Electrical stimulation in cerebral palsy: a randomized controlled trial

Claire Kerr BSc Physio, Research Physiotherapist;
Brona McDowell BSc Physio PhD, Clinical Specialist, Gait Analysis Laboratory;
Aidan Cosgrove MD FRCS, Consultant Orthopaedic Surgeon, Musgrave Park Hospital, Belfast;
Deirdre Walsh B Physio PhD, Professor, Health and Rehabilitation Sciences Research Institute;
Ian Bradbury BSc PhD, Lecturer in Epidemiology and Statistics, School of Biomedical Sciences;
Suzanne McDonough* B Physio PhD, Professor, Health and Rehabilitation Sciences Research Institute, University of Ulster, Northern Ireland, UK.

**Correspondence to last author at* Health and Rehabilitation Sciences Research Institute, Faculty of Life and Health Sciences, University of Ulster, Shore Road, Newtownabbey, Co. Antrim, Northern Ireland BT37 0QB, UK.
E-mail: s.mcdonough@ulster.ac.uk

A randomized placebo-controlled trial was carried out to investigate the efficacy of neuromuscular electrical stimulation (NMES) and threshold electrical stimulation (TES) in strengthening the quadriceps muscles of both legs in children with cerebral palsy (CP). Sixty children (38 males, 22 females; mean age 11y [SD 3y 6mo]; age range 5–16y) were randomized to one of the following groups: NMES (*n*=18), TES (*n*=20), or placebo (*n*=22). Clinical presentations were diplegia (*n*=55), quadriplegia (*n*=1), dystonia (*n*=1), ataxia (*n*=1), and non-classifiable CP (*n*=2). Thirty-four children walked unaided, 17 used posterior walkers, six used crutches, and the remaining three used sticks for mobility. Peak torque of the left and right quadriceps muscles, gross motor function, and impact of disability were assessed at baseline and end of treatment (16wks), and at a 6-week follow-up visit. No statistically significant difference was demonstrated between NMES or TES versus placebo for strength or function. Statistically significant differences were observed between NMES and TES versus placebo for impact of disability at the end of treatment, but only between TES and placebo at the 6-week follow-up. In conclusion, further evidence is required to show whether NMES and/or TES may be useful as an adjunct to therapy in ambulatory children with diplegia who find resistive strengthening programmes difficult.

The muscle strength of children with cerebral palsy (CP) is significantly less than that of their normally developing peers (van den Berg-Emons et al. 1996, Ross and Engsberg 2002). Research has demonstrated the functional benefits of strengthening weak muscles in this population (Damiano et al. 1995, MacPhail and Kramer 1995, Damiano and Abel 1998, Dodd et al. 2003); however, children with CP often lack the selective muscle control required for specific strengthening programmes and anecdotal evidence would suggest that compliance with home exercises can be a problem.

Electrical stimulation has been proposed as a potentially useful modality for muscle strengthening in children with CP; however, its clinical utility remains a topic for debate. Several recently published studies (Sommerfelt et al. 2001, Dali et al. 2002, van der Linden et al. 2003) did not detect any statistically significant improvements with electrical stimulation in spite of earlier reports to the contrary (Pape et al. 1993, Hazlewood et al. 1994, Steinbok et al. 1997). A recent literature review of this area (Kerr et al. 2004) highlighted that the majority of studies lacked adequate statistical power, and concluded that more high quality research was necessary to define effective treatment parameters and unequivocally determine the efficacy of the modality.

Essentially two variations of stimulation are used in children with CP: (1) neuromuscular electrical stimulation (NMES), a high intensity, short duration stimulation in which a muscle contraction is elicited; and (2) threshold electrical stimulation (TES), a low level sub-contraction stimulus traditionally applied at home during sleep. Delitto and Snyder-Mackler (1990) postulated two mechanisms of action for NMES: firstly by the overload principle, and secondly by the selective recruitment of type II muscle fibres. Alternatively, application of TES is proposed to increase blood flow to the target musculature at a time of heightened trophic hormone secretion, thus increasing the bulk of the muscle (Pape 1997); however, this mechanism has not been supported by laboratory-based studies.

As no study to date has examined the comparative efficacy of TES, NMES, and a placebo treatment, this study aimed to investigate these forms of stimulation in strengthening the quadriceps musculature of ambulatory children with bilateral CP.

Method

A randomized placebo-controlled study was chosen as the most appropriate research design for this investigation. Approval was granted by the University of Ulster Research Ethics Committee and written informed consent was obtained from all parents and children, where possible.

PARTICIPANTS

Sixty-three children with CP affecting both lower limbs were recruited in one of two ways: (1) via their orthopaedic consultant, or (2) via the Northern Ireland Cerebral Palsy Register. Inclusion and exclusion criteria are outlined in Table I. The sample size for this study was calculated to show significant differences between the means of three groups of participants at 80% power, alpha of 0.05 with a large effect size. The latter was calculated from data published by Damiano and Abel (1998) which showed a large-effect size for strengthening weak muscles in children with spastic diplegia following a resistive strengthening programme. It was anticipated that there would be a 10% drop out at each assessment point and, thus, a target of 60 participants was calculated.

STUDY DESIGN AND RANDOMIZATION

Recruited children were required to attend their regional orthopaedic service for assessment on four occasions. The first attendance comprised an informal assessment in order to ensure they fulfilled the inclusion criteria and to familiarize them with the assessor (Investigator 1), the environment, and the assessment tools. At the second attendance (baseline), participants were formally assessed by Investigator 1 and received their treatment units from a second investigator. Formal assessments were repeated at visits three (16wks later; end of treatment) and four (6wks after the end of treatment; follow-up). Parents were also asked to make one visit during the treatment phase (wk 8) to facilitate compliance monitoring and to discuss any difficulties they may be having with treatment.

Investigator 1, who was masked to treatment allocation, recruited participants and carried out all assessments. Investigator 2 randomized the participants into three groups (NMES, TES, and placebo) by minimization (based on sex, age, and baseline quadriceps strength; Pocock 1983), provided instruction on the application and use of the treatment units, met with parents at week 8, and maintained contact with the family throughout the treatment period. All children continued with their normal therapy regimens throughout the study period.

CLINICAL INTERVENTION

Initial training and instruction

Children were provided with identical Microstim Data Manager treatment units (Nidd Valley Medical Ltd, North Yorkshire, UK). Investigator 2 provided instruction and training on the application of electrodes, use of the units, and progression of treatment (as appropriate). All parents were contacted 1 to 2 weeks after the start of the treatment phase (by phone or mail) to ensure that there were no problems. Regular telephone contact with families was maintained throughout the treatment period as required.

Electrode position

Two sizes of hypoallergenic self-adhesive electrodes were used (5 or 7cm diameter) depending on the size of the child's thigh. The proximal electrode was placed on the anterolateral aspect of the thigh, one-third of the distance between the anterior superior iliac spine and the mid-point of the superior border of the patella. The distal electrode was placed 1 to 3cm proximal and medial from the mid-point of the superior border of the patella (depending on the length of the child's limb). Electrode position was altered slightly between patients to ensure that they spanned the muscle belly of vastus medialis. This was confirmed by palpation of the muscle while it was contracting. The instructing therapist marked the location of the electrodes on the children's legs with a permanent marker. Parents were asked to refresh these marks daily to ensure repeatability of electrode placement. Parents were also instructed to replace the electrodes after 3 weeks, or sooner if they became less adhesive. Both legs were stimulated concurrently.

Parameters

Participants were allocated to one of the following treatment interventions: (1) NMES: electrical stimulation was applied for 1 hour daily, 5 days per week, at the highest intensity the child could tolerate. In all children this produced an observable muscle contraction equivalent to an isometric contraction in the supine position with the knees being minimally flexed over a pillow. Participants were instructed to increase the intensity throughout the treatment phase to maintain this level of contraction. (2) TES: electrical stimulation was applied for 8 hours per night, 5 nights per week, at a sensory threshold level (<10mA). Participants were instructed to increase the intensity of the stimulation at the start of each treatment session as required to ensure that it was maintained at the level of the child's sensory threshold. (3) Placebo: treatment was applied for 8 hours at night, 5 nights per week, but no stimulation was delivered through the electrodes. All other treatment parameters were identical between the TES and NMES groups and are listed in Table II. Treatment was carried out at home for 16 weeks.

Compliance monitoring

Compliance with treatment time was recorded by a timer embedded in the stimulator, allowing a calculation of percentage compliance (actual hours of treatment/target hours of treatment × 100). Parents or children also maintained treatment diaries, in case the compliance monitor within the unit failed.

OUTCOME MEASURES

Primary outcome measure

The primary outcome measure in this study was quadriceps' peak torque. This was measured using an isokinetic dynamometer (Kinetic Communicator [KinCom] AP II version 5.31HS3,

Table I: Inclusion/exclusion criteria

Inclusion criteria	*Exclusion criteria*
Age 5–16y	Current ill health
Bilateral cerebral palsy (i.e. both legs affected)	Botulinum toxin A to the lower limbs in the previous 6mo
Ability to cooperate with assessment procedures	Lower limb surgery in the previous 12mo
Independent ambulation (with or without aids)	Unstable epilepsy or changing dose of antiepileptic medication
Quadriceps strength Grade 3–4 (Oxford grading; Clarkson and Gilewich 1989)	Current use of electrical stimulation, or use in the previous 6mo

Table II: Stimulation parameters

	NMES	*TES*
Intensity, mA	Maximum tolerable, muscle contraction elicited	Sensory threshold, always <10mA
Frequency, Hz	35	35
Pulse duration, ms	300	300
On:off, s	7:12	7:12
Ramp up, s	2	2
Ramp down, s	1	1
Daily treatment session, h	1	8
Days treatment per week	5	5
Total length of treatment, wks	16	16

NMES, neuromuscular electical stimulation; TES, threshold electrical stimulation.

Chattanooga, Tennessee, USA). Isokinetic testing has been shown to be reliable in children with CP at slower test speeds (Kramer and MacPhail 1994, Ayalon et al. 2000). Participants were positioned as described previously by MacPhail and Kramer (1995). After a warm-up, participants performed an isokinetic maximal knee extension contraction at 30° per second. The limb was returned passively to the start position. Up to five contractions were performed in this manner, with three being selected for analysis. Both legs were tested, with the order of testing being randomly assigned.

Table III: Mean (SD) values of sex, age, height, weight, and baseline strength across treatment groups and numbers of participants in each clinical group and ambulatory category

	TES (n=20)	*Placebo (n=22)*	*NMES (n=18)*
Sex			
M:F	11:9	15:7	12:6
Age, y	11.46 (3.15)	10.60 (3.91)	11.12 (3.43)
Height, m	1.41 (0.15)	1.40 (0.22)	1.37 (0.20)
Weight, kg	39.02 (9.6)	37.22 (15.87)	35.36 (13.8)
Strength, Nm			
Least affected leg	33.95 (19.22)	34.14 (35.50)	29.06 (24.28)
Most affected leg	26.65 (16.34)	27.59 (26.96)	22.78 (20.05)
Clinical presentation, *n*			
Diplegia	20	20	15
Quadriplegia	–	1	–
Dystonia	–	1	–
Ataxia	–	–	1
Non-classifiable CP	–	–	2
Walking aids, *n*			
None	13	14	7
Crutches/sticks	3	3	2
Posterior walker	4	5	9

TES, threshold electical stimulation; NMES, neuromuscular electrical stimulation; Nm, newton metres; CP, cerebral palsy.

Secondary outcome measures

The Gross Motor Function Measure (GMFM; Russell et al. 1989, 2002) and the impact of disability as measured by the Lifestyle Assessment Questionnaire – Cerebral Palsy (LAQ-CP; Mackie et al. 1998) were selected as secondary outcome measures. The GMFM was scored by a therapist trained in its administration. The LAQ-CP is a 37-item parent-completed questionnaire that measures the impact of disability experienced by a child with CP and their family. Parents also completed an exit questionnaire asking about satisfaction with treatment and any problems or changes experienced throughout the study duration.

DATA ANALYSIS

Intention-to-treat analysis was carried out by an investigator masked to treatment allocation. Data was checked for normal distribution using the Kolmogorov-Smirnov test. A χ^2 test was used to check the distribution of sex and baseline strength across the groups to ensure the minimization process had been effective. Multiple regression imputation analysis was implemented using the statistical package PROC MI Analyse (SAS, version 9.2) to replace any missing values. Five imputations were performed conditional on group, sex, age, and the baseline value of the outcome variable to be imputed. Analysis of covariance (ANCOVA), which allowed for time effect, sex, and baseline values to identify treatment differences between the three groups, was applied to each resulting data set of the results. Results of this analysis for each of the five imputations were combined and are tabulated as estimated marginal mean values in Table V.

Results

The flow of participants through the trial is documented as recommended by Moher et al. (2001) in Figure 1. Sixty children (38 males, 22 females; mean age 11y [SD 3y 6mo]; range 5–16y) were randomized into the three groups: NMES (*n*=18), TES (*n*=20), and placebo (*n*=22). Clinical presentations were diplegia (*n*=55), quadriplegia (*n*=1), dystonia

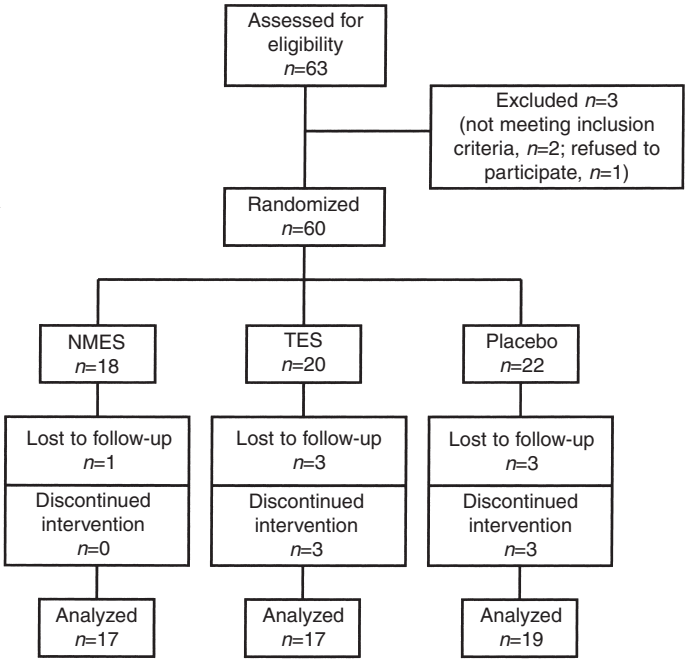

Figure 1: *Flow of participants through trial. Reasons for 'lost to follow-up' included family circumstances (n=2), medical reasons (n=2), and lost interest (n=3). Reasons for discontinued intervention included lost interest/treatment inconvenient (n=5), and development of rash at electrode site (n=1). NMES, neuromuscular electrical stimulation; TES, threshold electrical stimulation.*

($n=1$), ataxia ($n=1$), and non-classifiable CP ($n=2$) as per the Surveillance of Cerebral Palsy in Europe Classification (2000). Thirty-four children walked unaided, 17 used posterior walkers, six used crutches, and the remaining three used sticks for mobility.

BASELINE NORMALITY

The primary outcome measure of peak torque was log transformed so that parametric variance tests could be used. The secondary outcome measures of lifestyle assessment score (LAS; calculated from the LAQ-CP) and GMFM were normally distributed so similar parametric analysis was employed.

BASELINE COMPARABILITY

Table III shows the distribution of age, sex, and strength in the three groups. χ^2 tests demonstrated that the TES, NMES, and placebo groups were comparable at baseline for sex and strength; however, the placebo group differed significantly ($p=0.039$) in terms of age with the TES and NMES groups, being on average 5 months younger. Although no significant difference between baseline values of peak torque, GMFM, and LAS was identified, these values were used as covariates in the ANCOVA analysis.

DIFFERENCES BETWEEN TREATMENT GROUPS AND PLACEBO OVER TIME

The mean (SD) values for all outcome measures are shown in Table IV and estimates of treatment differences at each time point between NMES and placebo, and TES and placebo are presented in Table V. In the latter table, positive values for peak torque and GMFM represent improvements in strength and function respectively. Negative estimates for LAS also signify improvements, i.e. decreased impact of disability. No difference between active and placebo forms of stimulation

Table IV: Raw mean (SD) values for studied outcome measures

	TES			*Placebo*			*NMES*		
	Baseline	*End of treatment*	*Follow-up*	*Baseline*	*End of treatment*	*Follow-up*	*Baseline*	*End of treatment*	*Follow-up*
PT of least affected leg, Nm	33.95	37.00	40.31	34.14	26.39	30.05	29.06	31.06	30.65
	(19.22)	(17.30)	(18.15)	(35.50)	(28.23)	(27.05)	(24.26)	(26.43)	(25.70)
PT of most affected leg, Nm	26.65	34.33	37.56	27.59	24.44	30.16	22.78	28.24	27.24
	(16.34)	(17.98)	(20.14)	(31.25)	(25.94)	(27.47)	(20.05)	(21.86)	(20.35)
GMFM score, %	84.26	87.30	85.81	82.26	82.63	82.10	81.59	83.92	84.49
	(12.34)	(12.27)	(12.56)	(8.90)	(8.71)	(8.67)	(10.12)	(9.41)	(8.75)
LAS, %	39.52	33.02[a]	33.98[a]	37.16	40.67	39.98	41.33	36.84[a]	36.45
	(13.37)	(10.12)	(11.11)	(9.35)	(9.81)	(9.56)	(14.06)	(12.66)	(13.68)

[a]$p<0.05$. TES, threshold electrical stimulation; NMES, neuromuscular electrical stimulation; PT, peak torque; Nm, newton metres; GMFM, Gross Motor Function Measure; LAS, lifestyle assessment score.

Table V: Estimated marginal mean and 95% CI values for between-group differences for TES and NMES compared with placebo

Time point	*Group vs placebo*	*Estimate*	*CI*	*p*
Variable: peak torque (logged) of least affected leg				
End of treatment	TES	0.156	–0.09 to 0.41	0.22
	NMES	0.08	–0.15 to 0.31	0.51
Follow-up	TES	0.18	–0.09 to 0.45	0.19
	NMES	–0.05	–0.31 to 0.22	0.72
Variable: peak torque (logged) of most affected leg				
End of treatment	TES	0.13	–0.18 to 0.44	0.42
	NMES	0.20	–0.08 to 0.48	0.16
Follow-up	TES	0.08	–0.19 to 0.34	0.57
	NMES	–0.09	–0.34 to 0.17	0.50
Variable: GMFM				
End of treatment	TES	0.68	–1.28 to 2.6	0.50
	NMES	1.58	–0.41 to 3.59	0.12
Follow-up	TES	0.33	–1.80 to 2.26	0.76
	NMES	1.93	–0.17 to 4.04	0.07
Variable: LAS				
End of treatment	TES	**–4.87**	**–8.88 to –0.86**	**0.02**
	NMES	**–4.33**	**–8.49 to –0.16**	**0.04**
Follow-up	TES	**–5.70**	**–10.13 to –1.28**	**0.01**
	NMES	–4.31	–8.98 to 0.35	0.07

Each outcome measure, at end of treatment and at review, was adjusted for baseline value, age, and sex. Significant between-group differences are identified in bold text. Only significant differences at end of treatment were shown between TES and placebo and NMES and placebo; this significant difference was maintained at 6-week follow-up for TES only. CI, confidence interval; TES, threshold electrical stimulation; NMES, neuromuscular electical stimulation; GMFM, Gross Motor Function Measure; LAS, lifestyle assessment score.

were found for the primary outcome measure, peak torque (least and most affected leg), or for GMFM scores at the end of treatment or at follow-up. Significant differences were shown for the LAS between TES and placebo and NMES and placebo at the end of treatment, this significant difference was maintained at the 6-week follow-up for TES only.

COMPLIANCE

The average compliance in the TES and NMES groups was 38.3% and 71.1% respectively. The compliance data for the placebo group are not presented as they reflect the length of time that the unit was switched on and not whether the electrodes were actually attached to the limbs. In two units the compliance monitor failed, and in these instances treatment diaries were used to calculate total compliance.

EXIT QUESTIONNAIRE

Forty-nine of the 60 families participating completed an exit questionnaire. Only two of the 49 families were not satisfied with the treatment they were allocated (one receiving TES and one placebo) and 43 out of 49 families stated that they would be happy to receive some form of electrical stimulation again. All the respondents thought that the units were easy to operate and that the instructions provided were clear. Table VI shows the percentage frequencies of the main problems encountered in the use of the unit by each group.

Table VI: Percentage frequency of main problems encountered in use of treatment unit by each group (total *n*=49)

Problem/severity	*Percentage reported in each treatment group*		
	TES (n=14)	*Placebo (n=19)*	*NMES (n=16)*
Electrodes coming off			
None	26.7	11.1	87.5
A little	33.3	66.7	12.5
A lot	40	22.2	0
Leads coming out of unit			
None	40	22.2	87.5
A little	46.7	50	6.3
A lot	13.3	27.8	6.3
Difficulties charging unit			
None	100	77.8	68.8
A little	0	22.2	31.3
A lot	0	0	0

TES, threshold electrical stimulation; NMES, neuromuscular electrical stimulation.

Table VII: Sample size calculation based on effect sizes demonstrated in study

Outcome measure	*Total number of participants*
PT least affected leg	190
PT most affected leg	110
GMFM	140
LAS	90

PT, peak torque; GMFM, Gross Motor Function Measure; LAS, lifestyle assessment score.

POWER OF THE STUDY

A poststudy sample size calculation using the effect sizes of the interactions observed in this study was carried out. Table VII shows the results of this calculation, indicating that many more participants were required to achieve 80% power for measures of strength and function. Mean percentage improvements in the order of 29% for TES and 24% for NMES for the strength of the most affected leg were noted over the intervention phase of the trial. No such improvement was observed in the placebo group, indeed the strength of the most affected leg incurred a mean percentage decrease of 11%.

Discussion

This study was undertaken to assess the efficacy of two commonly used forms of electrical stimulation in children with CP. Analysis of the data revealed no statistically significant difference in the primary outcome measure of quadriceps isokinetic strength with active compared with placebo forms of electrical stimulation. There was also no statistically significant improvement in function. Alternatively, significant reductions in the impact of disability were obtained for both active forms of stimulation compared with placebo. Table IV indicates that this improvement (i.e. reduction in LAS score) was maintained at the 6-week follow-up but was significant for the TES group only. Furthermore, while not significant, changes in the mean values for peak torque and GMFM (Table IV) also indicated improvements in strength and function in both these groups, a trend not observed in the placebo group. Indeed a reduction in strength in the latter group was recorded over the treatment phase of the study.

Ultimately, the power of the study was shown to be insufficient to identify any significant change in our primary outcome measure. In retrospect, the use of strength changes obtained following a resistive strengthening programme for children with CP (Damiano and Abel 1998) to estimate sample size may not have been wholly appropriate; however, it was the best data available to the authors at the time of the study. Other studies failed to carry out power analysis (Sommerfelt et al. 2001, Dali et al. 2002), and van der Linden et al. (2003) acknowledged that their study had reduced statistical power due to an inability to recruit the required number of participants. In the current study, poststudy estimation of sample size suggested that many more participants would be required to demonstrate the efficacy of electrical stimulation in improving strength, function, and impact of disability in children with bilateral CP using the outcome measures employed here.

This retrospective analysis would suggest that the significant results in the current trial may be explained by chance and another trial should be completed to confirm this finding. Indeed it was surprising that the only significant improvement noted with both TES and NMES was a reduction in the impact of disability experienced by the child and the family. It is difficult to discern how the additional home therapy requirements imposed by participation in the study could contribute to such a result and so chance cannot be discounted in this case. However, as no reduction in the impact of disability was observed in the placebo group, the result could be attributed to the effects of active stimulation. This implies an apparent treatment effect with both TES and NMES, which is supported by the non-significant yet positive trends in the data presented in Table IV. The condition-specific nature of the LAQ-CP may have facilitated detection of subtle changes in day-to-day activities that

could not be identified by the more discrete measures of impairment or function. Furthermore, the large variations observed with peak torque measurement no doubt contributed to the reduced possibility of determining significant findings with this means of measurement in the studied population.

The improvements observed in peak torque and GMFM score, and significant improvements in LAS, indicate that there may be some beneficial effects with the use of both TES and NMES. Certainly, the improvements in the GMFM score of the active stimulation groups are similar to those suggested by Russell et al. (1989) as a minimal clinically important difference. However, they are less than those observed by Steinbok et al. (1997) in their evaluation of TES. This may be due to a variety of factors including shorter treatment phase and low compliance (38.3%) in the current study, or because the participants in the Steinbok study (1997) had previously undergone selective dorsal rhizotomy.

The guidelines for the strength improvements required for an intervention to be considered clinically useful are less clear. Improvements with various strengthening modalities have ranged from 19.6% (isokinetics, MacPhail and Kramer 1995) to over 100% (training machines, Horvat 1987; free weights, Damiano et al. 1995). The mean strength gains demonstrated in the current study (29% TES, 24% NMES) were substantially less than those obtained by other modalities. Although, on average, a clearly visible isometric contraction was achieved in the NMES participants, the intensity of the stimulation may not have been sufficient to elicit muscle contractions of the magnitude required to achieve substantial strength gains. Furthermore, the use of surface electrodes resulted in the stimulation of nocioceptors, consequently limiting the intensity of stimulation to patient tolerance and reducing the level of muscular contraction attainable.

This is the first study to our knowledge to objectively measure compliance with electrical stimulation programmes. Several authors reported excellent levels of treatment compliance using a diary record system (Steinbok et al. 1997 [93%]; Dali et al. 2002 [82%]) and others from parental report (Sommerfelt et al. 2001; van der Linden et al. 2003). The figures in the current study, particularly for the TES group (38.1%), were much lower than those previously reported. The compliance monitoring system and the comments on the exit questionnaire suggested, unsurprisingly, that the nighttime groups experienced more problems with the electrodes coming off and leads coming out of the unit. Complications reported were limited to an exacerbation of eczema in one child and four incidences of an itch or rash developing. The comments on the exit questionnaire indicated that the placebo stimulation was credible as only two out of 49 families were dissatisfied with the treatment they were allocated.

Despite a statistically significant reduction in the impact of disability, the strength gains and functional changes demonstrated in this study were modest and did not differ significantly between treatment and placebo. Further study with the use of a greater sample size would be required before the use of electrical stimulation, as employed in this study, could be recommended for use in children with diplegia. Alternatively, NMES and TES may provide an alternative means of targeted strengthening of the quadriceps in the studied population, who find resistive strengthening programmes difficult due to unmasked weakness (e.g. postsurgery) or comprehension. Further studies should identify which groups of patients are most likely to benefit from electrical stimulation, explore the dose/effect relationship, and closely monitor compliance with treatment.

DOI: 10.1017/S0012162206001915

Accepted for publication 25th May 2006.

Acknowledgements
We wish to express our thanks to all the families who participated in this study and acknowledge the support of the Wellcome Trust (Project grant 061312).

References

Ayalon M, Ben-Sira D, Hutzler Y, Gilad T. (2000) Reliability of isokinetic strength measurements at the knee in children with cerebral palsy. *Dev Med Child Neurol* **42:** 398–402.

Clarkson HM, Gilewich GB. (1989) *Musculoskeletal Assessment.* Baltimore, USA: Williams and Wilkins. p 23–25.

Dali C, Hansen FJ, Pedersen SA, Skov L, Hilden J, Bjornskov I, Strandberg C, Christensen J, Haugsted U, Herbst G, Lyskjaer U. (2002) Threshold electrical stimulation (TES) in ambulant children with CP: a randomized double-blind placebo-controlled clinical trial. *Dev Med Child Neurol* **44:** 364–369.

Damiano DL, Kelly LE, Vaughan CL. (1995) Effects of a quadriceps femoris strengthening programme on crouch gait in children with cerebral palsy. *Phys Ther* **75:** 658–667.

Damiano DL, Abel MF. (1998) Functional outcomes of strength training in spastic cerebral palsy. *Arch Phys Med Rehab* **79:** 119–125.

Delitto A, Snyder-Mackler L. (1990) Two theories of muscle strength augmentation using percutaneous electrical stimulation. *Phys Ther* **70:** 158–164.

Dodd KJ, Taylor NF, Damiano DL. (2002) A systematic review of the effectiveness of strength-training programs for people with cerebral palsy. *Arch Phys Med Rehab* **83:** 1157–1164.

Dodd KJ, Taylor NF, Graham HK. (2003) A randomized clinical trial of strength training in young people with cerebral palsy. *Dev Med Child Neurol* **45:** 652–657.

Hazlewood ME, Brown JK, Rowe PJ, Salter PM. (1994) The use of therapeutic electrical stimulation in the treatment of hemiplegic cerebral palsy. *Dev Med Child Neurol* **36:** 661–673.

Horvat M. (1987) Effects of a progressive resistance training program on an individual with spastic cerebral palsy. *Am Correct Ther J* **41:** 7–11.

Kerr C, McDowell B, McDonough S. (2004) Electrical stimulation in cerebral palsy: a review of the effects on strength and motor function. *Dev Med Child Neurol* **46:** 205–213.

Kramer JF, MacPhail HEA. (1994) Relationships among measures of walking efficiency, gross motor ability, and isokinetic strength in adolescents with cerebral palsy. *Ped Physl Ther* **6:** 3–8.

Mackie PC, Jessen EC, Jarvis SN. (1998) *The Lifestyle Assessment Questionnaire (LAQ-CP): An Instrument to Measure the Impact of Disability on the Lives of Children with Cerebral Palsy and their Families.* Newcastle upon Tyne, England: The Regional Maternity Survey's Office.

MacPhail HEA, Kramer JF. (1995) Effect of isokinetic strength-training on functional ability and walking efficiency in adolescents with cerebral palsy. *Dev Med Child Neurol* **37:** 763–775.

Moher D, Schulz KF, Altman DG for the CONSORT group. (2001) The CONSORT statement: revised recommendations for improving the quality of reports for parallel-group randomised trials. *The Lancet* **357:** 1191–1194.

Pape KE, Kirsch SE, Galil A, Boulton JE, White MA, Chipman M. (1993) Neuromuscular approach to the motor deficits of cerebral palsy. *J Ped Orth* **13:** 628–633.

Pape KE. (1997) Therapeutic electrical stimulation (TES) for the treatment of disuse muscle atrophy in cerebral palsy. *Ped Phys Ther* **9:** 110–112.

Pocock SJ. (1983) Methods of randomization. In: Pocock SJ, editor. *Clinical Trials: A Practical Approach.* Chichester, UK: Wiley. p 84–86.

Ross SA, Engsberg JR. (2002) Relation between spasticity and strength in individuals with spastic diplegic cerebral palsy. *Dev Med Child Neurol* **44:** 148–157.
Russell DJ, Rosenbaum PL, Cadman DT, Gowland C, Hardy S, Jarvis S. (1989) The gross motor function measure: a means to evaluate the effects of physical therapy. *Dev Med Child Neurol* **31:** 341–352.
Russell D, Rosenbaum P, Avery L, Lane M. (2002) *Gross Motor Function Measure (GMFM–66 & GMFM–88) User's Manual. Clinics in Developmental Medicine No. 159.* London: Mac Keith Press.
Sommerfelt K, Markestad T, Berg K, Saetesdal I. (2001) Therapeutic electrical stimulation in cerebral palsy: a randomized, controlled, crossover trial. *Dev Med Child Neurol* **43:** 609–613.
Steinbok P, Reiner A, Kestle JRW. (1997) Therapeutic electrical stimulation following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: a randomized clinical trial. *Dev Med Child Neurol* **39:** 515–520.
Surveillance of Cerebral Palsy in Europe Collaborative Group. (2000) Surveillance of cerebral palsy in Europe: a collaboration of cerebral palsy surveys and registers. *Dev Med Child Neurol* **42:** 816–824.
van den Berg-Emons RJG, van Baak MA, de Barbanson DC, Speth L, Saris WHM. (1996) Reliability of tests of aerobic power, anaerobic power, and isokinetic muscle strength in children with spastic cerebral palsy. *Dev Med Child Neurol* **38:** 1117–1125.
van der Linden ML, Hazlewood ME, Aitchison AM, Hillman SJ, Robb JE. (2003) Electrical stimulation of gluteus maximus in children with cerebral palsy: effects on gait characteristics and muscle strength. *Dev Med Child Neurol* **45:** 385–390.