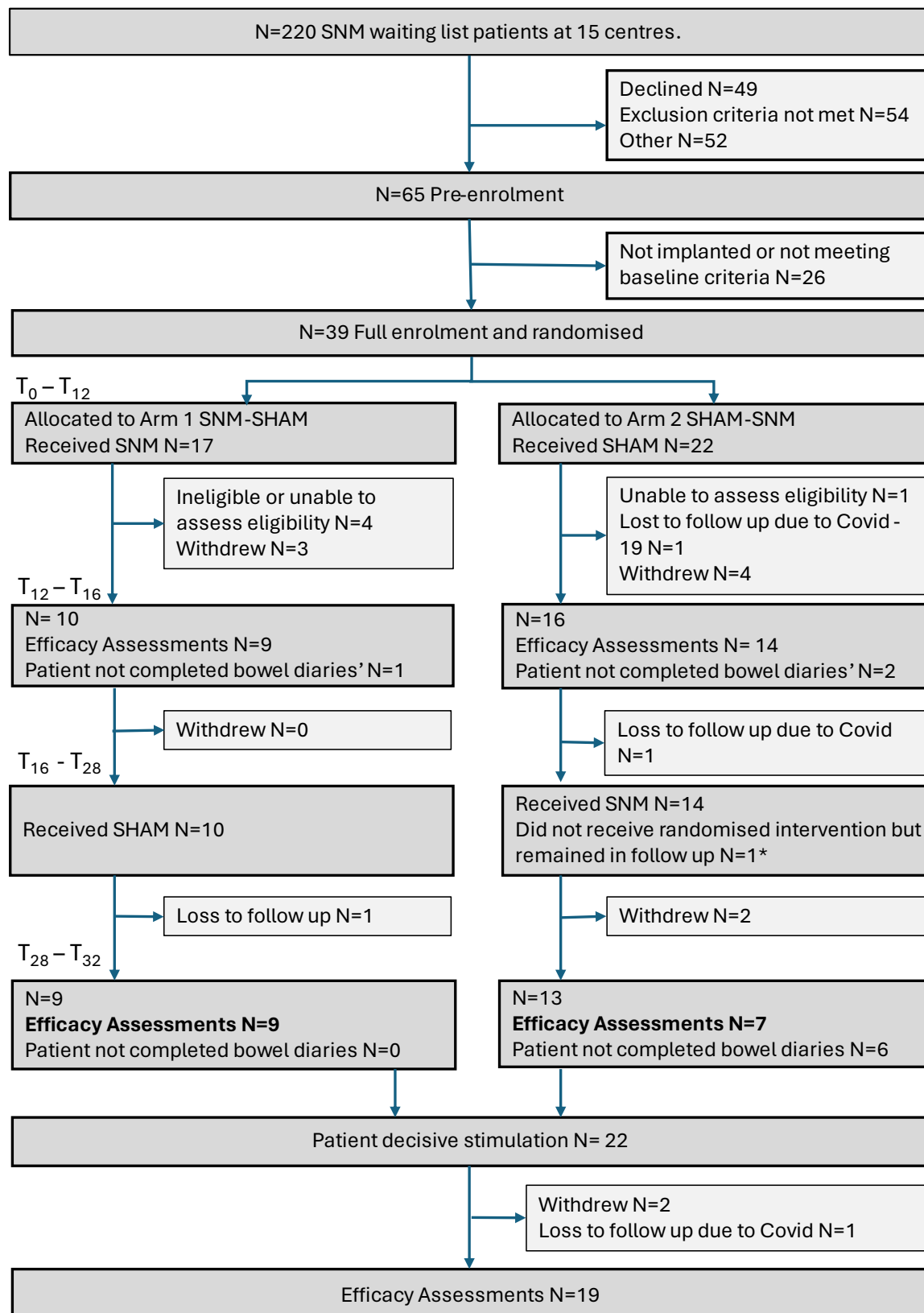


## Participant flow



\*Patient no longer wanted to be randomised and blinded to treatment, but remained in follow up for cohort analysis

## Key baseline demographic and clinical characteristics

	Randomised allocation	
	SNM/SHAM N=17*	SHAM/SNM N=22*
<b>Age (years)</b>	N=17	N=22
Mean (SD)	55.9 (14.1)	58.2 (11.8)
Median (IQR)	58.0 (44.0, 66.0)	63.5 (47.0, 66.0)
<b>Sex (%)</b>	N=17	N=22
Male	1 (6)	2 (9)
Female	16 (84)	20 (91)
<b>Ethnicity (%)</b>	N=17	N=22
White	17 (100)	19 (86)
Black	0 (0)	1 (5)
Asian	0 (0)	1 (5)
Mixed	0 (0)	1 (5)
Other	0 (0)	0 (0)
Missing	0	0
<b>BMI (kg/m<sup>2</sup>)</b>	N=17	N=18
Mean (SD)	29.5 (6.84)	28.6 (5.87)
Median (IQR)	28.3 (26.0, 30.2)	27.4 (23.9, 32.8)
<b>Significant medical history (%)</b>	N=17	N=22
No	4 (24)	6 (27)
Yes	13 (76)	16 (73)
Missing	0	0
<b>(If yes) Medical history<sup>1</sup> (%)</b>	N=13	N=16
Cardiovascular	2/13 (15)	6/16 (38)
Respiratory	2/13 (15)	2/16 (13)
Gastrointestinal	4/13 (31)	7/16 (44)
Metabolic	2/13 (15)	2/15 (13)
Haematological	2/13 (15)	0/15 (0)
Warfarin/Heparin Therapy	0/13 (0)	0/15 (0)
Hepatic	0/13 (0)	0/15 (0)
Renal	0/13 (0)	0/15 (0)
Genitourinary	1/13 (8)	4/15 (27)
Neurological/CNS	1/13 (8)	3/15 (20)
Psychiatric	2/13 (15)	5/15 (33)
Dermatological	1/13 (8)	1/15 (6)
Musculoskeletal	2/13 (15)	6/15 (40)
Any Other	5/13 (39)	1/14 (7)
<b>Significant surgical history (%)</b>	N=17	N=22
No	2 (12)	3 (14)
Yes	15 (94)	19 (86)
Missing	0	0
<b>(If yes) Surgical history<sup>1</sup> (%)</b>	N=15	N=19
Abdominal	7/15 (47)	8/18 (44)
Urogynaecological	8/15 (53)	13/19 (68)
Proctological and perineal	5/15 (33)	8/19 (42)
Neuromodulation	5/15 (33)	2/18 (11)
Other	5/14 (36)	6/18 (33)
<b>Duration of faecal incontinence symptoms (years)</b>	N=17	N=22
Mean (SD)	9.5 (4.8)	6.5 (4.0)
Median (IQR)	10.0 (6.0, 13.0)	5.5 (4.0, 8.4)
<b>Preceding events (%)</b>	N=17	N=21
No	6 (35)	9 (43)
Yes	11 (65)	12 (57)
Missing	0	1

<b>Faecal incontinence symptoms<sup>1</sup> (%)</b>		
Urgency	12/13 (92)	15/16 (94)
Passive incontinence	12/17 (71)	19/22 (86)
Urge incontinence	15/17 (88)	21/22 (96)
Flatus incontinence	13/17 (76)	20/22 (91)
<b>Prolapse symptoms<sup>1</sup> (%)</b>		
Sensation of rectal prolapse	3/17 (18)	3/22 (14)
Sensation of vaginal prolapse (female only)	3/16 (19)	2/20 (10)
Sensation of vaginal bulging (female only)	2/16 (13)	1/20 (5)
<b>Anti-diarrhoeal medications<sup>1</sup> (%)</b>		
Loperamide	14/17 (82)	16/22 (73)
Other	4/17 (24)	5/21 (24)
<b>Urinary symptoms history<sup>1</sup> (%)</b>		
Increased frequency	5/17 (29)	14/21 (67)
Urgency	5/17 (29)	14/22 (64)
Stress incontinence	7/17 (41)	10/22 (45)
Urge incontinence	6/17 (35)	12/22 (55)
<b>Previous faecal incontinence treatments<sup>1</sup> (%)</b>		
Pelvic floor exercises	16/17 (94)	19/22 (86)
Conservative management	17/17 (100)	22/22 (100)
Biofeedback	9/17 (53)	16/22 (73)
Anal irrigation	4/17 (24)	7/22 (32)
PTNS	8/17 (47)	9/22 (41)
Sphincter repair	3/17 (18)	2/22 (9)

Footnote: \* Percentages calculated excluding missing data <sup>1</sup> Where more than one response is possible, denominators may vary for individual items due to missing data.

## Main results crossover: clinical efficacy (bowel diaries).

Outcome	N=16			
	SNM Mean (SD) Median (IQR)	SHAM Mean (SD) Median (IQR)	Mean difference* (95% CI)	p <sup>a</sup>
<b>Primary</b>				
Number of FI episodes per week (urge + passive)	2.3 (2.8) 1.4 (0.5, 2.8)	3.0 (3.7) 1.4 (0.8, 4.3)	-0.7 (-1.5, 0.0)	0.06
<b>Secondary</b>				
Number of urgency episodes per week	3.2 (2.5) 3.1 (1.1, 4.5)	2.7 (2.6) 1.6 (0.8, 3.8)	0.5 (-0.4, 1.4)	0.23
Number of urge incontinence episodes per week	0.6 (0.8) 0.3 (0.0, 0.9)	0.9 (1.4) 0.5 (0.1, 1.0)	-0.3 (-0.8, 0.2)	0.27
Number of passive faecal incontinence episodes per week	1.7 (2.8) 0.8 (0.0, 1.4)	2.1 (3.8) 0.4 (0.0, 1.6)	-0.5 (-1.3, 0.4)	0.28
Number of episodes of leakage of flatus per week	15.0 (22.4) 4.8 (1.6, 19.1)	24.7 (38.2) 5.9 (1.4, 31.9)	-9.6 (-20.9, 1.6)	0.09
% of days patient used loperamide for their incontinence symptoms (%)	30.0 (37.3) 9.1 (1.8, 64.3)	32.7 (43.2) 7.3 (0.0, 83.9)	-2.7 (-8.6, 3.2)	0.34
% of days faecal incontinence limited a patient's social activities (%)	15.6 (25.9) 0.0 (0.0, 20.1)	18.7 (33.6) 3.7 (0.0, 15.4)	-3.1 (-19.4, 13.3)	0.69
<b>E-event recordings</b>				
N = 7				
Number of episodes of leakage of faecal material per week	0.8 (1.0) 0.5 (0.0, 1.3)	2.2 (2.0) 2.3 (0.0, 2.8)	-1.5 (-3.5, 0.5)	0.12
Number of episodes of leakage of flatus per week	8.8 (6.5) 9.0 (2.0, 15.8)	10.3 (11.7) 6.5 (3.5, 11.8)	-1.5 (-12.0, 8.9)	0.73
Number of episodes of urgency without incontinence per week	1.8 (1.7) 1.0 (0.8, 4.0)	1.4 (1.0) 1.0 (0.8, 2.0)	0.4 (-1.1, 1.9)	0.51

Footnote: a: 2-sided p-value from paired t-test. \*: direction of difference: SNM-SHAM; hence negative differences indicate fewer episodes with SNM vs SHAM

## Results for symptom questionnaires during crossover.

Questionnaire outcome	Treatment (regardless of period)		Mixed linear regression analysis	
	SNM	SHAM	Adjusted mean difference** (95% CI)	p-value
<b>St Mark's Incontinence Score</b>				
Original St Mark's Score	N=21	N=22	-0.15 (-2.11, 1.81)	0.88
Mean (SD)	13.9 (4.9)	14.2 (5.2)		
Median (IQR)	14.0 (11.0, 18.0)	16.5 (12.0, 18.0)		
Modified St Mark's Score	N=21	N=23	0.11 (-2.17, 2.39)	0.93
Mean (SD)	13.0 (5.7)	13.4 (5.6)		
Median (IQR)	14.0 (7.0, 16.0)	15.0 (11.0, 18.0)		
<b>Overactive Bladder symptoms (OAB-Q) short form</b>				
OAB-Q SF score	N=21	N=22	-10.80 (-23.02, 1.14)	0.08
Mean (SD)	13.9 (4.9)	14.2 (5.2)		
Median (IQR)	14.0 (11.0, 18.0)	16.5 (12.0, 18.0)		

<b>Faecal Incontinence Quality of Life (FI QOL)</b>				
Lifestyle mean score	N=20	N=23	-0.11 (-0.38, 0.16)	0.42
Mean (SD)	2.8 (0.9)	2.7 (0.9)		
Median (IQR)	2.9 (1.9, 3.5)	2.7 (1.9, 3.6)		
Coping behaviour mean score	N=19	N=24	0.06 (-0.24, 0.36)	0.71
Mean (SD)	2.1 (0.6)	1.9 (0.7)		
Median (IQR)	2.2 (1.7, 2.6)	1.8 (1.3, 2.7)		
Depression/self-perception mean score	N=20	N=23	-0.01 (-0.26, 0.24)	0.96
Mean (SD)	2.6 (0.7)	2.5 (0.8)		
Median (IQR)	2.5 (2.2, 3.1)	2.3 (1.8, 3.5)		
Embarrassment mean score	N=22	N=24	-0.05 (-0.29, 0.19)	0.68
Mean (SD)	2.2 (0.8)	2.1 (0.8)		
Median (IQR)	2.2 (1.7, 2.7)	2.0 (1.7, 2.5)		
<b>International Consultation on Incontinence Bowel (SF-ICIQ-B) questionnaire</b>				
SF-ICIQ-B mean score	N=22	N=24	-0.65 (-1.46, 0.17)	0.12
Mean (SD)	7.7 (1.7)	8.5 (1.4)		
Median (IQR)	8.0 (6.6, 9.0)	9.1 (7.4, 9.8)		
<b>EuroQol Health Outcome Measure (EQ-5D-5L)</b>	N=22	N=24		
Summary index value			-0.02 (-0.10, 0.05)	0.58
Mean (SD)	0.71 (0.26)	0.76 (0.20)		
Median (IQR)	0.77 (0.52, 0.92)	0.81 (0.70, 0.90)		
EQ-VAS score			1.58 (-3.72, 6.88)	0.56
Mean (SD)	71.5 (17.7)	71.0 (18.3)		
Median (IQR)	75.0 (60.0)	75.0 (60.0, 85.0)		
<b>Likert scale of patient's global impression of treatment success</b>				
Satisfaction score	N=22	N=24	-3.22 (-18.53, 12.10)	0.68
Mean (SD)	61.6 (28.2)	60.2 (31.7)		
Median (IQR)	67.5 (50.0, 80.0)	77.5 (30.0, 80.0)		

Footnote: \*\*Difference in means adjusted for period and sex (fixed effects) and random effects for centre and participant. Direction of difference: SNM-SHAM; hence negative differences indicate lower scores with SNM vs SHAM.

Paper bowel diary outcomes and e-event recordings at baseline and end of study (T58) for participants with data available at both timepoints.

<b>Outcomes</b>	<b>Baseline</b>	<b>End of study (T58)</b>
<b>Primary outcome:</b>	N=19	N=19
Number of FI episodes per week		
Mean (SD)	6.2 (5.9)	3.2 (3.3)
Median (IQR)	4.5 (2.3, 9.3)	2.5 (0.0, 5.3)
<b>Secondary outcomes:</b>		
<b>Other paper bowel diary measures</b>	N=19	N=19
Number of urgency episodes per week		
Mean (SD)	7.7 (6.0)	2.8 (3.2)
Median (IQR)	6.5 (3.8, 10.5)	2.0 (0.5, 3.8)
Number of urge incontinence episodes per week		
Mean (SD)	2.2 (1.7)	1.4 (2.1)
	2.0 (1.0, 2.8)	0.3 (0.0, 2.2)

Median (IQR)		
Number of passive faecal incontinence episodes per week		
Mean (SD)	4.0 (6.0)	1.8 (2.8)
Median (IQR)	1.5 (0.0, 5.6)	0.5 (0.0, 4.0)
Number of episodes of leakage of flatus per week		
Mean (SD)	28.2 (37.5)	15.3 (20.8)
Median (IQR)	13.3 (5.3, 37.3)	3.9 (0.8, 32.3)
% of days patient used loperamide for their incontinence symptoms (%)		
Mean (SD)	47.0 (35.6)	32.0 (42.0)
Median (IQR)	56.5 (11.1, 74.1)	7.1 (0.0, 78.6)
% of days faecal incontinence limited a patient's social activities (%)		
Mean (SD)	43.4 (37.9)	25.3 (41.5)
Median (IQR)	25.9 (10.7, 77.8)	0.0 (0.0, 61.5)
<b>E-event time-linked recordings</b>	N=3	N=3
Number of episodes of leakage of faecal material per week		
Mean (SD)	2.9 (3.1)	1.1 (1.1)
Median (IQR)	1.5 (0.8, 6.5)	1.0 (0.0, 2.3)
Number of episodes of leakage of flatus per week		
Mean (SD)	30.1 (4.9)	9.9 (7.5)
Median (IQR)	31.0 (24.8, 34.5)	9.3 (2.8, 17.8)
Number of episodes of urgency without incontinence per week		
Mean (SD)	10.8 (9.0)	0.8 (1.3)
Median (IQR)	8.3 (3.3, 20.8)	0.0 (0.0, 2.3)

## Adverse events.

	N=10	Allocation at time of AE/SADE	Severity	Causality	Outcome	Expectedness
<b>SADE</b>						
Fall leading to lead migration and device deficiency requiring revision	1	SHAM	severe	definite	resolved	unexpected
<b>AE</b>						
Ache at IPG site*	1	SHAM	mild	probable	unresolved	expected
Cramp in leg	1	SNM	mild	unlikely	resolved	unexpected
Pain in right abdominal area	1	SNM	mild	unlikely	resolved	unexpected
Wound infection	1	SHAM	mild	definite	resolved	expected
Diarrhoea and abdominal pain	1	SNM	moderate	possible	resolved	unexpected
Urinary tract infection	1	SNM	mild	possible	resolved	unexpected
Stress urinary incontinence	1	SNM	moderate	possible	resolved	unexpected
Shooting pains in leg	1	SHAM	mild	unlikely	resolved	expected
Numbness since insertion	1	SHAM	moderate	possible	resolved	unexpected

*Footnote: SADE: serious adverse device-related event; AE: adverse event; IPG: implanted pulse generator; \*patient complained of mild ache towards end study participation. The device was eventually removed after study completion.*