

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

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Trial recruitment status: excluding trials that were Suspended, Terminated, Withdrawn, or had an Unknown trial status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

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

	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

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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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	