**The ESCAPS study: a feasibility randomised controlled trial of early electrical stimulation to the wrist extensors and flexors to prevent post-stroke complications of pain and contractures in the paretic arm.**

**Running title:** The ESCAPS study

**Authors:**

Joanna C Fletcher-Smith1, Dawn-Marie Walker2, Kate Allatt1, Nikola Sprigg1, Marilyn James1, Sonia Ratib1, Janet Boadu1, Carla Richardson1, Anand D Pandyan3

1Faculty of Medicine & Health Sciences, University of Nottingham, Nottingham, UK

2Faculty of Health Sciences, University of Southampton, Southampton, UK

3School of Health and Rehabilitation, Keele University, Keele, UK

**Corresponding author:**

Dr Joanna C Fletcher-Smith

[Joanna.fletchersmith@gmail.com](mailto:Joanna.fletchersmith@gmail.com)

The University of Nottingham

Faculty of Medicine and Health Sciences (School of Medicine),

Division of Rehabilitation and Ageing,

B Floor,

Medical School,

Queen’s Medical Centre,

Nottingham,

NG7 2UH.

**Key words:** Stroke, upper extremity (arm), muscle contractures, pain, electric stimulation therapy

**Trial registration number:** ISRCTN1648908; Clinicaltrials.gov ID: NCT02324634.

**Abstract**

***Objective:***To establish feasibility of initiating electrical stimulation treatment of wrist extensors and flexors in patients early after stroke to prevent muscle contractures and pain.

***Design:*** Feasibility randomised controlled trial with economic evaluation.

***Setting:***  A specialist stroke unit in Nottinghamshire.

***Subjects:*** Forty patients with stroke and arm hemiparesis, recruited within 72 hours after stroke.

***Interventions:*** Participants were randomised to receive usual care or usual care and electrical stimulation to wrist flexors and extensors for 30 minutes, twice a day, five days a week for three months. Initial treatment was delivered by an occupational therapist or physiotherapist who trained the patient to self-manage subsequent treatments.

***Main measures:*** Measures of feasibility included recruitment and attrition rates, completion of treatment and successful data collection. Outcome data on wrist range of motion, pain, arm function, independence, quality of life and resource use were measured at 3, 6 and 12 months post-randomisation.

***Results:*** Forty participants recruited in 15 months [20 men; mean age 72 (SD 13.0)]. Attrition at three month follow-up was 12.5% [death (n=2), end-of-life care (n=2), unable to contact (n=1)]. Compliance varied [mean 65 (SD 53)] and ranged from 10 to 166 ES treatment sessions per patient. Target dosage was 120 sessions but participants were able to cease treatment when full arm function returned. Initial economic analysis suggested treatment was cost beneficial.

***Conclusion:*** Early initiation of ES treatment was acceptable and feasible when compared with usual care. The data collection methods used were shown to be feasible and acceptable to the trial participants.

**Introduction**

Impaired arm function is a permanent and disabling problem for an estimated 40%1 of stroke survivors1,2. In the presence of persistent paresis, arm muscles atrophy rapidly and patients, particularly those with spasticity and pain, are at an increased risk of developing painful muscle contractures (fixed joint deformities)3. Prevalence of hand and wrist contractures is unknown, but contractures can become established as early as six weeks after stroke3 and as many as 60% of care home dwelling stroke survivors develop at least one contracture within a year after a stroke4. It is possible that one cause for contracture is the lack of adequate upper limb therapy input1,5-6, i.e. on average patients spend between 0.9 and 7.9 minutes per physiotherapy session on arm rehabilitation7.

Evidence suggests that early initiation (24 hours post-stroke) of rehabilitation interventions and high intensity of treatment can enhance the chances of neurological recovery8-12, however, there is also the potential for risk of harm13,14. For those patients unlikely to make functional gains, prevention of complications such as pain and contractures (fixed joint deformity) should be the focus of therapeutic interventions and there is some evidence that treatment with electrical stimulation is of potential value15-18. Previous pilot trials of electrical stimulation have only focussed on stimulation of the extensor muscles and have not stimulated the flexor muscle group but have demonstrated some benefit in terms of slowing the rate of deterioration, and in some cases, facilitating recovery however effect sizes were small16-18. These studies concluded that the treatment was not given for long enough and premature discontinuation of therapy may have reduced any potential therapeutic effect. No extended trials have been conducted. Furthermore, the muscle at risk of shortening are the wrist and forearm flexors and the most effective method of loading the soft tissue structures of the flexors, in patients who are unable to fully activate their muscles, is by electrically stimulating these muscles.

The aim of this study was to evaluate the feasibility of conducting a future definitive randomised controlled trial of the efficacy and cost effectiveness of early, intensive electrical stimulation to prevent wrist joint deformities/muscle contractures, weakness and upper limb pain after stroke by stimulating the wrist flexors and extensors reciprocally.

**Methodology**

This single centre, unblinded randomised controlled trial was approved by the National Research Ethics Service, East Midlands Nottingham (UK) Research Ethics Committee (ref: 15/EM/0006) and was registered with ClinicalTrials.gov (Identifier: NCT02324634). This research was funded by the National Institute for Health Research (Research for Patient Benefit Programme; ref PB-PG-1013-32034). The study was hosted by Nottingham University Hospitals NHS Trust and coordinated by the University of Nottingham (the research sponsor). The full study protocol has been previously published in the British Medical Journal19 and is briefly described below.

Patients admitted to Nottingham University Hospitals’ stroke unit were eligible for participation if recruitment could be conducted within 72 hours of stroke. All participants were required to provide written informed consent and an ‘aphasia friendly’ version of the information sheets and consent form were available for those with communication difficulties. In cases where it was not possible to obtain informed consent from the patient due to communication and/or cognitive difficulties, consultee consent was obtained from the patient’s relative.

***Inclusion criteria***

* Confirmed clinical diagnosis of stroke
* First stroke event to affect the upper limb
* Aged >18 years
* Impaired arm movement and strength caused by stroke (determined by the National Institute for Health Stroke Scale20 (NIHSS) arm sub score ≥1)

***Exclusion criteria***

* An existing chronic arm condition (e.g. peripheral nerve injury)
* Cardiac pacemaker (Patients with pacemakers were not included as access to a Cardiologist to confirm the safety of treatment for individual patients was not possible)
* Pregnancy
* Epilepsy
* Undiagnosed pain or skin conditions affecting the arm (not related to the stroke)

Consenting participants were independently randomised into an intervention or a control group using a telephone randomisation service. Minimisation was based on: age; sex; side of stroke; and severity of arm weakness (as measured by the NIHSS20 arm sub score).

***Usual care control***

Participants randomised to the control group did not receive electrical stimulation therapy but received all usual care (which did not include the use of surface neuromuscular electrical stimulation). It was not possible to collect data on the nature or volume of usual care.

***Intervention treatment***

Participants randomised to the treatment group received treatment with electrical stimulation in addition to their routine care. Treatment with electrical stimulation was delivered using a two-channel constant current stimulator (maximum output 100 mA, pulse width 450μs and a frequency between 40 to 60Hz as per participant preference)\*A. The current intensity was increased to produce an alternating contraction of the flexors and extensors using a flex-hold-extend-hold pattern, ensuring that a pure movement was produced with no/minimal ulnar or radial deviation. A single stimulation and hold cycle lasted 20 seconds and this was cyclically repeated for 30 minutes (40 cycles of movement in a full treatment session). Treatment continued twice a day, 5 days a week (Monday to Friday), for a total period of 3 months.

The motor points for stimulation were selected to produce reciprocal flexion and extension through full range of movement21. The first treatment was provided by a qualified (NHS band 5 or above) physiotherapist or occupational therapist who was trained to identify the motor points for electrical stimulation. Following the initial treatment, the skin was marked with a skin-safe marker pen to show the correct area to place the electrodes for future treatments and the electrical stimulation device was locked to the selected settings. After the initial session, clinical staff (e.g. rehabilitation support workers, nursing support staff, or health care assistants) assisted the patient to apply the electrode pads to the pre-marked motor points and switch on the device with the pre-stored treatment setting (this took between 2-5 minutes) for subsequent treatments. Prior to hospital discharge, the patient and/or nominated carer were taught by a therapist how to self-manage the treatment.

***Outcome measures***

The primary outcomes related to feasibility aims:

* Recruitment/participation and exclusion rates
* Completion/attrition rates
* Compliance/adherence to treatment protocol
* Consultee consent rates
* Outcome measure completion rates

The secondary outcomes were demographic characteristics (age, gender, ethnicity and socioeconomic status), stroke characteristics (date, type and side of stroke), cognitive status (Montreal Cognitive Assessment - MoCA22) and Pre-morbid function state (Nottingham Extended ADL - NEADL23) were collected at baseline. In addition, participants completed the following assessments at 3, 6 and 12 months:

* Neurological outcome (NIHSS20 score)
* Independence in daily activities (Barthel ADL Index score24 and modified Rankin Scale – mRS25,26)
* Pain in the affected arm (Scale of Pain Intensity - SPIN27)
* Spasticity (was measured as stretch induced activation of muscles as described in Malhotra et al3)
* Arm function (Action Research Arm Test - ARAT28)
* Stroke related quality of life (Stroke Specific Quality of Life scale -SS-QOL29)
* Health status (EuroQol-5D - EQ-5D30)
* Patient resource use questionnaire
* Carer strain (Caregiver Strain Index - CSI31) completed by the participant’s nominated carer.

Baseline assessments were completed on the stroke unit by the patient’s bedside and 3, 6, and 12 month follow-ups were completed in the community at the patient’s discharge destination (e.g. home or care home).

***Statistical analysis & reporting***

* Total number of patients recruited within 72 hours of stroke event; average length of time post-stroke when patients received first treatment.
* Total number or patients screened, eligible and approached, consented, and excluded after screening.
* Total number of patients who completed the intervention; number who completed 3, 6 and 12 month follow-up assessments.
* Total number of participants receiving electrical stimulation per protocol (target number of treatments was 120); mean, minimum, and maximum number of electrical stimulation treatments received during the 3 month intervention period; qualitative patient/carer interview data, and electrical stimulation machine’s memory which records number of sessions and duration.
* Total number of patients unable to give informed consent; Number consented by consultee; Number of consultees who declined.
* Recruitment and attrition rates, number of patients lost to follow-up and reasons.
* Median scores and IQR for outcome measures were calculated.
* Completion and quality of health economic data between assessment points especially 6 to 12 months regarding sensitivity of the EQ5D in measuring outcome. Combined cost and outcome analysis to determine potential cost effectiveness of electrical stimulation verses usual care. Exploration of feasibility of using some of the other outcome measurements to determine cost effectiveness. A purposively designed patient collection data resource proforma was constructed.

**Results**

Recruitment began on the 1st June 2015. Of 230 potentially eligible patients, 40 were recruited in 15 months [20 men; mean age 72 years (SD 13.0)] (figure 1). Half of the participants (n=20) lacked the mental capacity to be able to provide informed consent and were therefore recruited by consultee consent. All participants were recruited within 72 hours following a first stroke and baseline characteristics are summarised in table 1. Attrition at 3 month follow-up was 12.5% [5/40] and at 12-months follow up was 32.5% [13/40]. Reasons for attrition are summarised in the CONSORT flow diagram (figure 1).

The total possible number of electrical stimulation treatments (as per protocol) was 120 treatment sessions. The number of treatments received ranged from 10 to 166 with a mean of 64.5 (SD 53). Five participants used the device in excess of the standard protocol. Reasons for participants not receiving the target number of treatments included the electrical stimulation device being locked in the hospital bedside cabinet by stroke unit staff or placed out of reach of the patient, illness that prevented engagement in any rehabilitation for a period of time, or the participant regaining full functional use of the upper limb and therefore discontinuing treatment. There was also one incident of protocol violation early on in the study, whereby a therapist did not agree with the concept of stimulating the flexor muscles and instead fabricated a thermoplastic static resting splint for the limb.

The 3, 6 and 12 month outcome measure completion rates of the participants by treatment allocation are summarised in table 2.

Of the 26 patients, 14 had an NIHSS arm score of zero (i.e. a marker of return in arm function), four had a score between one and three (a marker for some arm function) and eight had a score of four (a marker for no arm function).

Majority of participants had already developed spasticity (as defined by Malhotra et al3) at the time of recruitment. Almost all patients (38/40, i.e. 95%) demonstrated measurable forms of spasticity in the forearm flexors and 29/40 (72.5%) demonstrated velocity dependent spasticity. At the 6-months follow up measurement 26 of the 40 participants demonstrated some form of spasticity and 20 of these patients demonstrated velocity dependent spasticity. The primary reason for the missing values at the 6-month follow-up measurement was failure in measurements when patients were not in the hospital setting.

It was not feasible to use the Stroke Specific Quality of Life (SSQoL) measure and the Montreal Cognitive Assessment (MoCA) with this sample population. The SSQoL is a lengthy questionnaire-based assessment that relies heavily on the ability of the patient to understand verbal or written communication and select their chosen response to each question from a list of options. Likewise, the MoCA requires the ability to communicate and also includes some pen and paper drawing tasks. The sample population in this study included patients who were not yet fully conscious or were drowsy in the early days following their stroke. The sample also included patients with receptive, expressive and global aphasia. Those participants who had severe weakness in their usually dominant hand and arm were unable to complete the drawing and written tasks.

The patient resource collection was acceptable to patients. Completion rates fell overtime, but only slightly, and did not give the team cause for concern that this measure posed an unacceptable patient burden. The time point that caused most problems with completion was at baseline. It was felt this collection point could be sacrificed in favour of cost outcome comparisons with and without the intervention using an incremental effectiveness approach (ICER).

The intervention cost was determined by taking the cost of the electrical stimulation machine discounted at 3.5% (as recommended in the Green Book by Her Majesty’s Treasury32) over 5 years to yield an annual cost. Twelve electrical stimulation machines were used in this study and it was assumed that for each patient using the machine they had a spare set of batteries and electrodes. The cost of the intervention also included the therapists’ time to receive training on how to deliver the intervention (4 x therapists at Band 6B for 1 hour), and Band 3 therapist support staff time to receive training on how to deliver the intervention (4 x support staff for 30 minutes). The cost included the initial treatment time with the intervention by a Band 6 Therapist for 1 hour and further treatments delivered by support staff at Band 3 for 10 minutes per treatment (up to a total of 3). The total costs of the electrical stimulation machines (discounted), replacement batteries, replacement electrodes, and the total costs of staff time was calculated and further divided by the number of electrical stimulation patients (20) to provide an estimate of the electrical stimulation intervention cost per patient. This was £37.90 per patient (see health economics supplementary file for details of how this figure was calculated).

The study was focused on establishing the complete NHS and societal costs including those costs incurred by the patients and their families between the two groups, this included primary and secondary care costs associated with their arm function, out of pocket expenses and any effects on employment for either the patient or their carers’. This was completed at baseline, 3, 6 and 12 month follow-ups.

Table 3 displays the mean QALYs up to 12 months by the two arms. The results show that the intervention arm had higher QALY gains when compared to the usual care arm, however the incremental difference was small, and both groups improved over time.

Table 4 displays the resource use costs of electrical stimulation and usual care up to 12 months. The usual care arm had higher costs compared to the electrical stimulation arm, from both the health service (NHS) and societal perspective. Electrical stimulation was therefore associated with a lower consumption of resources and consequently lower costs, compared to those in the usual care arm.

A bootstrap analysis was done based on the complete case analysis, a method to infer about likely population data from a sample set. (Electrical stimulation n=11; Usual Care n= 6).

The scatter diagrams are presented in Figure 2 which represent the results from an NHS perspective and a societal perspective. The results show that the bootstrap replications cover all four quadrants of the cost effectiveness plane, indicating there is uncertainty around the interventions overall cost effectiveness, as would be expected in a feasibility pilot study. The majority of the points on the cost effectiveness plane were below the x-axis, indicating that electrical stimulation was less costly than the standard arm. The findings show that at 12 months, the electrical stimulation arm dominates the usual care arm, with higher outcomes and lower costs.

**Discussion**

This study was able to demonstrate that it is feasible to recruit patients early after stroke (within 72 hours) and for physiotherapists and occupational therapists to initiate electrical stimulation treatment of the wrist and finger extensor and flexor muscles. Furthermore, once treatment was initiated it was possible to continue to deliver treatment in a way that was compliant with the protocol. It is possible that the training protocol and the educational booklets contributed to the enhanced compliance. However, there will be a need to adjust sample size by 32.5% if the identified primary end point is 12-month. In this feasibility study, 83% of potentially eligible patients were excluded. This high number of excluded patients was not only due to the exclusion criteria but also due to the fact that the local specialist stroke service is an active research site with competing trials and many studies do not permit a patient to enrol in more than one active research trial. This was a barrier to recruitment at this site and is a factor that would need to be considered when selecting potential study sites for a future multi-centre trial.

A common barrier for electrical stimulation of flexors is the fear that treatment with electrical stimulation could exacerbate spasticity. This study has demonstrated an important safety finding that treatment with electrical stimulation is unlikely to lead to spasticity or exacerbate spasticity. Furthermore, the electromyography (EMG), National Institute for Health Stroke Scale (NIHSS) arm score and Action Research Arm Test (ARAT) data demonstrated that it was possible for patients to have spasticity yet still regain arm function during the trial.

An important aspect of this feasibility study was to determine the most suitable outcome measures for an ensuing definitive trial. The aim of the electrical stimulation intervention was to prevent painful muscle contractures which can lead to a permanent joint deformity. The primary outcome should therefore reflect this. The objective measurement of passive range of movement, stiffness and spasticity as measured by Malhotra et al3 was not considered feasible for use in a large multi-centre trial due to complexity and cost of equipment, need for training, and the possibility of equipment failure. A standard range of movement goniometer or measurement app for use on a tablet or mobile phone would be more feasible for use in any subsequent trial.

The Scale of Pain Intensity (SPIN) was a feasible measure for use in this patient population to capture severity of pain in the affected arm. The NIHSS, Barthel ADL Index, modified Rankin Scale, ARAT and Euro Qual 5D (five-level version) were feasible for measuring secondary outcomes in this patient population. The Stroke Specific Quality of Life scale was not a suitable measure for this patient population. The carer strain index was not suitable for completion at baseline and completion rates in general were low. In a future study it is recommended that carer burden is captured within the resource use questionnaire to reduce duplication and assessment burden.

The feasibility health economic evaluation demonstrated that the resource use questionnaire and EQ5D-5L could be used to capture economic data to determine cost effectiveness of the electrical stimulation intervention in a definitive trial and were acceptable to the patient group. They yield some promising early results in terms of an economic comparison of the treatment options. It was felt the baseline data collection point for resource could possibly be sacrificed to reduce patient burden and an ICER calculated between the two arms of a trial. Early post-stroke is a traumatic time for patients and families and trying to establish patient and carer resource use at this time is problematic.

In this feasibility study, limited resources meant that it was not possible to have an additional outcome assessor who was blinded to treatment allocation. The outcome measures were objective and were unlikely to have been biased, however, future studies should use independent assessors.

Furthermore, there are limitations involved in interpreting the data due to the small sample size and therefore no definitive conclusions can be drawn from this small sample.

Arm weakness and post-stroke complications pose a considerable threat to the independence and productivity of stroke survivors. This feasibility study was important because it addressed the needs of a significant proportion of severely disabled stroke patients with a poor prognosis for recovery and at a high risk for secondary complications. The ESCAPS feasibility study has data to inform the design of a multi-centre randomised controlled trial to evaluate the efficacy and cost-effectiveness of early electrical stimulation to the wrist flexors and extensors. A suitably powered trial with blinded outcome assessors is warranted to determine effectiveness and cost effectiveness of the intervention in preventing painful contractures to the wrist and hand post-stroke.

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**Figure 1: CONSORT 2010 Flow Diagram showing Attrition rates during the trial by treatment allocation**

Assessed for eligibility (n=2,295)

Excluded (n=2,255)

  Not meeting inclusion criteria (n=2,080)

  Declined to participate (n=22)

  Other reasons (n=153)

* Acutely unwell / end of life care (n=72)
* Enrolled on other trials (n=40)
* Lacked capacity and no consultee (n=25)
* Lived out of area (n=10)
* Already more than 72 hours post-stroke (n=6)

**Baseline data analysis:** Analysed (n=20)

**3m data analysis:** Analysed (n=17)

**6m data analysis:** Analysed (n=12)

**12m data analysis:** Analysed (n=10)

 Excluded from analysis (give reasons) (n= )

**3 month:** Unable to follow-up (n=3)

 Died (n=1)

 Unable to contact (n=1)

 Palliative care (n=1)

**6 month:** Unable to follow-up (n=8)

 Died (n=2)

 Unable to contact (n=2)

 Palliative care (n=4)

**12 month:** Unable to follow-up (n=10)

 Died (n=8)

 Unable to contact (n=2)

Allocated to usual care **CONTROL** (n=20)

 Received allocated intervention (n=19)

 Did not receive allocated intervention:

* Died (n=1)

**3 month:** Unable to follow-up (n=2)

 Died (n=1)

 Palliative care (n=1)

**6 month:** Unable to follow-up (n=2)

 Died (n=1)

 Palliative care (n=1)

**12 month:** Unable to follow-up (n=3)

 Died (n=3)

Allocated to ES **INTERVENTION** (n=20)

 Received allocated intervention (n=19)

 Did not receive allocated intervention:

* Treatment protocol violation (n=1)

**Baseline data analysis:** Analysed (n=20)

**3m data analysis:** Analysed (n=18)

**6m data analysis:** Analysed (n=18)

**12m data analysis:** Analysed (n=17)

## Allocation

## Analysis

## Follow-Up

Randomized (n=40)

## Enrolment

**Table 1: Baseline characteristics of participants and baseline outcome measure data by treatment allocation**

|  |  |  |
| --- | --- | --- |
|  | **Control**  **(n=20)** | **Intervention**  **(n=20)** |
| **Age** Median age  IQR | 67 years  59 – 84 years | 75 years  66.5 – 80 years |
| **Gender** Male n (%) | 13 (65%) | 7 (35%) |
| **Stroke classification**  Right sided n (%)  Ischaemic n (%)  NIHSS total score Median  IQR | 8 (40%)  18 (90%)  15  7.5 - 19 | 10 (50%)  17 (85%)  9  5 – 16.5 |
| **NIHSS arm**  Median  IQR  Missing | 4  2–4  0 | 3  2–4  0 |
| **Hand dominance**  Right n (%) | 18 (90%) | 16 (80%) |
| **Time since stroke (days)**  Median  Range | 2 days  1 – 3 days | 1.5 days  0 – 3 days |
| **ARAT**  Median  IQR  Missing | 0  0–5.5  0 | 0  0–6  0 |
| **Barthel ADL Index**  Median  IQR  Missing | 4.5  0–9.5  0 | 6.5  3–9.5  0 |
| **mRS**  Median  IQR  Missing | 4  4–5  0 | 4  4–4.5  0 |
| **SPIN**  Median  IQR  Missing | 0.5  0–2  2 | 0  0–2  4 |
| **MoCA**  Median  IQR  Missing | 22  19–27  11 | 19.5  16–23  6 |
| **Pre-stroke NEADL** **Index**  Median  IQR  Missing | 21  19–22  1 | 21  20–22  2 |

NIHSS: National Institute for Health Stroke Scale; ARAT: Action Research Arm Test; mRS: modified Rankin Scale; SPIN: Scale of Pain Intensity; MoCA: Montreal Cognitive Assessment; NEADL: Nottingham Extended Activities of daily living Index.

**Table 2: 3, 6 & 12 month outcome measures and completion rates by treatment allocation**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Control** | | | **Intervention** | | |
|  | 3m  (n=17) | 6m  (n=12) | 12m  (n=10) | 3m  (n=18) | 6m  (n=18) | 12m  (n=17) |
| **NIHSS arm**  Median  IQR  Missing | 1  0-4  0 | 0.5  0-4  0 | 0  0-2.5  0 | 0.5  0-2  0 | 0.5  0-3.25  0 | 0  0-3  0 |
| **ARAT**  Median  IQR  Missing | 9  0-56  0 | 45  0-57  0 | 57  0-57  0 | 39.5  0-52  0 | 34.5  0.75-54  0 | 42  0-56  0 |
| **Barthel**  Median  IQR  Missing | 17  7.5-20  0 | 16  7.5-20  0 | 20  14.3-20  0 | 17  9.5-20  0 | 17.5  9-20  0 | 18  7-20  0 |
| **mRS**  Median  IQR  Missing | 3  2-4.5  0 | 2.5  1.25-4  0 | 1.5  0-4  0 | 3  2-4  0 | 3  1-3.25  0 | 2  2-4  0 |
| **SPIN**  Median  IQR  Missing | 2  0.5-3  0 | 1.5  0.25-3.5  0 | 0  0-0.25  0 | 1  0-2.5  1 | 2  0-3  2 | 0  0-2  0 |

NIHSS: National Institute for Health Stroke Scale; ARAT: Action Research Arm Test; Barthel: Barthel Activities of Daily Living Index; mRS: modified Rankin Scale; SPIN: Scale of Pain Intensity.

**Table 3: QALYs\* up to 12 months by treatment arms**

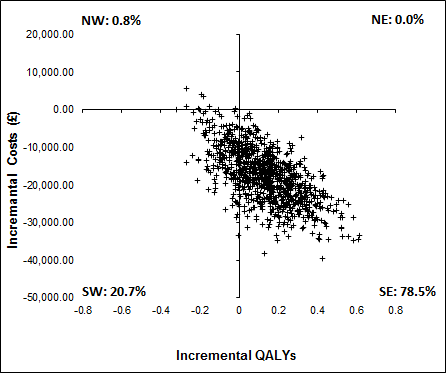
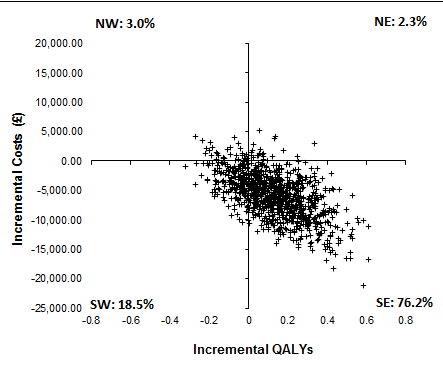
|  |  |  |  |
| --- | --- | --- | --- |
| **Complete Case** | | | |
|  | **Electrical Stimulation** | **Usual Care** | **Difference** |
| **QALYs 3 months** | **(n=12)** | **(n=10)** |
| **Mean (SD)** | **Mean (SD)** | **Incremental**  **(95% CI)** |
| 0.073  (0.073) | 0.070  (0.083) | 0.003  (-0.066 to 0.073) |
| **QALYs 6 months** | **(n=12)** | **(n=6)** |  |
| **Mean (SD)** | **Mean (SD)** | **Incremental**  **(95% CI)** |
| 0.210  (0.142) | 0.186  (0.186) | 0.024  (-0.143 to 0.191) |
| **QALYs 12 months** | **(n=11)** | **(n=6)** |  |
| **Mean (SD)** | **Mean (SD)** | **Incremental**  **(95% CI)** |
| 0.565  (0.196) | 0.445  (0.399) | 0.120  (-0.183 to 0.424) |

\*QALYs: quality adjusted life years.

**Table 4: The cost (£) derived from the resource use questionnaire by treatment group at 12 months**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Electrical Stimulation** | **Usual Care** | **Difference** |
| **(n= 17)** | **(n=10)** |
|  | **Mean (SD)** | **Mean (SD)** | **Incremental (95% CI)** |
| **NHS resource use costs** | £650.51 | £613.42 | £37.09 |
| (£1,038.26) | (£918.72) | (-£781.12 to £855.31) |
| **Total private costs** | £1,427.99 | £667.138 | £760.86 |
| (£3,066.54) | (£1,626.10) | (-£1,419.65 to £2,941.37) |
| **Cost of lost productivity** | £0.00 | £4,767.16 | -£4,767.16 |
| (£0.00) | (£11,051.05) | (-£10,594.33 to £1,060.02) |

**Figure 2: Scatter graph plots showing the bootstrap results on the cost effectiveness plane**



Scatter graph plot above: Societal perspective

Scatter graph plot below: NHS Personal Social Services (PSS) perspective