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A pilot investigation of the hypoalgesic effects of transcutaneous electrical nerve stimulation upon low back pain in people with multiple sclerosis

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Objective: To investigate the hypoalgesic effects of transcutaneous electrical nerve stimulation (TENS) upon low back pain (LBP) in people with multiple sclerosis (MS).
Design: A randomized double-blind placebo controlled clinical pilot study.
Subjects and setting: Fifteen people with MS were recruited and randomly allocated to one of the following groups under double blind conditions ($n = 5$ per group): TENS 1 (4 Hz, 200 μs), TENS 2 (110 Hz, 200 μs), placebo TENS.
Interventions: Treatment was applied for 45 minutes three times a week for six weeks with a four-week follow-up.
Outcome measures: The following outcome measures were taken at weeks 1, 6, and 10: visual analogue scale (VAS) (for current LBP, right leg pain, left leg pain); Leeds Multiple Sclerosis Quality of Life Questionnaire; Roland Morris Disability Questionnaire; Short Form-36 (SF-36) Version 1; and the McGill Pain Questionnaire (MPQ). VAS for current LBP, right and left leg pain were also taken before and after treatment, and once a week during the follow-up period.
Results: Analysis showed no statistically significant effects for any of the data. However, both active treatment groups showed a trend of improvement in the majority of the outcome measures.
Conclusion: Active TENS was more effective than placebo TENS in decreasing VAS scores following each treatment although results were not statistically significant. Further work in this area is warranted and should include a larger number of participants in the form of a randomized controlled clinical trial to determine the efficacy of this modality.

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Introduction

Multiple sclerosis (MS) is a chronic disease of the central nervous system in which persistent inflammation and demyelination results in varying degrees of neurological deficit.[1] Until the 1980s, MS was thought to be a relatively painless disease,[2] but there is now much evidence to the contrary. Reports of the incidence of pain in people with MS have ranged from 29% to 77% (e.g. refs 3–7). This variability is most likely to be due to differences in diagnostic criteria for both MS and pain, variability in people with MS, and disease duration.[8,9]

The prevalence of back pain in people with MS has been reported to be between 14% and 39%.[3,4,10,11] Indeed, several authors[2,3,12] have suggested that back pain and burning in the extremities are the most common complaints reported by this population. Thompson,[13] Moulin[14] and Maloni[12] have recently reported that chronic back pain is due to abnormal stresses on the paravertebral muscles resulting in degenerative changes and facet joint problems, in addition to the effects of spasticity, bad posture and improper seating. Maloni [2] has also emphasized that back pain can be caused by underlying conditions such as osteoporosis or demyelinating lesions in the spinal cord. A variety of treatment regimes for back pain are currently available which include physiotherapy, electrical stimulation, heat pads, anti-inflammatory drugs[1] as well as education, coping strategies and complementary therapies,[6] however these have been reported to have variable effects. A recent publication by The World of Multiple Sclerosis[15] suggested that people with MS complaining of pain benefit from education and counselling provided by occupational therapists or physiotherapists as well as from acupuncture and transcutaneous electrical nerve stimulation (TENS). TENS has been used to treat many pain syndromes and conditions including low back pain (LBP),[16] and musculoskeletal pain[17] amongst others.[18] However, to date there has been a lack of published research on the hypo-algesic effect of TENS upon low back pain in people with MS.

Thus, the aims of this pilot study were to investigate the effectiveness of TENS upon LBP in people with MS and to establish the most appropriate study design for a randomized controlled clinical trial.

Methods

Approval was obtained from the University of Ulster's Research Ethical Committee before the study commenced. The research team included one researcher who applied the treatment and two independent assessors who were blinded to group allocation.

Fifteen people clinically diagnosed with MS (male and female, aged 34–65 years) who were suffering from stable LBP (i.e., low back pain present for at least three months which had not responded to other conventional treatments) were recruited though branches of the MS Society in Northern Ireland (Figure 1). Recruitment continued until there were five participants in each group.

Inclusion criteria were as follows: age range between 18 and 65 years; people who were definitely diagnosed with multiple sclerosis and were suffering from low back pain in the lumbar spine for at least the last three months; antispasticity medication and physiotherapy stabilized for at least 30 days prior to recruitment; and medication for pain relief stabilized for at least 30 days prior to recruitment. Exclusion criteria were as follows: other serious illness likely to interfere with the study; presence of serious spinal pathology (red flags)[19] and/or psychosocial risk factors (yellow flags)[19]; any contraindication to TENS; participants who were judged not competent to give informed consent; analgesic abuse; sacral pressure ulcers; and participating in other research studies currently or within the previous three months.

The experimental procedure was explained fully to all participants, and an information sheet was supplied. The individual's consultant was advised of their interest to participate and the participant's written informed consent was gained prior to inclusion in the study.

All participants ($n = 15$) were randomly allocated to one of three experimental groups. A computer randomization list was generated and drawn up by a member of the research team not involved in the day-to-day running of the

study. The three experimental groups were: (1) TENS group 1 (4 Hz, 200 μs); (2) TENS group 2 (110 Hz, 200 μs); and (3) placebo TENS; ($n = 5$ all groups) (see Figure 1).

A 120Z TENS unit (ITO, Tokyo, Japan) was used to deliver treatment. In each case, the treatment current was applied through two self-adhering PALS neurostimulation electrodes (13×5

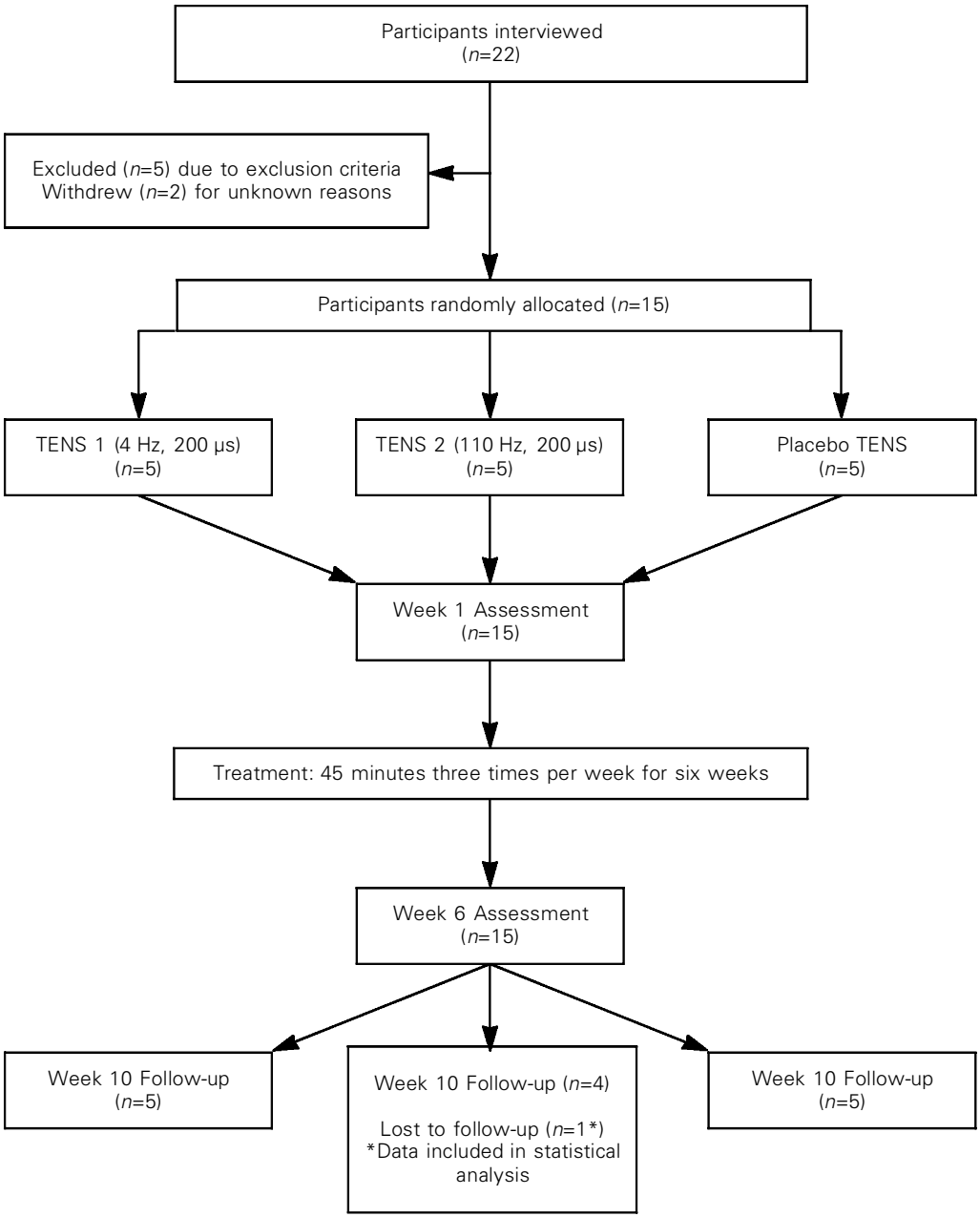

Figure 1 Flow chart demonstrating the timescale and methodological procedure for all groups.

cm; Nidd Valley Medical, North Yorkshire, UK). Prior to the commencement of the study, the parameters of the TENS units were calibrated using an oscilloscope (Gould Electronics, Sussex, UK).

Electrode placement was carried out by an independent assessor and was determined by the outcome of the physical assessment. The main target of the electrode placement was the lumbar and sacral nerve roots (L1–S2). Prior to the electrode placement, the skin was cleansed with alcohol swabs in order to reduce the electrical resistance of the epidermis.[20] The TENS electrode placement technique was as follows: (1) For unilateral pain, two electrodes were positioned 3 cm apart with the proximal electrode (cathode) positioned 2 cm lateral to the vertebral column. The electrodes were aligned parallel to the vertebral column and the centres of the electrodes were aligned with the centre of the pain. (2) For bilateral pain, the electrodes were positioned 2 cm lateral to the spinous processes of the lumbar spine, i.e., the electrodes were positioned 4 cm apart and parallel to the vertebral column, with the centre of the electrode aligned with the centre of the pain. In order to ensure that electrode placement was consistent each time the treatment was applied, the centre of the pain was marked on the skin with indelible ink. In addition, measurements of the interelectrode distance as well as the distance between the electrodes and the lumbar spinous processes were carried out prior to each treatment.

Prior to the first treatment, participants were given a brief demonstration of the treatment they had been allocated on the anterior aspect of the forearm. All participants were instructed that they may or may not perceive any sensation and an inactive TENS unit was used for the placebo group. Treatment was applied for 45 minutes three times a week for six weeks with participants in their preferred position of comfort. At the conclusion of the treatment session, participants were examined for any skin irritation.

In TENS groups 1 and 2, the intensity of the unit was increased until a 'strong but comfortable' sensation was experienced. To counteract habituation of electrical stimulation, participants were asked every 2 minutes if the reported sensation had decreased. If so, the intensity was increased to return it to the original level. The same method was applied in the placebo group except that the intensity control of the unit was increased to the midpoint on the dial if no sensation was perceived.

The following outcome measures were taken in the form of a semi-structured interview at baseline (prior to commencement of treatment in week 1), on completion of the six-week treatment period, and at the four-week follow-up. The outcome measures used were: Roland Morris Disability Questionnaire[21]; Short Form-36 (Version 1)[22]; McGill Pain Questionnaire[23]; Leeds MS Specific Quality of Life Questionnaire[24]; and the visual analogue scale (VAS)[24] (for current LBP, right and left leg pain). In addition, to measure short-term effects a VAS was administered prior to and immediately following each treatment during the six-week treatment period. Additionally, to measure longer term effects, participants rated their pain every week thereafter until week 10.

Logbooks were given to the participants on a weekly basis for 10 weeks. Participants were required to complete this daily logbook on their pain episodes and medication. Data analysis was carried out blind using SPSS version 9.0 (SPSS Inc. Illinois, USA).

Results

Visual analogue scale (VAS)

VAS scores for LBP, right and left leg pain were taken pre and post treatment and once a week over the follow-up period (i.e., at weeks 7, 8, 9 and 10). The daily treatment effect was calculated by subtracting pretreatment scores from post-treatment scores, thus a negative score indicates an improvement in current pain. Statistical analysis on VAS scores demonstrated no statistically significant change between groups over time for LBP and left leg pain ($p > 0.05$; two-way analysis of covariance). In addition, statistical analysis on difference scores for right leg pain indicated that there was no significant difference between groups ($p > 0.002$; Kruskal-Wallis) or within any of the groups over time ($p > 0.017$; Friedman test). (*Note*: for both these analyses, *p*-values were not statistically significant once the Bonferroni correction was applied.) However, an

obvious clinical improvement, although not statistically significant, was observed for the TENS group 1 (4 Hz, 200 μs) over the treatment period and at follow-up. Results are presented in Table 1.

Roland Morris Disability Questionnaire

A decrease in Roland Morris Disability Questionnaire mean scores represents an improvement in the participant's level of disability. There was an improvement in mean scores for all three groups over the treatment period (between weeks 1 and 6), however the most noticeable improvement was observed in TENS group 1. TENS group 2 mean scores improved slightly over the treatment period and showed further improvement over the follow-up period. Very little change was observed throughout the treatment and follow-up period in the placebo TENS group (Table 2).

Statistical analysis demonstrated no significant difference between groups over time ($p > 0.017$; Kruskal-Wallis), nor any significant difference in Roland Morris Disability Questionnaire scores within any of the groups over time ($p > 0.017$; Friedman Test). (*Note*: for both these analyses, p-values were not statistically significant once the Bonferroni correction was applied.)

Table 1 Summary of VAS difference scores for TENS group 1 (4 Hz, 200 μs) for low back pain, right leg pain and left leg pain (mm)

	Low back pain		Right leg pain		Left leg pain	
	Mean	SEM	Mean	SEM	Mean	SEM
Week 1						
Day 1	–19.6	10.6	–22.2	15.2	–2.8	5.8
Day 2	–18.2	10.3	–12.7	6.2	–10.7	8.7
Day 3	–28.2	9.9	–5.6	3.3	–4.2	9
Week 2						
Day 1	–25.2	16.8	1	12.9	5.7	9.9
Day 2	–5	–	–14	–	–9	–
Day 3	–17.2	15.6	–6.5	3.4	–17.5	14.5
Week 3						
Day 1	–9	8.3	–4	4.1	–12	8.3
Day 2	–41	21.2	1.2	2.9	–6	10.2
Day 3	–16.7	17.1	–1.7	1.7	–11.2	10.6
Week 4						
Day 1	–17.7	18.7	0.2	1.5	–19.2	20.9
Day 2	–18.5	15.7	3	2.3	–19.2	20.9
Day 3	–1.5	2.5	–6	1	–2.5	0.5
Week 5						
Day 1	–15	15.6	–17.3	11.6	–17.3	12.2
Day 2	–5	2.6	–7.6	3.9	–8	6.6
Day 3	–8.8	8.1	–4.6	3.7	–4.6	4.4
Week 6						
Day 1	–14	8.2	–2.2	1.8	–10	9.3
Day 2	–9	11	0.6	1.4	–11.4	10.9
Day 3	–22.7	16.5	–4.5	3.5	–13	13.4
Week 7	–12.3	19	–30.3	13.7	–15.8	4.5
Week 8	0.5	21.8	–4.5	15.3	–10.3	12.7
Week 9	–13.4	16	–20.6	16.5	–10	11.4
Week 10	–23.6	15.1	–37.6	18.7	–20.2	7.1

(–) Indicates a decrease in VAS scores, i.e., an improvement.

Table 2 Mean scores for the Roland Morris Disability Questionnaire, McGill Pain Questionnaire (PRI) and the Leeds MS Quality of Life at the three time points

Outcome measure	Groups	Week 1 Mean (SEM)	Week 6 Mean (SEM)	Week 10 Mean (SEM)
Roland Morris Disability Questionnaire	TENS 1	16.7 (1.0)	10 (2.3)	14.2 (2.2)
	Placebo TENS	16.4 (1.4)	15 (2.5)	17 (1.6)
	TENS 2	18.2 (1.8)	15.6 (1.9)	13.7 (2.9)
McGill Pain Questionnaire	TENS 1	42.6 (2.9)	33 (5.4)	29 (5.0)
	Placebo TENS	30.6 (2.5)	32.4 (4.6)	30.8 (4.2)
	TENS 2	21.4 (2.9)	22.2 (4.1)	21.7 (5.1)
Leeds MSQoL	TENS 1	15.6 (0.9)	8.4 (3.3)	11.2 (3.1)
	Placebo TENS	14.6 (2.2)	13.2 (3.3)	14.8 (2.4)
	TENS 2	12.2 (2.7)	10.6 (3.0)	11 (1.6)

NB: A decrease in score represents an improvement.

McGill Pain Questionnaire: Pain Rating Index (PRI)

Pain Rating Index is an accumulative total of the four subsections (sensory, affective, evaluative, and miscellaneous) of the McGill Pain Questionnaire; a decrease in score indicates an improvement in pain. There was a noticeable decrease in TENS group 1 mean scores at week 6 compared with baseline, which continued over the four weeks of the follow-up period. In contrast, mean scores for TENS group 2 and placebo TENS remained relatively unchanged throughout the study period (see Table 2). A two-way analysis of covariance showed no interactive effect between groups over time ($p > 0.05$).

Leeds Multiple Sclerosis Quality of Life Questionnaire

A decrease in mean scores indicates an improvement in quality of life. The Leeds MSQoL scores improved over the treatment period in all three groups, with the greatest improvement observed for TENS group 1. However, this improvement was not maintained at follow-up. The placebo TENS mean scores returned to baseline at week 10 and the TENS group 2 showed very little change between weeks 6 and 10 (see Table 2). A two-way analysis of covariance showed no interactive effect between groups over time ($p > 0.05$).

Short Form-36

An increase in mean scores indicates an improvement in physical and mental function. The mean scores for the physical component of the SF-36 for TENS group 1 increased over the treatment period and decreased slightly at week 10 but did not return to pretreatment values. A similar pattern was also observed for TENS group 2 mean scores. In the placebo TENS group, mean scores also increased over the treatment period; however, these decreased at week 10 to below pretreatment values (Table 3).

The mean scores for the mental component of the SF-36 for the TENS group 1 increased over the treatment period and decreased very slightly at week 10. Similarly, TENS group 2 mean scores increased over the treatment period and also decreased slightly at week 10. In contrast, mean scores for the placebo group varied little from baseline throughout the treatment and follow-up period (Table 3).

A two-way analysis of covariance performed on the physical and mental combined scores showed no interactive effect between groups over time ($p > 0.05$).

Discussion

It has previously been reported that back pain, which is usually confined to the lower back[14] is a common and debilitating problem for people with MS,[4] often resulting in long-term distress and reduced quality of life.[11,14] However, there has been a lack of published research investigating the use of TENS in the treatment of low back pain in people with MS. Therefore, this study was

Table 3 Mean values for the SF-36 physical and mental combined scores at the three time points

Outcome measure	Groups	Week 1 Mean (SEM)	Week 6 Mean (SEM)	Week 10 Mean (SEM)
SF-36 physical component	TENS 1	81.4 (22.0)	126 (27.5)	112.4 (36.8)
	Placebo TENS	115.2 (15.5)	140.8 (46.5)	102 (40.7)
	TENS 2	88.8 (29.7)	150 (25.6)	143.7 (9.0)
SF-36 mental component	TENS 1	182.5 (32.1)	234.2 (43.2)	230.3 (41.6)
	Placebo TENS	146.6 (30.6)	164 (67.9)	154.3 (38.0)
	TENS 2	146 (38.8)	217.6 (43.2)	212.1 (46.6)

NB: An increase in score represents an improvement.

Clinical messages

- The current pilot study has demonstrated that transcutaneous electrical nerve stimulation (TENS), at the parameters described herein, may have clinical relevance as a non-pharmacological method of pain relief for low back pain (LBP) in people with multiple sclerosis (MS).
- Frequency of treatment may influence the effectiveness of TENS upon LBP in people with MS.

designed to investigate the hypoalgesic effect of TENS upon low back pain within an MS population using various validated and reliable outcome measures.

Previous studies have shown effective management of LBP through the use of TENS, especially for short-term analgesia.[25] In the current study, the results revealed no significant interactive effect between groups either over time or within groups; however, trends were observed in favour of the active treatment groups investigated. These trends are consistent with previous research that has demonstrated a reduction in low back pain as a result of treatment with TENS.[26–28] In addition, there was an improvement in scores in the McGill Pain Questionnaire (PRI) observed in TENS group 1 over the trial period; these results are consistent with those demonstrated by Melzack *et al.*[26] in the study of low back pain. The findings of Hamza *et al.*[29] are also consistent with those demonstrated in the current study where the SF-36 physical combined mean scores showed an improvement over the treatment period and worsened slightly over the follow-up period, although values at follow-up remained above baseline. However, the findings of this pilot study should be interpreted with caution due to the small number of participants involved in the study.

Although in the current study logbooks provided only limited results due to inconsistencies in their completion, it was observed that participants in both active treatment groups reported improved pain levels following treatment, whilst participants in the placebo TENS group mainly reported unchanged pain levels. Interestingly, various participants in all three groups also reported a reduction in spasticity for areas including the lower back, legs and neck.

The findings of this pilot study have demonstrated a limited effect of TENS upon LBP in people with MS, which may be in part due to the low frequency of application. Previous work demonstrating beneficial effects of TENS, either alone or in combination, upon chronic LBP has employed daily treatment and/or self-application (e.g., ref. 30). In fact, Wynn Parry and Girgis[27] have suggested that the lack of efficacy of TENS for chronic pain may be due to insufficient frequency of applications per day. In addition, in the current study several participants reported a reduction in spasticity as a result of treatment; although these results are purely observational, this may be an area worthy of exploration. These findings thus suggest that further research is warranted, taking into consideration certain modifications in the study design, mainly in terms of the frequency of TENS application, and increasing

the number of participants to determine the potential clinical efficacy of this modality.

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