CHESS
Chronic Headache Education and Self-management Study
TEM

PLATE TABLES AND FIGURES

Migraine and Tension Type Headache

Version: 2.0

Migraine & T...

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Drug use data are not included in this report. Such data, in a mixed population of people with chronic migraine and chronic tension type headache, would be difficult to interpret as different drug use outcomes might be considered beneficial in the classification groups.

Table numbers are non-sequential to match table numbers in statistical report for the primary analysis.

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SECTION 1 - SCREENING THROUGH TO RANDOMISATION

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Figure 1: CONSORT diagram

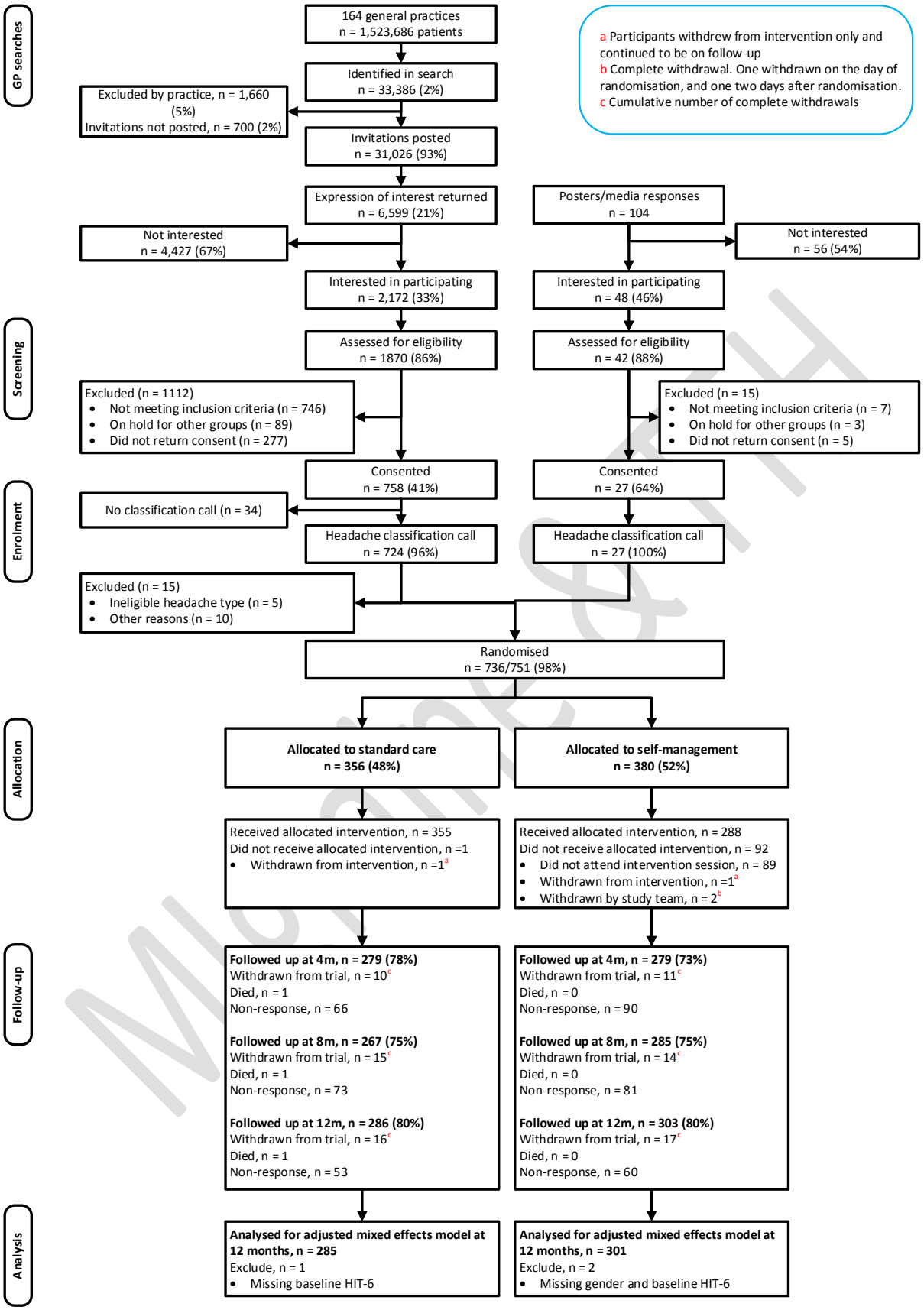

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Table 1: Number and percentage of participants randomised to standard care and self-management by geographical location

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

Table 2: Number and percentage of participants with different headache types by treatment

	Standard care	Self-management
Definite chronic migraine – with MOH	122 (48.2%)	131 (51.8%)
Probable chronic migraine – with MOH	74 (48.1%)	80 (51.9%)
Chronic tension type headache – with MOH	2 (66.7%)	1 (33.3%)
Definite chronic migraine – without MOH	69 (48.2%)	74 (51.8%)
Probable chronic migraine – without MOH	86 (48.6%)	91 (51.4%)
Chronic tension type headache – without MOH	3 (50.0%)	3 (50.0%)
TOTAL:	356 (48.4%)	380 (51.6%)

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SECTION 2 - PARTICIPANT BASELINE AND DEMOGRAPHIC DATA

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Table 3: Baseline demographic characteristics of all randomised participants by treatment group

	Standard care (N=356)	Self-management (N=380)	TOTAL (N=736)
Age (years)			
N	356	380	736
Mean (SD)	47.9 (15.0)	47.2 (15.0)	47.6 (15.0)
Median (IQR)	49 (37, 58.5)	49 (35.5, 57)	49 (36, 58)
Missing	0	0	0
Gender			
Male	71 (19.9%)	55 (14.5%)	126 (17.1%)
Female	285 (80.1%)	323 (85.0%)	608 (82.6%)
Missing	0	2 (0.5%)	2 (0.3%)
Ethnicity			
White	287 (80.6%)	308 (81.1%)	595 (80.8%)
Black or Black British	24 (6.7%)	18 (4.7%)	42 (5.7%)
Asian or Asian British	29 (8.2%)	31 (8.2%)	60 (8.2%)
Mixed	8 (2.2%)	13 (3.4%)	21 (2.8%)
Other	2 (0.6%)	6 (1.6%)	8 (1.1%)
Missing	6 (1.7%)	4 (1.0%)	10 (1.4%)
Employment status			
Employed	195 (54.8%)	223 (58.7%)	418 (56.8%)
Unemployed	9 (2.5%)	14 (3.7%)	23 (3.1%)
At school or full time education	10 (2.8%)	13 (3.4%)	23 (3.1%)
Unable to work due to long term sickness	36 (10.1%)	33 (8.7%)	69 (9.4%)
Looking after home/family	22 (6.2%)	22 (5.8%)	44 (6.0%)
Retired from paid work	61 (17.1%)	59 (15.5%)	120 (16.3%)
Other	16 (4.5%)	11 (2.9%)	27 (3.7%)
Missing	7 (2.0%)	5 (1.3%)	12 (1.6%)
Age left full time education			
Did not receive formal education	2 (0.6%)	2 (0.5%)	4 (0.5%)
Age 12 or less	3 (0.8%)	2 (0.5%)	5 (0.7%)
Age 13 to 16	94 (26.4%)	84 (22.1%)	178 (24.2%)
Age 17 to 19	93 (26.1%)	110 (29.0%)	203 (27.6%)
Age 20 or over	144 (40.5%)	163 (42.9%)	307 (41.7%)
Still in full time education	12 (3.4%)	15 (3.9%)	27 (3.7%)
Missing	8 (2.2%)	4 (1.1%)	12 (1.6%)
Headache classification			
Definite chronic migraine	191 (53.7%)	205 (54.0%)	396 (53.8%)

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Probable chronic migraine	160 (44.9%)	171 (45.0%)	331 (45.0%)
Chronic tension type headache	5 (1.4%)	4 (1.0%)	9 (1.2%)
Missing	0	0	0
Medication overuse			
No	158 (44.4%)	168 (44.2%)	326 (44.3%)
Yes	198 (55.6%)	212 (55.8%)	410 (55.7%)
Missing	0	0	0
Headache/migraine days over the last 4 weeks			
N	354	376	730
Mean (SD)	16.4 (7.0)	16.5 (6.8)	16.4 (6.9)
Median (IQR)	16 (10, 21)	16 (12, 20)	16 (11, 20)
Missing	2	4	6
Headache/migraine days over the last 4 weeks			
<15	140 (39.3%)	138 (36.3%)	278 (37.8%)
≥15	214 (60.1%)	238 (62.6%)	452 (61.4%)
Missing	2 (0.6%)	4 (1.1%)	6 (0.8%)
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)			
N	350	375	725
Mean (SD)	12.3 (7.3)	12.5 (7.5)	12.4 (7.4)
Median (IQR)	12 (8, 16)	12 (6, 17)	12 (7, 17)
Missing	6	5	11
Average number of hours the headache/migraine lasted on the days they had it			
N	239	258	497
Mean (SD)	10.3 (8.1)	10.4 (7.9)	10.4 (8.0)
Median (IQR)	7 (4, 15)	8 (4, 14)	7 (4, 14)
Missing	117	122	239
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine			
N	246	267	513

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Mean (SD)	6.7 (2.0)	6.8 (1.8)	6.7 (1.9)
Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)
Missing	110	113	223
How fatigued were you on average in the past seven days			
Not at all	4 (1.1%)	6 (1.6%)	10 (1.4%)
A little bit	44 (12.4%)	44 (11.6%)	88 (12.0%)
Somewhat	85 (23.9%)	80 (21.1%)	165 (22.4%)
Quite a bit	139 (39.0%)	147 (38.7%)	286 (38.8%)
Very much	82 (23.0%)	99 (26.0%)	181 (24.6%)
Missing	2 (0.6%)	4 (1.0%)	6 (0.8%)
Sleep quality in the past seven days			
Very poor	45 (12.6%)	57 (15.0%)	102 (13.9%)
Poor	115 (32.3%)	129 (34.0%)	244 (33.1%)
Fair	132 (37.1%)	135 (35.5%)	267 (36.3%)
Good	56 (15.7%)	49 (12.9%)	105 (14.3%)
Very good	7 (2.0%)	7 (1.8%)	14 (1.9%)
Missing	1 (0.3%)	3 (0.8%)	4 (0.5%)
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)			
N	350	373	723
Mean (SD)	4.5 (2.8)	4.4 (2.8)	4.5 (2.8)
Median (IQR)	5 (2, 7)	4 (2, 7)	5 (2, 7)
Missing	6	7	13

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Table 4: Baseline outcome measures by treatment arm

	Standard care (N=356)	Self-management (N=380)	TOTAL (N=736)
HIT-6			
N	355	378	733
Mean (SD)	64.4 (5.8)	64.3 (5.6)	64.4 (5.7)
Median (IQR)	64 (61, 68)	64 (61, 68)	64 (61, 68)
Missing	1	2	3
CH-QLQ – role restrictive			
N	356	378	734
Mean (SD)	54.7 (17.6)	54.7 (17.1)	54.7 (17.3)
Median (IQR)	57.1 (42.9, 66.7)	54.8 (42.9, 66.7)	54.8 (42.9, 66.7)
Missing	0	2	2
CH-QLQ – role preventive			
N	356	378	734
Mean (SD)	69.7 (21.3)	69.7 (20.6)	69.7 (20.9)
Median (IQR)	75 (54.2, 87.5)	70.8 (54.2, 87.5)	70.8 (54.2, 87.5)
Missing	0	2	2
CH-QLQ – emotional function			
N	356	377	733
Mean (SD)	57.4 (22.4)	57.2 (22.4)	57.3 (22.4)
Median (IQR)	58.3 (38.9, 77.8)	61.1 (38.9, 77.8)	61.1 (38.9, 77.8)
Missing	0	3	3
SF-12 Physical			
N	351	374	725
Mean (SD)	43.9 (11.0)	45.0 (10.0)	44.5 (10.5)
Median (IQR)	44.2 (36.9, 52.1)	45.9 (38.7, 52.8)	45.4 (37.6, 52.6)
Missing	5	6	11
SF-12 Mental			
N	352	374	726
Mean (SD)	39.7 (10.3)	39.9 (10.6)	39.8 (10.5)
Median (IQR)	39.6 (32.3, 47.2)	39.4 (32.2, 48.6)	39.5 (32.2, 47.9)
Missing	4	6	10
EQ-5D			
N	351	376	727
Mean (SD)	0.63 (0.25)	0.64 (0.26)	0.63 (0.25)
Median (IQR)	0.71 (0.53, 0.77)	0.72 (0.54, 0.78)	0.72 (0.53, 0.77)
Missing	5	4	9
EQ-5D VAS			
N	355	375	730
Mean (SD)	62.5 (19.6)	63.1 (20.5)	62.8 (20.0)
Median (IQR)	65 (50, 75)	68 (50, 80)	65 (50, 80)

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Missing	1	5	6
HADS Anxiety			
N	354	377	731
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
HADS Depression			
N	354	377	731
Mean (SD)	9.0 (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
HADS Anxiety - categorised			
0-7	34 (9.5%)	54 (14.2%)	88 (12.0%)
8-10	118 (33.2%)	140 (36.8%)	258 (35.0%)
11-21	202 (56.7%)	183 (48.2%)	385 (52.3%)
Missing	2 (0.6%)	3 (0.8%)	5 (0.7%)
HADS Depression - categorised			
0-7	77 (21.6%)	59 (15.5%)	136 (18.5%)
8-10	200 (56.2%)	232 (61.1%)	432 (58.7%)
11-21	77 (21.6%)	86 (22.6%)	163 (22.1%)
Missing	2 (0.6%)	3 (0.8%)	5 (0.7%)
PSEQ			
N	353	375	728
Mean (SD)	33.2 (13.4)	32.8 (13.8)	33.0 (13.6)
Median (IQR)	34 (24, 43)	34 (22, 44)	34 (23.5, 44)
Missing	3	5	8
HeiQ			
N	353	377	730
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

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Table 5: Baseline outcome measures summarised by headache type

	Definite chronic migraine (N=396)	Probable chronic migraine (N=331)	Chronic tension type headache (N=9)
HIT-6			
N	393	331	9
Mean (SD)	66.1 (4.9)	62.6 (5.5)	53 (11.2)
Median (IQR)	66 (63, 69)	63 (60, 66)	54 (42, 61)
Missing	3	0	0
CH-QLQ – role restrictive			
N	394	331	9
Mean (SD)	49.7 (16.4)	60.1 (16.1)	75.1 (23.1)
Median (IQR)	50 (38.1, 61.9)	61.9 (50, 71.4)	78.6 (69.0, 92.9)
Missing	2	0	0
CH-QLQ – role preventive			
N	394	331	9
Mean (SD)	63.9 (21.2)	76.0 (18.4)	90.3 (19.4)
Median (IQR)	66.7 (50, 79.2)	79.2 (66.7, 91.7)	100 (95.8, 100)
Missing	2	0	0
CH-QLQ – emotional function			
N	393	331	9
Mean (SD)	51.9 (21.8)	63.3 (21.4)	74.7 (24.1)
Median (IQR)	50 (33.3, 72.2)	66.7 (44.4, 83.3)	83.3 (61.1)
Missing	3	0	0
SF-12 Physical			
N	390	327	8
Mean (SD)	42.5 (10.6)	46.5 (10.0)	54.8 (6.5)
Median (IQR)	43.3 (36.1, 50.6)	48.5 (39.2, 54.1)	53.4 (50.9, 61.3)
Missing	6	4	1
SF-12 Mental			
N	391	327	8
Mean (SD)	39.4 (10.4)	40.0 (10.5)	47.4 (11.1)
Median (IQR)	39.0 (31.7, 47.1)	39.9 (32.5, 48.2)	47.8 (38.4, 57.3)
Missing	5	4	1
EQ-5D			
N	388	330	9
Mean (SD)	0.59 (0.28)	0.67 (0.22)	0.80 (0.14)
Median (IQR)	0.70 (0.48, 0.77)	0.74 (0.64, 0.80)	0.77 (0.72, 0.85)
Missing	8	1	0
EQ-5D VAS			
N	393	328	9
Mean (SD)	60.5 (21.6)	65.1 (17.7)	79.7 (12.7)
Median (IQR)	65 (42, 80)	70 (55, 75)	80 (70, 90)

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Missing	3	3	0
HADS Anxiety			
N	392	330	9
Mean (SD)	10.8 (2.8)	10.7 (2.6)	10.1 (2.7)
Median (IQR)	11 (9, 13)	11 (9, 12)	10 (8, 11)
Missing	4	1	0
HADS Depression			
N	392	330	9
Mean (SD)	9.2 (1.9)	9.0 (1.9)	10.1 (2.8)
Median (IQR)	9 (8, 10)	9 (8, 10)	9 (9, 11)
Missing	4	1	0
HADS Anxiety - categorised			
0-7	50 (12.6%)	37 (11.2%)	1 (11.1%)
8-10	131 (33.1%)	122 (36.9%)	5 (55.6%)
11-21	211 (53.3%)	171 (51.6%)	3 (33.3%)
Missing	4 (1.0%)	1 (0.3%)	0
HADS Depression - categorised			
0-7	69 (17.4%)	66 (19.9%)	1 (11.1%)
8-10	231 (58.3%)	197 (59.5%)	4 (44.4%)
11-21	92 (23.3%)	67 (20.3%)	4 (44.4%)
Missing	4 (1.0%)	1 (0.3%)	0
PSEQ			
N	392	327	9
Mean (SD)	30.0 (13.6)	36.0 (12.7)	50.7 (6.8)
Median (IQR)	30 (20, 40)	37 (27, 45)	52 (46, 57)
Missing	4	4	0
HeiQ			
N	393	328	9
Mean (SD)	2.7 (0.7)	2.9 (0.6)	3.2 (0.6)
Median (IQR)	2.8 (2.2, 3.2)	3 (2.6, 3.2)	3 (3, 4)
Missing	3	3	0

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Table 6: Baseline pain grid summarised for participants in the standard care arm

	No pain experienced	Not at all troublesome	Slightly troublesome	Moderately troublesome	Very troublesome	Extremely troublesome
Headache	3 (0.8%)	0	29 (8.4%)	92 (26.5%)	147 (42.4%)	76 (21.9%)
Neck pain	62 (18.3%)	18 (5.3%)	65 (19.2%)	96 (28.3%)	78 (23.0%)	20 (5.9%)
Shoulder pain	92 (27.5%)	20 (6.0%)	85 (25.4%)	68 (20.4%)	51 (15.3%)	18 (5.4%)
Elbow pain	234 (72.9%)	30 (9.3%)	22 (6.9%)	22 (6.9%)	9 (2.8%)	4 (1.2%)
Wrist / hand pain	167 (51.4%)	25 (7.7%)	62 (19.1%)	34 (10.4%)	25 (7.7%)	12 (3.7%)
Chest pain	209 (65.1%)	27 (8.4%)	48 (15.0%)	22 (6.8%)	10 (3.1%)	5 (1.6%)
Abdominal pain	146 (45.1%)	29 (8.9%)	72 (22.2%)	40 (12.3%)	29 (9.0%)	8 (2.5%)
Upper back pain	151 (46.2%)	22 (6.7%)	72 (22.0%)	39 (11.9%)	33 (10.1%)	10 (3.1%)
Lower back pain	89 (26.6%)	27 (8.1%)	79 (23.6%)	56 (16.8%)	55 (16.5%)	28 (8.4%)
Hip / thigh pain	181 (55.3%)	29 (8.9%)	38 (11.6%)	35 (10.7%)	26 (8.0%)	18 (5.5%)
Knee pain	163 (50.6%)	25 (7.8%)	45 (14.0%)	37 (11.5%)	29 (9.0%)	23 (7.1%)
Ankle / foot pain	186 (56.4%)	20 (6.0%)	53 (16.1%)	34 (10.3%)	18 (5.4%)	19 (5.8%)
Other pains	184 (68.7%)	17 (6.3%)	21 (7.8%)	13 (4.9%)	18 (6.7%)	15 (5.6%)

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Table 7: Baseline pain grid summarised for participants in the self-management arm

	No pain experienced	Not at all troublesome	Slightly troublesome	Moderately troublesome	Very troublesome	Extremely troublesome
Headache	2 (0.5%)	1 (0.3%)	23 (6.2%)	103 (27.7%)	156 (41.9%)	87 (23.4%)
Neck pain	68 (19.1%)	18 (5.1%)	86 (24.2%)	97 (27.2%)	58 (16.3%)	29 (8.1%)
Shoulder pain	97 (27.9%)	25 (7.2%)	92 (26.4%)	67 (19.2%)	42 (12.1%)	25 (7.2%)
Elbow pain	244 (73.0%)	28 (8.4%)	29 (8.7%)	21 (6.3%)	10 (3.0%)	2 (0.6%)
Wrist / hand pain	174 (51.0%)	24 (7.0%)	77 (22.6%)	35 (10.3%)	22 (6.5%)	9 (2.6%)
Chest pain	222 (66.7%)	29 (8.7%)	46 (13.8%)	19 (5.7%)	14 (4.2%)	3 (0.9%)
Abdominal pain	170 (49.8%)	36 (10.6%)	72 (21.1%)	34 (10.0%)	22 (6.5%)	7 (2.0%)
Upper back pain	153 (45.8%)	34 (10.2%)	64 (19.1%)	44 (13.2%)	26 (7.8%)	13 (3.9%)
Lower back pain	85 (24.1%)	33 (9.4%)	96 (27.3%)	66 (18.7%)	51 (14.5%)	21 (6.0%)
Hip / thigh pain	170 (50.0%)	30 (8.8%)	53 (15.6%)	49 (14.4%)	25 (7.4%)	13 (3.8%)
Knee pain	172 (49.4%)	22 (6.3%)	74 (21.3%)	38 (10.9%)	28 (8.1%)	14 (4.0%)
Ankle / foot pain	187 (55.5%)	28 (8.3%)	51 (15.1%)	38 (11.3%)	28 (8.3%)	5 (1.5%)
Other pains	193 (67.3%)	21 (7.3%)	25 (8.7%)	23 (8.0%)	14 (4.9%)	11 (3.8%)

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SECTION 3 - PARTICIPANT FOLLOW-UP

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Table 8: Overall summary of withdrawals requests by treatment arm*

	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 (4.5%)	15 (3.9%)	31 (4.2%)
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

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Table 9: Time from randomisation to withdrawal and follow-up summarised by treatment arm

	Standard care	Self-management	TOTAL
Time from randomisation to withdrawing completely from trial (months)			
N	16	17	33
Mean (SD)	5.6 (3.8)	5.5 (5.0)	5.6 (4.4)
Median (IQR)	4.7 (2.1, 9.1)	5.3 (0.5, 8.9)	5.2 (1.9, 8.9)
Missing time	0	0	0
Time from randomisation to 4-month follow-up			
N	280	280	560
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
Time from randomisation to 8-month follow-up			
N	268	286	554
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
Time from randomisation to 12-month follow-up			
N	287	306	593
Mean (SD)	13.3 (2.1)	12.9 (1.5)	13.1 (1.8)
Median (IQR)	12.6 (12.2, 13.1)	12.5 (12.2, 13.0)	12.6 (12.2, 13.1)
Missing time	0	0	0

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SECTION 4 - INTERVENTION DATA

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Table 10: Summary of intervention data

	Self-management
Time from randomisation to Session 1 (days)	
N	379
Mean (SD)	26.8 (31.5)
Median (IQR)	15 (11, 23)
Missing	0
Time from randomisation to Session 2 (days)	
N	379
Mean (SD)	33.9 (32.4)
Median (IQR)	22 (18, 30)
Missing	0
Session attendance	
Session 1 only	17 (4.5%)
Session 1 & 2 only	10 (2.6%)
Session 1 and one-to-one only	44 (11.6%)
Session 1 and 2 and one-to-one	217 (57.3%)
Did not attend session 1 (hence no other groups)	91 (24.0%)
Adherence	
Minimum adherence (Session 1 and one-to-one as a minimum)	261 (68.9%)
Full adherence (Session 1, session 2 and one-to-one)	217 (57.3%)
Group size as randomised	
Number of groups	42
Mean (SD)	9.0 (3.4)
Median (IQR)	9 (7, 12)
Missing	0

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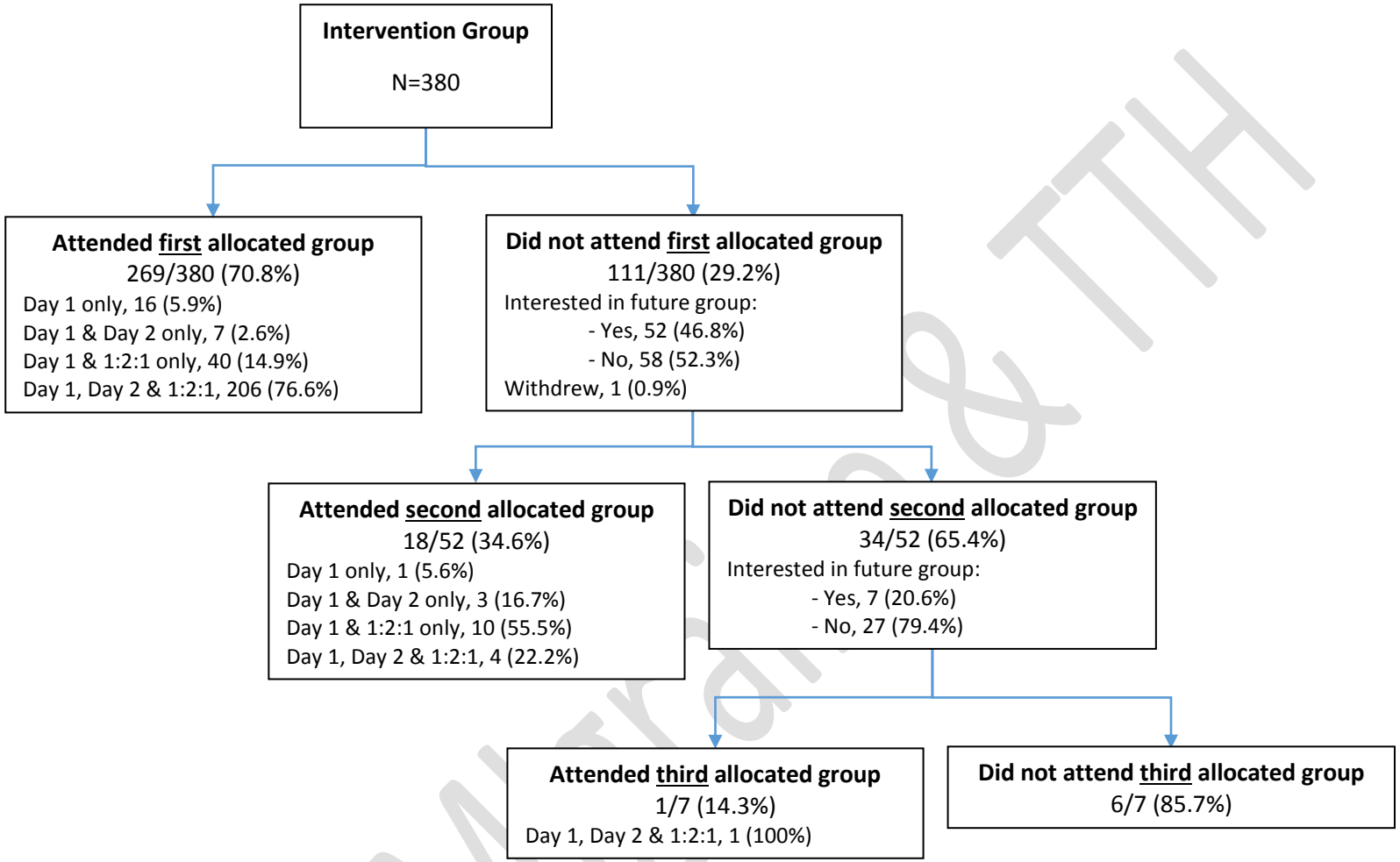
Figure 2: Intervention attendance flow diagram



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SECTION 5 - STUDY OUTCOME DATA

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Table 11: Study outcomes at 4 months follow-up

	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
HIT-6					
N	279	279	558	-1.3 (-2.50, -0.10); 0.034	-0.9 (-1.88, -0.004); 0.049
Mean (SD)	62.2 (7.3)	60.9 (7.2)	61.5 (7.3)		
Median (IQR)	63 (59, 66)	62 (58, 65)	62 (58, 66)		
Missing	1	1	2		
CH-QLQ – role restrictive					
N	247	254	501	2.6 (-0.76, 5.86); 0.131	1.5 (-0.97, 3.96); 0.234
Mean (SD)	61.8 (18.5)	64.4 (17.7)	63.1 (18.1)		
Median (IQR)	61.9 (50, 76.2)	66.7 (52.4, 76.2)	64.3 (50, 76.2)		
Missing	33	26	59		
CH-QLQ – role preventive					
N	247	254	501	2.5 (-1.16, 6.18); 0.180	1.6 (-0.80, 4.00); 0.191
Mean (SD)	76.1 (20.5)	78.9 (18.8)	77.5 (19.7)		
Median (IQR)	83.3 (62.5, 91.7)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)		
Missing	33	26	59		
CH-QLQ – emotional function					
N	247	254	501	1.9 (-2.21, 5.99); 0.366	1.2 (-1.85, 4.19); 0.447
Mean (SD)	64.9 (23.4)	66.8 (23.0)	65.9 (23.2)		
Median (IQR)	66.7 (44.4, 83.3)	72.2 (50, 88.9)	72.2 (50, 88.9)		
Missing	33	26	59		
SF-12 Physical					
N	245	254	499	0.2 (-1.59, 2.05);	-0.2 (-1.45, 1.07);

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				0.803	0.773
Mean (SD)	46.2 (10.8)	46.5 (10.0)	46.4 (10.4)		
Median (IQR)	48.8 (39, 54.5)	48.5 (40.9, 54.0)	48.6 (40.1, 54.4)		
Missing	35	26	61		
SF-12 Mental					
N	246	254	500	1.8 (-0.09, 3.64); 0.061	0.9 (-0.58, 2.38); 0.234
Mean (SD)	41.1 (10.9)	42.9 (10.2)	42.0 (10.6)		
Median (IQR)	41.7 (32.2, 50.4)	42.7 (35.4, 51.5)	42.3 (34.3, 51.1)		
Missing	34	26	60		
EQ-5D					
N	279	277	556	0.04 (-0.009, 0.09); 0.104	0.02 (-0.01, 0.06); 0.115
Mean (SD)	0.63 (0.28)	0.68 (0.26)	0.66 (0.27)		Non-parametric test: P=0.007
Median (IQR)	0.72 (0.55, 0.80)	0.75 (0.64, 0.84)	0.74 (0.59, 0.84)		
Missing	1	3	4		
EQ-5D VAS					
N	244	253	497	1.9 (-1.99, 5.89); 0.333	1.0 (-2.04, 3.94); 0.533
Mean (SD)	65.0 (20.6)	67.3 (20.6)	66.2 (20.6)		
Median (IQR)	70 (50, 80)	70 (56, 85)	70 (50, 80)		
Missing	36	27	63		
HADS Anxiety					
N	247	254	501	-0.2 (-0.66, 0.28); 0.425	0.2 (-0.22, 0.55); 0.404
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	33	26	59		
HADS Depression					
N	247	254	501	-0.11 (-0.44,	-0.15 (-0.46, 0.17);

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				0.23); 0.536	0.362
Mean (SD)	9.1 (1.9)	9.0 (1.7)	9.1 (1.8)		
Median (IQR)	9 (8, 10)	9 (8, 10)	9 (8, 10)		
Missing	33	26	59		
PSEQ					
N	247	253	500	2.5 (0.10, 4.98); 0.041	2.4 (0.62, 4.09); 0.008
Mean (SD)	35.5 (14.2)	38.1 (13.6)	36.8 (14.0)		
Median (IQR)	38 (24, 46)	40 (28, 48)	38.5 (26, 48)		
Missing	33	27	60		
HeiQ					
N	247	254	501	0.10 (-0.03, 0.23); 0.129	0.05 (-0.06, 0.16); 0.358
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	33	26	59		

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

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Table 12: Study outcomes at 8 months follow-up

	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
HIT-6					
N	267	285	552	-0.2 (-1.41, 0.96); 0.709	0.1 (-0.93, 1.11); 0.860
Mean (SD)	61.0 (7.3)	60.7 (6.5)	60.8 (6.9)		
Median (IQR)	62 (56, 66)	61 (58, 64)	61 (57, 65)		
Missing	1	1	2		
CH-QLQ – role restrictive					
N	231	256	487	0.8 (-2.72, 4.29); 0.661	-0.04 (-2.8, 2.71); 0.975
Mean (SD)	65.4 (19.6)	66.4 (17.9)	66.0 (18.7)		
Median (IQR)	66.7 (52.4, 81.0)	66.7 (54.8, 79.8)	66.7 (52.4, 81.0)		
Missing	37	30	67		
CH-QLQ – role preventive					
N	231	256	487	1.7 (-2.09, 5.55); 0.374	1.3 (-1.40, 3.98); 0.348
Mean (SD)	77.4 (22.0)	79.3 (19.2)	78.4 (20.6)		
Median (IQR)	83.3 (66.7, 95.8)	83.3 (70.8, 95.8)	83.3 (66.7, 95.8)		
Missing	37	30	67		
CH-QLQ – emotional function					
N	231	255	486	0.2 (-3.90, 4.26); 0.932	-0.4 (-3.62, 2.89); 0.827
Mean (SD)	69.2 (23.3)	69.3 (22.6)	69.3 (22.9)		
Median (IQR)	72.2 (55.6, 88.9)	72.2 (55.6, 88.9)	72.2 (55.6, 88.9)		
Missing	37	31	68		
SF-12 Physical					
N	229	254	483	0.5 (-1.39, 2.30);	-0.07 (-1.31, 1.17);

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				0.630	0.915
Mean (SD)	46.8 (10.8)	47.3 (9.9)	47.1 (10.3)		
Median (IQR)	49.4 (39.9, 54.8)	48.5 (41.6, 54.8)	48.9 (41.3, 54.8)		
Missing	39	32	71		
SF-12 Mental					
N	229	254	483	1.3 (-0.63, 3.20); 0.188	0.9 (-0.61, 2.38); 0.246
Mean (SD)	41.5 (10.3)	42.9 (10.5)	42.2 (10.4)		
Median (IQR)	41.2 (35.0, 49.3)	43.0 (35.4, 51.2)	42.0 (35.2, 50.4)		
Missing	39	32	71		
EQ-5D					
N	265	282	547	0.05 (-0.0003, 0.095); 0.051	0.03 (-0.001, 0.061); 0.056
Mean (SD)	0.65 (0.27)	0.70 (0.24)	0.67 (0.26)		Non-parametric test: P=0.027
Median (IQR)	0.74 (0.56, 0.80)	0.74 (0.65, 0.84)	0.74 (0.64, 0.84)		
Missing	3	4	7		
EQ-5D VAS					
N	227	254	481	2.9 (-0.90, 6.63); 0.135	2.3 (-0.61, 5.20); 0.122
Mean (SD)	66.1 (21.3)	69.0 (20.1)	67.6 (20.7)		
Median (IQR)	70 (50, 80)	75 (55, 85)	70 (55, 85)		
Missing	41	32	73		
HADS Anxiety					
N	229	254	483	-0.5 (-0.97, -0.001); 0.050	-0.2 (-0.64, 0.21); 0.311
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	39	32	71		
HADS Depression					
N	229	254	483	-0.1 (-0.38, 0.26);	-0.1 (-0.41, 0.16);

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				0.726	0.400
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	39	32	71		
PSEQ					
N	229	255	484	1.7 (-0.82, 4.18); 0.189	1.5 (-0.27, 3.35); 0.096
Mean (SD)	37.0 (14.7)	38.7 (13.3)	37.9 (14.0)		
Median (IQR)	40 (28, 49)	40 (28, 50)	40 (28, 49)		
Missing	39	31	70		
HeiQ					
N	227	255	482	0.06 (-0.06, 0.19); 0.324	0.04 (-0.06, 0.14); 0.402
Mean (SD)	2.9 (0.7)	3.0 (0.69)	2.9 (0.7)		
Median (IQR)	3 (2.4, 3.4)	3 (2.6, 3.4)	3 (2.6, 3.4)		
Missing	41	31	72		

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

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Table 13: Study outcomes at 12 months follow-up

	Standard care	Self-management	TOTAL	Unadjusted mean difference (95% CI); p-value	Adjusted mean difference* (95% CI); p-value
HIT-6					
N	286	303	589	-0.6 (-1.75, 0.52); 0.290	-0.3 (-1.22, 0.66); 0.555
Mean (SD)	60.6 (7.1)	60.0 (7.0)	60.3 (7.0)		
Median (IQR)	62 (57, 65)	61 (55, 64)	61 (56, 65)		
Missing	1	3	4		
CH-QLQ – role restrictive					
N	238	271	509	1.0 (-2.26, 4.21); 0.555	0.4 (-2.19, 2.95); 0.771
Mean (SD)	66.2 (19.0)	67.1 (18.2)	66.7 (18.6)		
Median (IQR)	66.7 (54.8, 81.0)	66.7 (57.1, 81.0)	66.7 (54.8, 81.0)		
Missing	49	35	84		
CH-QLQ – role preventive					
N	238	271	509	2.5 (-0.92, 5.84); 0.153	2.2 (-0.37, 4.80); 0.093
Mean (SD)	77.7 (20.3)	80.2 (18.5)	79.1 (19.4)		
Median (IQR)	83.3 (66.7, 95.8)	83.3 (70.8, 95.8)	83.3 (70.8, 95.8)		
Missing	49	35	84		
CH-QLQ – emotional function					
N	238	271	509	1.9 (-2.08, 5.82); 0.354	1.3 (-1.87, 4.53); 0.415
Mean (SD)	68.8 (23.3)	70.7 (22.1)	69.8 (22.7)		
Median (IQR)	72.2 (50, 88.9)	72.2 (55.6, 88.9)	72.2 (55.6, 88.9)		
Missing	49	35	84		
SF-12 Physical					
N	237	268	505	1.0 (-0.81, 2.74);	0.5 (-0.73, 1.83);

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				0.285	0.399
Mean (SD)	46.0 (10.8)	47.0 (9.4)	46.6 (10.1)		
Median (IQR)	47.3 (37.6, 54.5)	48.7 (40.8, 54.7)	48.1 (40.3, 54.6)		
Missing	50	38	88		
SF-12 Mental					
N	237	270	507	1.6 (-0.38, 3.62); 0.111	1.0 (-0.69, 2.71); 0.242
Mean (SD)	42.1 (11.0)	43.9 (10.6)	43.1 (10.8)		
Median (IQR)	41.5 (33.9, 50.7)	44.6 (37.1, 52.2)	43.4 (35.5, 51.4)		
Missing	50	36	86		
EQ-5D					
N	286	304	590	0.03 (-0.01, 0.07); 0.196	0.004 (-0.03, 0.04); 0.793
Mean (SD)	0.67 (0.26)	0.70 (0.25)	0.68 (0.25)		Non-parametric test: P=0.086
Median (IQR)	0.74 (0.60, 0.81)	0.74 (0.64, 0.84)	0.74 (0.63, 0.84)		
Missing	1	2	3		
EQ-5D VAS					
N	230	267	497	4.3 (0.28, 8.28); 0.036	4.0 (1.02, 6.95); 0.008
Mean (SD)	65.4 (22.4)	69.9 (20.7)	67.8 (21.6)		
Median (IQR)	70 (50, 80)	75 (60, 85)	75 (55, 85)		
Missing	57	39	96		
HADS Anxiety					
N	237	269	506	-0.1 (-0.61, 0.36); 0.600	0.2 (-0.19, 0.62); 0.302
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	50	37	87		
HADS Depression					
N	237	269	506	-0.004 (-0.32,	-0.03 (-0.33, 0.26);

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				0.31); 0.978	0.830
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	50	37	87		
PSEQ					
N	237	270	507	2.4 (-0.19, 4.94); 0.069	2.2 (0.31, 4.08); 0.022
Mean (SD)	37.1 (14.6)	39.6 (13.6)	38.4 (14.1)		
Median (IQR)	40 (27, 48)	42 (31, 50)	41 (29, 49)		
Missing	50	36	86		
HeiQ					
N	236	270	506	0.04 (-0.09, 0.18); 0.528	0.002 (-0.10, 0.10); 0.969
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	51	36	87		

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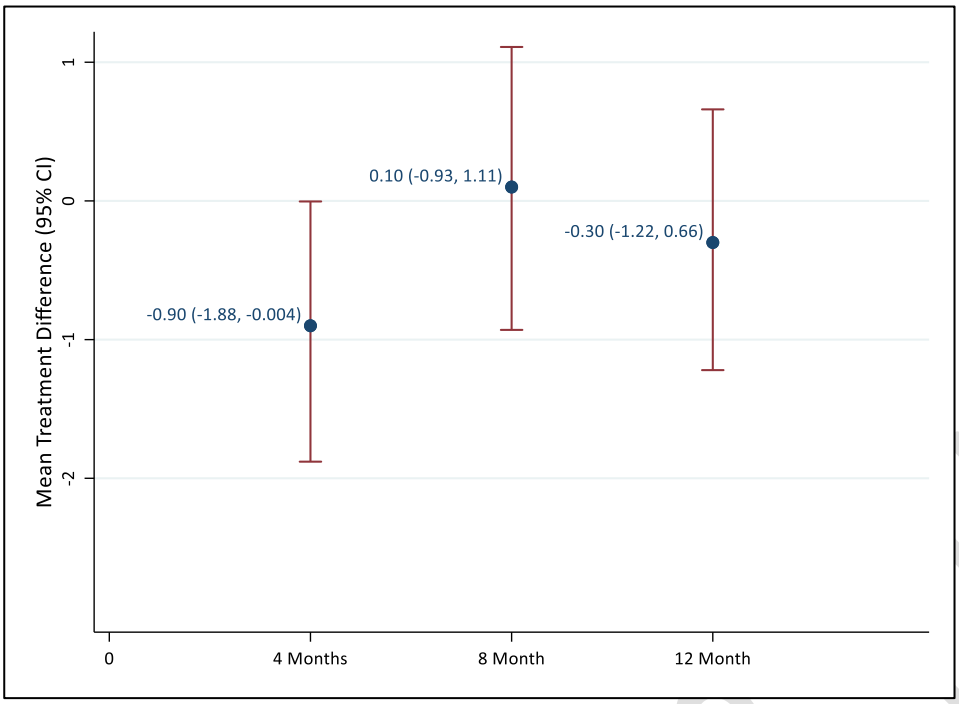
Figure 3: Plot of HIT-6 (Primary outcome) over time by treatment group



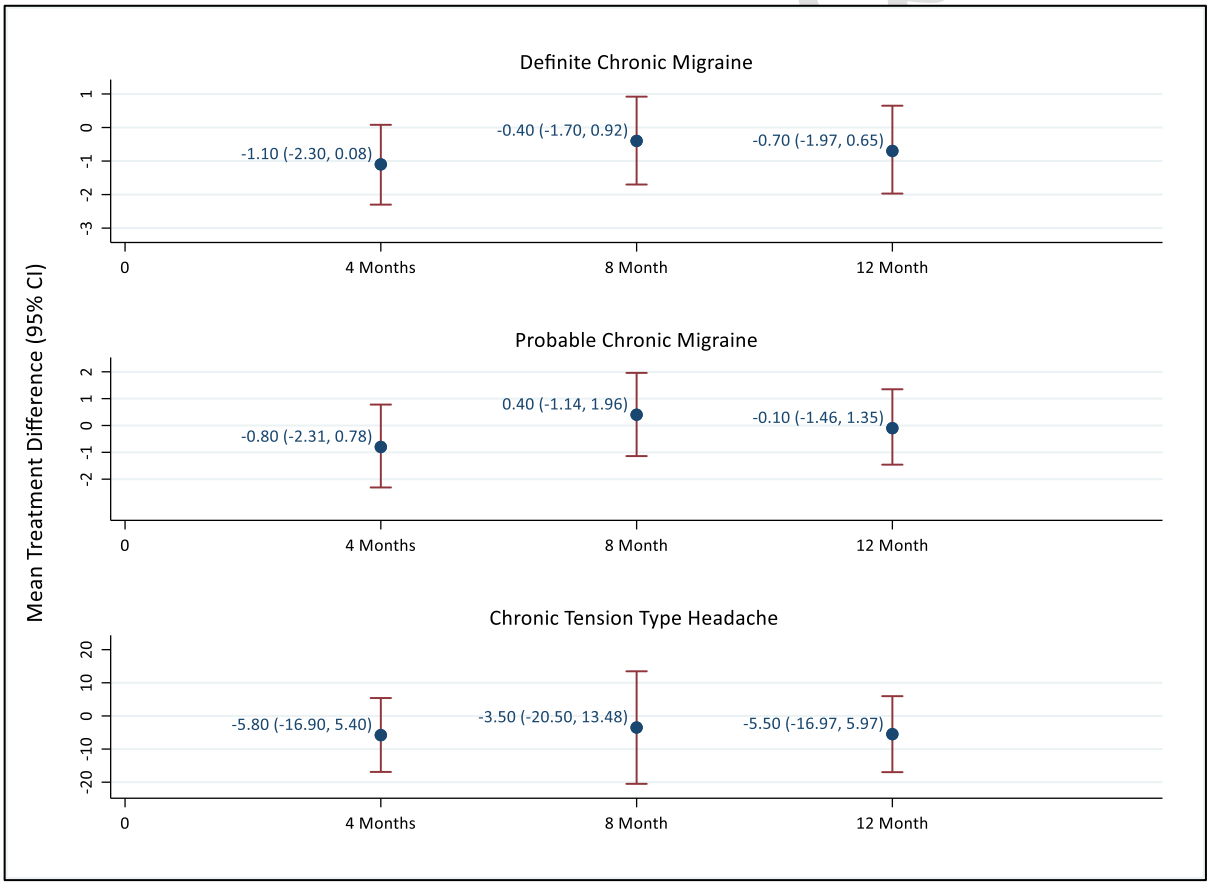


Figure 4: Plot of HIT-6 (Primary outcome) over time by headache type and treatment group

Note: Adjusted estimates used for definite and probable migraine. Unadjusted estimates used for chronic tension type headache due to there being a small number of participants.

Table 14: General health outcomes at 4 months follow-up

	Standard care	Self-management	TOTAL	Unadjusted mean difference	Adjusted mean difference* (95%

				(95% CI); p-value	CI); p-value
Headache/migraine days over the last 4 weeks					
N	241	251	492	0.9 (-0.43, 2.32); 0.180	1.4 (0.38, 2.47); 0.008
Mean (SD)	12.5 (7.6)	13.4 (7.6)	13.0 (7.6)		
Median (IQR)	10 (7, 16)	13 (7, 19)	12 (7, 18)		
Missing	39	29	68		
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)					
N	244	252	496	-0.1 (-1.36, 1.13); 0.853	0.2 (-0.89, 1.22); 0.758
Mean (SD)	9.5 (7.3)	9.3 (6.9)	9.4 (7.1)		
Median (IQR)	8 (4, 12)	8 (4, 13)	8 (4, 13)		
Missing	36	28	64		
Average number of hours the headache/migraine lasted on the days they had it					
N	226	223	449	0.004 (-1.28, 1.29); 0.995	0.06 (-1.21, 1.33); 0.931
Mean (SD)	8.5 (7.2)	8.5 (6.6)	8.5 (6.9)		Non-parametric test: P=0.477
Median (IQR)	6 (4, 12)	6 (4, 12)	6 (4, 12)		
Missing	54	57	111		
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine					
N	227	225	452	-0.1 (-0.51, 0.29); 0.596	-0.1 (-0.47, 0.24); 0.528
Mean (SD)	6.0 (2.1)	5.9 (1.9)	6.0 (2.0)		
Median (IQR)	6 (5, 8)	6 (5, 7)	6 (5, 7.5)		
Missing	53	55	108		

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How fatigued were you on average in the past seven days					
Not at all	4 (1.4%)	12 (4.3%)	16 (2.9%)	OR: 0.8 (-0.61, 1.14); 0.249	OR: 0.9 (0.63, 1.21); 0.419
A little bit	53 (18.9%)	54 (19.3%)	107 (19.1%)		
Somewhat	53 (18.9%)	52 (18.6%)	105 (18.8%)		
Quite a bit	76 (27.2%)	86 (30.7%)	162 (28.9%)		
Very much	60 (21.4%)	49 (17.5%)	109 (19.5%)		
Missing	34 (12.2%)	27 (9.6%)	61 (10.9%)		
Sleep quality in the past seven days					
Very poor	38 (13.6%)	33 (11.8%)	71 (12.7%)	OR: 1.0 (0.68, 1.33); 0.770	OR: 1.0 (0.73, 1.43); 0.895
Poor	62 (22.1%)	81 (28.9%)	143 (25.5%)		
Fair	105 (37.5%)	91 (32.5%)	196 (35.0%)		
Good	37 (13.2%)	42 (15.0%)	79 (14.1%)		
Very good	5 (1.8%)	6 (2.1%)	11 (2.0%)		
Missing	33 (11.8%)	27 (9.6%)	60 (10.7%)		
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)					
N	246	253	499	-0.3 (-0.83, 0.22); 0.250	-0.3 (-0.66, 0.14); 0.202
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	34	27	61		

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Table 15: General health outcomes at 8 months follow-up

	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	229	254	483	-0.1 (-1.55, 1.28); 0.850	0.3 (-0.89, 1.45); 0.636
Mean (SD)	11.9 (8.2)	11.8 (7.4)	11.9 (7.8)		
Median (IQR)	10 (5, 18)	10 (6, 16)	10 (5, 17)		
Missing	39	32	71		
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)					
N	229	254	483	-0.4 (-1.75, 0.86); 0.503	-0.1 (-1.28, 1.01); 0.819
Mean (SD)	9.3 (7.5)	8.8 (7.2)	9.0 (7.3)		
Median (IQR)	8 (3, 14)	7 (3, 12)	7 (3, 13)		
Missing	39	32	71		
Average number of hours the headache/migraine lasted on the days they had it					
N	226	248	474	1.3 (-0.16, 2.69); 0.082	1.9 (0.42, 3.28); 0.011
Mean (SD)	8.2 (7.1)	9.2 (7.2)	8.7 (7.2)		Non-parametric test: P=0.037
Median (IQR)	6 (3, 10)	7 (4, 12)	6 (4, 11)		
Missing	42	38	80		
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine					
N	225	248	473	0.1 (-0.24, 0.52);	0.3 (-0.09, 0.61);

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				0.461	0.139
Mean (SD)	5.9 (2.1)	6.1 (2.0)	6.0 (2.1)		
Median (IQR)	6 (5, 7)	6 (5, 7)	6 (5, 7)		
Missing	43	38	81		
How fatigued were you on average in the past seven days					
Not at all	14 (5.2%)	10 (3.5%)	24 (4.3%)	OR: 0.8 (0.60, 1.20); 0.342	OR: 0.9 (0.62, 1.19); 0.372
A little bit	36 (13.4%)	58 (20.3%)	94 (17.0%)		
Somewhat	57 (21.3%)	65 (22.7%)	122 (22.0%)		
Quite a bit	81 (30.2%)	81 (28.3%)	162 (29.2%)		
Very much	41 (15.3%)	41 (14.3%)	82 (14.8%)		
Missing	39 (14.5%)	31 (10.8%)	70 (12.6%)		
Sleep quality in the past seven days					
Very poor	35 (13.1%)	25 (8.7%)	60 (10.8%)	OR: 1.2 (0.88, 1.68); 0.238	OR: 1.3 (0.91, 1.86); 0.144
Poor	64 (23.9%)	71 (24.8%)	135 (24.4%)		
Fair	82 (30.6%)	107 (37.4%)	189 (34.1%)		
Good	40 (14.9%)	45 (15.7%)	85 (15.3%)		
Very good	7 (2.6%)	7 (2.5%)	14 (2.5%)		
Missing	40 (14.9%)	31 (10.8%)	71 (12.8%)		
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)					
N	229	255	484	-0.4 (-0.90, 0.11); 0.127	-0.3 (-0.67, 0.17); 0.235
Mean (SD)	4.3 (2.7)	3.9 (2.7)	4.1 (2.7)		
Median (IQR)	4 (2, 6)	4 (2, 6)	4 (2, 6)		
Missing	39	31	70		

Migraine & TTH

Table 16: General health outcomes at 12 months follow-up

	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	236	271	507	0.3 (-1.07, 1.69); 0.661	0.8 (-0.40, 1.94); 0.196
Mean (SD)	11.5 (7.9)	11.8 (7.8)	11.7 (7.9)		
Median (IQR)	10 (4.5, 16)	10 (6, 17)	10 (5, 16)		
Missing	51	35	86		
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)					
N	236	269	505	0.2 (-1.03, 1.51); 0.708	0.6 (-0.51, 1.69); 0.296
Mean (SD)	9.0 (7.2)	9.3 (7.4)	9.2 (7.3)		
Median (IQR)	8 (3, 12)	8 (3, 14)	8 (3, 13)		
Missing	51	37	88		
Average number of hours the headache/migraine lasted on the days they had it					
N	233	268	501	1.0 (-0.33, 2.24); 0.145	1.0 (-0.18, 2.20); 0.098 Non-parametric test: P=0.079
Mean (SD)	8.6 (7.2)	9.6 (7.4)	9.1 (7.3)		
Median (IQR)	6 (4, 12)	7 (4, 12)	6 (4, 12)		
Missing	54	38	92		
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine					
N	237	270	507	-0.04 (-0.37, 0.29); 0.821	-0.04 (-0.35, 0.27); 0.800

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Mean (SD)	6.0 (1.9)	6.0 (1.9)	6.0 (1.9)		
Median (IQR)	6 (5, 7)	6 (5, 7)	6 (5, 7)		
Missing	50	36	86		
How fatigued were you on average in the past seven days					
Not at all	14 (4.9%)	12 (3.9%)	26 (4.4%)	OR: 0.9 (0.66, 1.34); 0.738	OR: 0.9 (0.62, 1.25); 0.467
A little bit	65 (22.6%)	72 (23.5%)	137 (23.1%)		
Somewhat	59 (20.6%)	89 (29.1%)	148 (25.0%)		
Quite a bit	68 (23.7%)	65 (21.2%)	133 (22.4%)		
Very much	32 (11.1%)	32 (10.5%)	64 (10.8%)		
Missing	49 (17.1%)	36 (11.8%)	85 (14.3%)		
Sleep quality in the past seven days					
Very poor	28 (9.8%)	26 (8.5%)	54 (9.1%)	1.0 (0.72, 1.36); 0.952	1.0 (0.75, 1.43); 0.852
Poor	58 (20.2%)	74 (24.2%)	132 (22.3%)		
Fair	96 (33.4%)	107 (35.0%)	203 (34.2%)		
Good	47 (16.4%)	57 (18.6%)	104 (17.6%)		
Very good	9 (3.1%)	6 (2.0%)	15 (2.5%)		
Missing	49 (17.1%)	36 (11.7%)	85 (14.3%)		
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)					
N	237	270	507	-0.2 (-0.68, 0.32); 0.480	-0.1 (-0.51, 0.30); 0.612
Mean (SD)	4.1 (2.9)	3.9 (2.8)	4.0 (2.8)		
Median (IQR)	4 (2, 6)	4 (2, 6)	4 (2, 6)		
Missing	50	36	86		

Migraine & TTH

Table 17: Baseline demographic characteristics of randomised participants summarised by compliance status (minimum compliance)

	Standard care	Non-Complier	Complier	Complier vs Non-complier p-value[a]
Age (years)				
N	356	119	261	0.001
Mean (SD)	47.9 (15.0)	43.5 (15.7)	48.9 (14.4)	
Median (IQR)	49 (37, 58.5)	45 (28, 54)	50 (39, 58)	
Missing	0	0	0	
Gender				
Male	71 (19.9%)	16 (13.4%)	39 (14.9%)	0.713
Female	285 (80.1%)	102 (85.7%)	221 (84.7%)	
Missing	0	1 (0.9%)	1 (0.4%)	
Ethnicity				
White	287 (80.6%)	88 (73.9%)	220 (84.3%)	0.053
Black or Black British	24 (6.7%)	6 (5.0%)	12 (4.6%)	
Asian or Asian British	29 (8.2%)	15 (12.6%)	16 (6.1%)	
Mixed	8 (2.2%)	5 (4.2%)	8 (3.1%)	
Other	2 (0.6%)	4 (3.4%)	2 (0.8%)	
Missing	6 (1.7%)	1 (0.9%)	3 (1.1%)	
Employment status				
Employed	195 (54.8%)	64 (53.8%)	159 (60.9%)	0.045
Unemployed	9 (2.5%)	7 (5.9%)	7 (2.7%)	
At school or full time education	10 (2.8%)	7 (5.9%)	6 (2.3%)	
Unable to work due to long term sickness	36 (10.1%)	16 (13.4%)	17 (6.5%)	
Looking after home/family	22 (6.2%)	7 (5.9%)	15 (5.8%)	

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Retired from paid work	61 (17.1%)	14 (11.7%)	45 (17.2%)	
Other	16 (4.5%)	2 (1.7%)	9 (3.5%)	
Missing	7 (2.0%)	2 (1.7%)	3 (1.1%)	
Age left full time education				0.683
Did not receive formal education	2 (0.6%)	0	2 (0.8%)	
Age 12 or less	3 (0.8%)	0	2 (0.8%)	
Age 13 to 16	94 (26.4%)	24 (20.2%)	60 (22.9%)	
Age 17 to 19	93 (26.1%)	34 (28.6%)	76 (29.1%)	
Age 20 or over	144 (40.5%)	52 (43.7%)	111 (42.5%)	
Still in full time education	12 (3.4%)	7 (5.9%)	8 (3.1%)	
Missing	8 (2.2%)	2 (1.6%)	2 (0.8%)	
Headache classification				0.261
Definite chronic migraine	191 (53.7%)	58 (48.7%)	147 (56.3%)	
Probable chronic migraine	160 (44.9%)	59 (49.6%)	112 (42.9%)	
Chronic tension type headache	5 (1.4%)	2 (1.7%)	2 (0.8%)	
Missing	0	0	0	
Medication overuse				0.867
No	158 (44.4%)	55 (46.2%)	113 (43.3%)	
Yes	198 (55.6%)	64 (53.8%)	148 (56.7%)	
Missing	0	0	0	
Headache/migraine days over the last 4 weeks				0.423
N	354	116	260	
Mean (SD)	16.4 (7.0)	16.1 (7.0)	16.7 (6.7)	

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Median (IQR)	16 (10, 21)	15.5 (11, 20)	16 (12, 20)	
Missing	2	3	1	
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)				
N	350	117	258	0.743
Mean (SD)	12.3 (7.3)	12.7 (8.2)	12.4 (7.2)	
Median (IQR)	12 (8, 16)	12 (6, 18)	12 (6, 16)	
Missing	6	2	3	
Average number of hours the headache/migraine lasted on the days they had it				
N	239	78	180	0.527
Mean (SD)	10.3 (8.1)	10.0 (7.9)	10.7 (7.9)	
Median (IQR)	7 (4, 15)	7 (4, 12)	8 (4, 15)	
Missing	117	41	81	
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine				
N	246	82	185	0.455
Mean (SD)	6.7 (2.0)	6.9 (1.7)	6.7 (1.9)	
Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)	
Missing	110	37	76	
How fatigued were you on average in the past seven days				
Not at all	4 (1.1%)	2 (1.7%)	4 (1.5%)	0.543
A little bit	44 (12.4%)	10 (8.4%)	34 (13.0%)	
Somewhat	85 (23.9%)	26 (21.8%)	54 (20.7%)	

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Quite a bit	139 (39.0%)	43 (36.1%)	104 (39.9%)	
Very much	82 (23.0%)	36 (30.3%)	63 (24.1%)	
Missing	2 (0.6%)	2 (1.7%)	2 (0.8%)	
Sleep quality in the past seven days				
Very poor	45 (12.6%)	26 (21.9%)	31 (11.9%)	0.099
Poor	115 (32.3%)	41 (34.4%)	88 (33.7%)	
Fair	132 (37.1%)	36 (30.2%)	99 (37.9%)	
Good	56 (15.7%)	12 (10.1%)	37 (14.2%)	
Very good	7 (2.0%)	2 (1.7%)	5 (1.9%)	
Missing	1 (0.3%)	2 (1.7%)	1 (0.4%)	
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)				
N	350	117	256	0.322
Mean (SD)	4.5 (2.8)	4.6 (2.8)	4.3 (2.7)	
Median (IQR)	5 (2, 7)	5 (2, 7)	4 (2, 6)	
Missing	6	2	5	

[a] *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.

Migraine & TH

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

	Standard care	Non-Complier	Complier	Complier vs Non-complier p-value[a]
Age (years)				
N	356	163	217	0.007
Mean (SD)	47.9 (15.0)	44.8 (15.4)	49.0 (14.4)	
Median (IQR)	49 (37, 58.5)	46 (32, 55)	50 (39, 58)	
Missing	0	0	0	
Gender				
Male	71 (19.9%)	22 (13.5%)	33 (15.2%)	0.643
Female	285 (80.1%)	140 (85.9%)	183 (84.3%)	
Missing	0	1 (0.6%)	1 (0.5%)	
Ethnicity				
White	287 (80.6%)	123 (75.5%)	185 (85.3%)	0.148
Black or Black British	24 (6.7%)	10 (6.1%)	8 (3.7%)	
Asian or Asian British	29 (8.2%)	18 (11.0%)	13 (6.0%)	
Mixed	8 (2.2%)	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%)	
Employment status				
Employed	195 (54.8%)	92 (56.4%)	131 (60.4%)	0.135
Unemployed	9 (2.5%)	8 (4.9%)	6 (2.7%)	
At school or full time education	10 (2.8%)	7 (4.3%)	6 (2.7%)	
Unable to work due to long term sickness	36 (10.1%)	20 (12.3%)	13 (6.0%)	
Looking after home/family	22 (6.2%)	11 (6.8%)	11 (5.1%)	

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Retired from paid work	61 (17.1%)	20 (12.3%)	39 (18.0%)	
Other	16 (4.5%)	3 (1.8%)	8 (3.7%)	
Missing	7 (2.0%)	2 (1.2%)	3 (1.4%)	
Age left full time education				0.971
Did not receive formal education	2 (0.6%)	1 (0.6%)	1 (0.5%)	
Age 12 or less	3 (0.8%)	1 (0.6%)	1 (0.5%)	
Age 13 to 16	94 (26.4%)	38 (23.3%)	46 (21.2%)	
Age 17 to 19	93 (26.1%)	44 (27.0%)	66 (30.4%)	
Age 20 or over	144 (40.5%)	70 (42.9%)	93 (42.9%)	
Still in full time education	12 (3.4%)	7 (4.3%)	8 (3.6%)	
Missing	8 (2.2%)	2 (1.3%)	2 (0.9%)	
Headache classification				0.245
Definite chronic migraine	191 (53.7%)	82 (50.3%)	123 (56.7%)	
Probable chronic migraine	160 (44.9%)	78 (47.9%)	93 (42.8%)	
Chronic tension type headache	5 (1.4%)	3 (1.8%)	1 (0.5%)	
Missing	0	0	0	
Medication overuse				0.464
No	158 (44.4%)	78 (47.9%)	90 (41.5%)	
Yes	198 (55.6%)	85 (52.1%)	127 (58.5%)	
Missing	0	0	0	
Headache/migraine days over the last 4 weeks				0.819
N	354	160	216	
Mean (SD)	16.4 (7.0)	16.6 (7.1)	16.4 (6.6)	

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Median (IQR)	16 (10, 21)	16 (11, 20)	16 (12, 20)	
Missing	2	3	1	
Pain killer or triptan use for headache/migraine over the last 4 weeks (days)				
N	350	159	216	0.568
Mean (SD)	12.3 (7.3)	12.7 (8.0)	12.3 (7.1)	
Median (IQR)	12 (8, 16)	12 (6, 18)	12 (6, 16)	
Missing	6	4	1	
Average number of hours the headache/migraine lasted on the days they had it				
N	239	110	148	0.819
Mean (SD)	10.3 (8.1)	10.3 (7.9)	10.5 (7.9)	
Median (IQR)	7 (4, 15)	7 (4, 14)	8 (4, 14.5)	
Missing	117	53	69	
Average severity (0-10; No pain to Extremely severe pain) on the days you had a headache/migraine				
N	246	115	152	0.349
Mean (SD)	6.7 (2.0)	6.9 (1.8)	6.7 (1.8)	
Median (IQR)	7 (6, 8)	7 (6, 8)	7 (6, 8)	
Missing	110	48	65	
How fatigued were you on average in the past seven days				
Not at all	4 (1.1%)	2 (1.2%)	4 (1.8%)	0.841
A little bit	44 (12.4%)	17 (10.4%)	27 (12.5%)	
Somewhat	85 (23.9%)	34 (20.9%)	46 (21.2%)	

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Quite a bit	139 (39.0%)	61 (37.4%)	86 (39.6%)	
Very much	82 (23.0%)	47 (28.9%)	52 (24.0%)	
Missing	2 (0.6%)	2 (1.2%)	2 (0.9%)	
Sleep quality in the past seven days				
Very poor	45 (12.6%)	33 (20.2%)	24 (11.0%)	0.130
Poor	115 (32.3%)	49 (30.1%)	80 (36.9%)	
Fair	132 (37.1%)	56 (34.4%)	79 (36.4%)	
Good	56 (15.7%)	21 (12.9%)	28 (12.9%)	
Very good	7 (2.0%)	2 (1.2%)	5 (2.3%)	
Missing	1 (0.3%)	2 (1.2%)	1 (0.5%)	
Average pain (other than headache) in the past seven days (0-10; No pain to Worst imaginable pain)				
N	350	159	214	0.021
Mean (SD)	4.5 (2.8)	4.8 (2.9)	4.1 (2.6)	
Median (IQR)	5 (2, 7)	5 (2, 7)	4 (2, 6)	
Missing	6	4	3	

[a] *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 18: Baseline outcome measures of randomised participants summarised by compliance status (minimum compliance)

	Standard care	**Non-complier**	**Complier**	**Complier vs Non-complier p-value[a]**
HIT-6				
N	355	118	260	0.234
Mean (SD)	64.4 (5.8)	64.8 (6.2)	64.1 (5.4%)	
Median (IQR)	64 (61, 68)	66 (62, 69)	64 (61, 67.5)	
Missing	1	1	1	

Migraine & TH

CH-QLQ – role restrictive				
N	356	118	260	0.124
Mean (SD)	54.7 (17.6)	52.7 (17.6)	55.6 (16.8)	
Median (IQR)	57.1 (42.9, 66.7)	52.4 (40.5, 64.3)	57.1 (45.2, 66.7)	
Missing	0	1	1	
CH-QLQ – role preventive				
N	356	118	260	0.001
Mean (SD)	69.7 (21.3)	64.7 (21.3)	72.0 (19.9)	
Median (IQR)	75 (54.2, 87.5)	66.7 (50, 79.2)	75 (62.5, 87.5)	
Missing	0	1	1	
CH-QLQ – emotional function				
N	356	118	259	0.503
Mean (SD)	57.4 (22.4)	56.1 (24.3)	57.7 (21.5)	
Median (IQR)	58.3 (38.9, 77.8)	61.1 (33.3, 77.8)	61.1 (38.9, 77.8)	
Missing	0	1	2	
SF-12 Physical				
N	351	115	259	0.802
Mean (SD)	43.9 (11.0)	44.8 (10.5)	45.1 (9.8)	
Median (IQR)	44.2 (36.9, 52.1)	46.9 (37.6, 52.6)	45.6 (39.2, 52.8)	
Missing	5	4	2	
SF-12 Mental				
N	352	115	259	0.006
Mean (SD)	39.7 (10.3)	37.6 (10.3)	40.9 (10.7)	
Median (IQR)	39.6 (32.3, 47.2)	37.2 (29.2, 44.1)	40.6 (32.8, 49.7)	
Missing	4	4	2	
EQ-5D				
N	351	117	259	0.010
Mean (SD)	0.63 (0.25)	0.59 (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)	

Migraine & TH

Missing	5	2	2	
EQ-5D VAS				
N	355	117	258	0.261
Mean (SD)	62.5 (19.6)	61.4 (21.2)	63.9 (20.2)	
Median (IQR)	65 (50, 75)	60 (45, 75)	70 (50, 80)	
Missing	1	2	3	
HADS Anxiety				
N	354	117	260	0.051
Mean (SD)	10.9 (2.7)	10.9 (2.8)	10.3 (2.7)	
Median (IQR)	11 (9, 13)	11 (9, 13)	10 (8, 12)	
Missing	2	2	1	
HADS Depression				
N	354	117	260	0.040
Mean (SD)	9.0 (2.0)	9.5 (1.9)	9.1 (1.7)	
Median (IQR)	9 (8, 10)	9 (8, 11)	9 (8, 10)	
Missing	2	1	2	
PSEQ				
N	353	116	259	0.052
Mean (SD)	33.2 (13.4)	30.7 (15.0)	33.7 (13.2)	
Median (IQR)	34 (24, 43)	32 (19.5, 42)	35 (24, 45)	
Missing	3	3	2	
HeiQ				
N	353	117	260	0.061
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	

[a] *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.

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

	Standard care	Non-complier	Complier	Complier vs Non-complier p-value[a]
HIT-6				
N	355	162	216	0.071
Mean (SD)	64.4 (5.8)	64.9 (6.0)	63.9 (5.3)	
Median (IQR)	64 (61, 68)	66 (62, 69)	64 (61, 67)	
Missing	1	1	1	
CH-QLQ – role restrictive				
N	356	162	216	0.057
Mean (SD)	54.7 (17.6)	52.8 (17.9)	56.2 (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	
CH-QLQ – role preventive				
N	356	162	216	0.001
Mean (SD)	69.7 (21.3)	65.6 (21.7)	72.7 (19.2)	
Median (IQR)	75 (54.2, 87.5)	66.7 (50.0, 83.3)	75 (62.5, 87.5)	
Missing	0	1	1	
CH-QLQ – emotional function				
N	356	162	215	0.447
Mean (SD)	57.4 (22.4)	56.2 (23.5)	58.0 (21.6)	
Median (IQR)	58.3 (38.9, 77.8)	61.1 (38.9, 77.8)	61.1 (38.9, 77.8)	
Missing	0	1	2	
SF-12 Physical				
N	351	159	215	0.697
Mean (SD)	43.9 (11.0)	44.8 (10.3)	45.2 (9.8)	
Median (IQR)	44.2 (36.9, 52.1)	46.1 (37.6, 52.9)	45.6 (39.5, 52.8)	

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Missing	5	4	2	
SF-12 Mental				
N	352	159	215	0.033
Mean (SD)	39.7 (10.3)	38.5 (10.3)	40.9 (10.8)	
Median (IQR)	39.6 (32.3, 47.2)	37.5 (30.7, 44.6)	40.6 (32.7, 49.9)	
Missing	4	4	2	
EQ-5D				
N	351	161	215	0.002
Mean (SD)	0.63 (0.25)	0.59 (0.29)	0.67 (0.22)	
Median (IQR)	0.71 (0.53, 0.77)	0.70 (0.48, 0.77)	0.73 (0.63, 0.80)	
Missing	5	2	2	
EQ-5D VAS				
N	355	160	215	0.197
Mean (SD)	62.5 (19.6)	61.5 (21.7)	64.3 (19.5)	
Median (IQR)	65 (50, 75)	62.5 (45, 80)	70 (50, 80)	
Missing	1	3	2	
HADS Anxiety				
N	354	161	216	0.187
Mean (SD)	10.9 (2.7)	10.7 (2.8)	10.4 (2.7)	
Median (IQR)	11 (9, 13)	11 (9, 13)	10 (8, 12)	
Missing	2	2	1	
HADS Depression				
N	354	161	216	0.020
Mean (SD)	9.0 (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	
PSEQ				
N	353	160	215	0.092
Mean (SD)	33.2 (13.4)	31.4 (14.9)	33.8 (13.0)	

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Median (IQR)	34 (24, 43)	33 (20, 42.5)	34 (25, 44)	
Missing	3	3	2	
HeiQ				
N	353	161	216	0.210
Mean (SD)	2.8 (0.6)	2.8 (0.7)	2.9 (0.6)	
Median (IQR)	2.8 (2.4, 3.2)	3 (2.4, 3.2)	3 (2.4, 3.2)	
Missing	3	2	1	

[a] *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 19: Intention To Treat (ITT) and Complier Averaged Causal Effect (CACE) model estimates of treatment difference at each time point

	ITT model		CACE model (minimum adherence)		CACE model (full adherence)	
	Mean difference (95% CI)*	**p-value**	**Mean difference (95% CI)†**	**p-value**	**Mean difference (95% CI)†**	**p-value**
HIT-6						
4 months	-0.9 (-1.88, -0.004)	0.049	-1.3 (-2.54, -0.02)	0.046	-1.5 (-3.08, -0.01)	0.048
8 months	0.09 (-0.93, 1.11)	0.860	0.07 (-1.19, 1.34)	0.910	0.09 (-1.42, 1.59)	0.910
12 months	-0.3 (-1.22, 0.66)	0.555	-0.4 (-1.66, 0.86)	0.533	-0.5 (-2.00, 1.03)	0.533

**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.*
†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

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Table 20: 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
Anxiety			-0.2 (-2.02, 1.72); 0.875
≤10	122; 58.8 (7.1)	153; 58.6 (6.5)	
>10	164; 61.9 (6.8)	150; 61.3 (7.3)	
Depression			0.02 (-2.29, 2.34); 0.984
≤10	226; 60.3 (7.0)	239; 59.4 (7.0)	
>10	60; 61.7 (7.2)	64; 62.1 (6.5)	
Severity (HIT-6)			-1.7 (-3.72, 0.34); 0.102
≤64	147; 57.4 (6.5)	172; 57.8 (5.9)	
>64	139; 64.0 (6.0)	131; 62.8 (7.4)	

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ADDITIONAL ANALYSES

Table 21: Treatment effectiveness estimates for the primary outcome (HIT-6 at 12 months) for each of the headache types

Headache type	Standard care	Self-management	Adjusted mean difference (95% CI); p-value
Definite chronic migraine			
N	149	159	-0.7 (-1.97, 0.65); 0.325
Mean (SD)	62.7 (6.1)	61.4 (6.8)	
Median (IQR)	63 (60, 66)	62 (59, 66)	
Missing	0	0	
Probable chronic migraine			
N	133	141	-0.1 (-1.46, 1.35); 0.943
Mean (SD)	58.4 (7.3)	58.6 (6.7)	
Median (IQR)	60 (55, 63)	59 (54, 63)	
Missing	1	3	
Chronic tension type headache			
N	4	3	-5.5 (-17.0, 5.97); 0.347
Mean (SD)	53.5 (9.1)	48 (9.2)	
Median (IQR)	54.5 (46.5, 60.5)	50 (38, 56)	
Missing	0	0	

Note: Adjusted estimates used for definite and probable migraine. Unadjusted estimates used for chronic tension type headache due to there being a small number of participants.

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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	0.1 (-0.15, 0.43); 0.340	0.2 (-0.13, 0.44); 0.285
On the days you had a headache on average how long did they last, hours	0.2 (-0.68, 1.13); 0.624	0.3 (-0.54, 1.21); 0.456
On the days you had a headache on average how severe were they	0.2 (-0.08, 0.47); 0.171	0.2 (-0.08, 0.46); 0.163

Table 22: 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
HIT-6			
N	277	286	-0.4 (-1.40, 0.53); 0.376
Mean (SD)	60.6 (7.1)	59.8 (7.0)	
Median (IQR)	62 (57, 65)	61 (55, 64)	
Missing	1	3	

Table 23: Sensitivity analysis - treatment effectiveness estimate based on the primary outcome (at 12-month follow-up) having excluded those participants reporting less that 15 days of headache at baseline

	Standard care	Self-management	Estimate (95% CI); p-value
HIT-6			
N	174	188	-0.2 (-1.43, 0.96); 0.696
Mean (SD)	60.8 (7.0)	60.5 (6.7)	
Median (IQR)	62 (57, 65)	62 (56, 65)	
Missing	0	1	

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SECTION 6 - ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

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Table 24: Adverse events (AE) and serious adverse events (SAE) summarised by treatment group

	Standard care (N=356)	Self-management (N=380)	Total (N=736)
AE's			
Number of AE's reported	1 (0.3%)	6 (1.6%)	7 (1.0%)
SAE's			
Number of SAE's reported	2 (0.6%)	0	2 (0.3%)
Reason Serious Adverse Event deemed serious			
Death	2 (0.6%)	0	2 (0.3%)
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
SAE severity assessment			
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Fatal/life threatening	2 (0.6%)	0	2 (0.3%)

Table 25: Assessment of SAEs summarised by treatment group

Assessment of SAE's	Standard care	Self-management	TOTAL
SAE related to trial intervention:			
Definitely	0	0	0
Probably	0	0	0
Possibly	0	0	0
Unlikely	0	0	0
Unrelated	2 (0.6%)	0	2 (0.3%)
Expectedness of SAE:			
Expected	0	0	0
Unexpected	0	0	0
Missing	2 (0.6%)	0	2 (0.3%)

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