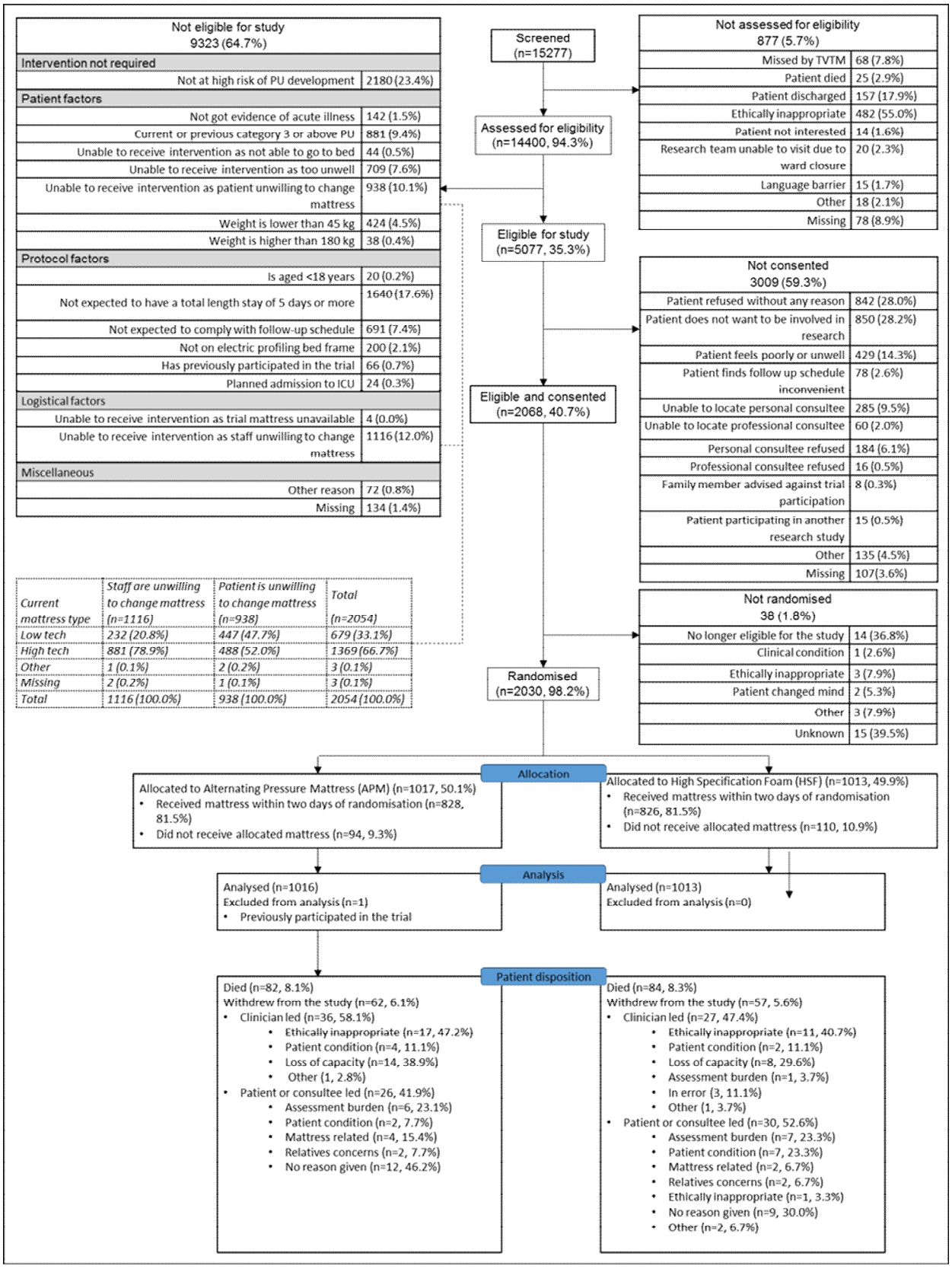
Participant Flow



Baseline characteristics

Demographics

Attribute	APM n=1016	HSF n=1013	Overall n=2029
Gender			
Male	462(45.5%)	445(43.9%)	907(44.7%)
Female	553(54.4%)	566(55.9%)	1119(55.2%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Age (years)			
Mean (S.D.)	77.8(13.42)	78.2(12.87)	78.0(13.1)
Median (range)	81(21.1,105)	81(21.9,101)	81(21,105)
IQR	(71.3,87.0)	(71.9,87.2)	(71.6,87.1)
Missing	0	0	0
Ethnicity			
White	1000(98.4%)	992(97.9%)	1992(98.2%)
Mixed race	3(0.3%)	3(0.3%)	6(0.3%)
Non-white	12(1.2%)	16(1.6%)	28(1.4%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Medical speciality			
Medical	641(63.1%)	669(66.1%)	1310(64.6%)
Surgical	83(8.2%)	72(7.1%)	155(7.6%)
Orthopaedics and trauma	233(22.9%)	220(21.7%)	453(22.3%)
Oncology	21(2.1%)	16(1.6%)	37(1.8%)
Critical care	10(1.0%)	6(0.6%)	16(0.8%)
Neurosciences	17(1.7%)	15(1.5%)	32(1.6%)
Spinal injury	8(0.8%)	9(0.9%)	17(0.9%)
Other	2(0.2%)	2(0.2%)	4(0.2%)
Missing	1(0.0%)	4(0.3%)	5(0.2%)
Consent type			
Written	706(69.5%)	696(68.7%)	1402(69.1%)
Witnessed verbal	151(14.9%)	152(15.0%)	303(14.9%)

Attribute	APM n=1016	HSF n=1013	Overall n=2029
Consultee agreement	159(15.6%)	163(16.1%)	322(15.9%)
Missing*	0(0.0%)	2(0.2%)	2(0.1%)
Healthcare setting			
Secondary care hospital	710(69.9%)	704(69.5%)	1414(69.7%)
Community hospital	191(18.8%)	188(18.6%)	379(18.7%)
NHS intermediate care/ rehabilitation facility	115(11.3%)	119(11.7%)	234(11.5%)
Missing**	0(0.0%)	2(0.2%)	2(0.1%)
Days between admission to randomising			
Mean (S.D.)	12.7(20.27)	13.3(21.23)	13.0(20.8)
Median (range)	6(0.0,306)	7(0.0,388)	7(0,388)
IQR	(3.0,15.0)	(3.0,17.0)	(3.0,16.0)
Missing	1	2	3

*These were entered on the 24 hour system, and therefore included in the analyses, as written consent.

**These were entered on the 24 hour system, and therefore included in the analyses, as Secondary care hospital.

Baseline clinical details (Pressure Ulcer risk factors)

Risk Factor	APM n=1016	HSF n=1013	Overall n=2029
BMI			
Underweight (<18.5kg/m^2)	52(5.1%)	49(4.8%)	101(5.0%)
Normal weight (18.5 to <25 kg/m^2)	455(44.8%)	392(38.7%)	847(41.7%)
Overweight (25 to <30 kg/m^2)	266(26.2%)	336(33.2%)	602(29.7%)
Obese (≥30kg/m^2)	235(23.1%)	217(21.4%)	452(22.3%)
Missing	8(0.8%)	19(1.9%)	27(1.3%)
History of falls in the past month			
Yes	458(45.1%)	451(44.5%)	909(44.8%)
No / not aware of any falls	554(54.5%)	559(55.2%)	1113(54.9%)
Missing	4(0.4%)	3(0.3%)	7(0.3%)
PURPOSE T subscales			
Analysis of independent movement			
Moves frequently / Major position changes	28(2.8%)	32(3.2%)	60(3.0%)
Moves frequently / Slight position changes	141(13.9%)	139(13.7%)	280(13.8%)
Moves occasionally / Major position changes	110(10.8%)	110(10.9%)	220(10.8%)
Moves occasionally / Slight position changes	624(61.4%)	621(61.3%)	1245(61.4%)

Risk Factor	APM n=1016	HSF n=1013	Overall n=2029
Doesn't move	109(10.7%)	107(10.6%)	216(10.6%)
Missing	4(0.4%)	4(0.4%)	8(0.4%)
Sensory Perception and Response			
No Problem	744(73.2%)	739(73.0%)	1483(73.1%)
Unable to feel and/or respond appropriately to discomfort from pressure	270(26.6%)	271(26.8%)	541(26.7%)
Missing	2(0.2%)	3(0.3%)	5(0.2%)
Moisture due to perspiration, urine, faeces or exudate			
No problem/ Occasional	693(68.2%)	686(67.7%)	1379(68.0%)
Frequent (2-4 times a day)	289(28.4%)	299(29.5%)	588(29.0%)
Constant	31(3.1%)	26(2.6%)	57(2.8%)
Missing	3(0.3%)	2(0.2%)	5(0.2%)
Perfusion			
No problem	554(54.5%)	555(54.8%)	1109(54.7%)
Conditions affecting peripheral circulation	166(16.3%)	169(16.7%)	335(16.5%)
Conditions affecting central circulation	234(23.0%)	224(22.1%)	458(22.6%)
Conditions affecting central and peripheral circulation	60(5.9%)	59(5.8%)	119(5.9%)
Missing	2(0.2%)	6(0.6%)	8(0.4%)
Nutrition			
No problem	544(53.5%)	553(54.6%)	1097(54.1%)
Problem	471(46.4%)	456(45.0%)	927(45.7%)
Missing	1(0.1%)	4(0.4%)	5(0.2%)
Previous PU history			
No known PU history	914(90.0%)	920(90.8%)	1834(90.4%)
PU history	101(9.9%)	90(8.9%)	191(9.4%)
Missing	1(0.1%)	3(0.3%)	4(0.2%)
Risk status recorded on PURPOSE T			
Not at risk	12(1.2%)	11(1.1%)	23(1.1%)
No PU but at risk	820(80.7%)	816(80.6%)	1636(80.6%)
PU Category ≥1 or scarring from previous PU	183(18.0%)	184(18.2%)	367(18.1%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Braden subscales			
Sensory perception			
No Impairment	657(64.7%)	678(66.9%)	1335(65.8%)
Slightly Limited	276(27.2%)	259(25.6%)	535(26.4%)
Very Limited	67(6.6%)	60(5.9%)	127(6.3%)
Completely Limited	15(1.5%)	14(1.4%)	29(1.4%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Moisture			
Rarely Moist	451(44.4%)	414(40.9%)	865(42.6%)
Occasionally Moist	360(35.4%)	419(41.4%)	779(38.4%)
Very Moist	177(17.4%)	153(15.1%)	330(16.3%)
Constantly Moist	27(2.7%)	25(2.5%)	52(2.6%)

Risk Factor	APM n=1016	HSF n=1013	Overall n=2029
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Activity			
Walks Frequently	13(1.3%)	9(0.9%)	22(1.1%)
Walks Occasionally	108(10.6%)	113(11.2%)	221(10.9%)
Chairfast	677(66.6%)	667(65.8%)	1344(66.2%)
Bedfast	217(21.4%)	222(21.9%)	439(21.6%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Mobility			
No Limitation	22(2.2%)	20(2.0%)	42(2.1%)
Slightly Limited	125(12.3%)	115(11.4%)	240(11.8%)
Very Limited	790(77.8%)	797(78.7%)	1587(78.2%)
Completely Immobile	78(7.7%)	79(7.8%)	157(7.7%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Nutrition			
Excellent	173(17.0%)	158(15.6%)	331(16.3%)
Adequate	528(52.0%)	539(53.2%)	1067(52.6%)
Probably Inadequate	279(27.5%)	285(28.1%)	564(27.8%)
Very Poor	35(3.4%)	29(2.9%)	64(3.2%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Friction and Shear			
No Apparent Problem	89(8.8%)	84(8.3%)	173(8.5%)
Potential Problem	752(74.0%)	770(76.0%)	1522(75.0%)
Problem	174(17.1%)	157 (15.5%)	331(16.3%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Overall Braden PU risk			
Not at risk (>18)	78(7.7%)	69(6.8%)	147(7.2%)
At risk (<=18)	937(92.2%)	942(93.0%)	1879(92.6%)
Missing	1(0.1%)	2(0.2%)	3(0.1%)

Skin status at baseline

Question	APM n=1016	HSF n=1013	Overall n=2029
Worst category of skin reported at baseline (patient level)			
0 (Category 0)	147(14.5%)	152(15.0%)	299(14.7%)
A (Category A)	673(66.2%)	674(66.5%)	1347(66.4%)
1 (Category 1)	125(12.3%)	110(10.9%)	235(11.6%)
2 (Category 2)	70(6.9%)	75(7.4%)	145(7.1%)

Question	**APM n=1016**	**HSF n=1013**	**Overall n=2029**
Missing	1(0.1%)	2(0.2%)	3(0.1%)
Pressure related pain on any skin site			
Yes	577(56.8%)	584(57.7%)	1161(57.2%)
No	393(38.7%)	388(38.3%)	781(38.5%)
Unable to assess	15(1.5%)	15(1.5%)	30(1.5%)
Combination of 'missing' and 'no'	6(0.6%)	6(0.6%)	12(0.6%)
Combination of 'No' and 'unable to assess	15(1.5%)	13(1.3%)	28(1.4%)
Missing	10(1.0%)	7(0.7%)	17(0.8%)
Pressure related pain on a healthy, altered or Category 1 skin site?			
Yes	541(53.2%)	543(53.6%)	1084(53.4%)
No	440(43.3%)	439(43.3%)	879(43.3%)
Unable to assess	15(1.5%)	15(1.5%)	30(1.5%)
Combination of 'missing' and 'no'*	2(0.2%)	1(0.1%)	3(0.1%)
Combination of 'No' and 'unable to assess*	5(0.5%)	3(0.3%)	8(0.4%)
Missing	9(0.9%)	5(0.5%)	14(0.7%)
No skin sites reported as healthy, altered or Category 1**	4(0.4%)	7(0.7%)	11(0.5%)

*Classified as 'No' in the analyses

**Classified as 'Missing' in analyses

Outcome Measures

Primary Outcome: Time to development of new PU Category ≥ 2 by 30-day final follow-up

Covariate	Level of covariate	Incidence	Reference level	HR point Estimate	HR 95% Wald Confidence limits		Wald P-value
Treatment	HSF	90/1013 (8.9%)	-	-	-	-	0.0890*
	APM	70/1016 (6.9%)	vs HSF	0.76	0.56 to	1.04	
Skin status	No PU	115/1648 (7.0%)	-	-	-	-	0.0057
	PU Category 1	27/236 (11.4%)	vs No PU	1.83	1.17 to	2.87	
	PU Category 2	18/145 (12.4%)	vs No PU	1.83	1.09 to	3.09	
Consent type	Written	100/1404 (7.1%)	-	-	-	-	0.3025
	Witnessed verbal	32/303 (10.6%)	vs Written	1.34	0.90 to	1.99	
	Consultee agreement	28/322 (8.7%)	vs Written	1.23	0.79 to	1.91	
Setting	Secondary care hospital	102/1416 (7.2%)	-	-	-	-	0.6182
	Community hospital	34/379 (9.0%)	vs Secondary care hospital	1.06	0.71 to	1.58	
	NHS intermediate care/ rehabilitation facility	24/234 (10.3%)	vs Secondary care hospital	1.26	0.79 to	1.99	
Pain on a healthy, altered or PU Category 1 skin site	No	67/890 (7.5%)	-	-	-	-	0.5070
	Yes	90/1084 (8.3%)	vs No	1.14	0.82 to	1.61	
	Unable to assess	1/30 (3.3%)	vs No	0.38	0.05 to	2.94	
	Missing	2/25 (8.0%)	vs No	2.02	0.43 to	9.45	
Presence of condition affecting peripheral circulation	No	120/1567 (7.7%)	-	-	-	-	0.5688
	Yes	39/455 (8.6%)	vs No	1.09	0.75 to	1.57	
	Missing	1/7 (14.3%)	vs No	2.91	0.35 to	24.51	

*P-values obtained from corresponding likelihood ratio tests for the effect of treatment is 0.0890

Secondary Outcome: Time to development of PU Category ≥ 3 by 30-day final follow-up

Covariate	Level of covariate	Incidence rate	Reference level	HR point Estimate	HR 95% Wald Confidence limits		Wald P-value
Treatment	HSF	18/1013 (1.8%)	-	-	-	-	0.5498*
	APM	14/1016 (1.4%)	vs HSF	0.81	0.40 to	1.62	
Skin status	No PU	22/1648 (1.3%)	-	-	-	-	0.0288
	PU Category 1	3/236 (1.3%)	vs No PU	0.85	0.24 to	2.98	
	PU Category 2	7/145 (4.8%)	vs No PU	3.20	1.33 to	7.71	
Consent type	Written	16/1404 (1.1%)	-	-	-	-	0.0335
	Witnessed verbal	6/303 (2.0%)	vs Written	1.68	0.66 to	4.28	
	Consultee agreement	10/322 (3.1%)	vs Written	2.97	1.31 to	6.74	
Setting	Secondary care hospital	26/1416	-	-	-	-	0.3045

		(1.8%)					
	Community hospital	3/379 (0.8%)	vs Secondary care hospital	0.43	0.13 to	1.41	
	NHS intermediate care/ rehabilitation facility	3/234 (1.3%)	vs Secondary care hospital	0.61	0.18 to	2.10	
Pain on a healthy, altered or PU Category 1 skin site	No	11/890 (1.2%)	-	-	-	-	<0.0001
	Yes	19/1084 (1.8%)	vs No	2.00	0.93 to	4.32	
	Unable to assess	0/30 (0.0%)	vs No	0.00	0.00 to	0.00	
	Missing	2/25 (8.0%)	vs No	5.90	1.19 to	29.32	
Presence of condition affecting peripheral circulation	No	22/1567 (1.4%)	-	-	-	-	<0.0001
	Yes	10/455 (2.2%)	vs No	1.49	0.70 to	3.15	
	Missing	0/7 (0.0%)	vs No	0.00	0.00 to	0.00	

*P-values obtained from corresponding likelihood ratio tests for the effect of treatment 0.5530

Secondary Outcome: Time to development of PU Category ≥ 1 by 30-day final follow-up

Covariate	Level of covariate	Incidence rate	Reference level	HR point Estimate	HR 95% Wald Confidence limits		Wald P-value
Treatment	HSF	190/1013 (18.8%)	-	-	-	-	0.0741*
	APM	160/1016 (15.7%)	vs HSF	0.83	0.67 to	1.02	
Skin status	No PU	272/1648 (16.5%)	-	-	-	-	0.0301
	PU Category 1	50/236 (21.2%)	vs No PU	1.52	1.11 to	2.09	
	PU Category 2	28/145 (19.3%)	vs No PU	1.18	0.79 to	1.75	
Consent type	Written	222/1404 (15.8%)	-	-	-	-	0.0140
	Witnessed verbal	59/303 (19.5%)	vs Written	1.15	0.86 to	1.53	
	Consultee agreement	69/322 (21.4%)	vs Written	1.52	1.15 to	2.01	
Setting	Secondary care hospital	226/1416 (16.0%)	-	-	-	-	0.0970
	Community hospital	67/379 (17.7%)	vs Secondary care hospital	0.95	0.72 to	1.26	
	NHS intermediate care/ rehabilitation facility	57/234 (24.4%)	vs Secondary care hospital	1.35	1.01 to	1.82	
Pain on a healthy or altered skin site	No	147/943 (15.6%)	-	-	-	-	0.0063
	Yes	198/1029 (19.2%)	vs No	1.38	1.11 to	1.71	
	Unable to assess	2/30 (6.7%)	vs No	0.28	0.07 to	1.15	
	Missing	3/27 (11.1%)	vs No	1.31	0.40 to	4.36	
Presence of condition affecting peripheral circulation	No	259/1567 (16.5%)	-	-	-	-	0.3258
	Yes	90/455 (19.8%)	vs No	1.19	0.93 to	1.51	
	Missing	1/7 (14.3%)	vs No	1.85	0.26 to	13.12	

*P-values obtained from corresponding likelihood ratio tests for the effect of treatment is 0.0733

Secondary Outcome: To compare time to healing of existing PUs

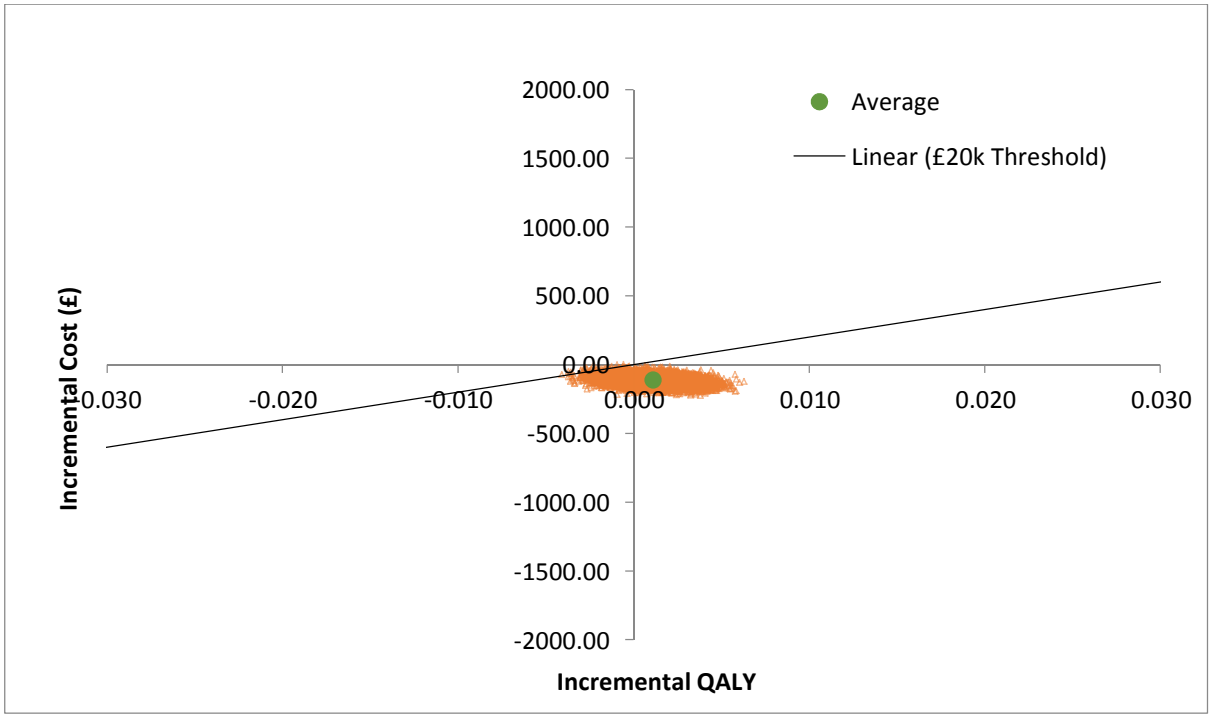
Covariate	Level of covariate	Healing rate	Reference level	HR point Estimate	HR 95% Wald Confidence limits	Wald P-value

Treatment	HSF	45/75 (60.0%)	-	-	-	-	0.5990*
	APM	44/70 (62.9%)	vs HSF	1.12	0.74 to	1.68	
Consent type	Written	63/102 (61.8%)	-	-	-	-	0.9193
	Witnessed verbal	14/23 (60.9%)	vs Written	1.08	0.65 to	1.81	
	Consultee agreement	12/20 (60.0%)	vs Written	1.12	0.57 to	2.19	
Setting	Secondary care hospital	71/111 (64.0%)	-	-	-	-	0.3093
	Community hospital	8/20 (40.0%)	vs Secondary care hospital	0.55	0.26 to	1.18	
	NHS intermediate care/ rehabilitation facility	10/14 (71.4%)	vs Secondary care hospital	0.91	0.44 to	1.86	
Presence of condition affecting peripheral circulation	No	20/38 (52.6%)	-	-	-	-	0.0469
	Yes	68/106 (64.2%)	vs No	0.59	0.36 to	0.97	
	Missing	1/1 (100.0%)	vs No	0.56	0.31 to	1.04	

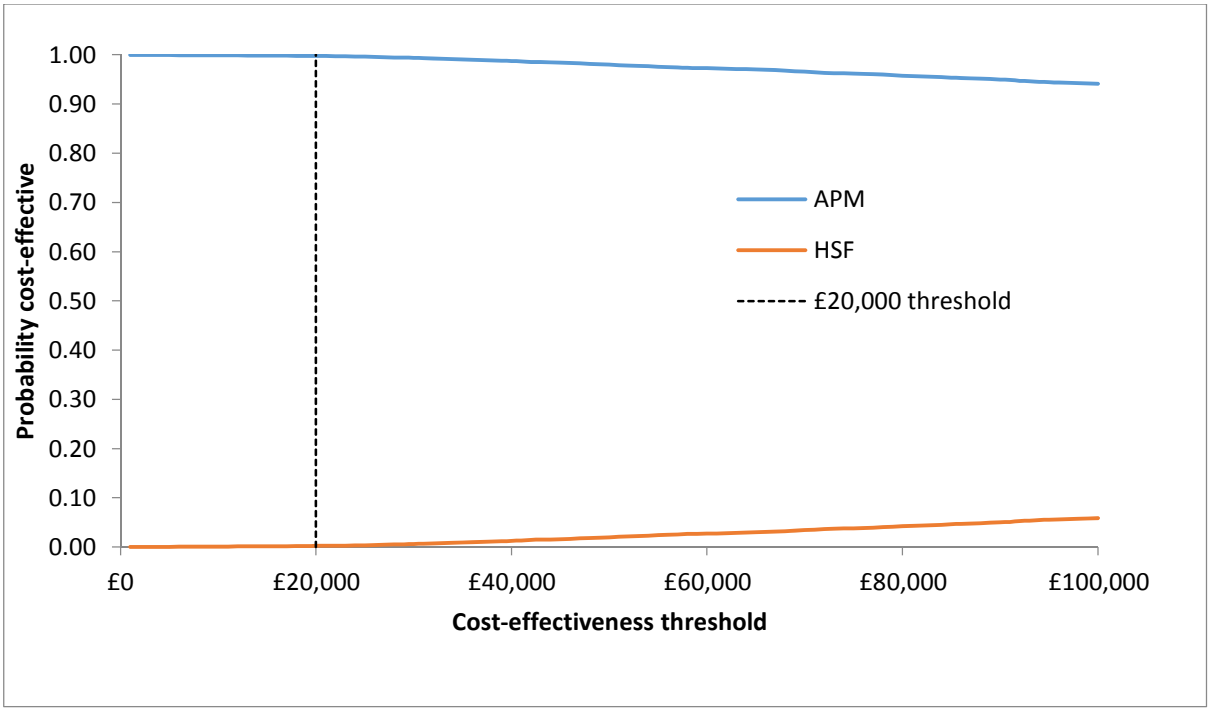
*The p-value from the corresponding likelihood ratio test was equal to 0.6122

Secondary Outcome: To determine the incremental cost effectiveness of HSF and APMs

Cost effectiveness plane



Cost Effectiveness Acceptability Curve



Secondary Outcome: Incidence of mattress change

	APM	**HSF**	**Overall**
Allocated mattress received on day 0			
Yes	491(48.3%)	660(65.2%)	1151(56.7%)
No	523(51.5%)	349(34.5%)	872(43.0%)
Mattress log not returned	2(0.2%)	4(0.4%)	6(0.3%)
Total	1016(100%)	1013(100%)	2029(100%)
If no, reasons why not			
Logistical reasons e.g. mattress unavailable or awaiting delivery	499(95.1%)	301(86.2%)	800(91.7%)
Clinical decision e.g. participants clinical condition	11(2.1%)	32(9.2%)	43(4.9%)
Patient request	8(1.5%)	13(3.7%)	21(2.4%)
Other reason/reason unknown/missing	5(1.0%)	3(0.9%)	8(0.9%)
Total	523(100%)	349(100%)	872(100%)
If no, mattress the patient on			
APM or other ‘high tech’ mattress	39(7.5%)	336(96.3%)	375(43.0%)
HSF or other ‘low tech’ mattress	481(92.0%)	10(2.9%)	491(56.3%)

	APM	**HSF**	**Overall**
Other	1(0.2%)	2(0.6%)	3(0.3%)
Missing	2(0.4%)	1(0.3%)	3(0.3%)
Total	523(100%)	349(100%)	872(100%)
Allocated mattress received within two days of randomisation			
Yes	828(81.5%)	826(81.5%)	1654(81.5%)
No	186(18.3%)	183(18.1%)	369(18.2%)
Missing	2(0.2%)	4(0.4%)	6(0.3%)
Total	1016(100%)	1013(100%)	2029(100%)
Mattress compliance (%) during treatment phase			
Mean (S.D.)	72.8(35.81)	72.8(37.81)	72.8(36.8)
Median (range)	92(0, 100)	100(0, 100)	95(0, 100)
IQR	(50.0, 100)	(47.1, 100)	(50.0, 100)
Missing	2	4	6
Frequency distribution			
0.0%	94(9.3%)	110(10.9%)	204(10.1%)
0.0% to <20.0%	74(7.3%)	78(7.7%)	152(7.5%)
20.0% to <40.0%	51(5.0%)	50(4.9%)	101(5.0%)
40.0% to <60.0%	59(5.8%)	51(5.0%)	110(5.4%)
60.0% to <80.0%	80(7.9%)	57(5.6%)	137(6.8%)
80.0% to 100.0%	656(64.6%)	663(65.4%)	1319(65.0%)
Missing	2(0.2%)	4(0.4%)	6(0.3%)
Total	1016(100%)	1013(100%)	2029(100%)
Changed from randomised mattress at least once			
Yes	222(24.1%)	220(24.4%)	442(24.2%)
No	698(75.7%)	679(75.2%)	1377(75.5%)
Mattress log not returned	2(0.2%)	4(0.4%)	6(0.3%)
Total	922(100%)	903(100%)	1825(100%)

	APM	HSF	Overall
Reason for first change from randomised mattress			
Participant requested mattress change - to aid movement	20(9.0%)	0(0.0%)	20(4.5%)
Participant requested mattress change - mattress not comfortable	90(40.5%)	28(12.7%)	118(26.7%)
Participant requested mattress change - participant no longer at risk	1(0.5%)	0(0.0%)	1(0.2%)
Ward led mattress change - participant no longer at risk	4(1.8%)	1(0.5%)	5(1.1%)
Ward led mattress change - to aid rehabilitation	29(13.1%)	5(2.3%)	34(7.7%)
Ward led mattress change - participant comfort	5(2.3%)	17(7.7%)	22(5.0%)
Ward led mattress change - participant clinical condition	3(1.4%)	130(59.1%)	133(30.1%)
Ward led mattress change - participant safety/health	4(1.8%)	2(0.9%)	6(1.4%)
Ward led mattress change - reason unknown	0(0.0%)	2(0.9%)	2(0.5%)
Ward led mattress change - in error	1(0.5%)	0(0.0%)	1(0.2%)
Ward Transfer	40(18.0%)	20(9.1%)	60(13.6%)
Technical fault	11(5.0%)	0(0.0%)	11(2.5%)
Mattress is required by another patient	3(1.4%)	0(0.0%)	3(0.7%)
Home leave	2(0.9%)	2(0.9%)	4(0.9%)
Slept in chair	1(0.5%)	1(0.5%)	2(0.5%)
Hospital Transfer	0(0.0%)	2(0.9%)	2(0.5%)
Reason unknown	8(3.6%)	10(4.6%)	18(4.0%)
Total	222(100.0%)	220(100.0%)	442(100.0%)

Adverse Events

AE/SAE by Mattress allocation

	APM (N=2017)*	**HSF (N=2013)**	**Total (N=2030)**
'Related and unexpected' serious adverse events	0	0	0
Number of Deaths	82(8.1%)	84(8.3%)	166(8.2%)
Number of participants who were re-admitted	82(8.1%)	62(6.1%)	144(7.1%)
Expected Adverse/Serious Adverse Events			
At least one AE/SAE reported	163(16.0%)	167(16.5%)	330(16.3%)
No AE/SAE reported	853(83.9%)	842(83.1%)	1695(83.5%)
CRF not received	1(0.1%)	4(0.4%)	5(0.2%)
Total	1017(100.0%)	1013 (100.0%)	2030(100.0%)
Total number of Adverse/Serious Adverse events	259	252	511
Number of falls	246(95.0%)	240(95.2%)	486(95.1%)
Number of device ulcers	12(4.6%)	10(4.0%)	22(4.3%)
Number of related AEs	1(0.4%)	2(0.8%)	3(0.6%)
Falls details			
Number of patients who experienced a fall	152(14.9%)	159(15.7%)	311(15.3%)
Total number of falls	246	240	486
On allocated mattress at time of fall			
Yes	61(24.8%)	64(26.7%)	125(25.7%)
No	15(6.1%)	18(7.5%)	33(6.8%)
Cannot be determined	6(2.4%)	10(4.2%)	16(3.3%)
Missing	4(1.6%)	5(2.1%)	9(1.9%)
Fall occurred after treatment phase	160(65.0%)	143(59.6%)	303(62.3%)
Injury sustained			
Yes	81(32.9%)	73(30.4%)	154(31.7%)

No	163(66.3%)	166(69.2%)	329(67.7%)
Missing	2(0.8%)	1(0.4%)	3(0.6%)
If injury sustained, was the injury serious?			
Yes*	11(13.6%)	16(21.9%)	27(17.5%)
No	70(86.4%)	57(78.1%)	127(82.5%)
If injury was serious, seriousness criteria:			
Requires prolonged hospitalisation	7(63.6%)	9(56.3%)	16(59.3%)
Significantly or permanently disabling or incapacitating	0(0.0%)	2(12.5%)	2(7.4%)
Requires surgical intervention	1(9.1%)	2(12.5%)	3(11.1%)
Laceration(s)	1(9.1%)	3(18.8%)	4(14.8%)
X-rays taken but clear	2(18.2%)	0(0.0%)	2(7.4%)
If injury was serious, causality of fall			
Unlikely to be related	0(0.0%)	1(6.3%)	1(3.7%)
Unrelated	8(72.7%)	11(68.8%)	19(70.4%)
Missing	3(27.3%)	4(25.0%)	7(25.9%)
If injury was serious, mattress type at time of fall			
Foam	2(18.2%)	5(31.3%)	7(25.9%)
Alternating pressure	0(0.0%)	1(6.3%)	1(3.7%)
Unknown/Participant at home	1(9.1%)	2(12.5%)	3(11.1%)
Domestic mattress	3(27.3%)	1(6.3%)	4(14.8%)
Missing	5(45.5%)	7(43.8%)	12(44.4%)
Device ulcer details			
Number of patients who experienced a device ulcer	12(1.2%)	8(0.8%)	20(1.0%)
Total number of device ulcers	12	10	22
On allocated mattress at time of device ulcer first observed			
Yes	7(58.3%)	2(20.0%)	9(40.9%)
No	1(8.3%)	8(80.0%)	9(40.9%)
Missing	2(16.7%)	0(0.0%)	2(9.1%)

Device ulcer occurred after treatment phase	2(16.7%)	0(0.0%)	2(9.1%)
Was the device ulcer serious?			
No	12(100%)	10(100%)	22(100%)
'Related' AEs			
Number of patients who experienced a mattress related AE	1(0.1%)	2(0.2%)	3(0.1%)
Total number of mattress related AEs	1	2	3
On allocated mattress at time of mattress related AE			
Yes	1(100.0%)	1(50.0%)	2(66.7%)
No	0(0.0%)	1(50.0%)	1(33.3%)
Was the mattress related AE serious?			
No	1(100%)	2(100%)	3(100%)

*safety population includes patient randomised twice