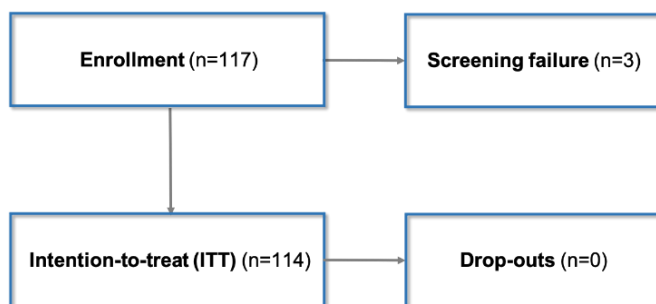


Participant flow



Baseline characteristics

Characteristic	Patients included (n=114)
Age: years	
<i>Mean (S.D.)</i>	55.8 (16.5)
<i>Range</i>	18 – 87
Gender: no (%)	
<i>Men</i>	66 (57.9%)
<i>Women</i>	48 (42.1%)
Weight (kg)	
<i>Mean (S.D.)</i>	77.7 (18.4)
<i>Range</i>	42 – 145
Height (cm)	
<i>Mean (S.D.)</i>	170.1 (8.7)
<i>Range</i>	150 – 188
BMI (kg/cm ²)	
<i>Mean (S.D.)</i>	26.8 (5.7)
<i>Range</i>	16 – 47
Time from surgery to V1 (days)	
<i>Mean (S.D.)</i>	159.9 (110.1)
<i>Range</i>	23 – 366
Time from discharge to V1 (days)	
<i>Mean (S.D.)</i>	148.1 (110.9)
<i>Range</i>	1 – 359
Stoma type: no (%)	
<i>Colostomy</i>	14 (12.3%)

<i>Ileostomy</i>	100 (87.7%)
Stoma sub-type: no (%)	
<i>End</i>	62 (54.4%)
<i>Loop</i>	48 (42.1%)
<i>Temporary</i>	4 (3.5%)
Size of the stoma (diameter on widest place in mm)	
<i>Mean (S.D.)</i>	32.0 (7.1)
<i>Range</i>	18 – 60
Size of the stoma (height in mm)	
<i>Mean (S.D.)</i>	26.5 (8.0)
<i>Range</i>	5 – 50
Shape of the stoma: no (%)	
<i>Irregular</i>	7 (6.1%)
<i>Oval</i>	47 (41.2%)
<i>Round</i>	60 (52.6%)
Reason for creation of stoma: no (%)	
<i>Cancer</i>	57 (50.0%)
<i>Ulcerative colitis</i>	17 (14.9%)
<i>Crohn's disease</i>	15 (13.2%)
<i>Other</i>	25 (21.9%)
S.D.: Standard deviation	

Outcome measures

Primary outcome	Intention-to-treat (n=114)
Patient-reported number of times with stoma effluent leakage outside the baseplate (e.g. onto clothes or bed sheets) within the last 2 weeks, collected using an online survey completed by subjects within 48 hours of nurse-led interview visit (Visit 1): Mean \pm SD (range)	1.3 \pm 2.5 (0; 14)

Adverse events

There were no adverse events associated with this trial.