventions – weight loss and other lifestyle interventions for prevent/treat FI | Surgery to correct congenital defects and/or malformations | Covered by other Cochrane groups |
| Pelvic floor exercises and other interventions to try to prevent and treat FI during and after pregnancy as well as longer term. We do cover long term effects of birth injuries as regards FI. | Hirschsprung's disease | Covered by another Cochrane group |
| Weight loss - treatment or prevention of FI | | |
| Encopresis | | |
| Specific mention of treatment, prevention, management, diagnostic test accuracy for, FI (with or without constipation) (with or without urinary incontinence) then it is a very definite include | | |

Appendix 3: Faecal incontinence domains

Bowel management

- General
- Assistive techniques
- Bowel habit/retraining
- Complementary therapies
- Dietary management
- Education
- Electrical stimulation
- Lifestyle
- Magnetic stimulation
- Pelvic floor muscle training/ biofeedback/ sphincter exercises
- Physiotherapy
- Psychological/ behavioural/ urgency suppression techniques
- Self-management
- Volumetric/breathing exercises
- Weight management

Bowel management for neurological conditions

- Anticholinesterase plus an anticholinergic drug
- Assistive techniques
- Bowel programmes/ bowel care
- Devices
- Electrical stimulation
- Fibre
- Physiotherapy
- Surgery

Bowel and bladder dysfunction

- Bladder pain syndrome
- Constipation (including in children)
- FI and delayed toilet training as a result of chronic constipation

- FI in children
- Link between constipation and urinary incontinence
- Urinary and/or FI

Drugs

- General
- Anti-diarrhoeal agents
- Botulinum toxin type A
- Clonidine
- Drugs acting on anal sphincter tone
- Enemas
- Fibre
- Laxatives
- Oestrogen therapy
- Pipeline drugs
- Repurposed drugs
- Stool-forming agents
- suppositories

Surgery

- General
- Antegrade irrigation
- Artificial anal sphincter
- Bariatric surgery
- Dynamic graciloplasty
- Gluteoplasty
- Injectable bulking agents
- levatorplasty (anterior) - repairing the pelvic floor
- Magnetic sphincter formation
- Microballoons
- Muscle transposition
- New surgical procedures
- Ostomies (colostomy and ileostomy)

- Post anal repair
- Posterior tibial nerve stimulation
- Radiofrequency
- Repair of posterior compartment prolapse
- Repair of rectal prolapse
- Sacral nerve stimulation (implanted)
- Slings
- Sphincteroplasty
- Sphincter repair
- Stem cells
- Total pelvic floor repair (TPFR)

Models of care

- Clinical pathway to diagnosis
- Evidence-based practice
- General - models of care
- GP
- Nurse led
- Transition of care

Mechanical devices

- Absorbent products
- Anal plugs
- Anal pouch
- Commodes
- Inserts (including vaginal inserts)
- Managing condition
- New devices (e.g. intra-rectal diversion devices)
- Rectal catheters (used for critically-ill patients)
- Rectal trumpet (off-label use)
- Vaginal-bowel devices

Other containment/ non-active/ other in non-neurogenic patients

- Toileting assistance programmes
- Trans-anal irrigation

Interventions in particular settings

- Acute care settings
- Bowel management in low-resource settings
- Improvements to physical environment
- Products for odour and sounds
- Toileting assistance programmes
- Wireless technology monitoring wetness sensors - nursing home

Interventions in particular populations

- Diabetes and FI
- Management of FI for cancer patients
- Post-menopausal women
- Pregnant/post-partum women

Other

- Compliance
- Dermatitis
- Diagnostic tools
- Financial support
- Microbial transplant
- Pressure sores
- Psychological support
- Qualitative research/ mixed methods/ lived experiences
- Quality of life
- Technology
- Treatments that are not pharmaceuticals or naturopathic
- Unsure

Out of scope

- Disposal of products
- Mechanisms and causes
- Prevalence
- Prevention of FI

Appendix 4: References identified through horizon scanning subsequently excluded

Detailed below are the clinical trials references identified through horizon scanning searches subsequently excluded. Exclusion was for one of the following reasons indicated in order of hierarchical importance:

| | |
|--|----------|
| Records removed after filtration by trial status (n=52) | 1-52 |
| Records excluded based on primary health condition studied (n=863) | 53-915 |
| Study's exclusion criteria included FI (n=4) | 916-919 |
| Healthy subjects (n=2) | 920, 921 |
| Questionnaire, screening and tool assessment validation (n=7) | 922-928 |
| Not relevant/within the scope (n=9) | 929-937 |

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- 2 ISRCTN Registry. A study investigating a continuous local anaesthetic infusion for pain relief after pelvic tumour surgery. Trial ID: ISRCTN60374925. 2015. Status: Stopped. Available from: <http://www.isrctn.com/ISRCTN60374925> [Accessed 11 August 2020].
- 3 Clinicaltrials.gov. Efficacy and Safety of Polyethylene Glycol 3350 (PEG 3350) for Relief of Constipation (MK-8114-005). Trial ID: NCT02292459. 2014. Status: Withdrawn. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02292459> [Accessed 11 August 2020].
- 4 Clinicaltrials.gov. Surgery With or Without Postoperative Intensity Modulated Radiation Therapy in Treating Patients With Urothelial Bladder Cancer. Trial ID: NCT02316548. 2014. Status: Terminated. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02316548> [Accessed 11 August 2020].
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- 7 Clinicaltrials.gov. Sacral Neuromodulation in Dual Incontinence: Ultrasound and Afferent Nerve Sensation Assessment (SaNDI). Trial ID: NCT02357784. 2015. Status: Suspended. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02357784> [Accessed 11 August 2020].
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- 11 Clinicaltrials.gov. The Influence of Probiotics on Body Weight and Composition (WLP). Trial ID: NCT02465294. 2015. Status: Withdrawn. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02465294> [Accessed 11 August 2020].
- 12 Clinicaltrials.gov. Comparison of Wash Wipes and Standard Care in the Prevention of Incontinence-associated Dermatitis in Elderly. Trial ID: NCT02475512. 2015. Status: Terminated. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02475512> [Accessed 11 August 2020].
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- 15 Clinicaltrials.gov. Talazoparib in Treating Patients With Advanced or Metastatic Solid Tumors That Cannot Be Removed by Surgery and Liver or Kidney Dysfunction. Trial ID: NCT02567396. 2015. Status: Withdrawn. Available from: <https://clinicaltrials.gov/ct2/show/record/NCT02567396> [Accessed 11 August 2020].
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Appendix 5: Included trials

| Parent code | Child code | n | References |
|---|--|----|---|
| Bowel management | | | |
| | General | | |
| | Assistive techniques | 5 | 145-149 |
| | Bowel habit/retraining | | |
| | Complementary therapies | 17 | 82-89,91-98,100 |
| | Dietary management | 4 | 152-155 |
| | Education | 6 | 158-163 |
| | Electrical stimulation | 13 | 91,99-103,105-111 |
| | Lifestyle | 9 | 153,159,161,162,174-178 |
| | Magnetic stimulation | 3 | 99,179,180 |
| | Pelvic floor muscle training/ biofeedback/ sphincter exercises | 13 | 96,101,103,113-122 |
| | Physiotherapy | 2 | 186,187 |
| | Psychological/ behavioural/ urgency suppression techniques | 3 | 145,159,162 |
| | Self-management | 4 | 145,158,159,162 |
| | Volumetric/breathing exercises | 0 | |
| | Weight management | 0 | |
| Bowel management for neurological conditions | | | |
| | Anticholinesterase plus an anticholinergic drug | 1 | 189 |
| | Assistive techniques | 2 | 193,194 |
| | Bowel programmes/ bowel care | 1 | 195 |
| | Devices | 0 | |
| | Electrical stimulation | 2 | 196,197 |
| | Fibre | 0 | |
| | Physiotherapy | 5 | 178,198-201 |
| | Surgery | 5 | 104,131,133,202,203 |
| Bowel and bladder dysfunction | | | |
| | Bladder pain syndrome | 0 | |
| | Constipation (including in children) | 27 | 82,125,158,206-215 84-87,89,93,94,97,98,102,216-220 |

| | | | |
|----------------|--|----|--------------------------------|
| | FI and delayed toilet training as a result of chronic constipation | 0 | |
| | FI in children | 0 | |
| | Link between constipation and urinary incontinence | 0 | |
| | Urinary and/or FI | 5 | 177,222-225 |
| Drugs | | | |
| | General | 0 | |
| | Anti-diarrhoeal agents | 0 | |
| | Botulinum toxin type A | 1 | 227 |
| | Clonidine | 0 | |
| | Drugs acting on anal sphincter tone | 0 | |
| | Enemas | 2 | 228,229 |
| | Fibre | 0 | |
| | Laxatives | 8 | 85,100,207,210,211,214,219,220 |
| | Oestrogen therapy | 0 | |
| | Pipeline drugs | 2 | 125,206 |
| | Repurposed drugs | 11 | 91,94,208-214,231,232 |
| | Stool-forming agents | 0 | |
| | Suppositories | 2 | 146,233 |
| Surgery | | | |
| | General | 0 | |
| | Antegrade irrigation | 0 | |
| | Artificial anal sphincter | 1 | 236 |
| | Bariatric surgery | 0 | |
| | Dynamic graciloplasty | 0 | |
| | Gluteoplasty | 0 | |
| | Injectable bulking agents | 3 | 114,132,247 |
| | Levatorplasty (anterior) - repairing the pelvic floor | 0 | |
| | Magnetic sphincter formation | 1 | 248 |
| | Microballoons | 0 | |
| | Muscle transposition | 0 | |
| | New surgical procedures | 1 | 250 |
| | Ostomies (colostomy and ileostomy) | 0 | |
| | Post anal repair | 0 | |

| | | | |
|--|---|----|-------------------------|
| | Posterior tibial nerve stimulation | 1 | 252 |
| | Radiofrequency | 1 | 253 |
| | Repair of posterior compartment prolapse | 0 | |
| | Repair of rectal prolapse | 2 | 218,260 |
| | Sacral nerve stimulation (implanted) | 12 | 114,202,203,248,263-270 |
| | Slings | 0 | |
| | Sphincteroplasty | 1 | 272 |
| | Sphincter repair | 0 | |
| | Stem cells | 3 | 104,131,133 |
| | Total pelvic floor repair (TPFR) | 0 | |
| Models of care | | | |
| | Clinical pathway to diagnosis | 0 | |
| | Evidence-based practice | 0 | |
| | General - models of care | 1 | 274 |
| | GP | 0 | |
| | Nurse led | 0 | |
| | Transition of care | 0 | |
| Mechanical devices | | | |
| | Absorbent products | 0 | |
| | Anal plugs | 3 | 278-280 |
| | Anal pouch | 0 | |
| | Commodes | 2 | 223,225 |
| | Inserts (including vaginal inserts) | 0 | |
| | Managing condition | 2 | 91,281 |
| | New devices (e.g. intra-rectal diversion devices) | 2 | 281,282 |
| | Rectal catheters (used for critically ill patients) | 1 | 283 |
| | Rectal trumpet (off-label use) | 0 | |
| | Vaginal-bowel devices | 3 | 111,284,285 |
| Other containment/ non-active/ other in non-neurogenic patients | | | |
| | Toileting assistance programmes | 0 | |
| | Trans-anal irrigation | 0 | |
| Interventions in particular settings | | | |
| | Acute care settings | 0 | |

| | | | |
|--|---|----|--|
| | Bowel management in low-resource settings | 0 | |
| | Improvements to physical environment | 2 | 223,225 |
| | Products for odour and sounds | 0 | |
| | Toileting assistance programmes | 0 | |
| | Wireless technology monitoring wetness sensors - nursing home | 1 | 286 |
| Interventions in particular populations | | | |
| | Diabetes and FI | 0 | |
| | Management of FI for cancer patients | 10 | 96,116,118,121,145,147,149,174,250,267 |
| | Post-menopausal women | 0 | |
| | Pregnant/post-partum women | 1 | 122 |
| Other | | | |
| | Compliance | 0 | |
| | Dermatitis | 4 | 177,222-224 |
| | Diagnostic tools | 5 | 127,215,217,269,287 |
| | Financial support | 0 | |
| | Microbial transplant | 1 | 135 |
| | Pressure sores | 0 | |
| | Psychological support | 0 | |
| | Qualitative research/ mixed methods/ lived experiences | 0 | |
| | Quality of life | 5 | 96,200,203,216,250 |
| | Technology | 1 | 158 |
| | Treatments that are not pharmaceuticals or naturopathic | 0 | |
| | Unsure | 0 | |
| Out of scope | | | |
| | Disposal of products | 0 | |
| | Mechanisms and causes | 0 | |
| | Prevalence | 0 | |
| | Prevention of FI | 0 | |