

ActiPatch

Healthcare Utilization Costs Study

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Executive Summary

Chronic pain is a major health concern due to its prevalence, detrimental effect on patient quality of life and exorbitant economic impact on society[1, 2]. Clinical evidence indicates that despite billions spent on healthcare, existing pain management therapies often do not provide adequate pain relief for sufferers[3-6]. There is a need for a more effective, economical approach towards managing chronic pain.

ActiPatch® is an electroceutical device which utilizes high-frequency, low-power, electromagnetic fields to non-invasively penetrate a painful area and provide relief. The efficacy of this device has been demonstrated in three randomized, placebo-controlled clinical trials[7-9]. Additionally, real world data on effectiveness was demonstrated in two large, registry-style studies as well as a durability study[10-12]. As an over-the-counter product, the ActiPatch can be used either as an adjunctive or standalone therapy to provide pain relief.

This document presents the results of a study, the goal of which was to assess the impact on direct healthcare expenditure when ActiPatch is used as a chronic pain therapy, specifically utilization of healthcare services and direct costs to the United Kingdom’s National Health Service (NHS). The study included 61 adults who met the inclusion criterion indicative of severe chronic pain: adults currently experiencing a VAS pain score of at least 6 (out of a maximum possible 10), for at least three consecutive months. Pain scores, quality of life scores and utilization of healthcare services were measured for each subject during two time periods, each lasting 3-months: the first period served as a baseline measure (control), while the second period served as an intervention measure, when ActiPatch was incorporated as a chronic pain therapy. Measurements related to utilization of healthcare services documented the number of appointments to General Practitioners, Pain Specialists and other professionals involved in chronic pain management, mainly constituting physical therapy and prescription medication use. Additionally, the time each subject spent discussing their pain with their General Practitioner was also documented.

Study subjects reported a statistically significant decrease in pain level VAS scores ($p < 0.001$) and an improvement in quality of life as measured by Oswestry Disability Index (ODI) ($p < 0.001$) and Pain and Sleep Questionnaire 3 (PSQ-3) item index (PSQ-3) (Table A). This improvement translated into reduced utilization of healthcare services, leading to a 42% reduction in health care costs to the NHS over a 3-month period, even after accounting for the cost of the ActiPatch device (figure 1).

Table A. Subjects reported a statistically significant pain decrease and an improvement in quality of life.

	Baseline 3- Month Period (Control)	Intervention 3-Month Period (ActiPatch)	P Value <
VAS (Pain 0-10)	7.93 ±1.4	5.07 ±2.5	0.001
ODI	48.8±18.3	35.7 ±20.6	0.001
PSQ-3	19.2	10.1	0.001

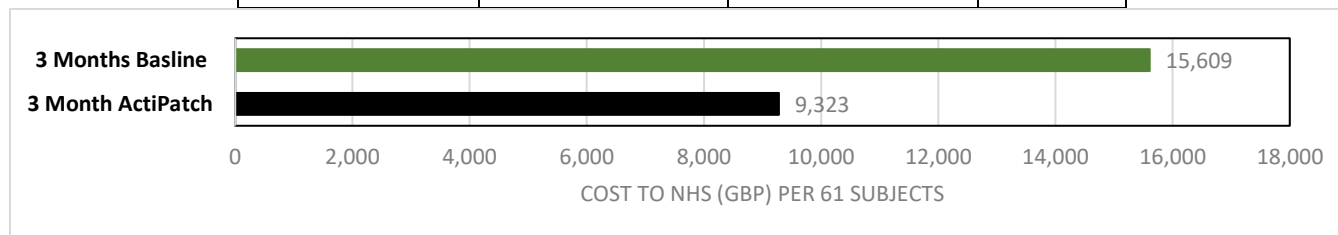


Figure 1. Chronic pain management costs (GBP) for the 61 subjects. For the baseline 3-Month period, costs were £15,609 and for the intervention 3-Month period (ActiPatch), costs were £9323. This represents a net savings of £6286 (41%), or £104 per subject over a 3-month period.

Conclusion

Utilizing ActiPatch as a chronic pain therapy treatment improves patient quality of life, while reducing the economic burden to the NHS.

Methods

Sixty-one chronic pain sufferers were recruited into the study and were assessed about their utilization of the NHS's healthcare services over two time periods, each lasting 3-months. The data was collected from two groups, the first of 30 subjects and the second of 31 subjects. The study was designed to collect details on 1) Number of general appointments to General Practitioners (GP), 2) Appointments to Pain Specialists, 3) as Appointments for physical therapy for other professionals involved in chronic pain management 4) Use of prescription medication for pain, and 5) The amount of time each subject spent with their GP, discussing their pain. Direct health care costs were then calculated for each of these components and the results statistically analyzed.

Health Care Cost Estimations

The cost of NHS services, GP, pain specialist and physical therapy were obtained from prior published data. The costs for each individual service are shown below in Table 1.

Service	Cost £
GP appointment[13]	£45*
Pain Specialist appointment[13]	£125
Physical Therapy appointments ¹	£45

*Contact lasting 11.7 minutes (Curtis L. Unit Costs of Health and Social Care 2013. Canterbury: University of Kent; 2013.)

¹ <http://www.pssru.ac.uk/pdf/uc/uc2010/uc2010.pdf>

Health Care Cost of Prescription Analgesics

Cost of analgesics were calculated from the NHS formulary and http://gmmmg.nhs.uk/docs/cost_comparison_charts.pdf.

Changes in quality of life for each subject were evaluated using four methods: 1) Visual analogue scale (VAS) pain scores; The VAS scale measures perceived pain levels in subjects across a horizontal, 10 cm line where scores range between 0 and 10. A score of 0 corresponds to no pain, while a score of 10 corresponds to the worst possible pain. 2) Oswestry Disability Index (ODI): The ODI is a questionnaire consisting of 10 questions, each with 6 possible answers and an associated score anywhere between 0 and 5. As a result, baseline ODI scores can have a possible score between 0 and 50, which are then converted into a 0-100 value. As an example, a score of 30 would equal $30/50 \times 100$, resulting in a score of 60 out of 100. 3) Pain and Sleep Questionnaire 3 item index (PSQ-3. Sleep disturbance is among the more common complaints reported by chronic pain patients. Because pain-related sleep disturbance may serve as a marker for the assessment of responses to treatment for chronic pain, inclusion of the PSQ-3 index is designed to assess the impact of pain on sleep quality. The three items in the index assess: being awakened by pain, difficulty falling sleep because of pain, and awakening in the morning

because of pain, each assessed on a 0-10 scale (0 = no affect, 10 = always). The scores are added together so that the range can therefore be 0-30. 4) Assess the number of side effects from prescription analgesic pain medications.

Results

Health Demographics Analysis

Subject Demographics:

The gender distribution was 50 women (82%) and 11 men (20%), while the majority of the population were over 35 years of age (Table 1). The average age of the subjects was 57.1±12.3 years.

Table 1. Gender Distribution and Age

Gender	N=61
Male	11
Female	50
Age	
18-24	1
25-34	1
35-44	9
45-54	12
55-64	16
65 or >	22

Eighty four percent (84%) of the subjects reported a pain duration of greater than 1 year, (Table 2), with a population mean pain duration of 8.9 ±7.9 years.

Table 2. Duration of Pain: Mean pain duration for the 61 subjects was 8.9 ±7.9 years.

Pain Duration	N=61
6 m – 1 yr	5
1 – 2 yrs	9
2- 5 yrs	16
5 -10 yrs	10
10 – 20 yrs	10
20 yrs +	11

Etiology of Pain

Subjects reported on the etiology of their pain (Table 3.). As is consistent with the general population, subjects reported on a wide range of etiologies, and sometimes multiple etiologies, that led to their chronic pain. However, more than 35% reported that osteoarthritis was the main cause of their pain.

Table 3. Etiology of Pain reported by the subjects

Etiology of Pain	N=61
Accident	2
Arthritis	2
Disc degeneration	9
Bursitis	2
Diffuse idiopathic skeletal hyperostosis	1
Ehlers-Danlos Syndrome	2
Fibromyalgia	7
Frozen Shoulder	1
Knee Deformity	1
Neuralgic Amyotrophy	1
Nerve damage	1
Osteoarthritis	22
Osteoporosis	1
Polygrypta rhymatica	1
Post-surgical pain	4
Piriformis Syndrome	1
Rheumatoid arthritis	3
Sciatica	6
Scoliosis	1
Spinal Stenosis	1
Spinal Fixation - Pain in sacro-iliac joint	1
Sports injury	1
Surgery	4
Trapped nerve	1

ActiPatch Use Location

The non-invasive design of the ActiPatch means that it can be placed on most anatomical locations on the body. The use location of ActiPatch by the subjects in the study were predominantly back (45%) and knee (45%) (Table 4).

Table 4. Anatomical placement locations of ActiPatch

	N=61
Back	32
Knee	24
Neck	3
Shoulder	8
Hip	5
Leg	1

Foot	1
Wrist	1
Hand	1

Pain: Visual Analogue Scale (VAS) scores

A 0-10 VAS scoring method was used to assess subject pain levels, with 0 representing not in pain and 10 representing the worst possible pain. At baseline 3-months (B-3M), the pain score was 7.93 ± 1.4 , which is consistent with prior reported pain scores from large scale Registry Studies[10, 12]. The pain scores in the ActiPatch 3-month (A-3M) period were 5.07 ± 2.5 , or 36% less than baseline. The reduction in pain scores was found to be statistically significant ($P < 0.001$).

Table 5. Baseline 3 Month and ActiPatch 3 Month VAS scores

Criterion	VAS N=61
Baseline average level of pain VAS	7.93 ± 1.4
ActiPatch average level of pain VAS	5.07 ± 2.5
VAS Difference	2.86
Percent Reduction	36%
P Value \leq	0.001

Oswestry Disability Index (ODI)

The Oswestry Disability Index (ODI) is a patient questionnaire that provides a subjective percentage score of level of function (disability) corresponding to activities in daily life. The average ODI score at B-3M was 48.8 ± 18.3 , indicating that pain has a significant impact on daily living. There was a 27% decrease in ODI at A-3M which was statistically significant $P < 0.001$, reflecting an improvement in quality of life (Table 6).

Table 6. Oswestry Disability Index scores at Baseline 3-Month and ActiPatch 3-Month

Criterion	ODI Score
Baseline 3-month	48.8 ± 18.3
ActiPatch 3 Month VAS	35.7 ± 20.6
Change	13.1
Percent Reduction	27%
P Value =	0.001

Pain and Sleep Questionnaire

A third measure of QOL was collected using a Pain and Sleep Questionnaire 3 item index (PSQ3) in this study (Table 7). However, this data was collected in a second wave measurements, and on 31 subjects.

Table 7. PSQ3 subjects reported a 47% improvement in sleep

Criterion	PSQ-3 (N=31)
Baseline 3-month	19.2
ActiPatch 3 Month	10.1
Change	9.1
Percent Reduction	47.4%
P Value <	0.001

Average sleep impact was 19.2 in the B-3M, which was reduced by 10.1 points or 47.4%. This result was statistically significant $P < 0.001$ (Table 7)

Prescription Analgesics Used to Manage Pain

A wide range of prescription analgesic medications were used by the subjects (Table 8). At B-3M, 41 subjects (67%) were on prescribed analgesic medications compared to 32 (52%) in the A-3M period who used prescription pain medications. The per subject average was 1.3 at B-3M which was reduced to 0.9 average per subject at A-3M. Subjects also reported a decreased use of their prescription medication with an average reported reduction of 38%. The B-3M and A-3M analgesic medication usage is shown in detail in Appendix 1. (Also see Analgesic Medication Costs page 16)

Table 8. Prescription analgesic medications used

Analgesic	Baseline N=41	ActiPatch N=36
Tramadol	10	8
Cocodamol	13	7
Zapian	1	1
Gabapentin	1	1
Baclofen	1	1
Cohydramol	3	3
Oral Morphine	5	5
Oycodone	1	1
MST	2	2
Mirtazapine	1	1
Morphine Patch	1	2
Amitriptyline	11	6

Nortriptyline	3	1
Mirtazapine	1	0
Pregabalin	6	4
Duloxetine	1	1
Diazepam	3	1
Piroxicam	1	0
Steroids	1	1
Epidural	1	1
Prescription NSAIDs	11	9
Prescription Cox-2 NSAIDs	2	0
Total	80	56

Over the Counter analgesics

Baseline data on over the counter (OTC) analgesic medications was not collected in this study. However, in the second wave of data acquisition (31 subjects), changes in OTC analgesic medication use was assessed by assessing changes in use patterns (Figure 1). Twenty-six (26) subjects reported using OTC analgesic medications. Of these 22 (85%) reported an elimination, or a reduction in their use in the A -3M period compared to their use in the B-3M period. Only 1 subject indicated increased use and noted that this was due to reducing prescription medication use.

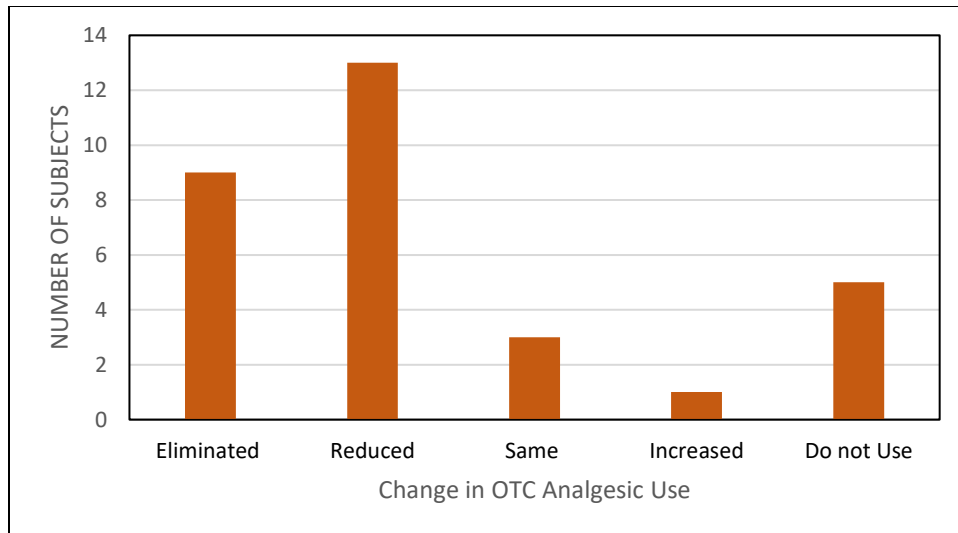


Figure 1. Of the subjects using OTC analgesics 85% indicated an elimination or a reduction in their use.

Analgesic Adverse effects

At B-3M, 36/61 (57%) subjects reported side effects from their analgesic medications. Those with side effects reported a total of 169 side effects, averaging 4.7 ± 3.8 per individual. At the ActiPatch 3-Month measurement, side-effects were reduced to 85, with only 29/61 (48%) experiencing pain medication side effects at an average of 2.9 ± 2.2 per individual. This represents a 50% reduction in side-effects associated with medication use (Figure 1).

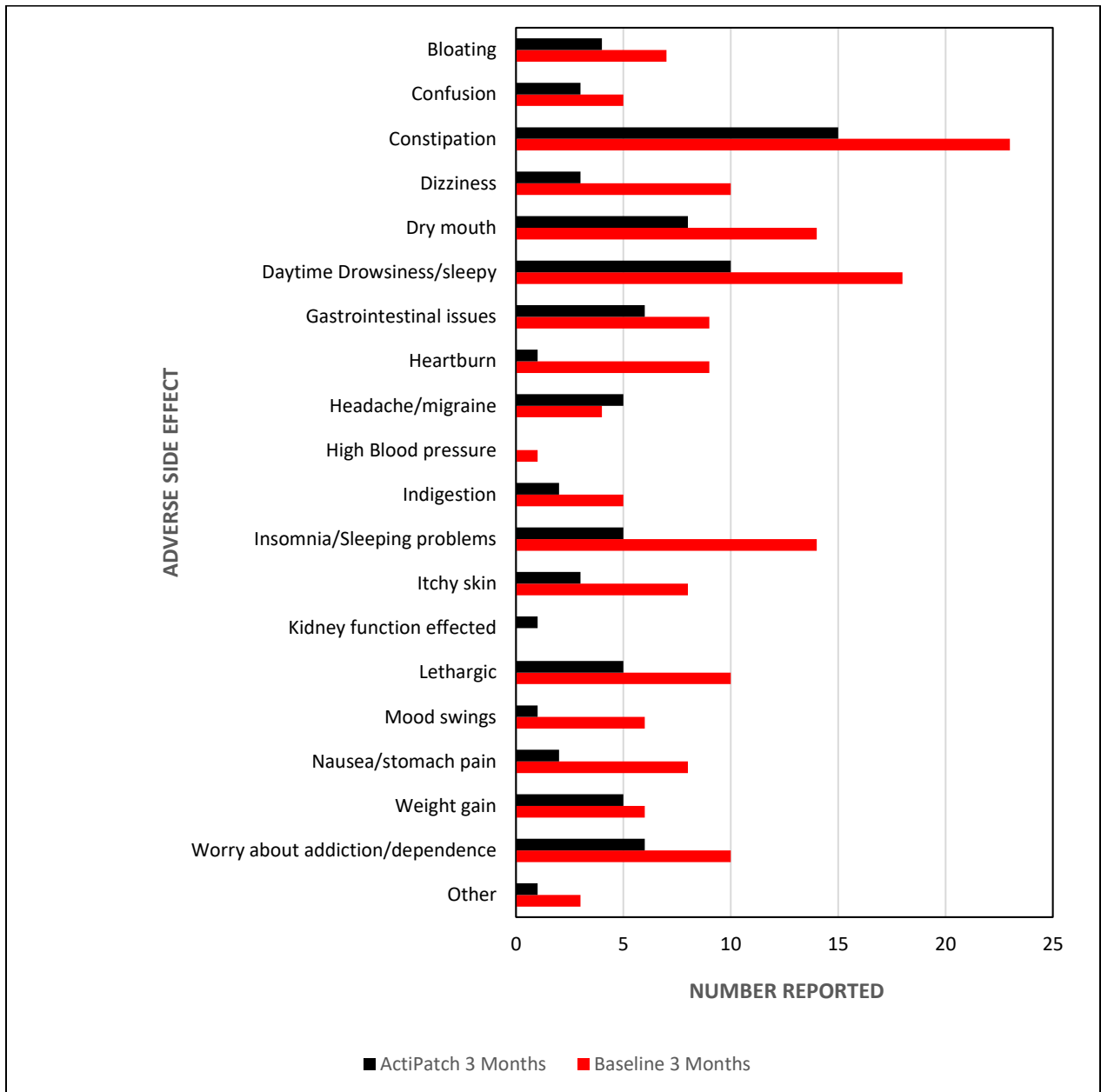


Figure 2. With ActiPatch use, adverse side effects associated with pain medication intake were reduced by 50%.

General Practitioner Appointments

For the B-3M, 43/61 (74%) subjects regularly visited their General Practitioner (GP). This amounted to a total of 135 GP appointments, or an average of 2.2 appointments per subject over the 3-month baseline period. For the A-3M, 28/61 (46%) had an appointment with their GP, resulting in a total of 58 appointments, averaging 0.9 appointments in this group. There were 77 less GP visits in the 3-month ActiPatch treatment period compared to baseline 3-month period, reflecting a 57% decrease (Figure 3).

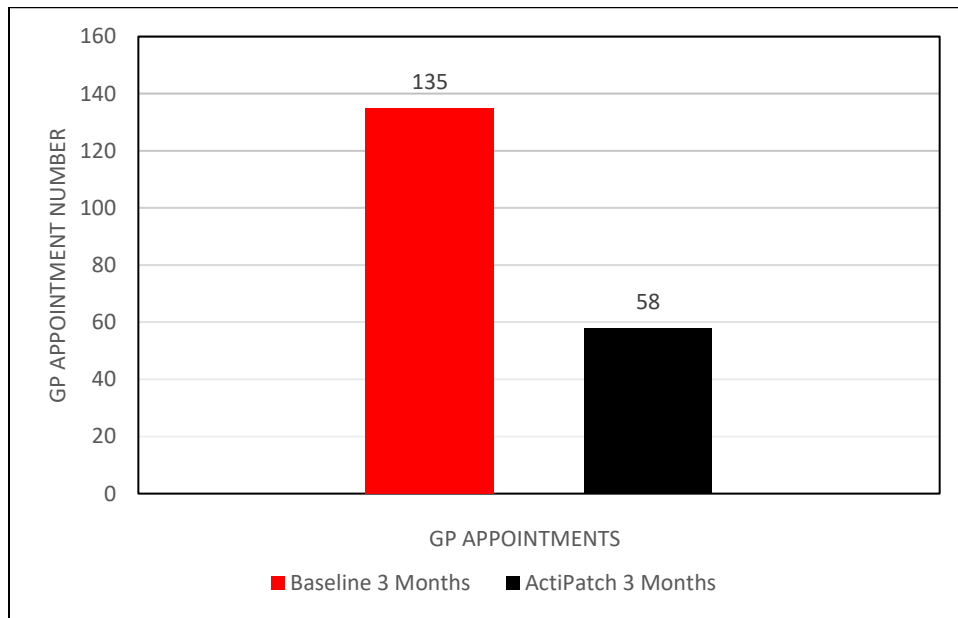


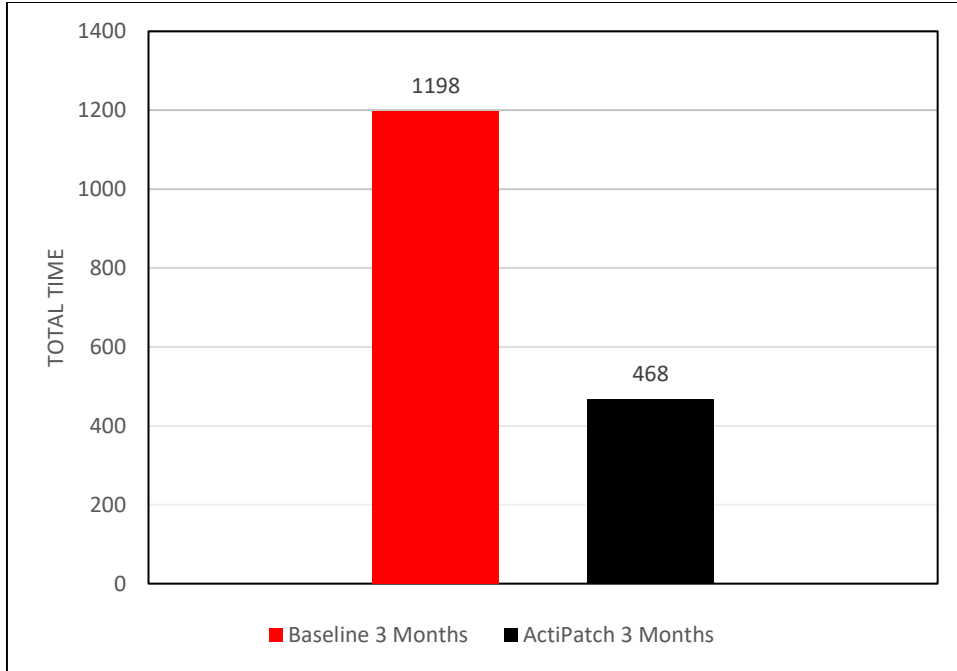
Figure 3. When compared to the Baseline 3-Months, the number of GP visits decreased by 57% in the ActiPatch 3-Month period.

Time Spent Discussing Pain

Of the 43 subjects who visited their GP in the B-3M period, the total time spent discussing pain is shown in Figure 4A. This was calculated by multiplying the number of appointments per individual with the average time of pain discussion. The total time discussing pain for the B-3M group was 1198 minutes. The average total time per subject spent discussing pain with their GP was 27.8 minutes for these 43 subjects over the B-3M period (Figure 4B).

For the A-3M period of which 28 subjects had appointments with their GP and the total time spent discussing “pain” was 468 minutes (Figure 4A) with a group average of the 28 subjects in the A-3M period of 16.7 minutes (Figure 4B).

A



B

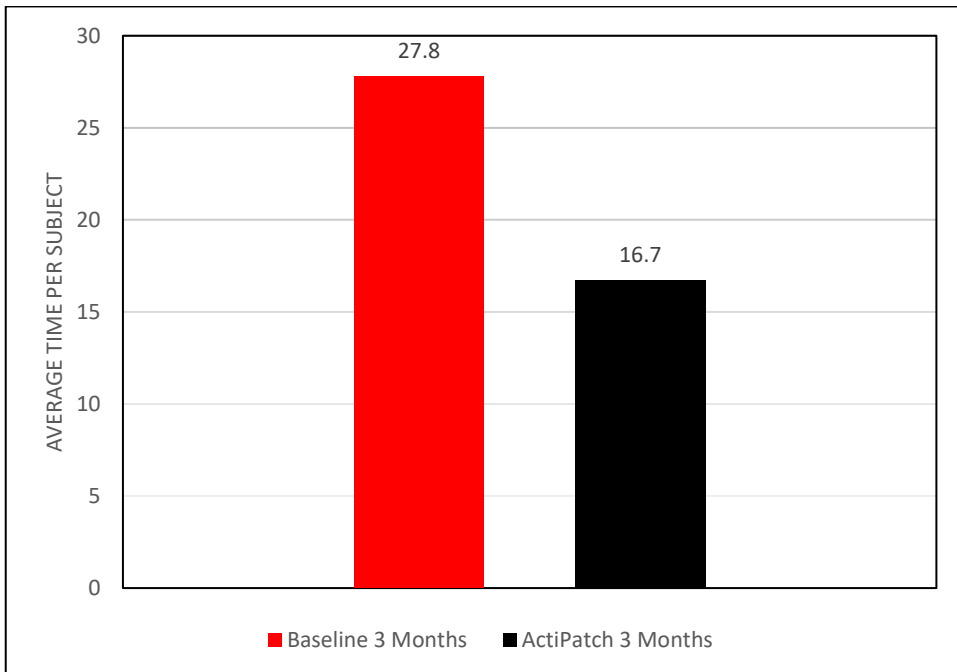


Figure 4. Total time spent (A) and average time (B) spent talking about pain in the Baseline 3 Month and ActiPatch 3 Month assessment periods. Both total time (61%) and average time (40%) spent talking about “pain” were reduced in the ActiPatch 3 Month assessment period, when compared to the Baseline 3 Month period.

Pain Specialist Appointments

During the B-3M period, 12 subjects reported 18 appointments with a pain specialist. During the A-3M period, 4 subjects reported 7 appointments to a pain specialist.

Physical Therapy Appointments

During the B-3M period 17 subjects reported having an appointment with a physical therapist. The total number of appointments during this period was 92, averaging 1.5 visits per subject for the 61 subjects. During the A-3M period, 14 subjects reported having an appointment with a physical therapist. The total number of appointments during this period was 39, averaging 0.6 visits per subject for the 61 subjects.

Economic Cost Analysis

ActiPatch Device Cost:

The 61 subjects independently purchased 148 devices over the study period. Retail cost of ActiPatch varies between £20-25 per device (720 hours of therapy), but discounted distribution costs to the National Health Service (NHS) would be £13.95 per device. If the cost of the ActiPatch devices used in the A-3M period were borne by the NHS, the direct costs would amount to $148 \times £13.95$, or £2065. At this rate, the projected one-year ActiPatch treatment cost for all 61 subjects would be £8258. The costs associated with providing ActiPatch therapy “per subject”, over a 3-month period and 1-year period are shown below in figure 5.

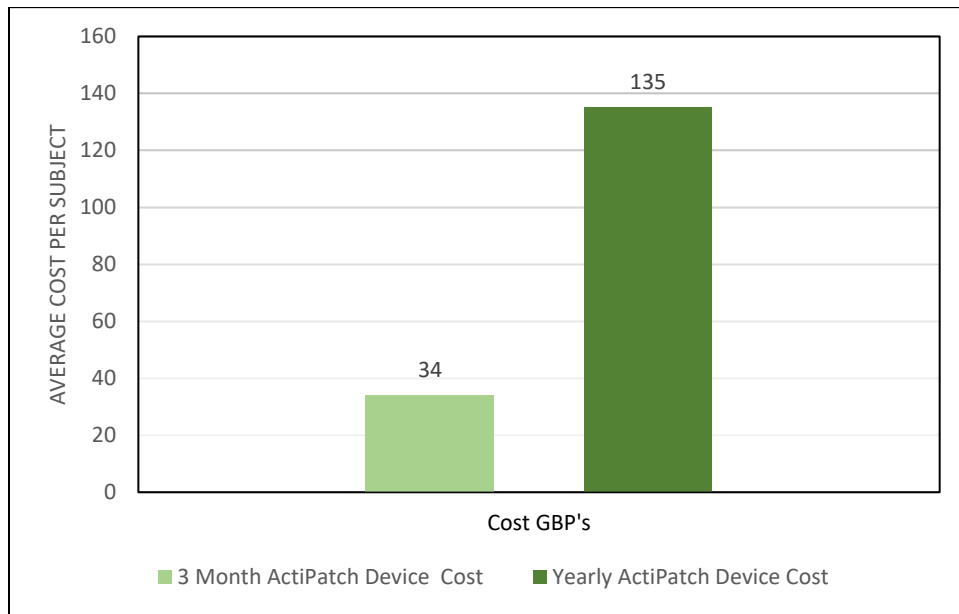


Figure 5. The 3-month costs (£34) and projected yearly costs (£135) to the NHS, per chronic pain subject, for providing ActiPatch therapy.

Appointment Cost to NHS Services Per 3-month Period

The cost in Pounds (GBP) to the NHS for healthcare services provided to each subject was calculated by multiplying the number of appointments with the costs for each service. In all cases, utilization of healthcare services by the subjects in the A-3M period was less than the B-3M period (Table 9, Figure 8). The decreased utilization of healthcare services by subjects in the study is indicative of an improvement in pain management and overall quality of life (QOL). (Table 9 & Figure 6).

Table 9. Calculation of Healthcare utilization for the 61 subjects.

Service/ Appointment	Cost (GBP)	B-3M Number of Appointments	A-3M Number of Appointments	B-3M Cost (GBP)	A-3M Cost (GBP)	Cost Difference (GBP)
General Practitioner	45	135	58	6,075	2,610	-3,465
Pain Specialist	125	18	7	2,250	875	-1,375
Physical Therapy	45	92	32	4,095	1,665	-2,430

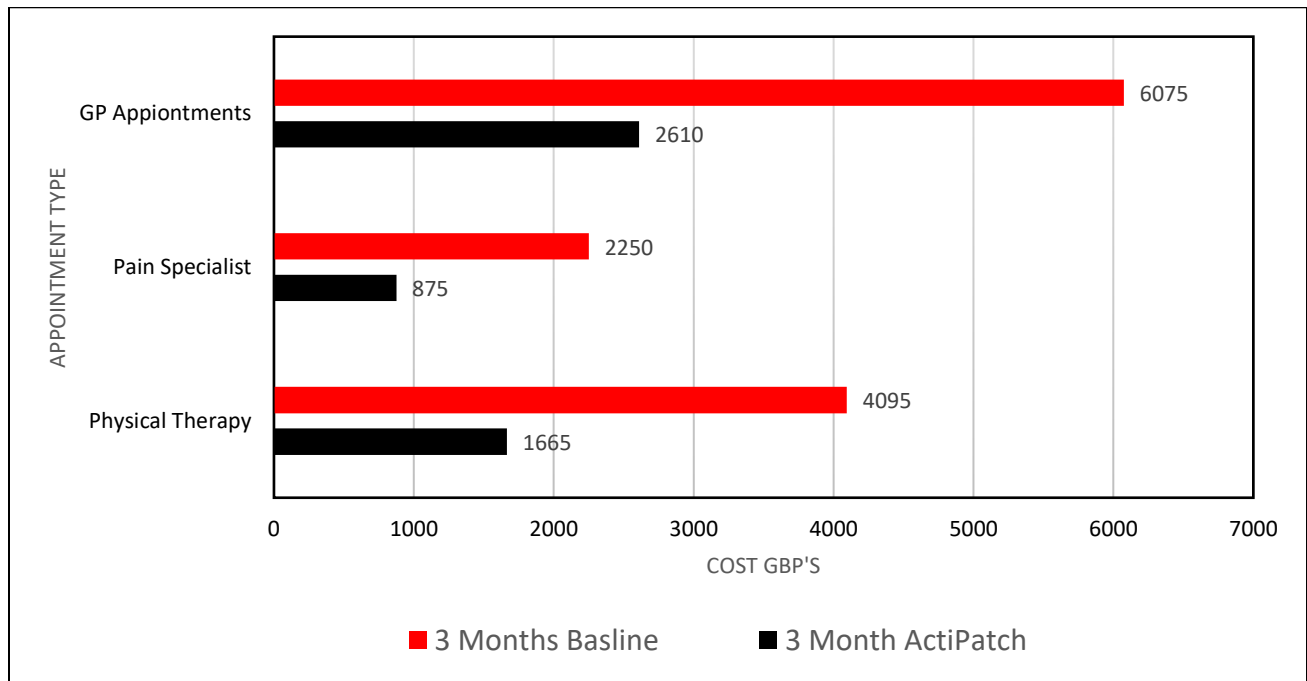


Figure 6. Total service costs in GBP for the Baseline 3 Month (red) and ActiPatch 3 Month (black) assessment periods.

Analgesic Medication Costs

Cost of analgesics used in the B-3M and A-3M assessment periods were estimated by utilizing data for basic NHS drug costs and the costs of each drug are shown in (Figure 7). The total analgesic prescription costs for the B-3M period were £3,189 and for the A-3M £2065. This a cost reduction of £1,124 or 35%. Prescription analgesics are detailed in Appendix 1. Due to the range of medications used, statistical analysis was done by comparing pill counts from both

assessment periods. The pill count for prescription drugs in the B-3M period was 284 and in the A-3M period 137.5. The difference was statistically significant $P=0.0035$.

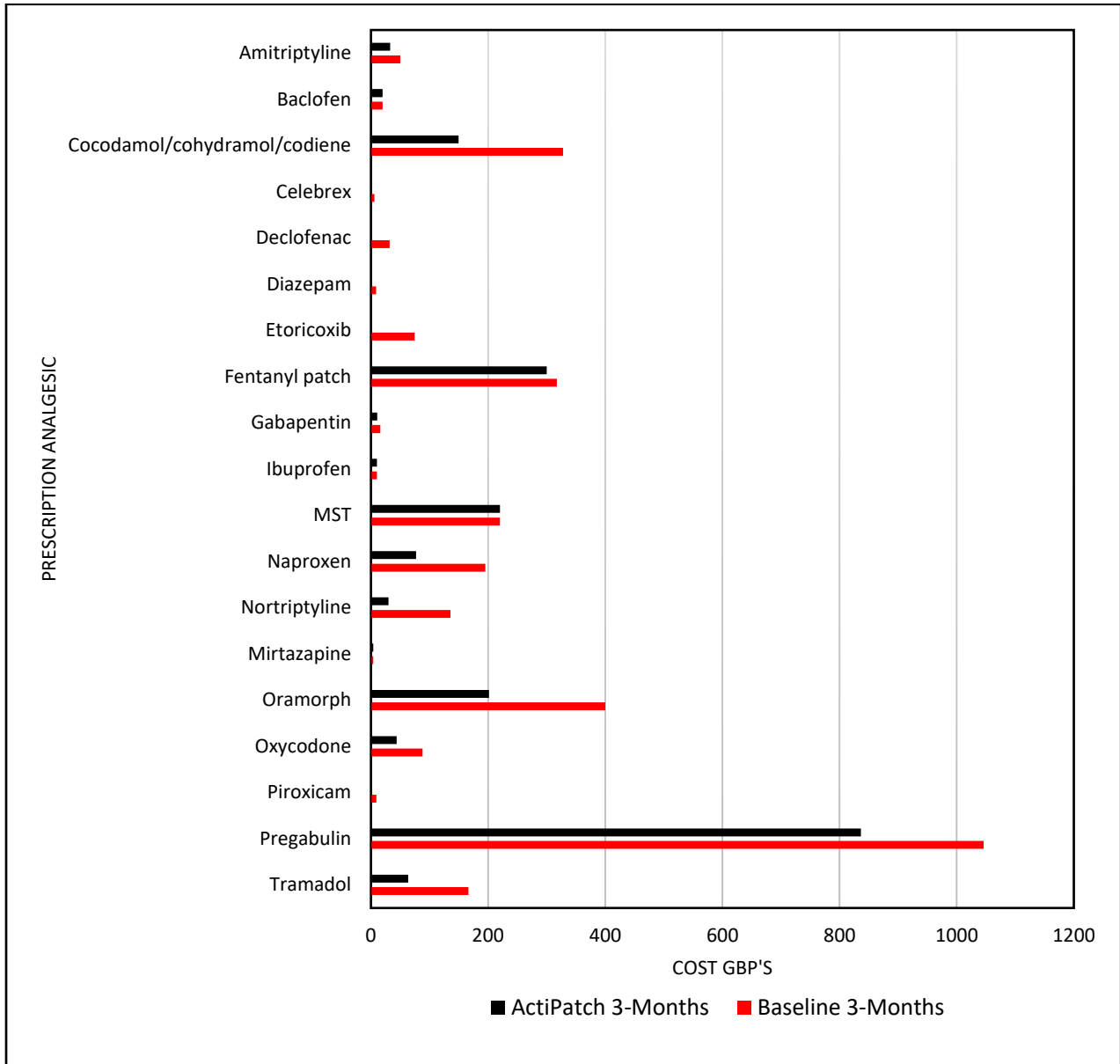


Figure 7. Individual analgesic medication costs shown for each of the 3-month assessment periods, Baseline 3 Month (red) and ActiPatch 3 Month (black).

Total Cost Comparison

The total cost for each 3-month period is shown in Table 10 and Figure 8, along with the differences in cost between these assessment periods. The total cost for each 3-month period was B-3M: £15,609 vs A-3M: £9,280 a cost reduction of £6286 (40% savings). This equates to a saving of £104 per subject over a 3-month period, or £412 per year (Table 10 and Figure 8).

Table 10. Total cost comparison between the Baseline 3 Month and ActiPatch 3 Month assessment periods.

Service/ Appointment	B-3M Cost (GBP)	A-3M Cost (GBP)	Cost Difference (GBP)
GP	6,075	2,610	-3,465
Pain Specialist	2,250	875	-1,375
Physical Therapy	4,095	1,665	-2,430
ActiPatch Device	0	2,078	+2,065
Analgesics	3,189	2,065	-1,124
TOTAL (3 month)	15,609	9,323	-6286
TOTAL (1 year)	62,436	37,292	-25,616

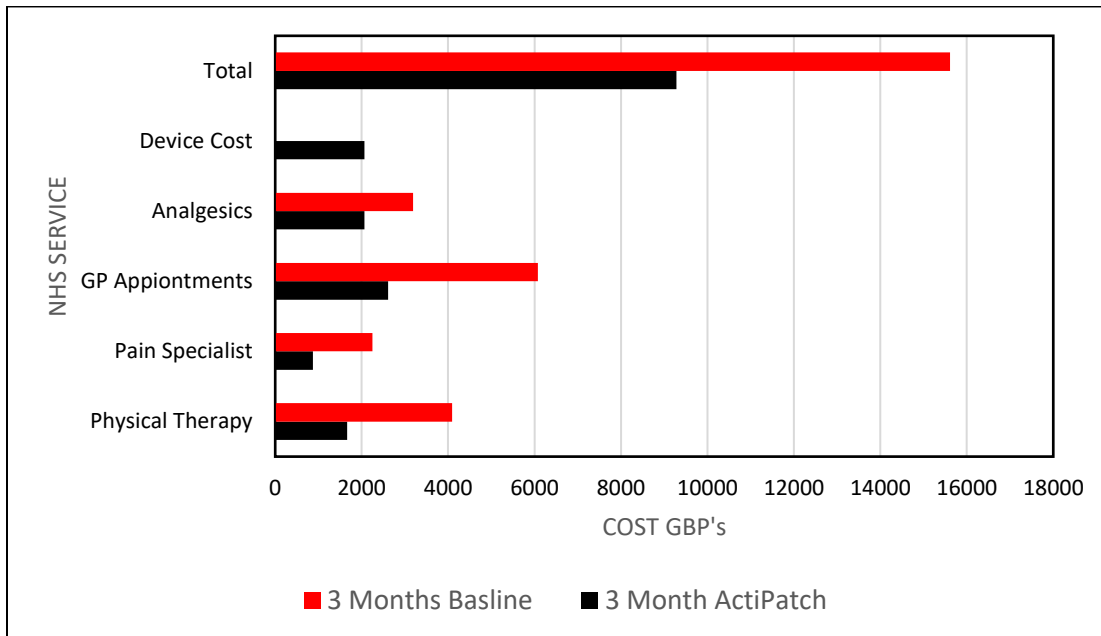


Figure 8. The total cost (GBP) for providing chronic pain treatment for 61 subjects. For the Baseline 3 Month period treatment costs were £15,609 and ActiPatch 3 Month period £9,280, a reduction of £6329 (41% total cost savings).

Statistical Analysis of Direct Healthcare Costs

Methods

Direct Healthcare costs from General Practitioner appointments, and secondary healthcare personnel (Pain Specialist and Physical Therapist) as well cost of prescription pain medications were analyzed to obtain 1) total direct healthcare costs and 2) individual direct healthcare costs. The baseline 3-month data (B-3M) was statistically tested against the 3-month data acquired from the same subjects after ActiPatch was incorporated as a chronic pain therapy (A-3M).

A student's t-test was employed (array 1, array 2, 2 tailed, paired) using the cost data in Great British Pounds (GBP), generated from the study (Standard error is shown for calculations). Statistical analysis was generated for:

- Total Healthcare costs (Total healthcare costs for ActiPatch treatment period include ActiPatch costs to the NHS)
- General Practitioner appointment costs (hourly costs estimated using clinical literature)
- Pain Specialist appointment costs (hourly costs estimated using clinical literature)
- Physical Therapist appointment costs (hourly costs estimated using clinical literature)
- Prescription Drug use costs (costs estimated using NHS published report)

Results

This represents a sample size of 61 per group, resulting in a total population size of 122. Raw data pertaining to individual direct healthcare costs is presented in Table 1, with costs reflected as Great British pounds (GBPs).

Table 1. Individual Direct Healthcare cost data (GBPs) from both 3 month periods is shown, as well as the cost of the ActiPatch device £13.95-unit cost (GP = General Practitioner, PS = Pain Specialist, PT = Physical Therapist, PM = Prescription Medications).

Subject No.	B-3M GP COST	B-3M PS Cost	B-3M PT COST	B-3M PM COST	Total Cost	A-3M GP COST	A-3M PS COST	A-3M PT COST	A-3M PM COST	ActiPatch cost	Total (without)	Total + ActiPatch
1	45	0	0	18.48	63.48	0	0	0	0	139.5	0	139.5
2	90	0	90	24.36	204.36	0	0	0	14.36	13.95	14.36	28.31
3	0	125	360	119.9	604.9	0	0	180	57.33	41.85	237.33	279.18
4	0	0	0	0	0	45	0	0	0	13.95	45	58.95
5	135	0	0	7.4	142.4	90	250	0	7.4	13.95	347.4	361.35
6	0	0	0	57.34	57.34	45	0	0	9.86	27.9	54.86	82.76
7	0	125	45	31.65	201.65	0	125	0	21.25	27.9	146.25	174.15
8	90	125	45	241.3	501.3	90	0	0	209.3	27.9	299.3	327.2
9	0	0	0	0	0	0	0	0	0	27.9	0	27.9
10	225	0	0	458.07	683.07	90	0	0	457.47	41.85	547.47	589.32

11	0	0	0	28.25	28.25	315	0	90	21.25	111.6	426.25	537.85
12	45	0	0	35.2	80.2	0	0	0	0	27.9	0	27.9
13	90	0	0	0	90	0	0	0	0	27.9	0	27.9
14	180	125	45	$\frac{107.6}{3}$	457.63	90	0	0	66.23	41.85	156.23	198.08
15	180	125	0	60.3	365.3	0	0	0	30.15	27.9	30.15	58.05
16	135	0	0	35.2	170.2	45	0	0	17.6	41.85	62.6	104.45
17	0	0	0	0	0	0	0	0	0	27.9	0	27.9
18	135	0	225	17.5	377.5	0	0	0	4.28	27.9	4.28	32.18
19	0	0	0	$\frac{103.6}{7}$	103.67	0	0	0	0	41.85	0	41.85
20	0	0	0	7.4	7.4	0	0	0	3.7	41.85	3.7	45.55
21	135	0	0	0	135	0	0	0	0	13.95	0	13.95
22	0	0	0	0	0	0	0	0	0	69.75	0	69.75
23	45	0	225	28.25	298.25	45	0	0	14.12	13.95	59.12	73.07
24	270	0	225	31.33	526.33	45	0	0	4.93	41.85	49.93	91.78
25	315	0	90	0	405	180	0	0	0	13.95	180	193.95
26	135	375	45	93.33	648.33	45	375	0	44.1	69.75	464.1	533.85
27	45	250	45	$\frac{102.8}{7}$	442.87	0	0	0	10.6	13.95	10.6	24.55
28	45	0	225	1.7	271.7	45	125	45	1.7	41.85	216.7	258.55
29	540	0	90	54.7	954.7	360	0	180	66.55	13.95	606.55	620.5
30	360	250	360	$\frac{558.9}{5}$	1438.95	45	0	0	$\frac{237.9}{7}$	41.85	282.97	324.82
31	0	0	0	0	0	0	0	0	0	13.95	0	13.95
32	360	0	0	0	360	0	0	0	0	27.9	0	27.9
33	135	0	0	$\frac{298.9}{8}$	433.98	135	0	0	$\frac{298.9}{8}$	27.9	433.98	461.88
34	45	0	225	3.8	273.8	45	0	0	3.8	13.95	48.8	62.75
35	0	0	0	0	0	0	0	0	0	83.7	0	83.7
36	90	0	0	0	90	0	0	0	0	13.95	0	13.95
37	45	0	0	18.56	63.56	45	0	90	18.56	41.85	153.56	195.41
38	135	125	270	15.12	545.12	0	0	0	7.6	41.85	7.6	49.45
39	270	250	270	30.5	820.5	90	0	0	13.4	27.9	103.4	131.3
40	45	0	0	0	45	45	0	0	0	13.95	45	58.95
41	0	0	0	0	0	0	0	0	0	27.9	0	27.9
42	0	0	90	0	90	45	0	45	0	55.8	90	145.8
43	90	250	90	40.28	470.28	0	0	0	0	27.9	0	27.9
44	0	0	0	7.56	7.56	0	0	45	3.5	27.9	48.5	76.4
45	135	0	0	13.36	148.36	0	0	90	8.9	27.9	98.9	126.8
46	45	0	90	12	147	0	0	45	13	41.85	58	99.85
47	135	0	135	18.8	288.8	0	0	0	0	41.85	0	41.85
48	45	0	0	0	45	0	0	0	0	13.95	0	13.95
49	0	0	0	0	0	45	0	0	0	13.95	45	58.95
50	360	0	180	28.88	568.88	90	0	180	28.88	27.9	298.88	326.78
51	45	0	0	0	45	45	0	45	0	27.9	90	117.9

52	0	0	0	0	0	0	0	0	0	69.75	0	69.75
53	90	0	0	0	90	0	0	0	0	27.9	0	27.9
54	135	0	0	15.2	150.2	0	0	0	15.2	13.95	15.2	29.15
55	225	0	45	16.93	286.93	225	0	540	19.5	27.9	784.5	812.4
56	180	125	45	6.32	356.32	135	0	0	6.32	27.9	141.32	169.22
57	90	0	90	15.2	195.2	0	0	0	0	13.95	0	13.95
58	0	0	0	0	0	0	0	0	0	13.95	0	13.95
59	45	0	0	93.8	138.8	45	0	0	75	27.9	120	147.9
60	45	0	90	0	135	45	0	90	0	41.85	135	176.85
61	45	0	135	371.2 1	551.21	0	0	0	282.1 4	41.85	282.14	323.99
Total	6,075	2,250	4,050	3,231	15,609	2,610	875	1,665	2,095	2,078	7,245	9,323

i). Total Healthcare Costs Analysis – Without including ActiPatch cost of treatment

Total direct healthcare costs were £15,606 for the baseline 3 months (Figure 1). For the 3 month period with ActiPatch use, the total direct healthcare costs were £7,245. This represents a 54% decrease in total direct healthcare costs between the two periods. The average individual baseline 3-month cost at was £256 ±36, which decreased to £119 ±22 in the ActiPatch 3-month period. The results were statistically significant, with $p = 0.000065$.

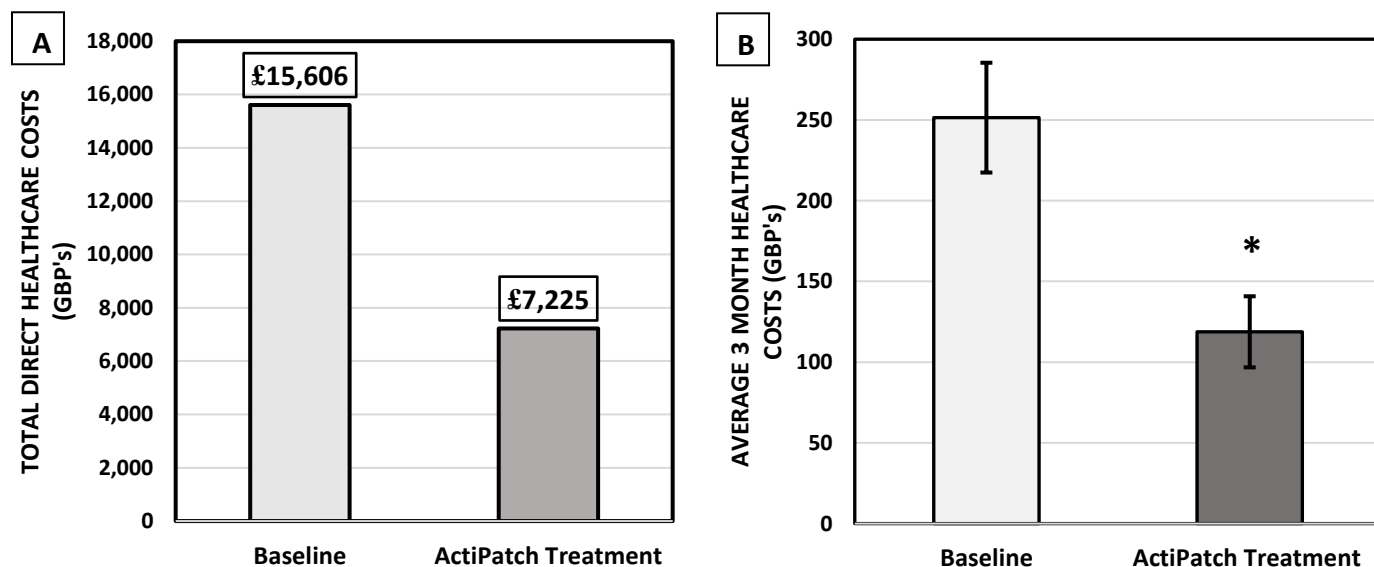


Figure 1. A) Total direct healthcare costs were £15,606 for the baseline 3-month period and £7,225 for the ActiPatch treatment 3-month period B) Average Healthcare Costs per subject for baseline 3-month was £256±36 and declined to £119±22 in the ActiPatch 3-month period. The decrease was statistically significant, with $*p = 0.000065$

ii). Total Healthcare Costs Analysis – Including ActiPatch cost of treatment

Total direct healthcare costs were £15,606 for the baseline 3 months. For the 3-month period involving ActiPatch use, the total cost was £9,323 when the cost of ActiPatch was factored in. This number represents a 40% decrease in total direct healthcare spending. The average baseline 3-month period spending was £256 ±36, which decreased to £153 ±22 in the ActiPatch 3-month treatment period. The results were found to be statistically significant, with $p = 0.0018$.

iii). General Practitioner Appointment Costs

Healthcare costs related to General Practitioner appointments were £6,075 for the baseline 3-month period. For the ActiPatch 3-month period the total cost was £2,610. This represents a 57% decrease in direct healthcare costs associated with General Practitioner appointments. The average individual baseline period costs were £100 ±15 which decreased to £43 ±9 in ActiPatch use period. The results were found to be statistically significant, with $p = 0.000037$.

iv). Pain Specialist Appointment Costs

Direct healthcare costs for pain specialist appointments were £2,250 for the baseline period. For the ActiPatch treatment period the total cost was £875. This represents a 61% decrease in total direct healthcare costs for pain specialist appointments. The average 3 month cost (per subject) at baseline was £37 ±11 which decreased to £14 ±8 in the ActiPatch 3-month period. The results were found to be statistically significant, with $p = 0.03$.

v). Physical Therapist Appointment costs

Direct healthcare costs for pain specialist appointments were £4,050 in the baseline period. For the ActiPatch treatment period the total cost was £1,665. This represents a 59% decrease in total direct healthcare costs for physical therapy appointments. The average 3 month cost (per subject) at baseline was £66 ±13 which decreased to £27 ±10 in the ActiPatch treatment period. The results were statistically significant $p = 0.0097$.

vi). Prescription Medication Analysis

Direct Healthcare costs for prescription pain medications were £3,231 at baseline. For the ActiPatch treatment period the total cost was £2095. This represents a 35% decrease in total direct healthcare costs for prescription medications (Figure 2). The average 3-month cost (per subject) at baseline was £53 ±14 which decreased to £34 ±11 in the ActiPatch treatment period. The results were found to be statistically significant, with $p = 0.0025$.

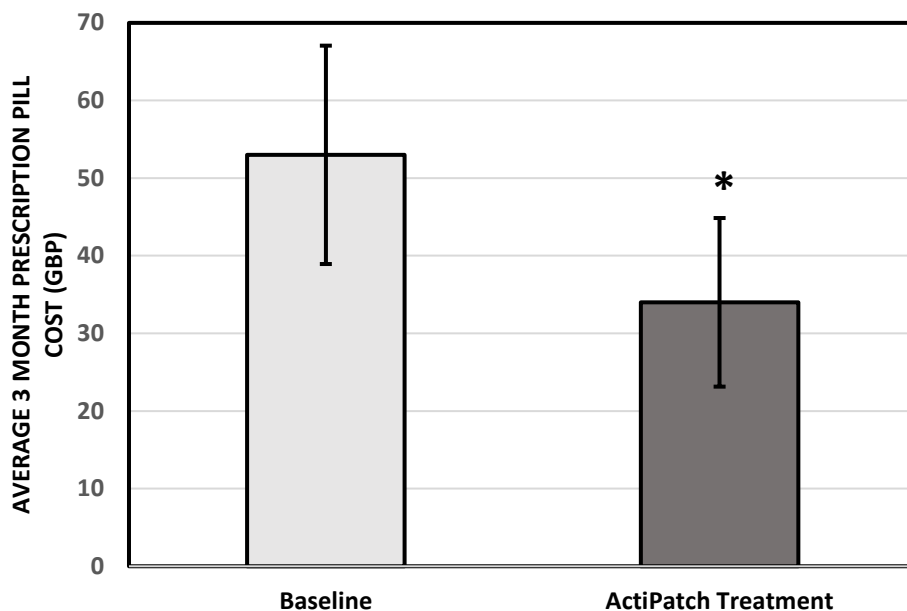


Figure 2. Average 3-month prescription medication cost was reduced from £53 ±14 at baseline to £34 ±11 following ActiPatch use. The results were statistically significant, with $*p = 0.0025$.

Summary Table.

Table 2. The mean ±SE and p value for each direct healthcare measure is shown. All the results are statistically significant.

Direct Healthcare Costs	B-3M Mean ± SE	A-3M Mean ± SE	P Value
Total	£256 ±36	£119 ±22	6.5E-05
General Practitioner	£100 ±15	£43 ±9	3.7E-05
Pain Specialists	£37 ±11	£14 ±8	0.03
Physical Therapy Direct Costs	£62 ±12	£37 ±10	0.021
Prescription Costs	£81 ±20	£52 ±16	0.0025
Total + ActiPatch	£256 ±36	£153 ±23	0.0018

Discussion

A decrease in pain and improvements in quality of life associated with ActiPatch also translate to reduced financial burden to the NHS. Utilization of healthcare services, such as visits to a General Practitioner (GP), pain specialist and/or other healthcare professionals for example physical therapist, as well as prescription analgesics were reduced in treatment 3-month period by 40%. NHS costs were reduced by £6329 over the ActiPatch 3 Month treatment period compared to the 3-month baseline period. On average, ActiPatch therapy was found to save the NHS £103 per subject over a 3-month period, or £412 yearly on chronic pain management costs. Analysis indicated that there was a statistical significant reduction in all aspects of direct healthcare costs

This study performs a pain management cost analysis and quality of life assessment for 61 chronic pain subjects, over two separate 3-month time periods: The first 3-month period served as a baseline measure, while the second 3-month period used ActiPatch as an interventional therapy as part of a multimodal treatment for chronic pain. The 61 subjects in this study reported on average a baseline pain of 7.93 ± 1.4 on a 10-point VAS. This is consistent with prior published data from two studies involving 6,400 subjects with chronic pain [11, 12], as well as data from a further 9,000+ subjects (unpublished) collected over a three-year period.

Quality of life was assessed in four ways: 1) Changes in pain level assessed through a 0 -10 VAS scale, 2) Changes in disability assessed through the Oswestry Disability Index (ODI), 3) Changes in sleep quality assessed through the Pain and Sleep Questionnaire 3 Item Index (PSQ-3), and 4) Changes in side-effects associated with analgesic drug use.

With ActiPatch use, average baseline pain was reduced to 5.07 ± 2.5 VAS points, resulting in an average pain decrease of 2.86 VAS points. This result was statistically significant ($p < 0.001$). Similarly, with ActiPatch use quality of life due to disability and sleep quality improved by 27% ($p < 0.001$) and 47.4% respectively. However, the sleep quality data was collected on the second wave of subjects, therefore only 31 of the 61 subjects. The fourth QOL measure, which assessed changes in drug-related side-effects, indicated a 50% reduction in side-effects. While the statistical significance of this reduction on QOL was not performed, it is understood that any reduction in drug-related side-effects leads to meaningful improvements in QOL. Figure 9 provides an overview of the four QOL measures and percent improvement from baseline after ActiPatch treatment.

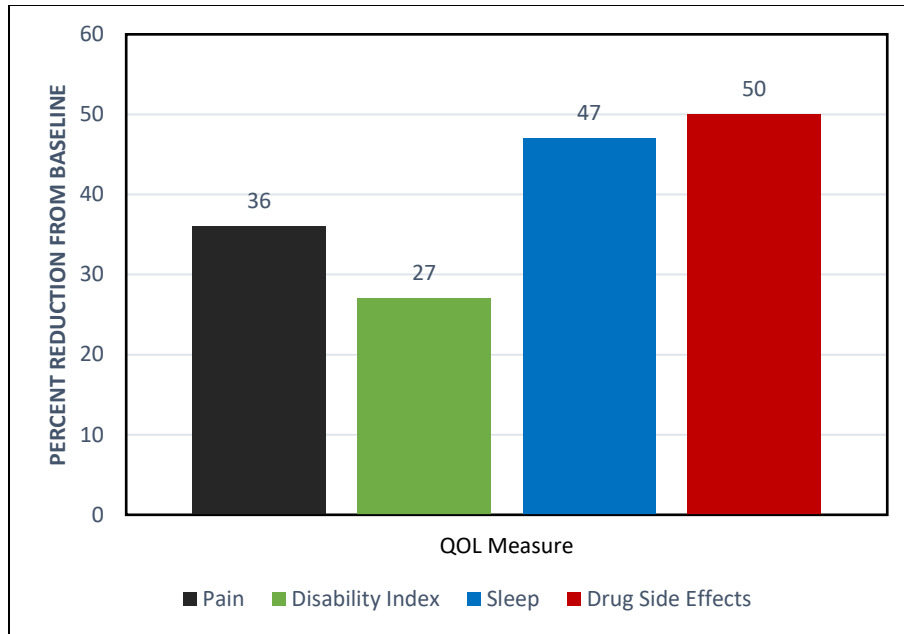


Figure 9. Each quality of life measure, Pain, Disability Index, Sleep and Drug Side Effects showed a large percentage improvement from baseline.

Conclusion

Introduction of ActiPatch as a chronic pain therapy results in significant improvements in patient quality of life, reduces pain medication use and reduces utilization of NHS healthcare services. In summary, employing the ActiPatch as a treatment modality for chronic pain sufferers will save the NHS 40% of direct healthcare costs (this factors in the cost of providing ActiPatch treatment).

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Appendix 1 – Prescription Drugs

Prescription medication use for the 61 Subjects in the study.

Note: over the counter drugs were often listed by the subjects but not requested.

Over the counter drugs were not counted in the pill count unless listed as prescribed.

	Baseline 3 Months	Pill Count	Pill Count	ActiPatch 3 Months
Subject 1	Amitriptyline 25mg x 2 Pregabalin 150mg x 3	5	0	none
Subject 2	Cocodamol 30/500 4 times a day Ibuprofen 400mg 3 times a day Steroid injection 6 monthly	7	0	none
Subject 3	Cocodamol 30/500mg 8 tablets a day Naproxen 500 2 tablets a day Oramorph 10mg 5ml 6 times a day	16	7	Cocodamol 30/500mg 2 x day Naproxen 500 2 tablets a day Oramorph 10mg 5ml 3 times a day
Subject 4	No Prescriptions	0	0	No prescription
Subject 5	Tramadol 2 x 50mg	2	3	Tramadol 1 pill X 3 times daily
subject 6	Tramadol 2 x 50mg 4 times daily Co-codamol 2 x 30/500mg 4 times daily Piroxicam 1 x 20mg daily	9	4	2 x 50mg Tramadol twice a day
Subject 7	cocodamol 30/500 2 four time a day amitryptaline 20 mg a day chircocaine injections every 8 weeks	9	8	2 x 30/500 cocodamol, 4 times a day Chirocaine injections every 8 weeks
Subject 8	pregabalin 150mg capsule twice a day Declofenac 75mg tablet once or twice a day	3.5	1	Pregabalin 150mg per day
Subject 9	none	0	0	none
Subject 10	Pregabalin 1 x 300mg twice a day MST 2 x 30mg twice a day	7	8	Pregabalin 1 300mg pill twice a day MST 2 pills 30mg twice a

	MST 1 x 15mg twice a day Amitriptyline Oral Morphine when needed Mirtazapine			day MST 15mgs 1 pill twice a day Amitriptyline 50mg 1 pill night time Amitriptyline 15mg 1 pill night time Mirtazapine 30mg 1 pill night time" "Oral Morphine when needed
Subject 11	cocodamol 4x2 a day 8/500 5x5mg predialone daily 2x 50 setraline daily naproxen	16	11	3 x5 predisone cocodamol 4x2 a day 8/500
Subject 12	Naproxen 1-500mg once a day	1	0	Naproxen no tablets per day unless needed
Subject 13	Diclofenac	1	0	none
Subject 14	Tramadol 1x4 a day amitriptyline 50mg 1 a day baclofen 10mg2x4 a day oramorph 10mg 1 5ml spoonful every 4hrs as required Nortriptyline 4 pills 10mg once a day	20	5	Tramadol 50mg 4x a day amatyline 50mg l at night oramorph 10mg as and when required
Subject 15	Nortriptyline 4 pills 10mg once a day	4	1.5	Nortriptyline 1/2 pills 10 mg once a day
Subject 16	Naproxen 250mg twice a day	2	1	1 x 250mg Naproxin at night, sometimes not needed
Subject 17	No prescriptions	0	0	none
Subject 18	Diazepam x 2 10mg per day Cocodamol 30mg x 4 times per day	6	3	Prescribed co-drydramol 500/10 used to take everyday bow taking as and when

				Diazepam 5mg as and when needed
Subject 19	Nortriptyline 50 mg at bedtime Codydramol 500/10 2 tablets 4 x daily	9	0	none
Subject 20	3 tramadol 50mg 3 x 400mg ibuprofen (when doing social care, taking client out)	3	1.5	1-2 50mg tramadol
Subject 21	None	0	0	None
Subject 22	None	0	0	None
Subject 23	Cocodamol 500/30 2 pills 4 times daily	8	3.4	Cocodamol 30mg/500mg 1 or 2 once or twice a day
Subject 24	Tramadol 2 x 50mg 4 times daily Diazepam 1x 5mg 4 times daily Amitriptyline 1x 20mg twice daily Naproxen 1 x 500mg 4 times daily Celebrex 1 x 30mg 3 times daily	21	2	Tramadol 1 tablet 50mg twice daily
Subject 25	pregabalin, morphine amitriptyline (details not given)	?	?	To many to mention an would rather not say
Subject 26	Oxycodone 2 pills 40mg twice a day Amitriptyline 4 pills 10 mg twice a day	12	2	Oxycodone 40 mg 2 times a day
Subject 27	1 x etoricoxib 60mg daily 2 x cocodamol 30/500 four times daily	9	1	1x gabepentin 100mg nocte
Subject 28	Amitriptyline 10mgs daily	1	1	Amitriptyline 1 tablet of 10mgs at night
Subject 29	Naproxen, 2, 500mg 2x day Codeine. 30mg 5 x day	12	15	naproxen 2 x 500mg codeine 8 x 30mg

	Amitriptyline 10 mg 3 x day			amitriptyline 3x 10mg
Subject 30	Naproxen, 500mg, up to 2 a day Fentanyl morphine patch, 25 microgram/hour release, change every 3 days.	2 Patches not counted	0 Patches not counted	I occasionally take a couple of Paracetamol 500 but usually for stress headaches, and one Naproxen 500 occasionally at night if the nerve pain is stronger than usual, typically no more than 2 a week. Fentanyl patches, 25mcg, which last for 3 days. I typically try to go for 4 days before changing them.
Subject 31	N/A	0	0	N/A
Subject 32	N/a. Only took the codeine once. Hated it	0	0	Dont need them now as I just use actipatch
Subject 33	Tramadol M/R 100mg x 2 daily Tramadol 50mg x 3 daily Baclofen 10mg x 3 daily Pregabalin 25mg x 3 daily	11	11	Tramadol MR 2 x 100mg daily Tramadol 2 x 50mg daily Pregabalin 3 x 25mg daily Baclofen 3 x 10mg daily Sertraline 1 x 200mg daily
Subject 34	Co codamol 2x 15 mg daily	2	2	Co codamol 30 mg
Subject 35	Paracetamol x2 occasionally Deep Freeze - once Hot and cold packs throughout the day	0	0	No drugs

Subject 36	2paracetamol four times daily	0	0	2paracetamol four times daily
Subject 37	Ibuprofen 400mg. One capsule three times daily Zapain Codeine Phosphate/Paracetamol 30/500mg 1or 2, four times a day as required. Omeprazole Gastro-resist 20mg taken once daily.	6	0	Now I take no more oral or external drugs ointments etc, for the condition. It is no longer so apparent. I do however get the odd pain in my hip and I use an Actipatch unit to suppress it.
Subject 38	Codydramol 1 to 2 pills 10mg/500mg at night	1.5	1	Codydramol 1 pill 10mg/500mg once at night Ibuprofen 2 pills 500mg at night
Subject 39	Tramadol unsure twice a day Cocodamol unsure twice a day Amitriptyline 2 x10mg once a day Ibuprofen 400mg 3 x a day Paracetamol 1000mg 3 x a day	6	6	Codydramol x 50mg 3 x a day Amitriptalene x 10mg 3 x a day Nsaid's' x 3 x a day
Subject 40	Just ibuprofen now and again	0	0	None
Subject 41	none	0	0	N/A
Subject 42	2 Paracetamol daily - more if required	0	0	1x paracetamol very occasionally on days when I'm not wearing the patch
Subject 43	Brufen retard 800 mg once a day	1	0	none
Subject	Co codymol 2 pills of	4	2	Cocodymol 2 pills of

44	8/500mg twice a day			500mg when required instead of 3 times everyday
Subject 45	30mg of codeine 2 a day, Naproxen 250 3 times a day, Paracetamol as and when required.	5	0	Only use paracetamol 1000mg per day
Subject 46	2 tables 4x a day zapain	8	1	Zapain 30mg x 1 per day Paracetamol 500mg x 1 per day
Subject 47	Cocodamol 30/500MG	1-8?	0	N/a
Subject 48	No prescription drugs but used ibuprofen 200mg long lasting capsules 2 a day , and ibuprofen gel on knees before exercise.	0	0	rarely use any medication prefer to use the actipatch if in pain because I feel it is better for my health
Subject 49	none	0	0	none
Subject 50	Tramadol 2 pills of 50mg 4 times a day Naproxen 1 pill of 500mg 2 times a day Amatryptaline 20mg at night	11	11	Tramadol 100mg 4 times a day Naproxen 500mg 2 times a day Amatryptaline 20mg at night
Subject 51	N/A	0	0	N/A
Subject 52	Na	0	0	Na
Subject 53	none	0	0	N/a
Subject 54	2cohydramol x 15/500 4x daily	8	8	Cocoadamol 30/500
Subject	2 Tramadol 50mg twice	5	4	1 5 mg morphine at

55	daily Paracetamol as required oral morphine 1 tablet at night			bedtime 2 to 4 250 mg naproxen 1 20 mg omeprazole 6 to 8 500 mg paracetamol
Subject 56	Tramadol 2 pills 100 mg 2 twice a day	4	8	Tramadol 2x100mg x4 when needed
Subject 57	none	0	0	None
Subject 58	Two to about six paracetamol on my worst days	0	0	I used to take paracetamol, but decided I didnt need them because if the pain gets worse, then I use the Actipatch
Subject 59	morphine mst 5mg twice a day cocodamol every 4 hours as required	10	2	10mg mst tablets morning and night
Subject 60	Paracetamol 2 pills of 500mg four times a day	0	0	2 x Paracetamol overnight
Subject 61	Pregabalin 1 pill of 100mg twice daily Zomorph 40mg twice daily Oramorph liquid 2.5 ml every 2 hours Duloxetine 120mg twice daily Coodamol 30/500 2 pills 4 times a day Diazepam 5mg every 6 hours as needed	16	3	Bupronophine 3 day patch 35mch/hr Duloxetine 120mg mornings Pregabalin 100mg twice daily
Pill Count Total				

