



**CHES**  
Chronic Headache Education  
and Self-management Study

## **Statistical report**

Version: 5.0

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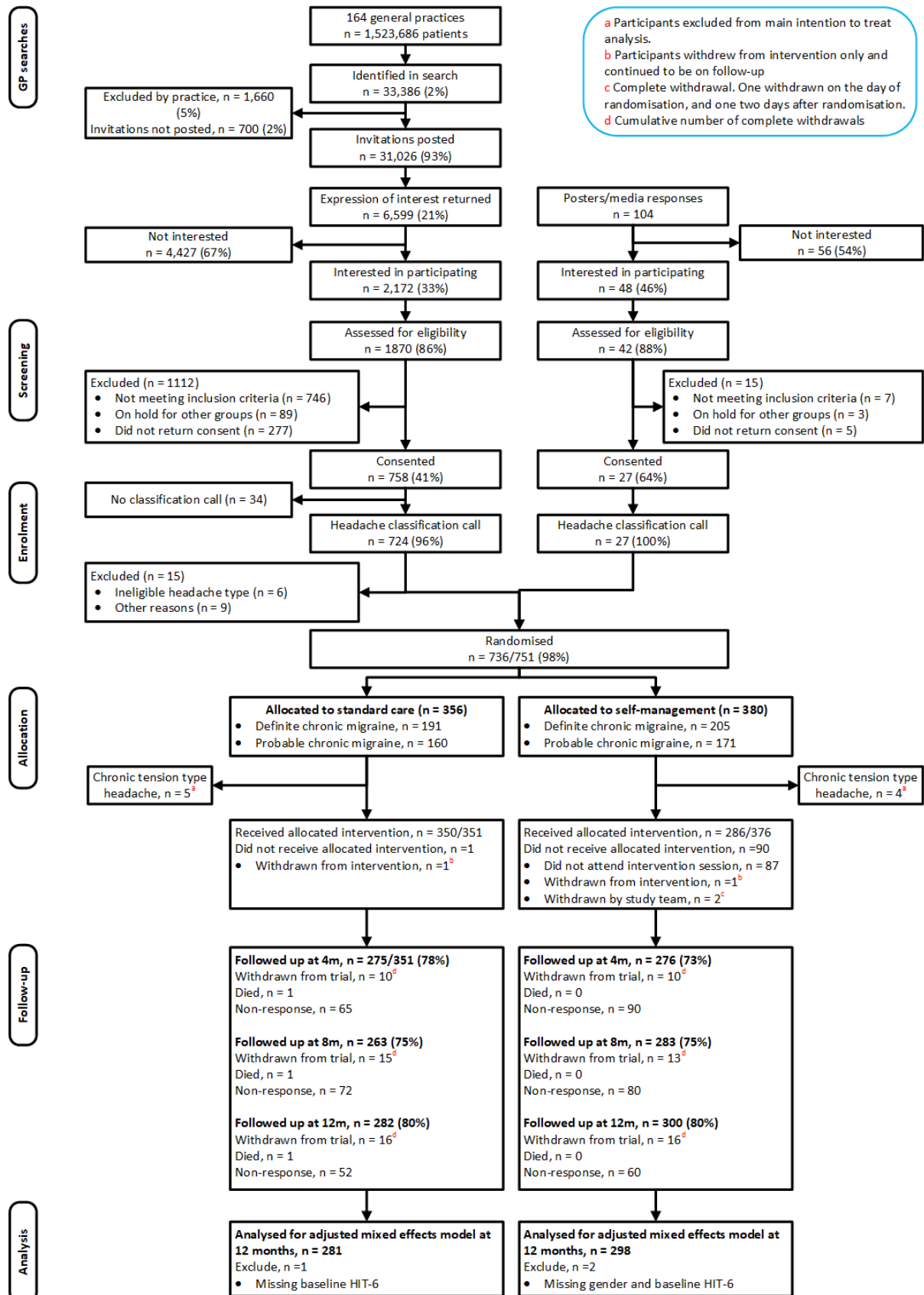
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## **SECTION 1 - SCREENING THROUGH TO RANDOMISATION**

**Figure 1: CONSORT diagram**



**Table 1: Screening of potential participants summarised by practice name**

**Table 2: Screening of potential participants summarised by CCG**

During final checking prior to submission of the CHES report to NIHR we identified some discrepancies between tables one and two. In order not to delay submission we have removed these tables. Once these discrepancies have been resolved we will forward an updated statistical report. These discrepancies do not affect the overall recruitment figures or any post-randomisation data.

***Table 3: Number and percentage of participants randomised to standard care and self-management by geographical location***

<b>Region</b>	<b>Standard care</b>	<b>Self-management</b>	<b>Total</b>
Midlands	249 (48.4%)	266 (51.6%)	515
Greater London	107 (48.4%)	114 (51.6%)	221
<b>TOTAL:</b>	356	380	736

***Table 4: Number and percentage of participants with different headache types by treatment***

<b>Headache type</b>	<b>Standard care</b>	<b>Self-management</b>
Definite chronic migraine – with MOH	122 (34.3%)	131 (34.5%)
Probable chronic migraine – with MOH	74 (20.8%)	80 (21.0%)
Chronic tension type headache – with MOH	2 (0.6%)	1 (0.3%)
Definite chronic migraine – without MOH	69 (19.4%)	74 (19.5%)
Probable chronic migraine – without MOH	86 (24.1%)	91 (23.9%)
Chronic tension type headache – without MOH	3 (0.8%)	3 (0.8%)

## **SECTION 2 - PARTICIPANT BASELINE AND DEMOGRAPHIC DATA**

**NOTE: GOING FORWARD, PARTICIPANTS WITH TENSION TYPE HEADACHE  
WILL BE EXCLUDED (N=9) AND ONLY THOSE WITH DEFINITE AND PROBABLE  
CHRONIC MIGRAINE WILL BE ANALYSED**



**Table 5: Baseline demographic characteristics of all randomised participants by treatment group**

	Standard care (N=351)	Self-management (N=376)	TOTAL (N=727)
<b>Age (years)</b>			
N	351	376	727
Mean (SD)	47.9 (15.0)	47.0 (14.9)	47.5 (15.0)
Median (IQR)	49 (37, 58)	49 (35, 57)	49 (36, 58)
Missing	0	0	0
<b>Gender</b>			
Male	67 (19.1%)	54 (14.4%)	121 (16.6%)
Female	284 (80.9%)	320 (85.1%)	604 (83.1%)
Missing	0	2 (0.5%)	2 (0.3%)
<b>Ethnicity</b>			
White	282 (80.3%)	304 (80.8%)	586 (80.6%)
Black or Black British	24 (6.8%)	18 (4.8%)	42 (5.8%)
Asian or Asian British	29 (8.3%)	31 (8.2%)	60 (8.2%)
Mixed	8 (2.3%)	13 (3.5%)	21 (2.9%)
Other	2 (0.6%)	6 (1.6%)	8 (1.1%)
Missing	6 (1.7%)	4 (1.1%)	10 (1.4%)
<b>Employment status</b>			
Employed	192 (54.7%)	221 (58.8%)	413 (56.8%)
Unemployed	9 (2.6%)	14 (3.7%)	23 (3.2%)
At school or full time education	10 (2.8%)	13 (3.5%)	23 (3.2%)
Unable to work due to long term sickness	36 (10.3%)	33 (8.8%)	69 (9.5%)
Looking after home/family	21 (6.0%)	22 (5.8%)	43 (5.9%)
Retired from paid work	60 (17.1%)	57 (15.2%)	117 (16.1%)
Other	16 (4.5%)	11 (2.9%)	27 (3.7%)
Missing	7 (2.0%)	5 (1.3%)	12 (1.6%)
<b>Age left full time education</b>			
Did not receive formal education	2 (0.6%)	2 (0.5%)	4 (0.6%)
Age 12 or less	3 (0.9%)	2 (0.5%)	5 (0.7%)
Age 13 to 16	92 (26.2%)	82 (21.8%)	174 (23.9%)
Age 17 to 19	90 (25.6%)	108 (28.7%)	198 (27.2%)
Age 20 or over	144 (41.0%)	163 (43.4%)	307 (42.2%)
Still in full time education	12 (3.4%)	15 (4.0%)	27 (3.7%)
Missing	8 (2.3%)	4 (1.1%)	12 (1.7%)
<b>Headache classification</b>			

Definite chronic migraine	191 (54.4%)	205 (54.5%)	396 (54.5%)
Probable chronic migraine	160 (45.6%)	171 (45.5%)	331 (45.5%)
Missing	0	0	0
<b>Medication overuse</b>			
No	155 (44.2%)	165 (43.9%)	320 (44.0%)
Yes	196 (55.8%)	211 (56.1%)	407 (56.0%)
Missing	0	0	0
<b>Headache/migraine days over the last 4 weeks</b>			
N	349	372	721
Mean (SD)	16.4 (6.9)	16.4 (6.8)	16.4 (6.8)
Median (IQR)	16 (10, 20)	16 (12, 20)	16 (11, 20)
Missing	2	4	6
<b>Headache/migraine days over the last 4 weeks</b>			
<15	137 (39.0%)	137 (36.4%)	274 (37.7%)
≥15	212 (60.4%)	235 (62.5%)	447 (61.5%)
Missing	2 (0.6%)	4 (1.1%)	6 (0.8%)
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>			
N	346	371	717
Mean (SD)	12.4 (7.3)	12.5 (7.4)	12.4 (7.4)
Median (IQR)	12 (8, 16)	12 (6, 17)	12 (7, 17)
Missing	5	5	10
<b>Average number of hours the headache/migraine lasted on the days they had it</b>			
N	236	255	491
Mean (SD)	10.3 (8.1)	10.4 (8.0)	10.4 (8.0)
Median (IQR)	7 (4, 15)	8 (4, 14)	7 (4, 15)
Missing	115	121	236
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine</b>			

	N	242	264	506
	Mean (SD)	6.7 (1.9)	6.8 (1.8)	6.8 (1.8)
	Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)
	Missing	109	112	221
<b>How fatigued were you on average in the past seven days</b>				
	Not at all	3 (0.8%)	6 (1.6%)	9 (1.2%)
	A little bit	43 (12.3%)	41 (10.9%)	84 (11.6%)
	Somewhat	83 (23.6%)	79 (21.0%)	162 (22.3%)
	Quite a bit	138 (39.3%)	147 (39.1%)	285 (39.2%)
	Very much	82 (23.4%)	99 (26.3%)	181 (24.9%)
	Missing	2 (0.6%)	4 (1.1%)	6 (0.8%)
<b>Sleep quality in the past seven days</b>				
	Very poor	45 (12.8%)	57 (15.2%)	102 (14.0%)
	Poor	113 (32.2%)	128 (34.0%)	241 (33.2%)
	Fair	132 (37.6%)	134 (35.6%)	266 (36.6%)
	Good	54 (15.4%)	47 (12.5%)	101 (13.9%)
	Very good	6 (1.7%)	7 (1.9%)	13 (1.8%)
	Missing	1 (0.3%)	3 (0.8%)	4 (0.5%)
<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>				
	N	346	369	715
	Mean (SD)	4.5 (2.7)	4.4 (2.7)	4.5 (2.7)
	Median (IQR)	5 (2, 7)	4 (2, 7)	5 (2, 7)
	Missing	5	7	12

**Table 5.1: Summary of medications at baseline**

Drug (n=727)	Median Dose mg/28 days (range, IQR)	Standard care				Self-management			
		Drug group (n= 351)	Median DDDs Median (IQR)	Type (n=351)	Median DDDs Median (IQR)	Drug group (n=376)	Median DDDs Median (IQR)	Type (n=376)	Median DDDs Median (IQR)
<b>Acute</b>									
Aspirin (n=86)	6250 (500-39600, 2400-16200)	Analgesic (n=244)	6 (2.3-14)	Acute (n=321)	14 (6.6-28)	Analgesic (n=251)	4.8 (1.8-11)	Acute (n=341)	12 (5.3-25)
Paracetamol (n=481)	15000 (250-224000, 5000-36000)								
Cyclizine (n=1)	100	Anti-emetic (n=18)	2.7 (2-3)			Anti-emetic (n=13)	2 (1-6.7)		
Domperidone (n=7)	80 (40-300, 50-250)								
Metoclopramide (n=11)	80 (10-840, 60-100)								
Prochlorperazine (n=13)	25 (3-225, 12-50)								
Diclofenac (n=8)	975 (50-2400, 450-1925)								
Ibuprofen (n=258)	5200 (200-67200, 2400-12000)								
Indometacin (n=2)	475 (200-750, 200-750)								
Mefenamic acid (n=3)	2500 (2000-3000, 2000-3000)								
Meloxicam (n=0)	-								
Naproxen (n=41)	4000 (250-56000, 1500-14000)	Opioids* (n=114)	2.4 (0.96-9)			Opioids* (n=86)	1.9 (0.67-5.8)		
Tofenamic acid (n=1)	800								
Fentanyl patches (n=0)	-								
Morphine (n=2)	70 (20-120, 20-120)								
Tramadol (n=16)	2450 (50-11200, 300-4900)								
Codeine (n=176)	192 (8-6944, 68-720)			Triptan (n=174)	8 (3-16)			Triptan (n=178)	8 (4-16)
Dihydrocodeine (n=16)	254 (40-1600, 95-404)								
Tapentadol (n=0)	-								
Almotriptan (n=2)	100 (75-125, 75-125)								
Eletriptan (n=4)	400 (280-960, 300-720)								
Frovatriptan (n=12)	26 (13-160, 16-38)								

Naratriptan (n=33)	15 (2.5-120, 10-35)												
Rizatriptan (n=41)	50 (10-360, 20-90)												
Sumatriptan injection (n=7)	24 (6-72, 6-60)												
Sumatriptan oral (n=204)	450 (50-4800, 200-800)												
Sumatriptan spray (n=8)	80 (40-400, 80-200)												
Zolmitriptan oral (n=48)	20 (0-360, 8.8-40)												
Zolmitriptan spray (n=12)	25 (5-75, 7.5-45)												
<b>Prophylaxis</b>													
Candesartan (n=9)	168 (40-448, 56-224)	Angiotensin receptor blocker (n=4)	32 (6-56)	Prophylaxis (n=114)	14 (5.3-32)	Angiotensin receptor blocker (n=6)	18 (14-28)	Prophylaxis (n=121)	14 (6.9-28)				
Losartan (n=1)	700	Anti-epileptic (n=18)	9.3 (4.7-15)			Anti-epileptic (n=33)	9.3 (4.7-14)						
Sodium valproate (n=8)	19600 (11200-39200, 11200-25200)					Beta blocker (n=31)	14 (7-28)			Beta blocker (n=35)	14 (7-28)		
Topiramate (n=43)	2800 (275-19600, 1400-4200)	Calcium channel blocker (n=1)	14							Calcium channel blocker (n=2)	23 (15-31)		
Atenolol (n=1)	700									Gabapentinoid (n=13)	24 (14-37)	Gabapentinoid (n=12)	14 (9.3-23)
Metoprolol (n=1)	2800	Other antidepressant (n=16)	25 (14-29)			Other antidepressant (n=12)	21 (14-42)						
Propranolol (n=64)	2240 (0-13440, 1120-4480)									Serotonergic antagonist (n=12)	28 (14-47)	Serotonergic antagonist (n=6)	23 (9.3-28)
Flunarizine (n=3)	150 (140-310, 140-310)												
Gabapentin (n=15)	27000 (16800-75600, 16800-50400)												
Pregabalin (n=10)	6400 (700-33600, 4200-16800)												
Citalopram (n=5)	560 (280-4480, 280-560)												
Duloxetine (n=3)	560 (560-1120, 560-1120)												
Escitalopram (n=1)	280												
Fluoxetine (n=2)	700 (280-1120, 280-1120)												
Mirtazepine (n=7)	420 (420-1260, 420-450)												
Sertraline (n=8)	1400 (700-2800, 1400-2150)												
Venlafaxine (n=3)	2100 (2100-2100, 2100-2100)												
Pizotifen (n=18)	42 (7-126, 14-56)												

Amitriptyline (n=76)	560 (30-5600, 280-1085)	Tricyclic antidepressant (n=47)	7.5 (3.7-15)			Tricyclic antidepressant (n=42)	7.5 (3.7-15)		
Dosulepin (n=2)	3150 (2100-4200, 2100-4200)								
Imipramine (n=0)	-								
Nortriptyline (n=11)	560 (100-2800, 280-1400)								
<b>Anxiolytic/sedative</b>									
Diazepam (n=6)	35 (2-112, 6-84)	Benzodiazepine (n=3)	2 (0.6-11)	Anxiolytic/sedative (n=3)	2 (0.6-11)	Benzodiazepine (n=4)	3.3 (0.9-6.7)	Anxiolytic/sedative (n=5)	5 (1.6-8.4)
Lorazepam (n=1)	4								
Zopiclone (n=1)	210	Cyclopyrrolone sedative (n=0)	-			Cyclopyrrolone sedative (n=1)	28		

\* Opioids reported as morphine equivalent quantities standardised to codeine DDDs to make dosage appropriate for non-malignant pain

**Table 5. 2: Daily defined dose (DDD) summarised by drug group and drug type across treatments arms at baseline**

<b>Medications</b>	<b>Standard care N; Median DDD (IQR)</b>	<b>Self-management N; Median DDD (IQR)</b>
<b>Drug group</b>		
Analgesic	244; 6 (2.3-14)	251; 4.8 (1.8-11)
Anti-emetic	18; 2.7 (2-3)	13; 2 (1-6.7)
NSAID	136; 4.7 (2-13)	159; 5.3 (2-11)
Opioids	114; 2.4 (0.96-9)	86; 1.9 (0.67-5.8)
Triptan	174; 8 (3-16)	178; 8 (4-16)
Angiotensin receptor block	4; 32 (6-56)	6; 18 (14-28)
Anti-epileptic	18; 9.3 (4.7-15)	33; 9.3 (4.7-14)
Beta blocker	31; 14 (7-28)	35; 14 (7-28)
Calcium channel blocker	1; 14	2; 23 (15-31)
Gabapentinoid	13; 24 (14-37)	12; 14 (9.3-23)
Other antidepressant	16; 25 (14-29)	12; 21 (14-42)
Serotonergic antagonist	12; 28 (14-47)	6; 23 (9.3-28)
Tricyclic antidepressant	47; 7.5 (3.7-15)	42; 7.5 (3.7-15)
Benzodiazepine	3; 2 (0.6-11)	4; 3.3 (0.9-6.7)
Cyclopyrrolone sedative	-	1; 28
<b>Drug type</b>		
Acute	321; 14 (6.6-28)	341; 12 (5.3-25)
Prophylaxis	114; 14 (5.3-32)	121; 14 (6.9-28)
Anxiolytic/Sedative	3; 2 (0.6-11)	5; 5 (1.6-8.4)

**Table 6: Baseline outcome measures by treatment arm**

<b>Baseline outcome measure</b>	<b>Standard care (N=351)</b>	<b>Self-management (N=376)</b>	<b>TOTAL (N=727)</b>
<b>HIT-6</b>			
N	350	374	724
Mean (SD)	64.6 (5.5)	64.4 (5.4)	64.5 (5.5)
Median (IQR)	64.5 (61, 68)	64 (62, 68)	64 (61, 68)
Missing	1	2	3
<b>CH-QLQ – role restrictive</b>			
N	351	374	725
Mean (SD)	54.5 (17.3)	54.4 (16.9)	54.4 (17.1)
Median (IQR)	57.1 (42.9, 66.7)	54.8 (42.9, 66.7)	54.8 (42.9, 66.7)
Missing	0	2	2
<b>CH-QLQ – role preventive</b>			
N	351	374	725
Mean (SD)	69.4 (21.2)	69.4 (20.5)	69.4 (20.8)
Median (IQR)	75 (54.2, 87.5)	70.8 (54.2, 87.5)	70.8 (54.2, 87.5)
Missing	0	2	2
<b>CH-QLQ – emotional function</b>			
N	351	373	724
Mean (SD)	57.2 (22.3)	57.0 (22.4)	57.1 (22.3)
Median (IQR)	55.6 (38.9, 77.8)	61.1 (38.9, 77.8)	61.1 (38.9, 77.8)
Missing	0	3	3
<b>SF-12 Physical</b>			
N	347	370	717
Mean (SD)	43.7 (10.9)	44.9 (10.0)	44.4 (10.5)
Median (IQR)	44.1 (36.9, 52.1)	45.7 (38.6, 52.7)	45.3 (37.6, 52.5)
Missing	4	6	10
<b>SF-12 Mental</b>			
N	348	370	718
Mean (SD)	39.6 (10.3)	39.8 (10.6)	39.7 (10.5)
Median (IQR)	39.5 (32.2, 47.1)	39.3 (32.2, 48.5)	39.5 (32.2, 47.8)
Missing	3	6	9
<b>EQ-5D</b>			
N	346	372	718
Mean (SD)	0.62 (0.25)	0.64 (0.26)	0.63 (0.26)
Median (IQR)	0.71 (0.53, 0.77)	0.72 (0.53, 0.78)	0.71 (0.53, 0.77)
Missing	5	4	9
<b>EQ-5D VAS</b>			



	N	350	371	721
	Mean (SD)	62.2 (19.6)	62.9 (20.5)	62.6 (20.0)
	Median (IQR)	65 (50, 75)	67 (50, 80)	65 (50, 80)
	Missing	1	5	6
<b>HADS Anxiety</b>				
	N	349	373	722
	Mean (SD)	10.9 (2.7)	10.5 (2.7)	10.7 (2.7)
	Median (IQR)	11 (9, 13)	10 (9, 13)	11 (9, 13)
	Missing	2	3	5
<b>HADS Depression</b>				
	N	349	373	722
	Mean (SD)	8.9 (2.0)	9.2 (1.8)	9.1 (1.9)
	Median (IQR)	9 (8, 10)	9 (8, 10)	9 (8, 10)
	Missing	2	3	5
<b>HADS Anxiety - categorised</b>				
	0-7	34 (9.7%)	53 (14.1%)	87 (12.0%)
	8-10	115 (32.8%)	138 (36.7%)	253 (34.8%)
	11-21	200 (57.0%)	182 (48.4%)	382 (52.5%)
	Missing	2 (0.5%)	3 (0.8%)	5 (0.7%)
<b>HADS Depression - categorised</b>				
	0-7	76 (21.6%)	59 (15.7%)	135 (18.5%)
	8-10	199 (56.7%)	229 (60.9%)	428 (58.9%)
	11-21	74 (21.1%)	85 (22.6%)	159 (21.9%)
	Missing	2 (0.6%)	3 (0.8%)	5 (0.7%)
<b>PSEQ</b>				
	N	348	371	719
	Mean (SD)	32.9 (13.3)	32.5 (13.8)	32.7 (13.5)
	Median (IQR)	34 (24, 43)	34 (22, 44)	34 (23, 43)
	Missing	3	5	8
<b>HeiQ</b>				
	N	348	373	721
	Mean (SD)	2.8 (0.6)	2.8 (0.7)	2.8 (0.7)
	Median (IQR)	2.8 (2.4, 3.2)	3 (2.4, 3.2)	3 (2.4, 3.2)
	Missing	3	3	6

***Table 7: Baseline outcome measures summarised by headache type***

Baseline outcome measure	Definite chronic migraine (N=396)	Probable chronic migraine (N=331)
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<b>HIT-6</b>	N	393	331
	Mean (SD)	66.1 (4.9)	62.6 (5.5)
	Median (IQR)	66 (63, 69)	63 (60, 66)
	Missing	3	0
	<b>CH-QLQ – role restrictive</b>		
	N	394	331
	Mean (SD)	49.7 (16.4)	60.1 (16.1)
	Median (IQR)	50 (38.1, 61.9)	61.9 (50, 71.4)
	Missing	2	0
	<b>CH-QLQ – role preventive</b>		
	N	394	331
	Mean (SD)	63.9 (21.2)	76.0 (18.4)
	Median (IQR)	66.7 (50, 79.2)	79.2 (66.7, 91.7)
	Missing	2	0
	<b>CH-QLQ – emotional function</b>		
	N	393	331
	Mean (SD)	51.9 (21.8)	63.3 (21.4)
	Median (IQR)	50 (33.3, 72.2)	66.7 (44.4, 83.3)
	Missing	3	0
	<b>SF-12 Physical</b>		
	N	390	327
	Mean (SD)	42.5 (10.6)	46.5 (10.0)
	Median (IQR)	43.3 (36.1, 50.6)	48.5 (39.2, 54.1)
	Missing	6	4
	<b>SF-12 Mental</b>		
	N	391	327
	Mean (SD)	39.4 (10.4)	40.0 (10.5)
	Median (IQR)	39.0 (31.7, 47.1)	39.9 (32.5, 48.2)
	Missing	5	4
	<b>EQ-5D</b>		
	N	388	330
	Mean (SD)	0.59 (0.28)	0.67 (0.22)
	Median (IQR)	0.70 (0.48, 0.77)	0.74 (0.64, 0.80)
	Missing	8	1
	<b>EQ-5D VAS</b>		
	N	393	328
	Mean (SD)	60.5 (21.6)	65.1 (17.7)
	Median (IQR)	65 (42, 80)	70 (55, 75)
	Missing	3	3
	<b>HADS Anxiety</b>		

	N	392	330
	Mean (SD)	10.8 (2.8)	10.7 (2.6)
	Median (IQR)	11 (9, 13)	11 (9, 12)
	Missing	4	1
<b>HADS Depression</b>			
	N	392	330
	Mean (SD)	9.2 (1.9)	9.0 (1.9)
	Median (IQR)	9 (8, 10)	9 (8, 10)
	Missing	4	1
<b>HADS Anxiety - categorised</b>			
	0-7	50 (12.6%)	37 (11.2%)
	8-10	131 (33.1%)	122 (36.9%)
	11-21	211 (53.3%)	171 (51.6%)
	Missing	4 (1.0%)	1 (0.3%)
<b>HADS Depression - categorised</b>			
	0-7	69 (17.4%)	66 (19.9%)
	8-10	231 (58.3%)	197 (59.5%)
	11-21	92 (23.3%)	67 (20.3%)
	Missing	4 (1.0%)	1 (0.3%)
<b>PSEQ</b>			
	N	392	327
	Mean (SD)	30.0 (13.6)	36.0 (12.7)
	Median (IQR)	30 (20, 40)	37 (27, 45)
	Missing	4	4
<b>HeiQ</b>			
	N	393	328
	Mean (SD)	2.7 (0.7)	2.9 (0.6)
	Median (IQR)	2.8 (2.2, 3.2)	3 (2.6, 3.2)
	Missing	3	3

**Table 8: Baseline pain grid summarised for participants in the standard care arm**

Pain symptom	No pain experienced	Not at all troublesome	Slightly troublesome	Moderately troublesome	Very troublesome	Extremely troublesome
Headache	2 (0.6%)	0	28 (8.2%)	91 (26.6%)	145 (42.4%)	76 (22.2%)
Neck pain	58 (17.4%)	18 (5.4%)	65 (19.5%)	96 (28.7%)	77 (23.0%)	20 (6.0%)
Shoulder pain	89 (27.1%)	20 (6.1%)	85 (25.8%)	68 (20.7%)	50 (15.2%)	17 (5.2%)
Elbow pain	231 (73.1%)	30 (9.5%)	21 (6.7%)	22 (7.0%)	8 (2.5%)	4 (1.3%)

Wrist / hand pain	165 (51.6%)	25 (7.8%)	60 (18.8%)	34 (10.6%)	24 (7.5%)	12 (3.8%)
Chest pain	205 (64.9%)	26 (8.2%)	48 (15.2%)	22 (7.0%)	10 (3.2%)	5 (1.6%)
Abdominal pain	142 (44.5%)	29 (9.1%)	71 (22.3%)	40 (12.5%)	29 (9.1%)	8 (2.5%)
Upper back pain	149 (46.3%)	22 (6.8%)	70 (21.7%)	39 (12.1%)	32 (9.9%)	10 (3.1%)
Lower back pain	86 (26.1%)	27 (8.2%)	77 (23.4%)	56 (17.0%)	55 (16.7%)	28 (8.5%)
Hip / thigh pain	176 (54.7%)	29 (9.0%)	38 (11.8%)	35 (10.9%)	26 (8.1%)	18 (5.6%)
Knee pain	161 (50.6%)	25 (7.9%)	45 (14.2%)	37 (11.6%)	27 (8.5%)	23 (7.2%)
Ankle / foot pain	183 (56.3%)	20 (6.2%)	51 (15.7%)	34 (10.5%)	18 (5.5%)	19 (5.9%)
Other pains	181 (68.6%)	17 (6.4%)	20 (7.6%)	13 (4.9%)	18 (6.8%)	15 (5.7%)

***Table 9: Baseline pain grid summarised for participants in the self-management arm***

<b>Pain symptom</b>	<b>No pain experienced</b>	<b>Not at all troublesome</b>	<b>Slightly troublesome</b>	<b>Moderately troublesome</b>	<b>Very troublesome</b>	<b>Extremely troublesome</b>
Headache	2 (0.5%)	1 (0.3%)	21 (5.7%)	102 (27.7%)	156 (42.4%)	86 (23.4%)
Neck pain	67 (19.0%)	18 (5.1%)	85 (24.2%)	96 (27.3%)	58 (16.5%)	28 (8.0%)
Shoulder pain	95 (27.5%)	25 (7.3%)	92 (26.7%)	66 (19.1%)	42 (12.2%)	25 (7.3%)
Elbow pain	241 (72.8%)	28 (8.5%)	29 (8.8%)	21 (6.3%)	10 (3.0%)	2 (0.6%)
Wrist / hand pain	171 (50.6%)	24 (7.1%)	77 (22.8%)	35 (10.4%)	22 (6.5%)	9 (2.7%)
Chest pain	219 (66.4%)	29 (8.8%)	46 (13.9%)	19 (5.8%)	14 (4.2%)	3 (0.9%)
Abdominal pain	168 (49.7%)	36 (10.7%)	71 (21.0%)	34 (10.1%)	22 (6.5%)	7 (2.1%)
Upper back pain	150 (45.3%)	34 (10.3%)	64 (19.3%)	44 (13.3%)	26 (7.9%)	13 (3.9%)
Lower back pain	84 (24.1%)	33 (9.5%)	94 (26.9%)	66 (18.9%)	51 (14.6%)	21 (6.0%)
Hip / thigh pain	168 (49.9%)	30 (8.9%)	53 (15.7%)	48 (14.2%)	25 (7.4%)	13 (3.9%)
Knee pain	169 (49.0%)	22 (6.4%)	74 (21.5%)	38 (11.0%)	28 (8.1%)	14 (4.1%)
Ankle / foot pain	184 (55.1%)	28 (8.4%)	51 (15.3%)	38 (11.4%)	28 (8.4%)	5 (1.5%)
Other pains	190 (66.9%)	21 (7.4%)	25 (8.8%)	23 (8.1%)	14 (4.9%)	11 (3.9%)

## **SECTION 3 - PARTICIPANT FOLLOW-UP**

**Table 10: Overall summary of withdrawals requests by treatment arm\***

Withdrawal status	Standard care	Self-management	TOTAL
Participant withdrew from intervention package only and will be followed up	1 (0.3%)	2 (0.5%)	3 (0.4%)
Participant withdrew from study completely and will not be followed up	16 (4.6%)	14 (3.7%)	30 (4.1%)
Study team withdrew participant from study completely and will not be followed up	0	2 (0.5%)	2 (0.3%)

\* Summary of total number of withdrawal requests i.e. participants may have more than one request

**Table 11: Number of withdrawals throughout the trial**

	Standard care	Self-management	TOTAL
Post-randomisation to 4 months follow-up	10/351 (2.8%)	10/376 (2.7%)	20
4 - 8 months follow-up	5/341 (1.5%)	3/366 (0.8%)	8
8 - 12 months follow-up	1/336 (0.3%)	3/363 (0.8%)	4
Overall	16 (4.6%)	16 (4.3%)	32

**Table 12: Time from randomisation to withdrawal and follow-up summarised by treatment arm**

	Standard care	Self-management	TOTAL
<b>Time from randomisation to withdrawing completely from trial (months)</b>			
N	16	16	32
Mean (SD)	5.6 (3.8)	5.8 (5.0)	5.7 (4.4)
Median (IQR)	4.7 (2.1, 9.1)	5.4 (1.3, 8.9)	5.2 (2.0, 8.9)
Missing time	0	0	0
<b>Time from randomisation to 4-month follow-up</b>			
N	276	277	553
Mean (SD)	4.6 (0.8)	4.5 (0.7)	4.6 (0.7)
Median (IQR)	4.4 (4.1, 4.8)	4.4 (4.1, 4.6)	4.4 (4.1, 4.7)
Missing time	0	0	0

<b>Time from randomisation to 8-month follow-up</b>			
N	264	284	548
Mean (SD)	8.7 (1.0)	8.7 (1.9)	8.7 (1.5)
Median (IQR)	8.5 (8.1, 9.0)	8.4 (8.1, 8.9)	8.5 (8.1, 9.0)
Missing time	0	0	0
<b>Time from randomisation to 12-month follow-up</b>			
N	283	303	586
Mean (SD)	13.3 (2.1)	12.9 (1.5)	13.1 (1.8)
Median (IQR)	12.7 (12.2, 13.1)	12.5 (12.2, 13.0)	12.6 (12.2, 13.1)
Missing time	0	0	0

## **SECTION 4 - INTERVENTION DATA**

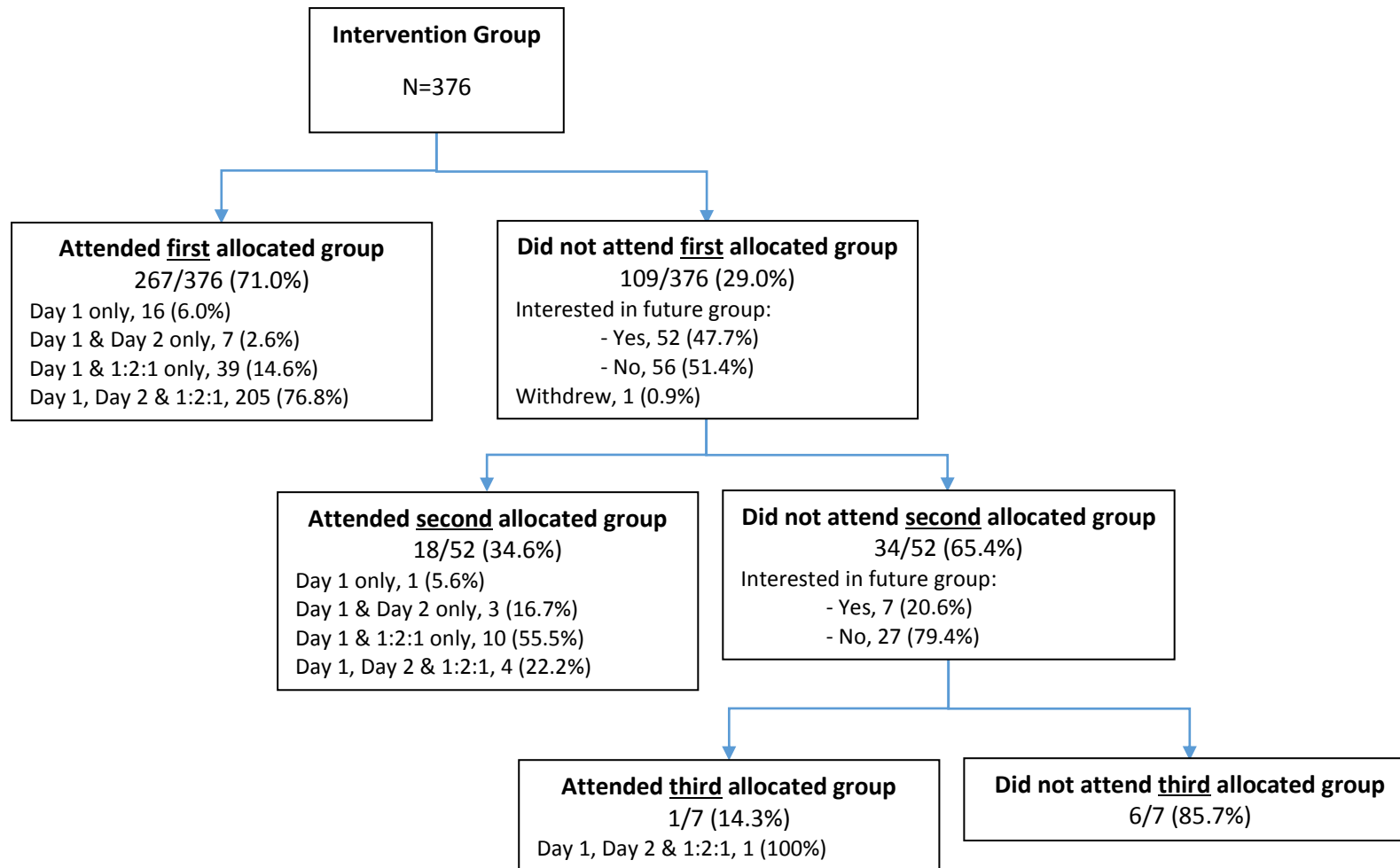


***Table 13: Summary of intervention data***

	Self-management
<b>Time from randomisation to Session 1 (days)</b>	
N	375
Mean (SD)	26.9 (31.7)
Median (IQR)	15 (11, 23)
Missing	1
<b>Time from randomisation to Session 2 (days)</b>	
N	375
Mean (SD)	34.1 (32.6)
Median (IQR)	22 (18, 30)
Missing	1
<b>Session attendance</b>	
Session 1 only	17 (4.5%)
Session 1 & 2 only	10 (2.7%)
Session 1 and one-to-one only	43 (11.5%)
Session 1 and 2 and one-to-one	216 (57.6%)
Did not attend session 1 (hence no other groups)	89 (23.7%)
<b>Adherence</b>	
Minimum adherence (Session 1 and one-to-one as a minimum)	259 (69.1%)
Full adherence (Session 1, session 2 and one-to-one)	216 (57.6%)
<b>Group size as randomised</b>	
Number of groups	42
Mean (SD)	9.0 (3.4)
Median (IQR)	9 (7, 12)

	Missing	0
<b>Group attendance on Day 1</b>		
	Number of groups	42
	Mean (SD)	6.8 (2.7)
	Median (IQR)	6.5 (5, 9)
	Missing	0

**Figure 2: Intervention attendance flow diagram**



## **SECTION 5 - STUDY OUTCOME DATA**

**Table 14: Study outcomes at 4 months follow-up**

Outcome	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value	
<b>HIT-6</b>	N	275	276	551	-1.3 (-2.47, -0.11); 0.033	-1.0 (-1.91, -0.006); 0.049
	Mean (SD)	62.3 (7.1)	61.0 (7.0)	61.7 (7.1)		
	Median (IQR)	63 (59, 66)	62 (58, 65)	62 (58, 66)		
	Missing	1	1	2		
<b>CH-QLQ – role restrictive</b>	N	244	251	495	2.5 (-0.86, 5.80); 0.146	1.5 (-1.01, 3.97); 0.243
	Mean (SD)	61.6 (18.3)	64.1 (17.6)	62.9 (18.0)		
	Median (IQR)	61.9 (50, 75)	66.7 (52.4, 76.2)	64.3 (50, 76.2)		
	Missing	32	26	58		
<b>CH-QLQ – role preventive</b>	N	244	251	495	2.5 (-1.20, 6.17); 0.187	1.6 (-0.84, 4.02); 0.199
	Mean (SD)	75.9 (20.5)	78.6 (18.7)	77.3 (19.6)		
	Median (IQR)	81.3 (62.5, 91.7)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)		
	Missing	32	26	58		
<b>CH-QLQ – emotional function</b>	N	244	251	495	1.7 (-2.45, 5.76); 0.429	1.0 (-2.07, 4.01); 0.531
	Mean (SD)	64.8 (23.4)	66.5 (23.0)	65.7 (23.2)		
	Median (IQR)	66.7 (44.4, 83.3)	72.2 (50, 88.9)	66.7 (50, 83.3)		
	Missing	32	26	58		

<b>SF-12 Physical</b>					
N	242	251	493	0.2 (-1.58, 2.07); 0.793	-0.2 (-1.49, 1.06); 0.739
Mean (SD)	46.1 (10.7)	46.3 (10.0)	46.2 (10.4)		
Median (IQR)	48.8 (38.7, 54.5)	48.4 (40.8, 53.9)	48.5 (40.1, 54.3)		
Missing	34	26	60		
<b>SF-12 Mental</b>					
N	243	251	494	1.6 (-0.32, 3.46); 0.103	0.7 (-0.80, 2.19); 0.361
Mean (SD)	41.2 (10.8)	42.8 (10.2)	42.0 (10.5)		
Median (IQR)	41.7 (32.3, 50.4)	42.7 (35.2, 51.3)	42.3 (34.5, 50.9)		
Missing	33	26	59		
<b>EQ-5D</b>					
N	275	274	549	0.04 (-0.01, 0.09); 0.113  Non-parametric test: P=0.011	0.02 (-0.008, 0.05); 0.150
Mean (SD)	0.63 (0.28)	0.68 (0.26)	0.66 (0.27)		
Median (IQR)	0.72 (0.55, 0.80)	0.74 (0.64, 0.84)	0.74 (0.58, 0.84)		
Missing	1	3	4		
<b>EQ-5D VAS</b>					
N	241	250	491	1.7 (-2.37, 5.71); 0.417	0.8 (-2.27, 3.79); 0.622
Mean (SD)	65.0 (20.7)	67.1 (20.6)	66.0 (20.6)		
Median (IQR)	70 (50, 80)	70 (56, 85)	70 (50, 80)		
Missing	35	27	62		
<b>HADS Anxiety</b>					
N	244	251	495	-0.2 (-0.65, 0.30); 0.472	0.2 (-0.22, 0.55); 0.393
Mean (SD)	10.5 (2.7)	10.3 (2.7)	10.4 (2.7)		
Median (IQR)	10 (8, 12)	10 (8, 12)	10 (8, 12)		

Missing	32	26	58		
<b>HADS Depression</b>					
N	244	251	495	-0.07 (-0.41, 0.27); 0.682	-0.1 (-0.43, 0.20); 0.477
Mean (SD)	9.1 (1.8)	9.0 (1.7)	9.1 (1.8)		
Median (IQR)	9 (8, 10)	9 (8, 10)	9 (8, 10)		
Missing	32	26	58		
<b>PSEQ</b>					
N	244	250	494	2.4 (-0.04, 4.84); 0.054	2.3 (0.51, 4.00); 0.011
Mean (SD)	35.4 (14.2)	37.8 (13.5)	36.6 (13.9)		
Median (IQR)	37.5 (24, 46)	39 (28, 48)	38 (26, 47)		
Missing	32	27	59		
<b>HeiQ</b>					
N	244	251	495	0.09 (-0.04, 0.22); 0.171	0.04 (-0.07, 0.15); 0.452
Mean (SD)	2.9 (0.70)	3.0 (0.70)	2.9 (0.7)		
Median (IQR)	3 (2.4, 3.2)	3 (2.6, 3.4)	3 (2.4, 3.4)		
Missing	32	26	58		

\* Models adjusted for age, gender, the baseline value of the dependent variable and baseline stratification factors (type of headache and geographical locality)

**Table 15: Study outcomes at 8 months follow-up**

Outcome	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
<b>HIT-6</b>					
N	263	283	546	-0.3 (-1.45, 0.93); 0.672	0.07 (-0.95, 1.09); 0.888
Mean (SD)	61.1 (7.2)	60.8 (6.4)	61.0 (6.8)		

Median (IQR)	62 (57, 66)	61 (58, 65)	61 (57, 65)		
Missing	1	1	2		
<b>CH-QLQ – role restrictive</b>					
N	228	254	482	0.7 (-2.81, 4.29); 0.683	-0.09 (-2.87, 2.69); 0.949
Mean (SD)	65.3 (19.6)	66.3 (17.8)	65.8 (18.7)		
Median (IQR)	66.7 (52.4, 81.0)	66.7 (54.8, 78.6)	66.7 (52.4, 81.0)		
Missing	36	30	66		
<b>CH-QLQ – role preventive</b>					
N	228	254	482	1.8 (-2.09, 5.62); 0.369	1.2 (-1.47, 3.97); 0.368
Mean (SD)	77.2 (22.1)	79.2 (19.2)	78.3 (20.6)		
Median (IQR)	83.3 (66.7, 95.8)	83.3 (70.8, 95.8)	83.3 (66.7, 95.8)		
Missing	36	30	66		
<b>CH-QLQ – emotional function</b>					
N	228	253	481	0.07 (-4.05, 4.20); 0.972	-0.5 (-3.74, 2.80); 0.778
Mean (SD)	69.2 (23.3)	69.3 (22.6)	69.2 (22.9)		
Median (IQR)	75 (55.6, 88.9)	72.2 (55.6, 88.9)	72.2 (55.6, 88.9)		
Missing	36	31	67		
<b>SF-12 Physical</b>					
N	226	253	479	0.5 (-1.36, 2.35); 0.602	-0.06 (-1.31, 1.18); 0.918
Mean (SD)	46.8 (10.7)	47.3 (9.9)	47.0 (10.3)		
Median (IQR)	49.2 (39.9, 54.8)	48.5 (41.6, 54.8)	48.8 (41.3, 54.8)		
Missing	38	31	69		
<b>SF-12 Mental</b>					



	N	226	253	479	1.4 (-0.55, 3.28); 0.161	0.9 (-0.55, 2.44); 0.215
	Mean (SD)	41.5 (10.1)	42.9 (10.4)	42.3 (10.3)		
	Median (IQR)	41.3 (35.0, 49.3)	43.1 (35.5, 51.2)	42.1 (35.2, 50.4)		
	Missing	38	31	69		
<b>EQ-5D</b>						
	N	261	280	541	0.05 (-0.002, 0.09); 0.059	0.03 (-0.002, 0.06); 0.069
	Mean (SD)	0.65 (0.27)	0.70 (0.24)	0.67 (0.26)	Non-parametric test: P=0.037	
	Median (IQR)	0.74 (0.56, 0.80)	0.74 (0.65, 0.84)	0.74 (0.64, 0.84)		
	Missing	3	4	7		
<b>EQ-5D VAS</b>						
	N	224	253	477	2.9 (-0.93, 6.67); 0.138	2.3 (-0.57, 5.27); 0.115
	Mean (SD)	66.1 (21.3)	69.0 (20.1)	67.7 (20.7)		
	Median (IQR)	70 (50, 80)	75 (55, 85)	70 (55, 85)		
	Missing	40	31	71		
<b>HADS Anxiety</b>						
	N	226	252	478	-0.5 (-0.94, -0.03); 0.067	-0.2 (-0.63, 0.23); 0.355
	Mean (SD)	10.5 (2.7)	10.0 (2.7)	10.2 (2.7)		
	Median (IQR)	10 (8, 12)	10 (8, 12)	10 (8, 12)		
	Missing	38	32	70		
<b>HADS Depression</b>						
	N	226	252	478	-0.04 (-0.37, 0.28); 0.789	-0.1 (-0.41, 0.17); 0.416
	Mean (SD)	9.1 (1.9)	9.0 (1.6)	9.1 (1.8)		
	Median (IQR)	9 (8, 10)	9 (8, 10)	9 (8, 10)		
	Missing	38	32	70		

<b>PSEQ</b>	N	226	253	479	1.7 (-0.86, 4.17); 0.198	1.5 (-0.31, 3.34); 0.103
	Mean (SD)	37.0 (14.8)	38.7 (13.2)	37.9 (14.0)		
	Median (IQR)	39.5 (28, 49)	40 (28, 50)	40 (28, 49)		
	Missing	38	31	69		
<b>HeiQ</b>	N	224	253	477	0.06 (-0.07, 0.19); 0.340	0.04 (-0.06, 0.14); 0.395
	Mean (SD)	2.9 (0.7)	3.0 (0.69)	2.9 (0.7)		
	Median (IQR)	3 (2.4, 3.3)	3 (2.6, 3.4)	3 (2.6, 3.4)		
	Missing	40	31	71		

\* Model adjusted for age, gender, the baseline value of the dependent variable and baseline stratification factors (type of headache and geographical locality)

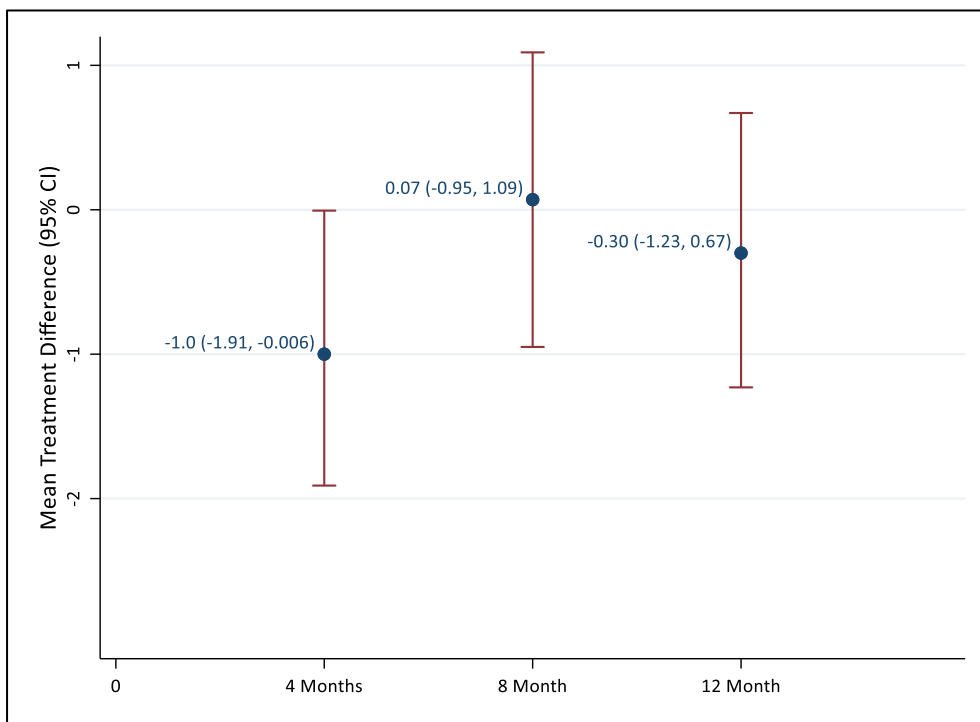
**Table 16: Study outcomes at 12 months follow-up**

Outcome	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value	
<b>HIT-6</b>	N	282	300	582	-0.6 (-1.72, 0.54); 0.303	-0.3 (-1.23, 0.67); 0.560
	Mean (SD)	60.7 (7.0)	60.1 (6.9)	60.4 (7.0)		
	Median (IQR)	62 (57, 65)	61 (55.5, 64.5)	61 (56, 65)		
	Missing	1	3	4		
<b>CH-QLQ – role restrictive</b>	N	235	268	503	0.9 (-2.33, 4.16); 0.582	0.3 (-2.25, 2.94); 0.794
	Mean (SD)	66.0 (19.0)	66.9 (18.1)	66.5 (18.5)		

Median (IQR)	66.7 (54.8, 81.0)	66.7 (57.1, 81.0)	66.7 (54.8, 81.0)		
Missing	48	35	83		
<b>CH-QLQ – role preventive</b>					
N	235	268	503	2.5 (-0.92, 5.84); 0.153	2.3 (-0.35, 4.88); 0.090
Mean (SD)	77.5 (20.3)	80.0 (18.4)	78.8 (19.3)		
Median (IQR)	83.3 (66.7, 95.8)	83.3 (70.8, 95.8)	83.3 (66.7, 95.8)		
Missing	48	35	83		
<b>CH-QLQ – emotional function</b>					
N	235	268	503	1.7 (-2.27, 5.69); 0.399	1.2 (-2.06, 4.40); 0.477
Mean (SD)	68.7 (23.3)	70.5 (22.1)	69.7 (22.7)		
Median (IQR)	72.2 (50, 88.9)	72.2 (55.6, 88.9)	72.2 (55.6, 88.9)		
Missing	48	35	83		
<b>SF-12 Physical</b>					
N	234	265	499	0.9 (-0.86, 2.72); 0.308	0.5 (-0.81, 1.77); 0.465
Mean (SD)	46.0 (10.8)	46.9 (9.4)	46.5 (10.1)		
Median (IQR)	47.3 (37.5, 54.5)	48.4 (40.8, 54.4)	48.1 (40.3, 54.5)		
Missing	49	38	87		
<b>SF-12 Mental</b>					
N	234	267	501	1.5 (-0.54, 3.48); 0.151	0.9 (-0.84, 2.58); 0.318
Mean (SD)	42.2 (10.9)	43.9 (10.5)	43.1 (10.7)		
Median (IQR)	41.6 (34.2, 50.7)	44.5 (37.1, 52.2)	43.4 (35.6, 51.4)		
Missing	49	36	85		
<b>EQ-5D</b>					
N	282	301	583	0.03 (-0.02, 0.07);	0.003 (-0.03, 0.03);

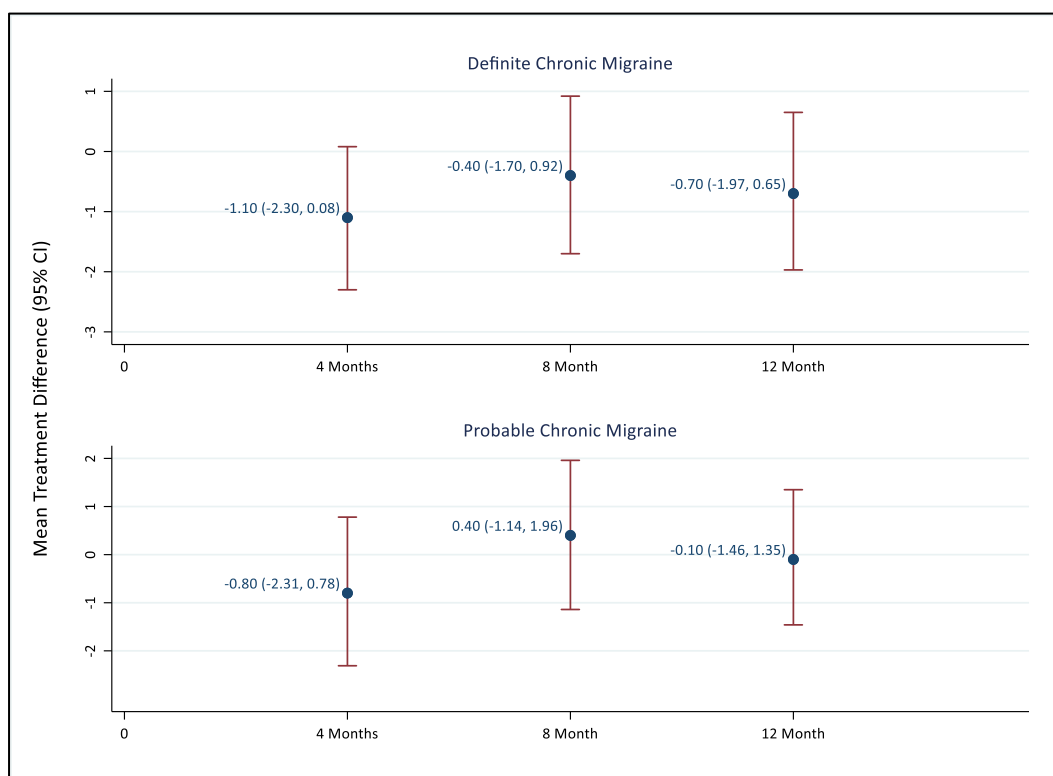
				0.216	0.875
Mean (SD)	0.67 (0.26)	0.69 (0.25)	0.68 (0.25)	Non-parametric test: P=0.107	
Median (IQR)	0.74 (0.60, 0.81)	0.74 (0.64, 0.84)	0.74 (0.63, 0.84)		
Missing	1	2	3		
<b>EQ-5D VAS</b>					
N	227	264	491	4.1 (0.10, 8.19); 0.045	3.9 (0.90, 6.88); 0.011
Mean (SD)	65.3 (22.5)	69.7 (20.7)	67.7 (21.6)		
Median (IQR)	70 (50, 80)	75 (60, 85)	75 (51, 85)		
Missing	56	39	95		
<b>HADS Anxiety</b>					
N	234	266	500	-0.1 (-0.61, 0.36); 0.610	0.2 (-0.21, 0.61); 0.337
Mean (SD)	10.3 (2.8)	10.2 (2.7)	10.2 (2.7)		
Median (IQR)	10 (8, 12)	10 (8, 12)	10 (8, 10)		
Missing	49	37	86		
<b>HADS Depression</b>					
N	234	266	500	-0.001 (-0.31, 0.31); 0.993	-0.03 (-0.33, 0.26); 0.818
Mean (SD)	9.1 (1.8)	9.1 (1.7)	9.1 (1.8)		
Median (IQR)	9 (8, 10)	9 (8, 10)	9 (8, 10)		
Missing	49	37	86		
<b>PSEQ</b>					
N	234	267	501	2.2 (-0.36, 4.81); 0.091	2.1 (0.17, 3.96); 0.033
Mean (SD)	37.1 (14.6)	39.4 (13.6)	38.3 (14.1)		
Median (IQR)	40 (27, 48)	41 (31, 50)	40 (29, 49)		
Missing	49	36	85		

HeiQ						
	N	233	267	500	0.04 (-0.10, 0.18); 0.558	0.001 (-0.10, 0.10); 0.988
	Mean (SD)	2.9 (0.70)	3.0 (0.7)	3.0 (0.7)		
	Median (IQR)	3 (2.6, 3.4)	3 (2.6, 3.4)	3 (2.6, 3.4)		
	Missing	50	36	86		



***Figure 3: Plot of HIT-6 (Primary outcome) treatment effect over time***

**Figure 4:**  
**Plot of HIT-6 (Primary outcome) over time by headache type and treatment group**



**Table 17: General health outcomes at 4 months follow-up**

Outcome	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
Headache/migraine days over the last 4 weeks					
	N				
	239	248	487	1.1 (-0.31,	1.5 (0.48,

				2.44); 0.127	2.56); 0.004	
	Mean (SD)	12.3 (7.5)	13.4 (7.6)	12.9 (7.5)		
	Median (IQR)	10 (7, 16)	13 (7, 18.5)	12 (7, 18)		
	Missing	37	29	66		
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>						
	N	241	249	490	-0.09 (-1.34, 1.61); 0.889	0.2 (-0.91, 1.23); 0.769
	Mean (SD)	9.5 (7.3)	9.4 (6.9)	9.5 (7.1)		
	Median (IQR)	8 (4, 12)	8 (4, 13)	8 (4, 13)		
	Missing	35	28	63		
<b>Average number of hours the headache/migraine lasted on the days they had it</b>						
	N	223	220	443	0.2 (-1.09, 1.49); 0.758	0.1 (-1.14, 1.43); 0.825
	Mean (SD)	8.4 (7.0)	8.6 (6.6)	8.5 (6.8)	Non-parametric test: P=0.335	
	Median (IQR)	6 (4, 12)	6 (4, 12)	6 (4, 12)		
	Missing	53	57	110		
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine</b>						
	N	224	222	446	-0.08 (-0.48, 0.31); 0.677	-0.1 (-0.47, 0.26); 0.569
	Mean (SD)	6.1 (2.1)	6.0 (1.9)	6.0 (2.0)		
	Median (IQR)	6 (5, 8)	6 (5, 7)	6 (5, 8)		
	Missing	52	55	107		
<b>How fatigued were you on average in the past seven days</b>						
	Not at all	4 (1.4%)	11 (4.0%)	15 (2.7%)	OR: 0.9 (-0.63, 1.11);	OR: 0.9 (0.65, 1.27);

				0.378	0.562
A little bit	53 (19.2%)	52 (18.8%)	105 (19.0%)		
Somewhat	53 (19.2%)	52 (18.8%)	105 (19.0%)		
Quite a bit	75 (27.2%)	86 (31.0%)	161 (29.1%)		
Very much	59 (21.4%)	49 (17.7%)	108 (19.5%)		
Missing	32 (11.6%)	27 (9.7%)	59 (10.7%)		
<b>Sleep quality in the past seven days</b>					
Very poor	38 (13.8%)	33 (11.9%)	71 (12.8%)	OR: 0.9 (0.66, 1.30); 0.665	OR: 1.0 (0.72, 1.42); 0.951
Poor	61 (22.1%)	81 (29.2%)	142 (25.7%)		
Fair	103 (37.3%)	90 (32.5%)	193 (34.9%)		
Good	37 (13.4%)	40 (14.4%)	77 (13.9%)		
Very good	5 (1.8%)	6 (2.2%)	11 (2.0%)		
Missing	32 (11.6%)	27 (9.8%)	59 (10.7%)		
<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>					
N	243	250	493	-0.3 (-0.80, 0.27); 0.331	-0.2 (-0.64, 0.16); 0.241
Mean (SD)	4.3 (2.8)	4.0 (2.6)	4.1 (2.7)		
Median (IQR)	4 (2, 6)	4 (2, 6)	4 (2, 6)		
Missing	33	27	60		



**Table 17.1: Summary of medications at 4 months**

Drug (n=495)	Median Dose mg/28 days (range, IQR)	Standard care				Self-management			
		Drug group (n= 243)	Median DDDs Median (IQR)	Type (n=243)	Median DDDs Median (IQR)	Drug group (n=252)	Median DDDs Median (IQR)	Type (n=252)	Median DDDs Median (IQR)
<b>Acute</b>									
Aspirin (n=47)	4800 (600-36000, 2400-7200)	Analgesic (n=161)	4.3 (1.3-8)	Acute (n=226)	9.3 (4.7-20)	Analgesic (n=173)	3.2 (1.3-6.7)	Acute (n=232)	8.3 (3.3-16)
Paracetamol (n=324)	10000 (250-234000, 4000-22500)								
Cyclizine (n=0)	-	Anti-emetic (n=9)	1 (0.75-2.7)						
Domperidone (n=1)	60								
Metoclopramide (n=5)	180 (80-840, 140-200)								
Prochlorperazine (n=9)	9 (6-40, 6-12)								
Diclofenac (n=3)	300 (100-300, 100-300)					NSAID (n=90)	4 (1.7-8)		
Ibuprofen (n=145)	3200 (200-39200, 1600-8000)								
Indometacin (n=1)	400								
Mefenamic acid (n=0)	-								
Meloxicam (n=0)	-								
Naproxen (n=21)	4000 (500-84000, 1750-10000)	Opioids* (n=63)	2.9 (1-7.6)						
Tolefenamic acid (n=1)	1000								
Fentanyl patches (n=1)	34								
Morphine (n=2)	135 (30-240, 30-240)								
Tramadol (n=7)	2800 (150-8400, 1000-7200)					Triptan (n=116)	6.5 (4-13)		
Codeine (n=96)	224 (10-6720, 64-640)								
Dihydrocodeine (n=10)	530 (22-6720, 40-1120)								
Tapentadol (n=0)	-								
Almotriptan (n=2)	75 (75-75, 75-75)	Triptan (n=130)	6 (4-12)						
Eletriptan (n=4)	260 (160-560, 180-440)								
Frovatriptan (n=7)	23 (7.5-45, 15-34)								
Naratriptan (n=20)	15 (2.5-28, 8.8-21)								
Rizatriptan (n=28)	35 (5-240, 20-60)								

Sumatriptan injection (n=3)	24 (18-90, 18-90)								
Sumatriptan oral (n=141)	400 (0-3900, 200-800)								
Sumatriptan spray (n=7)	80 (10-300, 20-160)								
Zolmitriptan oral (n=37)	18 (2.5-140, 10-30)								
Zolmitriptan spray (n=8)	15 (0-50, 7.5-30)								
<b>Prophylaxis</b>									
Candesartan (n=7)	168 (56-448, 112-448)	Angiotensin receptor blocker (n=3)	56 (21-56)	Prophylaxis (n=80)	14 (7.2-28)	Angiotensin receptor blocker (n=5)	21 (14-28)	Prophylaxis (n=86)	14 (4.7-28)
Losartan (n=1)	4200					Anti-epileptic (n=28)	5.8 (3.5-11)		
Sodium valproate (n=4)	22400 (11200-28000, 16800-25200)	Anti-epileptic (n=10)	7.2 (4.7-15)			Beta blocker (n=24)	28 (14-28)		
Topiramate (n=34)	1750 (175-8400, 1400-2800)					Calcium channel blocker (n=0)	-		
Atenolol (n=2)	2450 (700-4200, 700-4200)	Beta blocker (n=25)	14 (11-28)			Gabapentinoid (n=13)	9.3 (4.7-14)		
Metoprolol (n=0)	-					Other antidepressant (n=7)	21 (14-28)		
Propranolol (n=47)	2240 (320-8960, 2240-4480)					Serotonergic antagonist (n=5)	19 (9.3-21)		
Flunarizine (n=2)	140 (140-140, 140-140)	Calcium channel blocker (n=2)	14 (14-14)			Tricyclic antidepressant	4.7 (3.7-11)		
Gabapentin (n=14)	21000 (2100-75600, 8400-25200)	Gabapentinoid (n=10)	12 (7-37)						
Pregabalin (n=9)	2800 (1050-33600, 2100-16800)								
Citalopram (n=4)	420 (240-560, 260-560)	Other antidepressant (n=11)	28 (20-28)						
Duloxetine (n=3)	3360 (1680-3360, 1680-3360)								
Escitalopram (n=0)	-								
Fluoxetine (n=3)	560 (400-560, 400-560)								
Mirtazepine (n=1)	420								
Sertraline (n=5)	1400 (700-1400, 700-1400)								
Venlafaxine (n=2)	3150 (2100-4200, 2100-4200)								
Pizotifen (n=11)	28 (7-84, 14-42)	Serotonergic antagonist (n=6)	14 (9.3-28)						
Amitriptyline (n=49)	560 (20-6300, 280-1120)	Tricyclic antidepressant	9.3 (3.7-17)						
Dosulepin (n=3)	2100 (1400-4200, 1400-4200)								

Imipramine (n=1)	840	(n=35)				(n=25)			
Nortriptyline (n=7)	840 (210-2800, 280-1240)								
<b>Anxiolytic/sedative</b>									
Diazepam (n=3)	112 (4-180, 4-180)	Benzodiazepine (n=1)	11	Anxiolytic/sedative (n=1)	11	Benzodiazepine (n=2)	9.2 (0.4-18)	Anxiolytic/sedative (n=2)	9.2 (0.4-18)
Lorazepam (n=0)	-		Cyclopyrrolone sedative (n=0)			-	Cyclopyrrolone sedative (n=0)		
Zopiclone (n=0)	-								

\* Opioids reported as morphine equivalent quantities standardised to codeine DDDs to make dosage appropriate for non-malignant pain

**Table 17. 2: Daily defined dose (DDD) summarised by drug group and drug type across treatments arms at 4 months**

Medications	Standard care N; Median DDD (IQR)	Self-management N; Median DDD (IQR)	P-value*
<b>Drug group</b>			
Analgesic	161; 4.3 (1.3-8)	173; 3.2 (1.3-6.7)	0.094
Anti-emetic	9; 1 (0.75-2.7)	6; 1.7 (0.5-6)	0.634
NSAID	90; 4 (1.7-8)	74; 2.8 (1.3-6.7)	0.199
Opioids	63; 2.9 (1-7.6)	51; 2 (0.64-9.6)	0.486
Triptan	116; 6.5 (4-13)	130; 6 (4-12)	0.841
Angiotensin receptor block	3; 56 (21-56)	5; 21 (14-28)	0.500
Anti-epileptic	10; 7.2 (4.7-15)	28; 5.8 (3.5-11)	0.324
Beta blocker	25; 14 (11-28)	24; 28 (14-28)	0.005
Calcium channel blocker	2; 14 (14-14)	-	-
Gabapentinoid	10; 12 (7-37)	13; 9.3 (4.7-14)	0.435
Other antidepressant	11; 28 (20-28)	7; 21 (14-28)	0.248
Serotonergic antagonist	6; 14 (9.3-28)	5; 19 (9.3-21)	0.905
Tricyclic antidepressant	35; 9.3 (3.7-17)	25; 4.7 (3.7-11)	0.289
Benzodiazepine	1; 11	2; 9.2 (0.4-18)	1.00
Cyclopyrrolone sedative	-	-	-
<b>Drug type</b>			
Acute	226; 9.3 (4.7-20)	232; 8.3 (3.3-16)	0.165
Prophylaxis	80; 14 (7.2-28)	86; 14 (4.7-28)	0.921
Anxiolytic/Sedative	1; 11	2; 9.2 (0.4-18)	1.00

\* P-value computed using a non-parametric test

**Table 18: General health outcomes at 8 months follow-up**

Outcome		Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
<b>Headache/migraine days over the last 4 weeks</b>	N	226	252	478	-0.01 (-1.44, 1.42); 0.990	0.3 (-0.86, 1.49); 0.598
	Mean (SD)	11.8 (8.1)	11.8 (7.4)	11.8 (7.7)		
	Median (IQR)	10 (5, 18)	10 (6, 16)	10 (5, 17)		
	Missing	38	32	70		
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>	N	226	252	478	-0.4 (-1.73, 0.90); 0.532	-0.1 (-1.27, 1.05); 0.852
	Mean (SD)	9.3 (7.5)	8.9 (7.2)	9.1 (7.3)		
	Median (IQR)	8 (3, 14)	7.5 (3.5, 12)	7 (3, 13)		
	Missing	38	32	70		
<b>Average number of hours the headache/migraine lasted on the days they had it</b>	N	223	246	469	1.5 (0.06, 2.90); 0.041  Non-parametric test: P=0.021	2.0 (0.55, 3.42); 0.007
	Mean (SD)	8.0 (6.9)	9.2 (7.3)	8.6 (7.1)		
	Median (IQR)	6 (3, 10)	7 (4, 12)	6 (4, 11)		
	Missing	41	38	79		
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you</b>						

<b>had a headache/migraine</b>						
	N	222	246	468	0.2 (-0.22, 0.53); 0.436	0.3 (-0.06, 0.65); 0.101
	Mean (SD)	6.0 (2.1)	6.1 (2.0)	6.0 (2.0)		
	Median (IQR)	6 (5, 7)	6 (5, 7)	6 (5, 7)		
	Missing	42	38	80		
<b>How fatigued were you on average in the past seven days</b>						
	Not at all	14 (5.3%)	9 (3.2%)	23 (4.3%)	OR: 0.8 (0.60, 1.20); 0.357	OR: 0.9 (0.63, 1.22); 0.429
	A little bit	35 (13.3%)	58 (20.4%)	93 (17.0%)		
	Somewhat	56 (21.2%)	64 (22.5%)	120 (21.9%)		
	Quite a bit	80 (30.3%)	81 (28.5%)	161 (29.4%)		
	Very much	41 (15.5%)	41 (14.5%)	82 (15.0%)		
	Missing	38 (14.4%)	31 (10.9%)	69 (12.6%)		
<b>Sleep quality in the past seven days</b>						
	Very poor	35 (13.3%)	25 (8.8%)	60 (10.9%)	OR: 1.2 (0.86, 1.65); 0.296	OR: 1.3 (0.91, 1.84); 0.153
	Poor	62 (23.5%)	71 (25.0%)	133 (24.3%)		
	Fair	81 (30.7%)	106 (37.3%)	187 (34.1%)		
	Good	40 (15.1%)	44 (15.5%)	84 (15.3%)		
	Very good	7 (2.6%)	7 (2.5%)	14 (2.6%)		
	Missing	39 (14.8%)	31 (10.9%)	70 (12.8%)		
<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>						
	N	226	253	479	-0.4 (-0.90, 0.13); 0.139	-0.3 (-0.68, 0.17); 0.234
	Mean (SD)	4.3 (2.8)	3.9 (2.7)	4.1 (2.7)		
	Median (IQR)	4 (2, 6)	4 (2, 6)	4 (2, 6)		

Missing	38	31	69		
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**Table 18.1: Summary of medications at 8 months**

Drug (n=486)	Median Dose mg/28 days (range, IQR)	Standard care				Self-management			
		Drug group (n= 229)	Median DDDs Median (IQR)	Type (n=229)	Median DDDs Median (IQR)	Drug group (n=257)	Median DDDs Median (IQR)	Type (n=257)	Median DDDs Median (IQR)
<b>Acute</b>									
Aspirin (n=48)	5000 (325-50400, 2650-8700)	Analgesic (n=136)	3.4 (1.3-8)	Acute (n=203)	10 (4-17)	Analgesic (n=155)	2.7 (1.2-6.4)	Acute (n=225)	7.7 (3-16)
Paracetamol (n=276)	9000 (250-126000, 3175-19750)								
Cyclizine (n=3)	500 (300-500, 300-500)	Anti-emetic (n=10)	3.7 (2.5-6.7)						
Domperidone (n=1)	40								
Metoclopramide (n=5)	200 (100-2520, 150-210)								
Prochlorperazine (n=6)	24 (12-75, 18-48)								
Diclofenac (n=3)	3000 (800-4200, 800-4200)	NSAID (n=78)	3.3 (1.5-8)						
Ibuprofen (n=132)	3200 (200-33600, 1600-7000)								
Indometacin (n=1)	400								
Mefenamic acid (n=1)	3000								
Meloxicam (n=1)	210								
Naproxen (n=20)	3000 (500-56000, 1750-10250)								
Tofenamic acid (n=1)	800	Opioids* (n=54)	2.6 (0.96-9)						
Fentanyl patches (n=0)	-								
Morphine (n=2)	1260 (840-1680, 840-1680)								
Tramadol (n=7)	1600 (100-6300, 200-5600)								
Codeine (n=86)	174 (0-3360, 64-480)								
Dihydrocodeine (n=7)	240 (0-6720, 60-1120)								
Tapentadol (n=0)	-	Triptan (n=106)	7.8 (4-12)						
Almotriptan (n=2)	106 (63-150, 63-150)								
Eletriptan (n=3)	80 (40-300, 40-300)								
Frovatriptan (n=8)	16 (5-30, 11-23)								
Naratriptan (n=23)	10 (2.5-75, 5-18)								
Rizatriptan (n=33)	60 (5-280, 40-120)								



Sumatriptan injection (n=4)	18 (6-36, 9-30)										
Sumatriptan oral (n=124)	300 (50-8000, 200-613)										
Sumatriptan spray (n=5)	120 (20-240, 20-180)										
Zolmitriptan oral (n=36)	21 (2.5-101, 10-33)										
Zolmitriptan spray (n=7)	20 (0-125, 5-45)										
<b>Prophylaxis</b>											
Candesartan (n=5)	112 (44-224, 56-224)	Angiotensin receptor blocker (n=1)	28	Prophylaxis (n=73)	14 (7-28)	Angiotensin receptor blocker (n=5)	14 (7-28)	Prophylaxis (n=84)	12 (4.3-27)		
Losartan (n=1)	1400									Anti-epileptic (n=25)	4.7 (2.3-12)
Sodium valproate (n=5)	12000 (11200-22400, 11200-16800)	Anti-epileptic (n=11)	9.3 (4.7-18)							Beta blocker (n=25)	14 (14-28)
Topiramate (n=32)	1400 (0-16800, 700-4025)									Calcium channel blocker (n=0)	-
Atenolol (n=1)	700	Beta blocker (n=24)	14 (8.2-28)							Gabapentinoid (n=4)	12 (7-19)
Metoprolol (n=0)	-									Other antidepressant (n=9)	42 (28-56)
Propranolol (n=48)	2240 (360-8960, 1680-4480)									Serotonergic antagonist (n=3)	19 (9.3-28)
Flunarizine (n=1)	140	Calcium channel blocker (n=1)	14							Tricyclic antidepressant	7.5 (3.7-11)
Gabapentin (n=5)	33600 (19600-67200, 25200-44800)	Gabapentinoid (n=7)	14 (9.3-37)								
Pregabalin (n=6)	2800 (600-14700, 1400-4200)										
Citalopram (n=5)	560 (280-1120, 560-560)	Other antidepressant (n=11)	14 (7-28)								
Duloxetine (n=3)	420 (140-560, 140-560)										
Escitalopram (n=0)	-										
Fluoxetine (n=2)	570 (20-1120, 20-1120)										
Mirtazepine (n=4)	420 (300-1260, 360-840)										
Sertraline (n=6)	2800 (1400-5600, 1400-4200)										
Venlafaxine (n=0)	-										
Pizotifen (n=11)	42 (14-84, 14-42)	Serotonergic antagonist (n=8)	28 (9.3-28)								
Amitriptyline (n=49)	560 (0-4200, 280-840)	Tricyclic antidepressant	8.9 (3.7-15)								
Dosulepin (n=3)	800 (700-2800, 700-2800)										

Imipramine (n=1)	840	(n=30)				(n=34)			
Nortriptyline (n=11)	840 (100-2800, 160-1120)								
<b>Anxiolytic/sedative</b>									
Diazepam (n=2)	77 (42-112, 42-112)	Benzodiazepine (n=1)	11	Anxiolytic/sedative (n=1)	11	Benzodiazepine (n=1)	4.2	Anxiolytic/sedative (n=1)	4.2
Lorazepam (n=0)	-		Cyclopyrrolone sedative (n=0)			-	Cyclopyrrolone sedative (n=0)		
Zopiclone (n=0)	-								

\* Opioids reported as morphine equivalent quantities standardised to codeine DDDs to make dosage appropriate for non-malignant pain

**Table 18. 2: Daily defined dose (DDD) summarised by drug group and drug type across treatments arms at 8 months**

Medications	Standard care N; Median DDD (IQR)	Self-management N; Median DDD (IQR)	P-value*
<b>Drug group</b>			
Analgesic	136; 3.4 (1.3-8)	155; 2.7 (1.2-6.4)	0.095
Anti-emetic	10; 3.7 (2.5-6.7)	5; 1.3 (1-5)	0.140
NSAID	78; 3.3 (1.5-8)	76; 3 (1.3-7.6)	0.562
Opioids	54; 2.6 (0.96-9)	46; 1.4 (0.6-3.6)	0.020
Triptan	106; 7.8 (4-12)	127; 6 (4-12)	0.636
Angiotensin receptor block	1; 28	5; 14 (7-28)	1.00
Anti-epileptic	11; 9.3 (4.7-18)	25; 4.7 (2.3-12)	0.056
Beta blocker	24; 14 (8.2-28)	25; 14 (14-28)	0.872
Calcium channel blocker	1; 14	-	-
Gabapentinoid	7; 14 (9.3-37)	4; 12 (7-19)	0.612
Other antidepressant	11; 14 (7-28)	9; 42 (28-56)	0.140
Serotonergic antagonist	8; 28 (9.3-28)	3; 19 (9.3-28)	0.727
Tricyclic antidepressant	30; 8.9 (3.7-15)	34; 7.5 (3.7-11)	0.603
Benzodiazepine	1; 11	1; 42	1.00
Cyclopyrrolone sedative	-	-	-
<b>Drug type</b>			
Acute	203; 10 (4-17)	225; 7.7 (3-16)	0.162
Prophylaxis	73; 14 (7-28)	84; 12 (4.3-27)	0.170
Anxiolytic/Sedative	1; 11	1; 4.2	1.000

\* P-value computed using a non-parametric test

**Table 19: General health outcomes at 12 months follow-up**

Outcome		Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
<b>Headache/migraine days over the last 4 weeks</b>	N	233	268	501	0.5 (-0.94, 1.87); 0.517	0.9 (-0.29, 2.05); 0.141
	Mean (SD)	11.4 (7.8)	11.8 (7.8)	11.6 (7.8)		
	Median (IQR)	10 (4, 15)	10 (6, 17)	10 (5, 16)		
	Missing	50	35	85		
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>	N	233	266	499	0.4 (-0.88, 1.66); 0.546	0.7 (-0.39, 1.80); 0.209
	Mean (SD)	9.0 (7.1)	9.4 (7.3)	9.2 (7.2)		
	Median (IQR)	8 (3, 12)	8 (3, 14)	8 (3, 13)		
	Missing	50	37	87		
<b>Average number of hours the headache/migraine lasted on the days they had it</b>	N	230	265	495	1.1 (-0.17, 2.41); 0.089 Non-parametric test: P=0.054	1.1 (-0.10, 2.30); 0.072
	Mean (SD)	8.5 (7.1)	9.6 (7.4)	9.1 (7.3)		
	Median (IQR)	6 (4, 12)	7 (4, 12)	6 (4, 12)		
	Missing	53	38	91		
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine</b>	N	234	267	501	-0.03 (-0.36, 0.30); 0.841	-0.02 (-0.34, 0.30); 0.841

				0.30); 0.869	0.29); 0.886
Mean (SD)	6.1 (1.9)	6.0 (1.8)	6.1 (1.9)		
Median (IQR)	6 (5, 7)	6 (5, 7)	6 (5, 7)		
Missing	49	36	85		
<b>How fatigued were you on average in the past seven days</b>					
Not at all	14 (4.9%)	11 (3.6%)	25 (4.3%)	OR: 1.0 (0.67, 1.38); 0.831	OR: 0.9 (0.63, 1.29); 0.561
A little bit	63 (22.3%)	70 (23.1%)	133 (22.7%)		
Somewhat	59 (20.8%)	89 (29.4%)	148 (25.3%)		
Quite a bit	67 (23.7%)	65 (21.4%)	132 (22.5%)		
Very much	32 (11.3%)	32 (10.6%)	64 (10.9%)		
Missing	48 (17.0%)	36 (11.9%)	84 (14.3%)		
<b>Sleep quality in the past seven days</b>					
Very poor	28 (9.9%)	26 (8.6%)	54 (9.2%)	1.0 (0.72, 1.36); 0.962	1.0 (0.75, 1.45); 0.793
Poor	58 (20.5%)	74 (24.4%)	132 (22.5%)		
Fair	94 (33.2%)	105 (34.6%)	199 (34.0%)		
Good	46 (16.2%)	56 (18.5%)	102 (17.4%)		
Very good	9 (3.2%)	6 (2.0%)	15 (2.6%)		
Missing	48 (17.0%)	36 (11.9%)	84 (14.3%)		
<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>					
N	234	267	501	-0.1 (-0.63, 0.37); 0.614	-0.1 (-0.51, 0.32); 0.651
Mean (SD)	4.1 (2.8)	4.0 (2.7)	4.0 (2.8)		
Median (IQR)	4 (2, 6)	4 (2, 6)	4 (2, 6)		
Missing	49	36	85		

**Table 19. 1: Summary of medications at 12 months**

Drug (n=504)	Median Dose mg/28 days (range, IQR)	Standard care				Self-management			
		Drug group (n=236)	Median DDDs Median (IQR)	Type (n=236)	Median DDDs Median (IQR)	Drug group (n=268)	Median DDDs Median (IQR)	Type (n=268)	Median DDDs Median (IQR)
<b>Acute</b>									
Aspirin (n=49)	4000 (600-39000, 2400-9600)	Analgesic (n=143)	3 (1.3-10)	Acute (n=212)	9.8 (3.1-18)	Analgesic (n=171)	3.3 (1.3-7.8)	Acute (n=247)	8 (3.3-16)
Paracetamol (n=301)	9000 (400-90000, 4000-22000)								
Cyclizine (n=2)	325 (200-450, 200-450)	Anti-emetic (n=9)	4.5 (1.7-6)						
Domperidone (n=3)	60 (10-200, 10-200)								
Metoclopramide (n=8)	120 (0-460, 35-210)								
Prochlorperazine (n=8)	24 (3-72, 15-60)								
Diclofenac (n=4)	500 (150-3600, 225-2150)					NSAID (n=81)	3.3 (1.3-9)		
Ibuprofen (n=148)	3400 (200-50400, 1600-9600)								
Indometacin (n=1)	450								
Mefenamic acid (n=0)	-								
Meloxicam (n=0)	-								
Naproxen (n=17)	3500 (250-51000, 1500-14000)								
Tofenamic acid (n=1)	1000	Opioids* (n=57)	1.9 (0.64-5.1)						
Fentanyl patches (n=0)	-								
Morphine (n=1)	3640								
Tramadol (n=6)	1250 (100-9200, 200-5600)								
Codeine (n=86)	186 (0-4800, 72-576)								
Dihydrocodeine (n=8)	155 (10-1120, 45-760)								
Tapentadol (n=1)	700	Triptan (n=106)	8 (3-15)						
Almotriptan (n=3)	63 (50-88, 50-88)								
Eletriptan (n=3)	320 (160-840, 160-840)								
Frovatriptan (n=8)	7.5 (2.5-60, 5-23)								
Naratriptan (n=21)	18 (5-100, 10-25)								
Rizatriptan (n=25)	50 (10-300, 30-100)								

Sumatriptan injection (n=4)	36 (18-672, 21-360)														
Sumatriptan oral (n=141)	300 (50-27200, 150-600)														
Sumatriptan spray (n=5)	40 (20-240, 20-240)														
Zolmitriptan oral (n=36)	20 (2.5-140, 11-41)														
Zolmitriptan spray (n=6)	20 (5-50, 10-40)														
<b>Prophylaxis</b>															
Candesartan (n=7)	112 (4-224, 28-224)	Angiotensin receptor blocker (n=2)	21 (14-28)	Prophylaxis (n=69)	14 (7-28)	Angiotensin receptor blocker (n=6)	11 (3.5-28)	Prophylaxis (n=84)	14 (7.5-28)						
Losartan (n=1)	1400					Anti-epileptic (n=10)	7.2 (4.7-14)			Anti-epileptic (n=20)	8.2 (3.5-17)				
Sodium valproate (n=4)	22400 (11200-33600, 16800-28000)					Beta blocker (n=22)	28 (14-28)			Beta blocker (n=31)	14 (14-28)				
Topiramate (n=26)	2100 (350-6300, 1400-4200)					Calcium channel blocker (n=1)	14			Calcium channel blocker (n=0)	-				
Atenolol (n=0)	-					Gabapentinoid (n=5)	14 (14-20)			Gabapentinoid (n=6)	12 (4.7-28)				
Metoprolol (n=0)	-					Other antidepressant (n=9)	19 (9.3-28)			Other antidepressant (n=7)	21 (14-28)				
Propranolol (n=53)	2520 (160-8960, 2240-4480)											Serotonergic antagonist (n=8)	28 (14-28)	Serotonergic antagonist (n=4)	14 (9.3-19)
Flunarizine (n=1)	140											Tricyclic antidepressant	7.5 (3.7-11)	Tricyclic antidepressant	7.5 (3.7-15)
Gabapentin (n=6)	30800 (16800-67200, 25200-67200)														
Pregabalin (n=5)	1400 (700-8400, 1400-4200)														
Citalopram (n=3)	280 (135-560, 135-560)														
Duloxetine (n=4)	490 (140-1120, 280-840)														
Escitalopram (n=0)	-														
Fluoxetine (n=2)	560 (560-560, 560-560)														
Mirtazepine (n=2)	1050 (420-1680, 420-1680)														
Sertraline (n=3)	1400 (1400-1400, 1400-1400)														
Venlafaxine (n=2)	2100 (2100-2100, 2100-2100)														
Pizotifen (n=12)	28 (11-42, 14-42)														
Amitriptyline (n=44)	560 (30-4200, 280-840)														
Dosulepin (n=2)	3150 (2100-4200, 2100-4200)														

Imipramine (n=1)	1120	(n=29)				(n=27)			
Nortriptyline (n=9)	560 (210-1400, 560-800)								
<b>Anxiolytic/sedative</b>									
Diazepam (n=1)	16	Benzodiazepine (n=1)	1.6	Anxiolytic/sedative (n=1)	1.6	Benzodiazepine (n=0)	-	Anxiolytic/sedative (n=0)	-
Lorazepam (n=0)	-		Cyclopyrrolone sedative (n=0)			-	Cyclopyrrolone sedative (n=0)		
Zopiclone (n=0)	-								

\* Opioids reported as morphine equivalent quantities standardised to codeine DDDs to make dosage appropriate for non-malignant pain



**Table 19. 2: Daily defined dose (DDD) summarised by drug group and drug type across treatments arms at 12 months**

Medications	Standard care N; Median DDD (IQR)	Self-management N; Median DDD (IQR)	P-value*
<b>Drug group</b>			
Analgesic	142; 3 (1.3-10)	171; 3.3 (1.3-7.8)	0.637
Anti-emetic	9; 4.5 (1.7-6)	12; 2 (0.5-2.8)	0.239
NSAID	81; 3.3 (1.3-9)	85; 3 (1.7-8)	0.754
Opioids	57; 1.9 (0.64-5.1)	45; 1.9 (1.1-6.3)	0.344
Triptan	106; 8 (3-15)	137; 6 (4-12)	0.585
Angiotensin receptor block	2; 21 (14-28)	6; 11 (3.5-28)	0.643
Anti-epileptic	10; 7.2 (4.7-14)	20; 8.2 (3.5-17)	0.940
Beta blocker	22; 28 (14-28)	31; 14 (14-28)	0.539
Calcium channel blocker	1; 14	-	-
Gabapentinoid	5; 14 (14-20)	6; 12 (4.7-28)	0.623
Other antidepressant	9; 19 (9.3-28)	7; 21 (14-28)	0.811
Serotonergic antagonist	8; 28 (14-28)	4; 14 (9.3-19)	0.186
Tricyclic antidepressant	29; 7.5 (3.7-11)	27; 7.5 (3.7-15)	0.709
Benzodiazepine	1; 1.6	-	-
Cyclopyrrolone sedative	-	-	-
<b>Drug type</b>			
Acute	212; 9.8 (3.1-18)	247; 8 (3.3-16)	0.614
Prophylaxis	69; 14 (7-28)	84; 14 (7.5-28)	0.860
Anxiolytic/Sedative	1; 1.6	-	-

\* P-value computed using a non-parametric test

**Table 19.3: Medication overuse headache defined by pain killer or triptan use for  $\geq 10$  days over the last 4 weeks**

Time point	Standard care	Self-management	Adjusted OR (95% CI); p-value
Medication overuse (Yes), n (%)			
Baseline	218/351 (62%)	243/376 (65%)	
4 months	106/243 (44%)	110/252 (44%)	1.1 (0.71, 1.68); 0.679
8 months	96/229 (42%)	99/257 (39%)	0.9 (0.62, 1.40); 0.741
12 months	105/236 (44%)	113/268 (42%)	0.9 (0.63, 1.36); 0.704

**Table 19.4: Medication overuse headache defined by pain killer or triptan use for  $\geq 15$  days over the last 4 weeks**

Time point	Standard care	Self-management	Adjusted OR (95% CI); p-value
Medication overuse (Yes), n (%)			
Baseline	125/351 (36%)	150/376 (40%)	
4 months	50/243 (21%)	53/252 (21%)	1.2 (0.66, 2.03); 0.606
8 months	47/229 (21%)	45/257 (18%)	0.9 (0.54, 1.49); 0.681
12 months	47/236 (20%)	61/268 (23%)	1.4 (0.86, 2.20); 0.186

**Table 20: Baseline demographic characteristics of randomised participants summarised by compliance status (minimum compliance)**

Characteristic	Standard care	Non-Complier	Complier	Complier vs Non-complier p-value <sup>a</sup>
<b>Age (years)</b>				
N	351	117	259	0.001
Mean (SD)	47.9 (15.0)	43.1 (15.3)	48.8 (14.4)	
Median (IQR)	49 (37, 58)	43 (28, 53)	50 (39, 58)	
Missing	0	0	0	
<b>Gender</b>				
Male	67 (19.1%)	16 (13.7%)	38 (14.7%)	0.812
Female	284 (80.9%)	100 (85.4%)	220 (84.9%)	

Missing	0	1 (0.9%)	1 (0.4%)	
<b>Ethnicity</b>				0.047
White	282 (80.3%)	86 (73.5%)	218 (84.2%)	
Black or Black British	24 (6.8%)	6 (5.1%)	12 (4.6%)	
Asian or Asian British	29 (8.3%)	15 (12.8%)	16 (6.2%)	
Mixed	8 (2.3%)	5 (4.3%)	8 (3.1%)	
Other	2 (0.6%)	4 (3.4%)	2 (0.8%)	
Missing	6 (1.7%)	1 (0.9%)	3 (1.1%)	
<b>Employment status</b>				0.037
Employed	192 (54.7%)	63 (53.8%)	158 (61.0%)	
Unemployed	9 (2.6%)	7 (6.0%)	7 (2.7%)	
At school or full time education	10 (2.8%)	7 (6.0%)	6 (2.3%)	
Unable to work due to long term sickness	36 (10.3%)	16 (13.7%)	17 (6.6%)	
Looking after home/family	21 (6.0%)	7 (6.0%)	15 (5.8%)	
Retired from paid work	60 (17.1%)	13 (11.1%)	44 (17.0%)	
Other	16 (4.5%)	2 (1.7%)	9 (3.5%)	
Missing	7 (2.0%)	2 (1.7%)	3 (1.1%)	
<b>Age left full time education</b>				0.685
Did not receive formal education	2 (0.6%)	0	2 (0.8%)	
Age 12 or less	3 (0.9%)	0	2 (0.8%)	
Age 13 to 16	92 (26.2%)	24 (20.6%)	58 (22.4%)	
Age 17 to 19	90 (25.6%)	32 (27.3%)	76 (29.3%)	
Age 20 or over	144 (41.0%)	52 (44.4%)	111 (42.8%)	
Still in full time education	12 (3.4%)	7 (6.0%)	8 (3.1%)	

Missing	8 (2.3%)	2 (1.7%)	2 (0.8%)	
<b>Headache classification</b>				0.195
Definite chronic migraine	191 (54.4%)	58 (49.6%)	147 (56.8%)	
Probable chronic migraine	160 (45.6%)	59 (50.4%)	112 (43.2%)	
Missing	0	0	0	
<b>Medication overuse</b>				0.835
No	155 (44.2%)	54 (46.2%)	111 (42.9%)	
Yes	196 (55.8%)	63 (53.8%)	148 (57.1%)	
Missing	0	0	0	
<b>Headache/migraine days over the last 4 weeks</b>				0.405
N	349	114	258	
Mean (SD)	16.4 (6.9)	16.0 (7.0)	16.6 (6.7)	
Median (IQR)	16 (10, 20)	15.5 (11, 20)	16 (12, 20)	
Missing	2	3	1	
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>				0.835
N	346	115	256	
Mean (SD)	12.4 (7.3)	12.6 (8.1)	12.5 (7.2)	
Median (IQR)	12 (8, 16)	12 (6, 18)	12 (6.5, 16.5)	
Missing	5	2	3	
<b>Average number of hours the headache/migraine lasted on the days they had it</b>				

	N	236	76	179	0.580
	Mean (SD)	10.3 (8.1)	10.1 (8.0)	10.7 (8.0)	
	Median (IQR)	7 (4, 15)	7 (4, 12)	8 (4, 15)	
	Missing	115	41	80	
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine</b>					
	N	242	80	184	0.359
	Mean (SD)	6.7 (1.9)	7.0 (1.6)	6.8 (1.8)	
	Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)	
	Missing	109	37	75	
<b>How fatigued were you on average in the past seven days</b>					
	Not at all	3 (0.8%)	2 (1.7%)	4 (1.5%)	0.355
	A little bit	43 (12.3%)	8 (6.8%)	33 (12.7%)	
	Somewhat	83 (23.6%)	26 (22.2%)	53 (20.5%)	
	Quite a bit	138 (39.3%)	43 (36.8%)	104 (40.2%)	
	Very much	82 (23.4%)	36 (30.8%)	63 (24.3%)	
	Missing	2 (0.6%)	2 (1.7%)	2 (0.8%)	
<b>Sleep quality in the past seven days</b>					
	Very poor	45 (12.8%)	26 (22.2%)	31 (12.0%)	0.093
	Poor	113 (32.2%)	40 (34.2%)	88 (34.0%)	
	Fair	132 (37.6%)	36 (30.8%)	98 (37.8%)	
	Good	54 (15.4%)	11 (9.4%)	36 (13.9%)	
	Very good	6 (1.7%)	2 (1.7%)	5 (1.9%)	
	Missing	1 (0.3%)	2 (1.7%)	1 (0.4%)	

<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>				
N	346	115	254	0.232
Mean (SD)	4.5 (2.7)	4.7 (2.8)	4.3 (2.7)	
Median (IQR)	5 (2, 7)	5 (2, 7)	4 (2, 6)	
Missing	5	2	5	

<sup>a</sup> Univariate comparison between compliers and non-compliers in self-management intervention arm  
Note: Compliance will be of two levels - Minimal compliance with the intervention is defined as the participant attending day 1 of the intervention plus the one-to-one session.

**Table 20. 1: Baseline demographic characteristics of randomised participants summarised by compliance status (full compliance)**

<b>Characteristic</b>	<b>Standard care</b>	<b>Non-Complier</b>	<b>Complier</b>	<b>Complier vs Non-complier p-value<sup>a</sup></b>
<b>Age (years)</b>				0.004
N	351	160	216	
Mean (SD)	47.9 (15.0)	44.5 (15.2)	48.9 (14.4)	
Median (IQR)	49 (37, 58)	46 (31.5, 54)	50 (39, 58)	
Missing	0	0	0	
<b>Gender</b>				0.561
Male	67 (19.1%)	21 (13.1%)	33 (15.3%)	
Female	284 (80.9%)	138 (86.3%)	182 (84.2%)	

Missing	0	1 (0.6%)	1 (0.5%)	
<b>Ethnicity</b>				0.129
White	282 (80.3%)	120 (75.0%)	184 (85.2%)	
Black or Black British	24 (6.8%)	10 (6.3%)	8 (3.7%)	
Asian or Asian British	29 (8.3%)	18 (11.3%)	13 (6.1%)	
Mixed	8 (2.3%)	6 (3.7%)	7 (3.2%)	
Other	2 (0.6%)	4 (2.5%)	2 (0.9%)	
Missing	6 (1.7%)	2 (1.2%)	2 (0.9%)	
<b>Employment status</b>				0.119
Employed	192 (54.7%)	90 (56.2%)	131 (60.6%)	
Unemployed	9 (2.6%)	8 (5.0%)	6 (2.8%)	
At school or full time education	10 (2.8%)	7 (4.4%)	6 (2.8%)	
Unable to work due to long term sickness	36 (10.3%)	20 (12.5%)	13 (6.0%)	
Looking after home/family	21 (6.0%)	11 (6.9%)	11 (5.1%)	
Retired from paid work	60 (17.1%)	19 (11.9%)	38 (17.6%)	
Other	16 (4.5%)	3 (1.9%)	8 (3.7%)	
Missing	7 (2.0%)	2 (1.2%)	3 (1.4%)	
<b>Age left full time education</b>				0.951
Did not receive formal education	2 (0.6%)	1 (0.6%)	1 (0.5%)	
Age 12 or less	3 (0.9%)	1 (0.6%)	1 (0.5%)	
Age 13 to 16	92 (26.2%)	37 (23.1%)	45 (20.8%)	
Age 17 to 19	90 (25.6%)	42 (26.3%)	66 (30.6%)	
Age 20 or over	144 (41.0%)	70 (43.8%)	93 (43.0%)	
Still in full time education	12 (3.4%)	7 (4.4%)	8 (3.7%)	

Missing	8 (2.3%)	2 (1.2%)	2 (0.9%)	
<b>Headache classification</b>				
Definite chronic migraine	191 (54.4%)	82 (51.2%)	123 (56.9%)	0.273
Probable chronic migraine	160 (45.6%)	78 (48.8%)	93 (43.1%)	
Missing	0	0	0	
<b>Medication overuse</b>				
No	155 (44.2%)	76 (47.5%)	89 (41.2%)	0.476
Yes	196 (55.8%)	84 (52.5%)	127 (58.8%)	
Missing	0	0	0	
<b>Headache/migraine days over the last 4 weeks</b>				
N	349	157	215	0.938
Mean (SD)	16.4 (6.9)	16.5 (7.0)	16.4 (6.6)	
Median (IQR)	16 (10, 20)	16 (11, 20)	16 (12, 20)	
Missing	2	3	1	
<b>Pain killer or triptan use for headache/migraine over the last 4 weeks (days)</b>				
N	346	156	215	0.559
Mean (SD)	12.4 (7.3)	12.8 (7.9)	12.3 (7.1)	
Median (IQR)	12 (8, 16)	12 (7, 18)	12 (6, 16)	
Missing	5	4	1	
<b>Average number of hours the headache/migraine lasted on the days they had it</b>				



	N	236	107	148	0.893
	Mean (SD)	10.3 (8.1)	10.4 (8.0)	10.5 (7.9)	
	Median (IQR)	7 (4, 15)	7 (4, 14)	8 (4, 14.5)	
	Missing	115	53	68	
<b>Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine</b>					
	N	242	112	152	0.172
	Mean (SD)	6.7 (1.9)	7.0 (1.7)	6.7 (1.8)	
	Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)	
	Missing	109	48	64	
<b>How fatigued were you on average in the past seven days</b>					
	Not at all	3 (0.8%)	2 (1.3%)	4 (1.9%)	0.663
	A little bit	43 (12.3%)	14 (8.7%)	27 (12.5%)	
	Somewhat	83 (23.6%)	34 (21.2%)	45 (20.8%)	
	Quite a bit	138 (39.3%)	61 (38.1%)	86 (39.8%)	
	Very much	82 (23.4%)	47 (29.4%)	52 (24.1%)	
	Missing	2 (0.6%)	2 (1.3%)	2 (0.9%)	
<b>Sleep quality in the past seven days</b>					
	Very poor	45 (12.8%)	33 (20.7%)	24 (11.1%)	0.115
	Poor	113 (32.2%)	48 (30.0%)	80 (37.0%)	
	Fair	132 (37.6%)	55 (34.4%)	79 (36.6%)	
	Good	54 (15.4%)	20 (12.5%)	27 (12.5%)	
	Very good	6 (1.7%)	2 (1.2%)	5 (2.3%)	
	Missing	1 (0.3%)	2 (1.2%)	1 (0.5%)	

<b>Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)</b>				
N	346	156	213	0.010
Mean (SD)	4.5 (2.7)	4.9 (2.9)	4.1 (2.6)	
Median (IQR)	5 (2, 7)	5 (2.5, 7)	4 (2, 6)	
Missing	5	4	3	

<sup>a</sup> Univariate comparison between compliers and non-compliers in self-management intervention arm  
Note: Full compliance is defined as the participant attending both days, plus individualised contact with the nurse

**Table 21: Baseline outcome measures of randomised participants summarised by compliance status (minimum compliance)**

<b>Outcome</b>	<b>Standard care</b>	<b>Non-complier</b>	<b>Complier</b>	<b>Complier vs Non-complier p-value<sup>a</sup></b>
<b>HIT-6</b>				0.125
N	350	116	258	
Mean (SD)	64.6 (5.5)	65.1 (5.7)	64.2 (5.3%)	
Median (IQR)	64.5 (61, 68)	66 (62, 69)	64 (61, 68)	
Missing	1	1	1	
<b>CH-QLQ – role restrictive</b>				0.099
N	351	116	258	
Mean (SD)	54.5 (17.3)	52.3 (17.3)	55.4 (16.7)	
Median (IQR)	57.1 (42.9, 66.7)	51.2 (40.5, 64.3)	57.1 (45.2, 66.7)	
Missing	0	1	1	

<b>CH-QLQ – role preventive</b>				0.001
N	351	116	258	
Mean (SD)	69.4 (21.2)	64.3 (21.2)	71.7 (19.8)	
Median (IQR)	75 (54.2, 87.5)	64.6 (50, 79.2)	75 (62.5, 87.5)	
Missing	0	1	1	
<b>CH-QLQ – emotional function</b>				0.424
N	351	116	257	
Mean (SD)	57.2 (22.3)	55.6 (24.2)	57.6 (21.5)	
Median (IQR)	55.6 (38.9, 77.8)	61.1 (33.3, 77.8)	61.1 (38.9, 77.8)	
Missing	0	1	2	
<b>SF-12 Physical</b>				0.775
N	347	113	257	
Mean (SD)	43.7 (10.9)	44.7 (10.5)	45.0 (9.8)	
Median (IQR)	44.1 (36.9, 52.1)	46.4 (37.6, 52.5)	45.5 (39.2, 52.8)	
Missing	4	4	2	
<b>SF-12 Mental</b>				0.002
N	348	113	257	
Mean (SD)	39.6 (10.3)	37.3 (10.0)	40.9 (10.7)	
Median (IQR)	39.5 (32.2, 47.1)	37.2 (29.2, 43.8)	40.6 (32.8, 49.7)	
Missing	3	4	2	
<b>EQ-5D</b>				Non-parametric 0.036
N	346	115	257	
Mean (SD)	0.62 (0.25)	0.58 (0.30)	0.66 (0.23)	
Median (IQR)	0.71 (0.53, 0.77)	0.70 (0.43, 0.77)	0.73 (0.58, 0.80)	
Missing	5	2	2	
<b>EQ-5D VAS</b>				0.177
N	350	115	256	
Mean (SD)	62.2 (19.6)	60.8 (20.9)	63.9 (20.2)	

	Median (IQR)	65 (50, 75)	60 (45, 75)	70 (50, 80)	
	Missing	1	2	3	
<b>HADS Anxiety</b>					
	N	349	115	258	0.028
	Mean (SD)	10.9 (2.7)	11.0 (2.8)	10.3 (2.7)	
	Median (IQR)	11 (9, 13)	11 (9, 13)	10 (8, 12)	
	Missing	2	2	1	
<b>HADS Depression</b>					
	N	349	115	258	0.035
	Mean (SD)	8.9 (2.0)	9.5 (1.9)	9.1 (1.7)	
	Median (IQR)	9 (8, 10)	9 (8, 11)	9 (8, 10)	
	Missing	2	2	1	
<b>PSEQ</b>					
	N	348	114	257	0.037
	Mean (SD)	32.9 (13.3)	30.3 (14.8)	33.5 (13.2)	
	Median (IQR)	34 (24, 43)	31.5 (19, 41)	35 (24, 44)	
	Missing	3	3	2	
<b>HeiQ</b>					
	N	348	115	258	0.042
	Mean (SD)	2.8 (0.6)	2.7 (0.7)	2.9 (0.6)	
	Median (IQR)	2.8 (2.4, 3.2)	2.8 (2.2, 3.2)	3 (2.4, 3.2)	
	Missing	3	2	1	

<sup>a</sup> Univariate analysis comparing compliers and non-compliers in self-management intervention arm

Note: Compliance will be of two levels - Minimal compliance with the intervention is defined as the participant attending day 1 of the intervention plus the one-to-one session.

**Table 21. 1: Baseline outcome measures of randomised participants summarised by compliance status (full compliance)**

Outcome	Standard care	Non-complier	Complier	Complier vs Non-complier
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				<b>p-value<sup>a</sup></b>	
<b>HIT-6</b>	N	350	159	215	0.022
	Mean (SD)	64.6 (5.5)	65.2 (5.6)	63.9 (5.3)	
	Median (IQR)	64.5 (61, 68)	66 (62, 69)	64 (61, 67)	
	Missing	1	1	1	
<b>CH-QLQ – role restrictive</b>	N	351	159	215	0.032
	Mean (SD)	54.5 (17.3)	52.3 (17.6)	56.1 (16.3)	
	Median (IQR)	57.1 (42.9, 66.7)	52.4 (40.5, 64.3)	57.1 (45.2, 66.7)	
	Missing	0	1	1	
<b>CH-QLQ – role preventive</b>	N	351	159	215	0.001
	Mean (SD)	69.4 (21.2)	65.1 (21.6)	72.6 (19.1)	
	Median (IQR)	75 (54.2, 87.5)	66.7 (50.0, 83.3)	75 (62.5, 87.5)	
	Missing	0	1	1	
<b>CH-QLQ – emotional function</b>	N	351	159	214	0.325
	Mean (SD)	57.2 (22.3)	55.7 (23.3)	58.0 (21.7)	
	Median (IQR)	55.6 (38.9, 77.8)	61.1 (33.3, 77.8)	61.1 (38.9, 77.8)	
	Missing	0	1	2	
<b>SF-12 Physical</b>	N	347	156	214	0.633
	Mean (SD)	43.7 (10.9)	44.6 (10.3)	45.1 (9.8)	
	Median (IQR)	44.1 (36.9, 52.1)	45.9 (37.5, 52.7)	45.6 (39.5, 52.7)	
	Missing	4	4	2	
<b>SF-12 Mental</b>	N	348	156	214	0.016

	Mean (SD)	39.6 (10.3)	38.2 (10.1)	40.9 (10.8)	
	Median (IQR)	39.5 (32.2, 47.1)	37.4 (30.7, 44.6)	40.6 (32.8, 49.9)	
	Missing	3	4	2	
<b>EQ-5D</b>					
	N	346	158	214	Non-parametric: P=0.014
	Mean (SD)	0.62 (0.25)	0.59 (0.30)	0.67 (0.22)	
	Median (IQR)	0.71 (0.53, 0.77)	0.70 (0.43, 0.77)	0.73 (0.63, 0.80)	
	Missing	5	2	2	
<b>EQ-5D VAS</b>					
	N	350	157	214	0.135
	Mean (SD)	62.2 (19.6)	61.1 (21.6)	64.3 (19.5)	
	Median (IQR)	65 (50, 75)	60 (45, 80)	70 (50, 80)	
	Missing	1	3	2	
<b>HADS Anxiety</b>					
	N	349	158	215	0.124
	Mean (SD)	10.9 (2.7)	10.8 (2.8)	10.4 (2.7)	
	Median (IQR)	11 (9, 13)	11 (9, 13)	10 (8, 12)	
	Missing	2	2	1	
<b>HADS Depression</b>					
	N	349	158	215	0.023
	Mean (SD)	8.9 (2.0)	9.5 (1.9)	9.0 (1.7)	
	Median (IQR)	9 (8, 10)	9 (8, 11)	9 (8, 10)	
	Missing	2	2	1	
<b>PSEQ</b>					
	N	348	157	214	0.052
	Mean (SD)	32.9 (13.3)	30.9 (14.6)	33.7 (13.0)	
	Median (IQR)	34 (24, 43)	32 (20, 42)	34 (25, 44)	
	Missing	3	3	2	

HeiQ				0.163	
	N	348	158		215
	Mean (SD)	2.8 (0.6)	2.8 (0.7)		2.9 (0.6)
	Median (IQR)	2.8 (2.4, 3.2)	2.9 (2.2, 3.2)		3 (2.4, 3.2)
	Missing	3	2		1

<sup>a</sup> Univariate analysis comparing compliers and non-compliers in self-management intervention arm  
Note: Full compliance is defined as the participant attending both days, plus individualised contact with the nurse

**Table 22: Intention To Treat (ITT) and Complier Averaged Causal Effect (CACE) model estimates of treatment difference at each time point**

Time point	ITT model		CACE model (minimum adherence)		CACE model (full adherence)	
	Mean difference (95% CI)*	p-value	Mean difference (95% CI) <sup>†</sup>	p-value	Mean difference (95% CI) <sup>†</sup>	p-value
<b>HIT-6</b>						
4 months	-1.0 (-1.91, -0.006)	0.049	-1.3 (-2.57, -0.02)	0.046	-1.6 (-3.10, -0.01)	0.048
8 months	0.07 (-0.95, 1.09)	0.888	0.04 (-1.22, 1.31)	0.945	0.05 (-1.46, 1.56)	0.945
12 months	-0.3 (-1.23, 0.67)	0.560	-0.4 (-1.67, 0.87)	0.540	-0.5 (-2.00, 1.05)	0.540

\*Based on a multi-level model adjusted for age, sex, headache type, geographical locality and baseline measure of the outcome. The intervention group was included as a random effect to account for partial clustering in one arm.

<sup>†</sup>Based on a single equation instrumental variable regression model with outcome adjusted for age, sex, headache type, geographical locality and baseline measure of the outcome.

Note: Compliance will be of two levels - Minimal compliance with the intervention is defined as the participant attending day 1 of the intervention plus the one-to-one session. Full compliance is defined as the participant attending both days, plus individualised contact with the nurse

**Table 23: Sub-group analyses of the 12-month HIT-6 outcome**

Subgroups	Standard care N; mean(sd)	Self-management N; mean(sd)	Treatment by subgroup Interaction effect (95% CI); p-value
<b>HADS Anxiety</b>			
≤10	120; 58.9 (7.0)	151; 58.8 (6.3)	-0.2 (-2.10, 1.69); 0.831
>10	162; 62.0 (6.8)	149; 61.4 (7.3)	
<b>HADS Depression</b>			
≤10	225; 60.4 (6.9)	237; 59.5 (6.9)	0.04 (-2.31, 2.40); 0.971
>10	57; 61.9 (7.2)	63; 62.3 (6.4)	
<b>Severity (HIT-6)</b>			
≤64	144; 57.5 (6.4)	169; 58.0 (5.7)	-1.7 (-3.76, 0.31); 0.097

>64	138; 64.0 (6.1)	131; 62.8 (7.4)
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**ADDITIONAL ANALYSES**

***Table 24: Treatment effectiveness estimates for the primary outcome (HIT-6 at 12 months) for each of the headache types and medication overuse***

Headache type	Standard care	Self-management	Adjusted mean difference (95% CI); p-value
<b>Definite chronic migraine</b>			-0.7 (-1.97, 0.65); 0.325
N	149	159	
Mean (SD)	62.7 (6.1)	61.4 (6.8)	
Median (IQR)	63 (60, 66)	62 (59, 66)	
Missing	0	0	
<b>Probable chronic migraine</b>			-0.1 (-1.46, 1.35); 0.943
N	133	141	
Mean (SD)	58.4 (7.3)	58.6 (6.7)	
Median (IQR)	60 (55, 63)	59 (54, 63)	
Missing	1	3	
<b>Medication overuse – No</b>			-0.4 (-1.85, 0.95); 0.532
N	120	134	
Mean (SD)	60.4 (6.8)	59.3 (7.2)	
Median (IQR)	61 (57, 65)	60.5 (55, 64)	
Missing	1	3	
<b>Medication overuse - Yes</b>			-0.03 (-1.31, 1.26); 0.967
N	162	166	
Mean (SD)	60.9 (7.2)	60.7 (6.6)	
Median (IQR)	62 (57, 66)	62 (56, 65)	
Missing	0	0	

***Table 24.1: Longitudinal analysis for the number of headache days summarised by treatment group***

	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference (95% CI); p-value
On how many of the last 7 days have you had a headache, days	0.2 (-0.12, 0.46); 0.239	0.2 (-0.11, 0.46); 0.234
On the days you had a headache on average how long did they last, hours	0.4 (-0.52, 1.26); 0.418	0.4 (-0.47, 1.28); 0.361
On the days you had a headache on average how severe were they	0.2 (-0.09, 0.46); 0.181	0.2 (-0.08, 0.46); 0.163

***Table 25: Sensitivity analysis - treatment effectiveness estimate based on the primary outcome (at 12-month follow-up) having excluded those participants included in the process evaluation interviews***

	Standard care	Self-management	Estimate (95% CI); p-value
<b>HIT-6</b>			
N	273	284	-0.4 (-1.40, 0.54); 0.389
Mean (SD)	60.7 (7.0)	59.9 (6.9)	
Median (IQR)	62 (57, 65)	61 (55, 64)	
Missing	1	3	

***Table 26: Sensitivity analysis - treatment effectiveness estimate based on the primary outcome (at 12-month follow-up) having excluded those participants reporting less than 15 days of headache at baseline***

	Standard care	Self-management	Estimate (95% CI); p-value
<b>HIT-6</b>			
N	172	186	-0.2 (-1.45, 0.97); 0.696
Mean (SD)	60.9 (7.0)	60.6 (6.7)	
Median (IQR)	62 (57, 65.5)	62 (56, 65)	
Missing	0	1	

## **SECTION 6 - ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS**

**Table 27: Adverse events (AE) and serious adverse events (SAE) summarised by treatment group**

Event details	Standard care (N=351)	Self-management (N=376)	Total (N=727)
<b>AE's</b>			
Number of AE's reported	1 (0.3%)	6 (1.6%)	7 (1.0%)
<b>SAE's</b>			
Number of SAE's reported	1 (0.3%)	0	1 (0.1%)
<b>Reason Serious Adverse Event deemed serious</b>			
Death	1 (0.3%)	0	1 (0.1%)
Life-threatening	0	0	0
Hospitalisation or prolongation of existing hospitalisation	0	0	0
Persistent or significant disability or incapacity	0	0	0
Congenital anomaly/birth defect	0	0	0
Other	0	0	0
<b>SAE severity assessment</b>			
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Fatal/life threatening	1 (0.3%)	0	1 (0.1%)

**Table 28: Assessment of SAE's summarised by treatment group**

Assessment of SAE's	Standard care	Self-management	TOTAL
<b>SAE related to trial intervention:</b>			
Definitely	0	0	0
Probably	0	0	0
Possibly	0	0	0
Unlikely	0	0	0
Unrelated	1 (0.3%)	0	1 (0.1%)
<b>Expectedness of SAE:</b>			
Expected	0	0	0
Unexpected	0	0	0
Missing	1 (0.3%)	0	1 (0.1%)