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Original article

The influence of transcutaneous electrical nerve stimulation parameters on the level of pain perceived by participants with painful diabetic neuropathy: A crossover study

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ABSTRACT

Aims: This pilot study aimed to investigate and compare the perceived pain relief effectiveness of two different modes of TENS in people with painful diabetic neuropathy (PDN).
Methods: A cross-over study was conducted at Charles Sturt University, Orange. Five participants with PDN were assessed with a McGill Pain Questionnaire before and after each of the two TENS treatments. Participants were randomly allocated to Traditional TENS (80 Hz, 200 ms) or Acupuncture-like TENS (2 Hz, 200 ms) and the treatments were applied daily for 30 min over ten days. Following a seven day washout period, the alternate mode of TENS was carried out using the same method. Wilcoxon Signed Rank tests were used to statistically analyse the results.
Results: All five participants reported personally meaningful pain relief during one or both of the TENS treatments. The Wilcoxon signed rank testing showed no statistical significance, $p = 1$, likely due to the small sample size. Acupuncture-like TENS had a large effect size ($z = -1.625$, $r = 0.514$), whilst Traditional TENS produced a medium effect size ($z = -1.214$, $r = 0.384$). No adverse effects were reported.
Conclusion: Acupuncture-like TENS may be more effective for PDN than traditional TENS. A larger scale replication of this pilot study is warranted.

1. Introduction

Diabetes mellitus is a common disease, affecting around 347 million people worldwide [1]. Painful Diabetic Neuropathy (PDN) is a complication experienced by more than 26% of people with diabetes [2]. This complication significantly impacts on work, sleep, mood, social activities and quality of life [3,4]. The mechanism of PDN is not completely understood but it may involve abnormal activation of damaged or regenerating peripheral nerves [5].

Many pharmacological interventions are ineffective at relieving pain for people with PDN and therefore other modalities should be considered [2]. There has been some research into alternative pain relief treatments, including the use of Transcutaneous Electrical Nerve Stimulation (TENS). TENS is a modality that can be used to treat a range of painful conditions including PDN and involves the stimulation of peripheral nerves via electrodes to reduce pain [6]. TENS is widely used because it is easy, can be self-administered and has a low incidence of adverse effects [7]. A meta-analysis of three randomised control trials compared the effectiveness of TENS therapy to routine care, pharmaceutical treatment or a placebo device for people with PDN [6]. This analysis showed statistically significant pain relief after six weeks for the TENS treatment group, as well as an improvement in overall neuropathic symptoms after ten weeks [6]. While this meta-analysis concluded that TENS is an effective treatment for PDN, insufficient information was provided about treatment parameters used and this produces a challenge when trying to reproduce this treatment clinically.

Whilst TENS is an effective treatment for PDN, it is currently unclear if there are ideal stimulation parameters for this condition [6]. Bulut et al. achieved statistically significant reductions in pain scores using high frequency stimulation (80 Hz) for 30 min per day over a 20 day period [7]. Although we now know that these

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parameters are effective for this population group, it would be beneficial to determine if there are more optimal TENS settings for PDN.

A study on the use of TENS in post-operative pain illustrated that TENS at mixed frequencies (2 Hz and 100 Hz) of stimulation produced a greater analgesic effect than high (100 Hz) or low (2 Hz) frequency TENS [6]. This implies that TENS parameters do alter the level of pain perceived by patients with postoperative pain [6]. Finding the most optimal TENS parameters for the treatment of PDN should similarly enable more optimal pain relief using this modality.

The aim of the study was to compare the analgesic effects of two different modes of TENS for people with PDN using the McGill Pain Questionnaire (MPQ) along with other outcome measures. The motive behind this investigation was to assist health professionals make evidence-based clinical decisions when treating people with PDN. This is important as there is currently a knowledge gap when it comes to selecting optimal TENS parameters for this population group, and health professionals are currently required to use a trial and error approach when using this treatment. This project utilised a cross-over design to answer the following question: Does the mode of TENS applied to lumbosacral region, in PDN treatment change the level of perceived pain by patients as measured using McGill Pain Questionnaire?

2. Subjects

2.1. Sampling

The sampling population for the study involved individuals living in Orange and nearby areas of NSW. Convenience sampling was utilised due to the project's time restriction and cost limitation. In addition, a purposive sampling scheme allows for generalisations of findings to be made for this population [8]. The subject population consisted of people with Type 2 Diabetes Mellitus (T2DM) and PDN as indicated by scoring four or higher on a DN4 questionnaire (Appendix C in Supplementary data). To be eligible for this study the participants must have experienced PDN symptoms for at least six months to ensure that any changes were measurable [7]. Additional criteria excluded anyone with contra-indications to using TENS on their lower back for safety precautions. The research project was open to males and females of all ages and nationalities, however it was expected that the majority of recruits would be over 45 years old as many Australians over that age are at risk of developing T2DM through lifestyle factors [9].

Collins and associates recommend including a minimum of 21 participants per group in experimental research designs [8]. Despite a number of recruitment strategies being used, strict eligibility criteria meant that only six willing participants were invited to partake in this study.

2.2. Recruitment

In association with Charles Sturt University (CSU) Media Relations, potential participants were recruited through advertisements in local newspapers and television news stations. In addition, posters were displayed in local physiotherapy practices, medical practices and at the Orange Health Service. Local broadcasting of information was appropriate as the study required individuals to attend a series of appointments in Orange. Potential participants were required to register their interest in volunteering for the study and after screening for inclusion criteria, a total of six people were eligible for the study. Five of those went on to complete the whole process; while one participant dropped out after developing an unrelated medical condition.

3. Materials and methods

All participants were provided with a participant information sheet and were required to sign a consent form before commencing the study (Appendix A in Supplementary data). Participants were encouraged to ask questions and were made aware that they were permitted to withdraw from the study at any stage.

A subjective examination was carried out to collect data including age, gender, neurological symptoms, duration of diabetes, neuropathy duration and current medications. The most recent HbA1c scores were requested to gauge the participant's blood glucose level control over the last three months [10]. These assessment items were necessary as they were all included in similar research projects and would allow for a thorough analysis, as well as ensuring each participant met the inclusion criteria. Participants were requested to report any changes in medication during the experiment to allow us to account for any changes when analysing results, however no changes were reported. Volunteers were screened for PDN using a validated and reliable DN4 questionnaire. This sensitive and highly specific tool is shown to have high diagnostic accuracy for diabetic neuropathy [11].

TENS is a safe treatment with minimal risk of adverse effects [6]. To maximise the safety of this trial, volunteers with contra-indications to TENS treatments were excluded from the study. Participants were monitored for any adverse effects during and after the first treatment. They were also educated on how to monitor adverse effects at home and what actions to take if this occurred.

TENS units have various settings including frequency, pulse width and duration [12]. The two TENS modes selected for the study were based on similar research studies and represent TENS frequencies commonly used in clinical practice. 'Traditional TENS' consists of a high frequency (110 Hz) with a wide pulse duration (200 μs) [13]. This mode was compared to 'Acupuncture-like TENS' which consists of a low frequency (4 Hz) with a wide pulse duration (200 μs) [13].

A cross over design was used because patients act as their own controls, removing the need for a control group and eliminating subject differences [14]. This was desirable as TENS has already been shown to have a statistically significant analgesic effect on DPN [7]. This method allowed the study to investigate if one mode of TENS is more effective than another while addressing the issue of a limited number of possible participants [14]. This also ensured that a control group was not deprived of treatment for the duration of the experiment. All participants received both modes of TENS, however a random numbers table was used to randomly allocate each person to their initial treatment group. To blind the participants as much as possible, they were told that they will receive two types of TENS stimulation over the duration of the experiment, without specifying which mode they are receiving or which mode is expected to be more effective. In this experiment each treatment was applied 30 min daily for ten days with a seven day washout period. A ten day treatment duration was chosen due to a combination of time limitations and existing literature showing statistical significance after ten days [7]. The washout period of seven days was selected to minimise the chance of having a residual effect after the first treatment [7]. The participants each borrowed a TENS machine from the university to use for the duration of the study.

Based on the statistically significant finding by Bulut and associates, the TENS electrodes were placed 3 cm laterally to the vertebral column at lumbosacral (low back) region [7]. Diabetic neuropathy involves the damage of peripheral nerves, hence the theory behind the electrode placement was to deliver stimulus through non-pathological nerves that innervate the lower extremities [15]. In addition, this population commonly has

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impaired skin integrity and sensation on their legs and feet which present safety risks when applying TENS over the affected area [16].

On the first day of each treatment group, the participants were individually instructed on how to place the electrodes on their lower back and a marker pen was used to ensure that they placed the electrodes consistently in the same position each day. A demonstration, along with a diagram and written instructions on how to use the machine were provided to each participant.

The MPQ (Appendix D in Supplementary data) was chosen as the quantitative outcome measure for this study as it is sufficiently sensitive to detect changes from different pain relief methods [17]. This reliable tool allowed valid conclusions to be drawn from this research project as the study aimed to assess participant's perceived pain, and this measure did not place a large demand on participant's time as it only takes between five and ten minutes to complete. Instructions were read out to the participants each time they filled out the questionnaire to minimise the risk of obtaining incorrect and unreliable data [17]. A MPQ was completed before and after each treatment period, in order to record a baseline score and an outcome measurement. The change in scores were analysed, allowing for potential carry-over effects from the initial treatment to be taken into account.

A 10 g monofilament test was conducted on the feet of each participant before and after each TENS treatment to determine if there was an impact on foot sensation. The use of the monofilament test in this study was justified by the efficacy of the test in a number of trials [18]. Moreover, it is used worldwide by podiatrists to screen for sensory loss in patients with diabetes.

In addition to these outcome measures, a number of questions were asked at the end of the trial to get an understanding of the participant's perceptions of the TENS treatments (Appendix E in Supplementary data). The 'Patient's Global Impression of Change' questionnaire (PGIC) was also included to gauge the participants overall effectiveness of the treatment. These outcome measures were not included in the previous studies on PDN and TENS, but were included in this experiment in order to provide more outcome measures to analyse and to address the research question thoroughly by getting an understanding of the participant's perceptions of the different TENS treatments and the effect it may have on their pain and other symptoms.

Confidentiality was maintained by assigning a unique code to each participant during data collection to avoid recording their names on the assessment sheets. In addition, all participants remained anonymous in the dissertation. The electronic data was safely stored using password protection and the assessment forms are protected in a secure filing cabinet. A summary of the findings was sent to participants who nominated to be informed of the study results.

It is worth mentioning here that a pilot study was carried out on four people to streamline the methodology and ensure maximum compliance potential for the actual study. During this time the TENS equipment was tested to ensure they were all in safe working condition.

3.1. Data analysis

The MPQ measures were used for data analysis. This consisted of the number of words chosen (NWC), present pain intensity (PPI) and a pain rating index (PRI) which is calculated using values assigned to symptom descriptors. Other measures that were analysed include the 10 g monofilament test, PGIC and participant's responses to questions concerning the patient's impression of TENS as a treatment for PDN.

The Wilcoxon signed rank test was utilised to compare the non-parametric repeated measures data. Whilst it would have been more ideal to use the parametric equivalent, (paired samples *t*-test) it would not have been appropriate as the MPQ data was ordinal [19]. The Wilcoxon signed rank test allowed a comparison of the mean change in MPQ score after each of the TENS treatments [19]. This test was also used to determine if the effect sizes were significant for either of the TENS treatments.

A paired-samples *t*-test was conducted on the change in Monofilament test scores for both treatments, as this data is parametric. This analysis allowed the researchers to evaluate the impact of interventions on foot sensation.

Statistical significance was set at $p < 0.05$ [19]. SPSS version 20.0 was utilised for data analysis, as it freely available for use by CSU research students. The data from five participants was analysed, as the sixth participant had to drop out due to an unrelated medical condition.

4. Results

The mean age of participants was 71.6 years old. The average duration of T2DM was 12.2 years. Table 1 presents other participant demographic characteristics.

Hypothesis testing was carried out using Wilcoxon signed rank tests, which showed that there was no statistically significant difference in between-group analysis of the changes in NWC ($z = 0.000$, $p = 1.00$) and PRI score ($z = 0.000$, $p = 1.00$) from baseline for each of the treatments.

A Wilcoxon Signed Rank test also indicated that there was no statistically significant difference in pre and post MPQ (NWC and PRI) test scores for Acupuncture-like TENS ($p = 0.102$, 0.104, respectively) or traditional TENS ($p = 0.465$, 0.225, respectively), as presented in Table 2. Despite not achieving statistical significance, effect sizes for the change in PRI scores of each of the treatment groups were calculated using a Wilcoxon signed rank test. Acupuncture-like TENS had a large effect size ($z = -1.625$, $r = 0.514$), whilst Traditional TENS has a medium effect size ($z = -1.214$, $r = 0.384$).

The paired-samples *t*-test on the 10 g monofilament test scores showed no statistically significant difference between Traditional TENS ($M = -1.8$, $SD = 1.789$) and Acupuncture-like TENS treatments ($M = -0.60$, $SD = 2.608$), $t(4) = -0.82$, $p > 0.10$ (two tailed).

A trend was observed in the participant responses to the questions at the end of the study. 60% of the participants ($n = 3$) selected Acupuncture-like TENS as being more effective at relieving their diabetic neuropathy pain than traditional TENS. Only one person perceived Traditional TENS as the more effective treatment and the other participant did not find a difference between treatment groups as their pain and symptoms did not return to baseline after the first treatment. 100% of participants reported that they experienced pain relief during the TENS treatment, and all but one participant felt continued pain relief for at least 1–2 h after removing the electrodes. 100% of participants would recommend TENS to other people suffering with PDN. No adverse effects reported during the study.

Table 1
Baseline Demographic Characteristics of the participants.

Characteristic	Score	Range
Age (years)	71.6 ± 12.12	61–88
Sex: (Female/Male)	2/3	–
Duration of diabetes (years)	12.2 ± 8.29	5 to 25
Duration of neuropathy (years)	4.93 ± 3.35	0.66 (8 months)–10
HBA1c%	7.43 ± 3.04	4.8–11.8

Note: Parameters are listed using the mean ± standard deviation.

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Table 2
McGill Pain Questionnaire (MPQ) and 10 g Monofilament Test scores before and after treatment.

Outcome Measures	Traditional TENS			Acupuncture-Like TENS		
	Baseline Mean (SD)	Post Treatment Mean (SD)	Change P. Value	Baseline Mean (SD)	Post Treatment Mean (SD)	Change P. Value
MPQ NWC	13.2 (4.55)	12.2 (5.93)	0.465	11.2 (6.54)	9.0 (6.21)	0.102
MPQ PRI	33.6 (12.28)	27.6 (18.06)	0.225	25.8 (12.97)	21.00 (16.54)	0.104
MPQ PPI	1.8 (1.30)	1.4 (0.89)	0.414	1.2 (0.84)	1.2 (0.45)	1.00
Monofilament Test	16.4 (6.07)	18.2 (6.62)	0.109	18.2 (2.05)	17.6 (3.78)	0.655

Note: MPQ NWC = McGill Pain Questionnaire: Number of words chosen, MPQ PRI = McGill Pain Questionnaire: Pain Rating Index, MPQ PPI = McGill Pain Questionnaire: Present Pain Intensity, TENS = Transcutaneous Electrical Nerve Stimulation.

5. Discussion

This study aimed to compare the analgesic effects of two different modes of TENS for people with PDN, as there is currently a knowledge gap when it comes to selecting optimal TENS parameters for this population group. The study utilised a cross-over design to compare the effects on patient's perceived pain after using Acupuncture-like and Traditional TENS in people with PDN as measured using the MPQ and other outcome measures.

The trends showed that Acupuncture-like TENS may be more effective than Traditional TENS for people with PDN, however statistical significance was not achieved likely due to the small sample size. The change in treatment scores is more promising for Acupuncture-like TENS and the effect size calculation was also larger for this treatment. Whilst effect sizes are not meaningful without a significant P value, these results suggest that TENS parameters do influence the treatment effectiveness for PDN. The trends, along with effect size differences between treatments, indicates the need for the study to be repeated on a larger scale.

Two participants initially received full scores in the 10 g monofilament test; hence no changes were evident after the treatments. The remaining participant's monofilament scores fluctuated between the four tests, and did not appear to correlate with treatments. For example, one participant scored between 16 and 18 (out of a possible 20) on each test, except after 'treatment A' when they scored 13. The patient did not wear socks on this cold day in attempt to make testing easier, hence the results can potentially be explained by external factors such as temperature. A statistical analysis on the monofilament scores was conducted, however the results did not add any value to this experiment, and we suggest a 10 g monofilament test does not need to be included in future studies similar to this one, unless participants have a more severe level of neuropathy.

This study attempted to build on previous research that concluded TENS was effective in this population of patients [6]. These results indicate to health professionals that while there is no statistical significant evidence to justify the choice of one mode of TENS over another when treating PDN, the effect sizes and trends suggest that it may be better to trial Acupuncture-like TENS as the first option. These results could also be included in practice guidelines for the management of PDN, in the absence of results from a larger, more conclusive study. This study was worthwhile doing to encourage future research on this topic but also to inform health professionals that the current trial and error approach used when prescribing TENS as a treatment is still the most appropriate action.

The present pain intensity (PPI) component of the MPQ added little value to this study. People with PDN usually experience greater pain and symptoms during the night, yet the questionnaire was conducted during the day. This assessment item specifically asks participants to score their current pain levels, hence the scale potentially failed to accurately reflect the treatment outcome. To improve the research method, future studies should include questions about perceived changes in night pain or overall level of pain rather than focussing only on present pain. Also, future researchers may prefer to use a 10 point visual analogue scale rather than the 5 point PPI scale, as it may be more sensitive to change. Whilst the MPQ is sufficiently sensitive to detect changes from different pain relief methods, it is important to consider the specific symptoms of the sample population, to ensure it will provide relevant treatment outcomes [17].

The participant with the lowest HbA1c level, 4.8%, reported less severe symptoms on the MPQ compared to the other participants and interestingly experienced major symptom relief after using Traditional TENS, the first treatment. The majority of their neuropathy symptoms were alleviated after ten days, and symptoms did not return to their baseline level even after the seven day washout period. After using Acupuncture-like TENS for a further ten days, the only pain this participant reported was dull knee arthritis pain. Whilst this result makes it difficult to effectively compare the two TENS modes, the results may be promising for other people with mild PDN. Whilst it is unknown why this participant experienced such great results from the TENS, it can potentially be explained by the severity of his neuropathy. There is a correlation between HbA1c and nerve excitability and this may suggest that mild neuropathies, with less nerve damage, are likely to respond better to treatment than those with a more severe neuropathy [20].

In comparison, the participant with the highest HbA1c level, 11.8%, did not experience any significant relief from either of the TENS treatments. This can potentially be explained by having an insufficient level of stimulus from the TENS unit or perhaps the treatment duration was too short. A more likely explanation is that severe PDN involves reduced nerve excitability and axonal loss, reducing the effectiveness of the TENS intervention. This theory links with the other case previously mentioned, where the participant had a mild version of PDN and experienced far more effective results from the TENS treatments.

The two cases mentioned above suggest that the severity of PDN impacts on the treatment outcomes, hence it would be interesting to see a comparison of TENS treatment on people with various levels of PDN severity. This knowledge could further assist health practitioners when they are deciding if TENS is likely to be effective for patients with PDN, depending on the severity level of their patient's neuropathy. Peripheral neuropathy can be classified into three stages of severity, as explained in Table 3. All participants in this current study are either classified as a level 2 or 2a stage of peripheral neuropathy, however ankle dorsiflexion strength testing should have been conducted to see if any of the participants could be classified as level 2b [21]. Future researchers should be

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Table 3
Staging the severity of Diabetic Neuropathy.

Stage	Criteria
Stage 1	Asymptomatic neuropathy
Stage 1a	No symptoms or signs but nerve conduction velocity abnormalities or autonomic test abnormalities
Stage 1b	1a criteria + neurological examination abnormality. Vibration detection threshold abnormality
Stage 2	Symptomatic neuropathy
Stage 2a	Symptoms, signs and test abnormalities
Stage 2b	2a criteria + significant weakness of ankle dorsiflexion
Stage 3	Disabling polyneuropathy

Note: Tests include nerve conduction, quantitative sensory and quantitative autonomic testing.Adapted from Handbook of Diabetes (p. 131), by R. Bilous and R. Donnelly, 2010, Hoboken: Wiley. Copyright (2010) by Wiley.

encouraged to incorporate this classification system into their study to distinguish between various levels of severity, which would allow them to evaluate the impact of severity on the treatment effectiveness.

This study highlights the importance of screening for co-morbidities and co-existing musculoskeletal conditions in participants, in order to ensure results are specific to PDN. It was difficult for the participant with dull knee arthritic pain to accurately convey a perceived change in treatment score. He stated that he had received complete relief from his PDN symptoms, although interestingly he only gave a score of 3 on the Patient's Global Impression of Change (PGIC) questionnaire, indicating that he believed the change in pain was only "a little better". This was surprising considering he reported zero pain on the PPI scale and only chose three words to describe his arthritic pain. Excluding other co-morbidities is a consideration that needs to be made by future researchers, however this may drastically limit sample size potential due to the nature of the 21st century healthcare, in which 46.5% of Australian adults aged 45–64 have two or more comorbidities and increases to 83.2% of people aged over 75 years [22]. If future researchers are unable to exclude these co-morbidities, it would still be beneficial to record any conditions to look at during data analysis, and to clearly explain to the participants which symptoms you are focussing on. This issue may also suggest that PGIC instructions needs to be explained more clearly in order to collect accurate data.

Participants all selected similar pain descriptors in the MPQ. The most commonly reported symptoms, in order, were tingling, throbbing, sharp, burning, cramping, aching and numb. These correlate with commonly reported symptoms of PDN in literature [22]. Using this knowledge of commonly reported PDN symptoms, researchers in future studies may choose to design their own questionnaire to make it very specific to this condition.

Participant compliance during the study was very high. One participant reported being unable to use it one night as they couldn't get the unit to work due to incorrectly inserting the lead, and then they also missed a day of treatment in round 2. All other participants reported using the TENS treatment daily as instructed. One of the six participants had to drop out of the study as they developed shingles, which impaired their skin condition over the desired electrode location. 100% of participants in this study said they experienced pain and/or symptom relief from TENS. Strong participant compliance in this study suggests that TENS is a worthwhile non-pharmaceutical treatment option for practitioners to trial with patients suffering with PDN.

The exclusion criteria and the rural location of the study are the most likely reasons for the small sample size. The main reasons people were excluded from the study were for having DPN less than six months or for having Type 1 diabetes. Many expressions of interest were received from people who did not live locally, and it was not practical for them to attend four appointments in Orange. Some of these people were willing to travel if there was some form of reimbursement for their travel, however there were no funds available for this purpose unfortunately. Other people were hoping they could participate by distance; but this was not possible due to the face-to-face requirements of assessment and treatment procedures. Perhaps, if this study was conducted in a metropolitan area it may have attracted more participants. Due to the high prevalence of Type 2 Diabetes in rural areas it is expected that there would be a large number of people in and around Orange NSW with this condition, however it is unknown why many chose not to participate in this study. This limitation means that the results can only be seen as trends, even though statistical analysis has been performed. When commencing this research it was understood that the small sample size would make it unlikely that statistically significant results would be achieved, however it was still worth conducting as a pilot study see if any clinically significant results were found and to direct further research in this field. The effect sizes and clinical effects achieved warrant a larger scale replication of the study, and many suggestions have been made in order to make future studies more valuable and increase their chances of achieving statistical significance.

The main limitations of this study include time and funding. The study had to be conducted, analysed and written up in less than 12 months in order to satisfy subject requirements. This honours project had no financial backing, however the study utilised existing TENS equipment from the university. Because of both of these limitations, convenience sampling was the most appropriate sampling method however it resulted in a small sample size. If time permitted a longer treatment duration could have been used or the study could have been conducted in other rural towns in NSW to increase the sample size. Despite the limitations, trends have been identified, challenges have been encountered and suggestions have been made to assist future research in this topic to be more appropriate. So, whilst this study did not have statistically significant results, it discovered certain trends in treatment results that may guide clinical treatment and can provide important information to other researchers in this field.

This study compared the patient's perceptions of pain before and after using Traditional TENS and Acupuncture-like TENS settings, however it did not compare these to Burst mode TENS. A larger study with more time, funds and participants could compare the three main TENS treatment settings. Electrode placement is another aspect of this treatment has not yet been explored in research and it would be beneficial to see if the location of the electrode placement has an impact on the treatment effectiveness. An example of this would be to compare the application of the electrodes to the lumbosacral area of the back to placement directly over painful areas of the lower leg. Caution needs to be taken with this as impaired skin sensation is risk when using a TENS intervention.

This study has identified many suggestions for future research related to the topic of using TENS as a treatment for PDN. The most important potential study would be conducting this same study on a larger scale, and also comparing Burst Mode of TENS to the two modes used in this study. Additional outcome measures that could

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be addressed in similar studies in the future should include night pain reporting in order to make the results more appropriate for people with PDN. Despite the small sample size, this study has tested a protocol and provided valuable information that can assist future research.

Conflict of interest

This study had no commercial or similar relationships to products or companies mentioned in or related to the subject matter of the article being submitted.

Ethics approval

This study was granted ethics approval on 12th November 2014 by the Charles Sturt University Human Research Ethics Committee (HREC). The ethics project number is 2014/198. Ethics documentation has been included in Appendix A Supplementary data.

Paid editorial assistance

No paid editorial assistance was obtained by the candidate during the conduct of the research and the production of examinable work.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.dsx.2016.08.016.

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