Implementation fidelity of self-administered Transcutaneous Electrical Nerve Stimulation (TENS) in patients with chronic back pain: An observational study.

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ABSTRACT

Objectives: The efficacy of transcutaneous electrical nerve stimulation (TENS) for pain relief has not been reliably established. Inconclusive findings could be due to inadequate TENS delivery and inappropriate outcome assessment. Electronic monitoring devices were used to determine patient compliance with a TENS intervention and outcome assessment protocol, to record pain scores before, during and after TENS and measure electrical output settings.

Methods: Patients with chronic back pain consented to use TENS daily for two weeks and to report pain scores before, during and after 1-hour treatments. A ≥30% reduction in pain scores was used to classify participants as TENS-responders. Electronic monitoring devices 'TLOG' and 'TSCORE' recorded time and duration of TENS-use, electrical settings and pain scores.

Results: Forty-two patients consented to participate. 1/35 (3%) patients adhered completely to the TENS-use and pain score reporting protocol. 14/33 (42%) were TENS responders according to electronic pain score data. Analgesia onset occurred within 30-60 minutes for 13/14 (93%) responders. It was not possible to correlate TENS amplitude, frequency or pulse width measurements with therapeutic response.

Discussion: Findings from TENS research studies depend on the timing of outcome assessment; pain should be recorded during stimulation. TENS device sophistication might be an issue and parameter restriction should be considered. Careful protocol design is required to improve adherence and monitoring is necessary to evaluate the validity of findings. This observational study provides objective evidence to support concerns about poor implementation fidelity in TENS research.

Key Words: Transcutaneous electrical nerve stimulation; pain measurement; electronic data capture; reproducibility; data collection

INTRODUCTION

Transcutaneous electrical nerve stimulation (TENS) is a widely-used, patient-directed analgesic technique but randomised controlled trials (RCTs) have been inconclusive (1). This could be due to poor 'implementation fidelity', the extent to which interventions are delivered and assessed as intended (2). Inappropriate timing of outcome assessments, inadequate patient compliance and suboptimal dosing could reduce reported TENS efficacy (3).

TENS analgesia has rapid onset and offset (4, 5, 6, 7) suggesting that pain should be reported *during* stimulation. However, only 4/41 RCTs (8, 9, 10, 11) in Cochrane systematic reviews (12, 13, 14) measure pain *during* TENS. Retrospective weekly pain report has been shown to be higher than averaged daily pain scores, emphasising the need for real-time reporting (15). Retrospective recall can also overestimate TENS-use (6). TENS dosing depends on stimulation intensity, frequency and duration. Strong, comfortable paraesthesia gives clinical benefit (3) and increases mechanical pain threshold in healthy participants, but stimulation at the sensory threshold does not (16). Implementation fidelity also depends on outcome assessment, but paper pain diaries can be unreliable (17) and electronic diaries require competent users, expensive hardware and software.

Two electronic data-logging devices (Figure 1) have been developed: 'TLOG' records time, date and duration of TENS treatments and stimulus frequency, pulse duration and amplitude. It attaches to a commercially-available TENS machine and its use requires no action by patients. 'TSCORE' is a 0-10 numerical rating scale (NRS) comprising 11 buttons spaced 1cm apart in a plastic enclosure; pressing a button records pain score, time and date. TSCORE is a simple-to-use, single-function device for instant use; no computer skills are required and battery life is several months. The devices' internal clocks allow pain report to be time-linked to TENS-use; data are stored for download to computer. TLOG and TSCORE data have been shown to be equivalent to paper diary data (18). Electronic monitoring has been used to record treatment duration, pain scores and the intensity of TENS with frequency and pulse-duration fixed (19). However pain was not reported during stimulation. The temporal relationship between TENS-use and pain

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report has been investigated using retrospective questionnaires (6) and single researcher-administered treatments (4, 5). We are not aware of any studies using electronic devices to record pain scores before, during and after TENS and monitor output settings and compliance when users are asked to titrate TENS to provide strong comfortable paraesthesia. We report an observational study using devices to monitor compliance with TENS intervention and outcome assessment protocols, pain intensity before, during and after TENS and electrical parameters selected by patients.

MATERIALS AND METHODS

Participants

Participants (≥ 18 years) were outpatients with chronic low back pain (≥3 months' duration attending physiotherapy or chronic pain clinics at the University Hospitals of Leicester (UHL) NHS Trust. Patients were pre-screened by clinic staff for non-specific low back pain and a willingness to trial TENS therapy in addition to their existing medication. No threshold for initial pain intensity was set because this observational work was a secondary part of a study designed primarily to test equivalence of paper and electronic data collection (18). Participants were of any ethnic origin but fluent in English. Those with illiteracy, learning difficulties or contraindications for use of TENS machines, as described in guidelines for the clinical use of electro-physical agents (20), were excluded. Invitation letters and patient information sheets were given to all eligible patients by clinic staff and interested patients were asked to return a reply slip to the research team. Invitation letters were distributed to patients until 42 patients had consented to participate. The study was approved by the Leicestershire, Northamptonshire and Rutland research ethics committee. Participants were reimbursed for travelling costs.

Sample size

Data for the current study were collected during a TLOG and TSCORE validation study (18), which used Bland Altman limits of agreement analysis, (21). Sample size was calculated using Bland and Altman's formula for determining limits of agreement between two measurement methods using a standard deviation of

1.28. Based on a difference of ±1 on the 0-10 pain intensity numerical rating scale indicating 'agreement' between paper and TSCORE data, the required sample size was n = 40.

Materials

1. Fourteen commercially-available CE-marked TENS machines ('COM-TENS': Apex Medical Corporation, Taiwan, ROC), each with a battery-powered TLOG device attached by Velcro fastening.

2. One pair of electrodes and spare 9 volt batteries for each participant.

3. Fourteen TSCORE pain scoring devices. Users press a button to record a pain score with time and date. A light confirms that the score has been logged.

All TLOG and TSCORE devices were designed and built at UHL NHS Trust. Before use, each device was tested and approved for use with UHL patients by the UHL Medical Physicist. The TENS machine with TLOG device attached, a pair of electrodes and the TSCORE pain scoring device are shown in Fig. 1.

Insert Fig. 1 (photo of TENS with TLOG attached and TSCORE)

Procedure

All procedures carried out during this study were in accordance with the ethical standards required by the Leicestershire, Northamptonshire and Rutland research ethics committee and with the Helsinki Declaration of 1975 (revised 1983). Patients who responded to the invitation letter were telephoned by a researcher who assessed suitability for the study and invited eligible patients to attend study visit 1. After giving written informed consent participants were given a study TENS machine with TLOG attached. They were given full verbal instructions and were shown how to use the TENS machine with one output channel and one pair of electrodes. Patients were asked to use TENS for one hour per day for two weeks and to record pain scores at prescribed time intervals before, during and after each one-hour TENS treatment.

Patients were expected to use TENS daily even if they were not experiencing pain; however informed consent ensured that patients could leave the study at any time without explanation.

Patients were shown how to adjust frequency, pulse duration and intensity settings on the TENS machine and were asked to do this at each treatment session in order to achieve pain relief and/or a comfortable TENS sensation. Emphasis was given to explaining how to achieve a strong but comfortable paraesthesia using the amplitude (intensity) setting. The range of pulse frequencies and pulse durations available to patients was 2-150Hz and 60-250 μs respectively. The amplitude dial was marked 0-8, with 80V the maximum voltage. A monophasic rectangular pulse waveform was delivered to patients via two 5x5cm square reusable electrodes placed on the lower back, either side of the spine. Only 1 channel (2 electrodes) of the TENS machine was used for treatment since TLOG only contained hardware for processing a single channel. It would normally be possible for patients to use two channels, with independent intensity control, to target chronic low back pain that might not be well localised. A lead with a pair of electrodes attached was directly wired to TLOG/TENS machine channel one, no lead was provided for the second channel. Patients could only use channel one and were shown how to adjust the corresponding intensity dial. The TENS machines had 'burst' and 'modulation' modes disabled for the study and users were restricted to using continuous mode only. To overcome sensory habituation (22), participants were told that if they felt that the stimulation sensation had decreased, they should increase the intensity setting, (23).

The TSCORE device was demonstrated and patients were given a device so that they could practise recording pain scores. They were asked to use it to report pain scores four times daily: (i) Just before starting a one-hour TENS treatment ('baseline'); (ii) 30 minutes after starting TENS ('TENS_30'); (iii) 60 minutes after starting TENS (i.e. at the end of the one-hour treatment) ('TENS_60'); (iv) 30 minutes after switching the TENS machine off ('post_TENS'). Patients were asked if they had understood what they were being asked to do and were given detailed written instructions reiterating the verbal instructions already given. They were given the researcher's telephone number and email address and were asked to contact the researcher if they had any queries. Participants were advised to continue their usual medication regime throughout the study. The researcher telephoned patients after one week to troubleshoot and to remind

patients of the need to adhere to the protocol. Approximately two weeks after the first visit patients returned their equipment and medication diaries. Data were retrieved from TSCORE and TLOG devices and they were cleared and tested for re-issue. The associated TENS machine output levels were verified using an oscilloscope and a 1KΩ resistor test load.

Statistical analysis

Statistical analyses were performed using PASW Statistics 18 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel 2007 (Microsoft Corporation, Redmond, WA, USA). Participant characteristics were reported using descriptive statistics. Compliance with TENS implementation and pain score reporting protocols was calculated and analysed using descriptive statistics.

Pain scores before, during and after TENS

For each individual, daily pain scores were averaged over the number of days for which data were available, to give mean pain scores for baseline, TENS_30, TENS_60 and post_TENS. The percentage changes in mean pain scores from baseline to the three post-baseline time points were calculated for each patient. A ≥30% reduction in mean pain scores from baseline classified a patient as a TENS 'responder' at that time point, based on the minimum clinically important difference needed to indicate response to treatment being defined as ≥30% (24). Patients who reported an increase in mean pain scores from baseline or a reduction in pain scores <30% were 'non-responders' at that time-point. Each patient's maximum percentage change in mean pain scores from baseline was determined by comparing changes in pain scores at the three post-baseline time points.

Electrical characteristics

TLOG records the frequency, amplitude and width of the TENS pulse. These output parameters are reported and discussed.

RESULTS

1. Participant characteristics and course through the study

Forty two patients with back pain of ≥ 3 months' duration consented to participate in the study. After consenting one patient was unable to understand how to use TENS and was excluded. The mean age of

participants (n=41) was 52 years (range 23 to 80; 24 females (59%)).   Attrition in participant numbers and

the course of all participants through the study is shown in Fig.2. Two patients did not administer any study

treatments: One person cited "lack of time" as the reason for not using TENS, while the other tried TENS

for a short period and reported that it made the pain worse.

Insert Fig. 2 (flow chart) here

2. Compliance with TENS implementation protocol

   Forty one participants were given a TENS machine with TLOG attached and asked to use it for one hour

per day for 13 or 14 days. Three TLOG devices failed to collect data due to faulty components;

consequently TENS-use data were available for 38 patients. The mean and SD of the duration of all study

treatments were calculated for each patient. Patients were considered to have adhered fully to the duration

of treatments protocol if the mean of their daily treatment durations was 60 ± 10 minutes with SD≤10

minutes. Table 1 shows compliance rates with the protocol for TENS usage pattern and daily duration of

TENS treatments that participants consented to adhere to.

Insert Table 1 here

3. Compliance with TSCORE pain score reporting protocol

   (i)   **Compliance with prescribed *number* of pain reports**

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Forty one participants were asked to use TSCORE to report pain at four prescribed time-points baseline, TENS_30, TENS_60 and post_TENS for 14 daily TENS treatments. One TSCORE device failed due to a technical problem. Forty participants had fully functioning TSCORE devices with which to report pain scores. Figure 3 shows the numbers of patients who reported pain scores at the four time points on ≥13 days, 7-12 days and ≤6 days.

Insert Fig. 3 (Number of patients reporting pain scores at any of four time points) here

(ii)   **Overall compliance with required *number* of pain reports at all prescribed time points**

The study protocol required 56 pain reports (4 time points x14 days) to be made using TSCORE. 14/40 (35%) participants made more than 80% of the required pain reports; 11/40 (28%) made 50-80% and 15/40 (38%) made less than half of the prescribed pain reports.

(iii)   **Compliance with prescribed *timing* of pain reports relative to TENS use**

Further analyses time-linking TENS-use and pain report required both TLOG and TSCORE data for each participant. 6/41 (15%) did not have both TLOG and TSCORE data: 3 had faulty TLOG devices (1 of these patients did not use TSCORE); 1 had a faulty TSCORE device and 2 did not use TENS or TSCORE. The remaining 35 participants had both TLOG and TSCORE data. Table 2 shows compliance rates with the protocol for the timing of pain reports that participants consented to adhere to.

Insert Table 2 here

4. Overall compliance with TENS implementation AND pain score reporting protocols

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1/35 (3%) patients adhered fully to the study protocol for TENS-use *and* pain score reporting. 7/35 (20%) had 'good' compliance in that they used TENS for 60±10 minutes for ≥ 13 days and reported pain at the prescribed times on all but 1-5 occasions. The remaining 27/35 (77%) adhered only partially to the study protocol, either using TENS on fewer days or for more or less than the prescribed treatment time, making fewer pain reports than required or reporting pain at times other than the prescribed time points.

5. Identification of TENS responders and non-responders from TSCORE data

The mean (SD) baseline pain score of TSCORE-users (N=35) before their first TENS treatment was 5.2 (2.2), (range 1-8). 2/35 participants reported baseline pain scores only, therefore changes in pain scores from 33 participants were used to classify them as TENS 'responders' or 'non-responders'. A ≥30% reduction in pain scores at any post-baseline time point defined 'response' to TENS. 14/33 (42%) participants were TENS responders of which 4/14(29%) complied with 1 hour/day for 13-14 day usage pattern. Half of these responders (7/14) reported analgesia onset within 30±10 minutes and for 13/14 (93%) it occurred within 60±10 minutes. 1/14 (7%) responders experienced pain relief post-TENS only. 9/13 participants who were responders during TENS, reported pain scores afterwards; all were responders at the post_TENS time point. 19/33 (58%) patients were classified as non-responders at all-time points, from their TSCORE data.

6. Medication use

Of the 33 participants who could be classified as TENS-responders or non-responders, 12 (36%) did not use analgesic medication during the study of which 6/12 were responders and 6/12 were non-responders. Medication diaries were not returned by 2(6%) of participants. The remaining 19/33 (58%) adhered to their usual medication regime. 6/19 (32%) patients taking medication for analgesia used only 1 type of drug while 13/19 (68%) used a combination of drugs. No patients altered their drug doses or frequency of use during the study.

7. TENS-use and electrical output parameters

Participants were asked to adjust electrical stimulation parameters to deliver a strong but comfortable paraesthesia. Of the 41 patients given TENS machines, 36 had data recorded by TLOG, which sampled the

electrical output signal every ten minutes. 13/36 (36%) patients selected only stimulus frequencies ≤100 Hz throughout the study and 20/36 (56%) used a wider range of frequencies including >100 Hz. In 3/36 (8%) data sets TLOG was not able to record any frequency data. Peak amplitude measurements were available for 33/36(92%) of TLOG datasets and ranged from 0 to 58V. There were problems associated with measuring the pulse duration of the TENS output waveform causing data recorded by TLOG to be unsuitable for further analyses; these issues are discussed in the next section. Descriptive statistics regarding pain intensity and electrical characteristics were calculated. (See Table 3 and Fig.4, Supplemental Digital Content 1, which indicates the relationship between mean summed pain intensity scores and mean TENS voltage for responders and non- responders.)

DISCUSSION

The use of electronic data monitoring in this observational study showed that patients did not adhere to the study protocol and self-administered TENS treatment protocol. Bennett et al (3) expressed concerns regarding the extent to which TENS interventions are delivered and assessed as intended and this study provides evidence that there are grounds for such concerns. Johnson and Bjordal (25) identify TENS treatments that are too short, too infrequent or with inadequate technique, as causes of low fidelity leading to inconclusive research findings. Our study shows that the use of electronic data monitoring is essential to validate the findings of studies where TENS is self-administered at home.

A surprising finding was the poor compliance with the study protocol given that patients were aware that their TENS-use and pain reporting was being monitored. Only one participant adhered fully to instructions for both TENS machine-use and pain score reporting. One possible explanation for poor compliance is that the requirement to use TENS daily for 1 hour for 2 weeks and to report 4 pain scores daily at specified time intervals was too demanding. However, if this is the case, it raises concerns about the fidelity of more

demanding studies such as one requiring chronic pain patients to self-administer TENS for multiple sessions providing 168 hours of stimulation over 4 weeks (26).

Failure to adhere to the prescribed daily usage pattern for TENS may have resulted from poor motivation in some patients who had initial pain scores as low as 1. These low scores could have been attributable to recently administered analgesia. Many clinical trials use a baseline pain score ≥4 as an eligibility criterion and failure to set such an inclusion criterion is a limitation of our study. However, limiting baseline scores at study enrolment might not appropriately reflect the variability of pain intensity prior to each TENS treatment. This demonstrates the need for robust recording methods to record pain intensity before, during and after TENS. This requirement could be applied to include studies that use other interventions.

This observational work was a secondary part of a study designed primarily to test equivalence of paper and electronic data collection (18); consequently no threshold for initial pain intensity was set and no baseline pain history taken. Similarly we did not look at quality of life, pain with respect to activity and movement, behavioural or psychological measures.

The high attrition rate shown in Figure 2 was not anticipated in the sample size calculation and could be addressed in future work by utilising the established 20% attrition rate used in clinical trials.

Furthermore it was not possible to derive a meaningful correlation between treatment compliance and pain response due to small sample size and poor protocol compliance for use of TSCORE and TLOG. This is an important measurement to be considered in future research utilising time linked electronic measurement devices.

Another explanation for under-use of TENS was that some patients did not experience pain relief and may have lacked motivation to continue using it. In contrast, the majority of cases of non-compliance with the prescribed 1-hour duration of TENS treatments were due to patients using TENS for longer than the specified time. Some patients said that when TENS was relieving their pain they chose not switch the machine off after an hour while others reported that they often forgot to switch TENS off. The latter

situation more likely reflects clinical practice. An alarm or built-in timer to stop stimulation could overcome this problem for research studies demanding that TENS is used for prescribed periods of time. In clinical practice there is debate regarding alarm use since some commentators believe that TENS should be used in prescribed regimens whereas others do not (25).

Overall compliance in using TSCORE to make the prescribed number of pain reports was rather poor with 37% of participants reporting fewer than half the required number of pain scores. The most likely explanation for this is that participants forgot to use TSCORE at the prescribed times and this was confirmed by patient report. A possible explanation for poor compliance with the protocol was that initial training in TENS-use and pain reporting was insufficient. However at the first study visit, TENS-use, electrode placement and TSCORE were demonstrated and patients had the opportunity to practise using the equipment before taking it home. Full verbal and written instructions and contact details were given and patients were asked if they understood what they were being asked to do. The provision of written and verbal instructions and a telephone contact is common to other studies testing the efficacy of TENS for chronic pain (27, 19, 28, 29).   In some of these studies (27, 29) patients used paper diaries to record TENS-use and these data were used as evidence of high compliance with the trial protocols. However Stone et al. (17) demonstrated that paper diary data is unreliable as there is no record of time of report. In the study by Lewis et al., (19), patients were required to use TENS for 30-60 minutes ≥3 times daily for 3 successive 3-week phases. Electronic data monitoring was used and compliance with the pain score reporting protocol was found to be 88%. Such high compliance might have resulted from an audible alarm prompting pain reporting 4 times daily. These findings suggest that the implementation fidelity of future TENS research could be improved by using reminders to help participants adhere to TENS-use and pain reporting protocols. The issue of training is an important one and there is an absence of literature relating to the adequacy of training in TENS-use and its association with compliance.

The novel and innovative aspect of this study was the use of electronic data logging devices to time-link pain report to TENS-use and allow participants to be classified as TENS-responders or non-responders. Data monitoring in the current study showed a ≥30% reduction in pain scores within 30-60 minutes of starting TENS in 86% of responders, which is in good agreement with previous studies investigating analgesia onset (5, 7). Using a ≥30% reduction in mean pain scores from baseline to any prescribed pain-reporting time point to define response, 42% of participants were TENS-responders. However, this outcome should be interpreted with the proviso that more than three quarters of participants adhered only partially to the study protocol, the use of data monitoring devices prove the 42% responder finding is not robust. It is precisely this information that has been missing from previous TENS research. The use of data monitoring will allow implementation fidelity of future studies to be assessed and findings to be weighted accordingly. In interpreting the TENS response findings the use of only one TENS channel could have reduced response rates compared with the use of two channels. In addition, coverage of the TENS sensation over the back might not have been maximal or optimised and this factor is a limitation of our study.

A further research application for TLOG and TSCORE is the facilitation of enriched enrolment randomised withdrawal (EERW) designs. Conventional RCTs are vulnerable to Type II errors in failing to show analgesic efficacy where it actually exists because RCTs report mean outcomes, averaging genuine benefit derived by responders with absence of benefit in non-responders. This is not representative of the true situation because few patients have an 'average' response to analgesia (30); consequently there is a move towards EERW designs (31, 32, 33, 34). These are 2-stage designs where treatment-responders are identified and selected in stage 1. Only those responding to treatment in stage 1 are randomised to receive active intervention or placebo in stage 2. The use of data monitoring devices provides objective evidence allowing TENS-responders to be identified and compliance with the protocol to be assessed. We are not aware of any clinical TENS trials using EERW, but its use would allow TENS efficacy to be evaluated with greater assay sensitivity. The use of TENS data monitoring devices also has clinical application in screening

patients to identify those deriving clinically important benefit from TENS and those for whom assistance with implementation has potential to increase benefit.

In this study three TLOG devices failed due to faulty components supplied by the manufacturer and one TSCORE device failed due to a design problem. These problems were rectified and did not recur. The detection of TENS electrical output by TLOG was highly robust and allowed detailed compliance data to be recorded irrespective of patient applied waveform characteristics. Where patients selected non-therapeutic amplitude settings of less than one on the TENS dial (i.e. machine just turned on) the TLOG algorithm was configured to record detailed timing of treatment session but not amplitude, frequency and pulse duration settings. Possible reasons for low amplitude measurement and selection are: fear of electrical currents, dislike of paraesthesia, poor understanding of how to use TENS, or TENS worsening the pain but patient still trying to adhere to the protocol to please the investigator. Other less likely reasons might include very low patient impedance or electrode shorting.

It was found that only 4/14 responders used TENS on 13 or 14 days, as required by the TENS-use protocol and so it was not possible to correlate TENS amplitude, frequency or pulse width measurements with therapeutic response for such a small sample size. Two of these responders had no pain relief medication and two were taking an analgesic. It should be noted that medication diaries were kept to monitor pharmaceutical treatment and this could have influenced patient views regarding the value of the TENS intervention.

All patients received continuous mode stimulation so that numerical processing requirements and power consumption for TLOG could be minimised. Further study would be required to determine if this restriction influences compliance and pain outcomes.

TENS applied voltage waveform to *in-vivo* human skin exhibits a non-linear relationship with stimulation current (35), resulting in asymmetrical distortion of the applied rectangular voltage waveform. This led to inaccuracies in pulse duration measurement and hence these data were not analysed. For the TENS machines used, the rise and fall times of the voltage waveform were extended when applied to patients. TLOG used the leading edge and falling edge from the base of the assumed rectangular voltage waveform to calculate duration. Recordings indicated that a large proportion of pulse duration measurements exceeded the 250uS eight bit measurement capability of TLOG. This resulted in a discrepancy between the TENS dial markings and the measured TLOG values. TLOG recorded the peak voltage of the rectangular pulse. This method was chosen so that "TENS switch on" and "TENS switch off" events could be robustly detected irrespective of patient electrode connectivity and impedance issues associated with self-administered field use. It also simplified device design and allowed for increased battery life. Calculation of TENS current is dependent on knowing electrode and patient impedance but these were unknown and can vary widely during treatment. A revised model of TLOG now incorporates additional circuitry for the measurement of current waveform characteristics for use in future work.

Temporal recording of TENS parameters and electronic pain scores has not been widely adopted by manufacturers since it provides no immediate clinical benefit and increases the cost of treatment equipment. However, more expensive equipment can be justified for research purposes where TENS treatment can be studied and optimised for future patient benefit.

TENS devices, with three adjustable parameters could be too sophisticated for some patients which might influence willingness to use the devices. Device simplification could be addressed by restricting frequency (low/high) and pulse duration parameters. Temporal recording of pain scores and TENS machine output monitoring could be used in clinical trials to optimise and validate applied restrictions in addition to providing reliable adherence data.

This observational work suggests that study findings are potentially unreliable when interventions are self-administered in unsupervised settings without adequate monitoring. However, further work might be required to dichotomise TENS therapy into supervised and unsupervised applications to determine if there is a significant difference in outcomes and patient fidelity. The impact of this study is broader than TENS research; treatment fidelity is important in all pharmacological and non-pharmacological trials, which emphasises the need for implementation-monitoring.

Bjordal (36) calls for urgent action to address the problem of low fidelity in studies assessing the efficacy of TENS and other physical interventions for pain relief. The use of TLOG and TSCORE together has allowed pain report to be time-linked to TENS-use and compliance with the study protocol to be determined. It has shown pain relief to occur during TENS, highlighting the importance of assessing outcome during stimulation. A revised version of TLOG could monitor intensity settings selected by TENS-users, thus providing an indication of dosing. This innovative approach provides an opportunity for a consensus to be reached on the standards required for high fidelity TENS research.

REFERENCES

1. Johnson MI, Walsh DM. Continued uncertainty of TENS' effectiveness for pain relief. *Nat Rev Rheumatol.* 2010*;* **6**, 314-316.

2. Carroll C, Patterson M, Wood S, et al. Conceptual framework for implementation fidelity. *Implement Sci.* 2007*;* 2, 40.

3. Bennett MI, Hughes N, Johnson MI. Methodological quality in randomised controlled trials of transcutaneous electric nerve stimulation for pain: Low fidelity may explain negative findings. *Pain.* 2011; **152**, 1226-1232.

4. Andersonn SA, Hansson G, Holmgren E, et al. Evaluation of the pain suppressive effect of different frequencies of peripheral electrical stimulation in chronic pain conditions. *ActaOrthop Scand.* 1976*;* **47**, 149-157.

5. Hansson P, Ekblom A. Transcutaneous electrical nerve stimulation (TENS) as compared to placebo TENS for the relief of acute oro-facial pain. *Pain.* 1983; **15**, 157–165.

6. Johnson MI, Ashton CH, Thompson JW. An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS. *Pain.* 1991*;***44**, 221-229.

7. Bertalanffy A, Kober A, Bertalanffy et al. Transcutaneous electrical nerve stimulation reduces acute low back pain during emergency transport. *AcadEmerg Med.* 2005*;* **12**, 607-611.

8. Thorsteinsson G, Stonnington HH, Stillwell GK. The placebo effect of transcutaneous electrical stimulation. *Pain.* 1978*;***5**, 31-41.

9. Smith CR, Lewith GT, Machin D. TENS and osteo-arthritic pain. Preliminary study to establish a controlled method of assessing transcutaneous nerve stimulation as a treatment for the pain caused by osteo-arthritis of the knee.*Physiotherapy.* 1983; **69**, 266-268.

10. Cheing GL, Hui-Chan CW. Transcutaneous electrical nerve stimulation: nonparallel antinociceptive effects on chronic clinical pain and acute experimental pain. *Arch Phys Med Rehab.* 1999; **80**, 305-312.

11. Hruby G, Ames C, Chen C, et al. Assessment of efficacy of transcutaneous electrical nerve stimulation for pain management during office-based flexible cystoscopy. *Urology.* 2006*;***67**, 914-917.

12. Khadilkar A, Odebiyi DO, Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. *Cochrane Database System Rev.* 2008; **4**, CD003008.

13. Nnoaham KE, Kumbang J. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. *Cochrane Database System Rev.* 2008*;* **3**, CD003222.

14. Walsh DM, Howe TE, Johnson MI, et al. Transcutaneous electrical nerve stimulation for acute pain. *Cochrane Database System Rev.* 2009*;***2**:CD006142.

15. Giske L, Sandvik L, Røe C. Comparison of daily and weekly retrospective reported pain intensity in patients with localized and generalized musculoskeletal pain. *Eur J Pain.* 2010*;***14**, 959-965.

16. Aarskog R, Johnson MI, Demmink JH, et al. Is mechanical pain threshold after transcutaneous electrical nerve stimulation (TENS) increased locally and unilaterally? A randomized placebo-controlled trial in healthy subjects. *Physiother Res Int.*2007; **12**, 251–263.

17. Stone AA, Shiffman S, Schwartz JE, et al. Patient compliance with paper and electronic diaries. *Control Clin Trials.* 2003*;***24**, 182-199.

18. Pallett EJ., Rentowl P, Watson PJ. Validation of two novel electronic devices to time-link Transcutaneous Electrical Nerve Stimulation (TENS) and pain report in patients with chronic back pain. *Clin J Pain.* 2013; **29**, 35-42.

19. Lewis B, Lewis D, Cumming G. The comparative analgesic efficacy of transcutaneous electrical nerve stimulation and a non-steroidal anti–inflammatory drug for painful osteoarthritis. *Br J Rheumatol.* 1994*;***33**, 455–460.

20. Chartered Society of Physiotherapy. *Guidance for the clinical use of electrophysical agents*. London, UK: Chartered Society of Physiotherapy. 2006.

21. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet.* 1986*;***1**, 307-310.

22. Pantaleão MA, Laurino MF, Gallego NL, et al. Adjusting pulse amplitude during transcutaneous electrical nerve stimulation (TENS) application produces greater hypoalgesia. *J Pain.* 2011*;***12**, 581-590.

23. Spielholz NI, Nolan MF. Conventional TENS and the phenomena of accommodation, adaption, habituation and.electrode polarization. *J. ClinElectrophysiol* 1995;**7**,16-19.

24. Farrar JT, Young JPJ, LaMoreaux L. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain.* 2001; **94**, 149-158.

25. Johnson MI, BjordalJM. Transcutaneous electrical nerve stimulation for the management of painful conditions: focus on neuropathic pain. *Expert Rev Neurother.* 2011*;***11**, 735-753.

26. Köke AJ, Schouten JS, Lamerichs-Geelen MJ, et al. Pain reducing effect of three types of transcutaneous electrical nerve stimulation in patients with chronic pain: a randomized crossover trial. *Pain.* 2004*;***108**, 36-42.

27. Deyo RA, Walsh NE, Martin DC, et al. A controlled trial of transcutaneous electrical stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med.* 1990*;***322**, 1627–1634.

28. Jarzem PF, Harvey EJ, Arcaro N, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic low back pain. *J Musculoskeletal Pain.* 2005 **13**, 3–8.

29. Warke K, Al S, Baxter D, et al. Efficacy of transcutaneous electrical nerve stimulation tens for chronic low-back pain in a multiple sclerosis population: a randomized, placebo-controlled clinical trial. *Clin J Pain.* 2006; **22**, 812–819.

30. Moore RA, Edwards JE, McQuay HJ. Acute pain: Individual patient meta-analysis shows the impact of different ways of analysing and presenting results. *Pain.* 2005*;* **116**, 322–331.

31. Schnitzer TJ, Gray WL, Paster RZ, et al. Efficacy of tramadol in treatment of chronic low back pain. *J Rheumatol.* 2000*;***27**, 772-778.

32. Hale ME, Dvergsten C, Gimbel J. Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study.*J Pain.* 2005; **6**, 21-28.

33. Hale ME, Ahdieh H, Ma T, et al, Oxymorphone ER Study Group 1. Efficacy and safety of OPANA ER (oxymorphone extended release) for relief of moderate to severe chronic low back pain in opioid-experienced patients: a 12-week, randomized, double-blind, placebo-controlled study. *J Pain. 2007;***8**, 175-184.

34. Katz N. Enriched enrolment randomized withdrawal trial designs of analgesics. Focus on methodology. *Clin J Pain.* 2009; **25**, 797–807.

35. Kaczmarek KA, Webster JG. Voltage-current characteristics of the electrotactile skin-electrode interface. IEEE Engineering in Medicine and Biology Society 11TH Annual International Conference. 1989.

36. Bjordal JM. Time for a paradigm shift in pain treatment: reassessing transcutaneous electrical nerve stimulation (TENS). *Pain.* 2011*;* **152**, 1213-1214.

FIGURE LEGENDS

FIGURE 1. Photograph showing TENS machine with TLOG device attached and one pair of electrodes; also TSCORE electronic pain scoring device.

FIGURE 2. Flow chart showing: TENS-use, TSCORE-use and participant attrition during the course of the study.

FIGURE 3. Number of patients reporting pain scores at any of four time points before, during and after TENS on at least 13 days, 7-12 days or fewer than 6 days.

TABLE 1. Compliance with TENS implementation protocol (N=38). Timing data retrieved from TLOG devices

TABLE 2. Compliance with timing of pain reports relative to TENS use (N=35). Timing data retrieved from TSCORE device.

Supplemental Digital Content

TABLE 3. Summed pain intensity difference(SPID) and electrical output parameters for TENS responders and non-responders. Medications and CLBP is shown for reference.

FIGURE 4. Comparison of mean summed pain intensity difference(SPID) with respect to mean TENS voltage for responders and non-responders.

TABLE 1. Compliance with TENS implementation protocol (N=38) (Timing data retrieved from TLOG devices).

Number of patients adhering to required TENS usage pattern: (Full compliance is defined as daily TENS use for 13 or 14 days).

Fully compliant	Partially compliant (TENS used on 7-12 days)	Non-compliant (TENS used ≤ 6 days)
19 (50%)	13 (34%)	6 (16%)

Number of patients adhering to required TENS treatment duration: (Full compliance = Mean treatment duration of 60±10 minutes *and* SD≤10 minutes).

Fully compliant	Partially compliant (Mean duration=60±10 mins, but SD>10 mins)	Non-compliant (no TENS treatments)
25 (66%)	11 (29%)	2 (5%)

Number of patients adhering to both the required TENS usage pattern AND required TENS treatment duration:

Fully compliant with TENS implementation protocol	Partially or non-compliant with TENS implementation protocol
13 (34%)	25 (66%)

TABLE 2. Compliance with timing of pain reports relative to TENS use (N=35). Timing data retrieved from TSCORE devices

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Compliance with required timing of Baseline pain report (i.e. TENS switch-on time ±5 minutes)

Fully compliant	Partially compliant (≥1 report made outside the reporting time window)
25 (71%)	10 (29%)

Compliance with required timing of TENS_30 report (i.e. 30±10 minutes after TENS switch-on time)

Fully compliant	Partially compliant (reports outside time window)	Non-compliant (no reports made)
22 (63%)	10 (29%)	3 (8%)

Compliance with required timing of TENS_60 report (i.e. 60±10 minutes after TENS switch-on time)

Fully compliant	Partially compliant (reports outside time window)	Non-compliant (no reports made)
20 (57%)	13 (37%)	2 (6%)

Compliance with required timing of post_TENS report (i.e. 30±10 minutes after TENS switch-off time)

Fully compliant	Partially compliant (reports outside time window)	Non-compliant (no reports made)
11 (32%)	20 (57%)	4 (11%)

Compliance with required timing of all reports (Baseline *and* TENS_30 *and* TENS_60 *and* post_TENS)

Fully compliant (all reports as per protocol)	Partially compliant	Non-compliant (Baseline scores only)
2 (6%)	31 (88%)	2 (6%)

TABLE 3.Summed pain intensity difference (SPID) and electrical output parameters for TENS

responders and non-responders. Medication(s) and CLBP duration is shown for reference.

[1]Responder classified as >=30% reduction in mean pain score from baseline at time points T30, T60 and PoT.

Pat No	No. of 1 Hr TENS Sess.	TENS Responder[1] Time TMins	SPID (PI-NRS) (PrT-T30)+(PrT-T60) Mean(SD), Peak	Voltage Mean(SD), Peak /V	Freq. Mean(SD) /Hz	Pulse Dur.* Min /uS	Med. Qty.[Type]	CLBP (Yrs)
				Responders				
20	13	PoT	1.1(1.2),3	8.5(11.3), 37.1	80.9(50.4)	64	None	1
5	11	T60,PoT	1.9(1.9),4	30.1(8.5),50.8	21.2(12.2)	150	>1[n,a,ad]	5
8	14	T30,T60,PoT	1.9(1.6),5	24.0(9.4),49.4	25.5(28.9)	213	1	>6
10	9	T60,PoT	1.9(1.8),5	32.4(18.3),59.7	71.7(46.1)	95	None	>3
7	9	T60	2.7(1.9),6	11.3(10.8),56.4	24.0(23.0)	198	>1[o,a]	>1
11	12	T60	2.7(2.3),7	34.8(16.0),53.1	105(15.9)	66	None	8
37	14	T60,PoT	2.8(1.3),5	15.0(3.76),20.7	135(46.5)	23	>1[a]	7
2	n/a	T30,T60,PoT	4.2(0.9),5	n/a	n/a	n/a	>1	30
40	14	T30,T60,PoT	4.3(3),9	12.2(3.6),21.2	84.9(29.6)	77	>1[a]	n/a
35	4	T60	4.5(4.4),11	8.0(12.7),33.4	n/a	n/a	None	2
31	12	T30,T60	4.6(2.8),9	27.7(13.6),57.8	78.9(28)	>250	>1[o,n,a,at,ad]	1
13	12	T30,T60,PoT	5.8(2.8),11	4.7,(7.5),38.5	82.3(29.7)	>250	None	5
41	10	T30,T60,PoT	7.6(2.0),10	1.2(2.0),15.5	n/a	>250	None	n/a
23	11	T30,T60,PoT	7.8(1.3),11	14.1(7.5),34.8	154(2.2)	>250	1[o,a,n(p)]	7
				Non-Responders				
30	6	n/a	-1(1.4),1	23.0(13.2),43.2	82.5(39.4)	56	1[a]	0.5
22	14	n/a	-0.5(0.9),1	10.8(7.1),23.5	98.7(37.8)	57	None	11
12	14	n/a	0.5(1.3),3	16.9(12.2),57.3	104(50.4)	71	>1[a,n,ad]	2
15	14	n/a	0.5(0.7),2	17.9(5.6),29.6	54.1(34.1)	>250	None	26
33	9	n/a	0.5(0.8),2	15.0(20.7),55.9	134(3.9)	39	None	n/a
9	13	n/a	0.6(0.9),2	40.0(9.4),52.2	113(26.5)	104	1[n]	2
14	14	n/a	0.6(1.2),4	6.1(1.8),10.8	62.2(18.2)	>250	None	2
17	14	n/a	0.9(1.1),3	15.0(4.7),23.5	81.1(22.3)	>250	1[at]	1
27	14	n/a	0.9(1.2),3	4.0(1.6),10.8	35.5(6.84)	62	None	8
28	6	n/a	0.9(1.5),4	12.5(3.9),16.9	101.7(34.5)	100	1[o,n,a,at,ad]	>15
42	14	n/a	0.9(0.9),2	10.8(6.1),50.3	84.9(9.1)	25	>1[a,at]	n/a
1	12	n/a	1(3.2),5	n/a	142(0.6)	n/a	>1[a,ad]	28
24	12	n/a	1(0.9),2	7.5(3.7),18.3	129(48.6)	42	>1[n,a]	0.5
26	13	n/a	1(0.9),2	16.5(9.4),32.4	99.3(60.8)	30	>1[a,n]	17
38	12	n/a	1.1(1.2),4	6.1(6.1),54.1	54.1(1.0)	87	>1[o,a,at]	2
36	13	n/a	1.6(0.7),3	14.1(14.6),57.8	n/a	93	1[a]	>1
18	13	n/a	1.7(1.6),4	13.6(6.1),38.5	128(50.8)	106	None	7
29	14	n/a	1.9(1.1),5	22.1(10.3),32.4	65.3(8.3)	33	1[o(p)]	10
39	11	n/a	2.5(2.2),6	19.7(10.3),40.9	100(29)	66	>1[a,ad]	>7
				Excluded				
3	n/a	n/a	n/a[#]	n/a	n/a	142	>1[o,n]	20
6	13	n/a	n/a[#]	3.7(6.58),20.2	n/a	n/a	>1[o,n,at]	4
21	13	n/a	n/a[#]	10.3(3.1),16.0	21.3(15.3)	59	>1[o,a,ad]	12

[1]Responder classified as >=30% reduction in mean pain score from baseline at time points T30, T60 and PoT.

(Abbreviations No.: Number, Sess.: Sessions, Min.: Minutes, Freq.: Frequency, Dur.: Duration, Med.: Medication, Qty.:Quantity, Yrs.: Years)
PI-NRS Pain intensity numerical rating scale

PI-NRS measurement time coded as :-

PrT: Pre_TENS baseline, T30 : TENS_30, T60:TENS_60, PoT:post_TENS.

Rows sorted for increasing SPID

#Insufficient TSCORE data for response classification

*In all patients maximum pulse width extends beyond 250 uS

Medications: [a]Analgesic, [n]NSAID, [o]Opiate, [at]Atypical analgesic (Gabapentin, pregabalin), [ad]Antidepressant, [(p)]Patch

(Other medications for BP, Diabetes etc. not coded)

Pain intensity difference PID values were determined from pain scores by subtracting TENS_30 and TENS_60 from the pre-TENS baseline score respectively. These were summed to obtain SPID for each 1 Hour TENS therapy session. (Please note post_TENS was not included in SPID calculation) The mean, SD and peak SPID are shown in table 3 sorted in ascending order for comparison with TENS machine electrical characteristics which include voltage (mean, SD and peak), frequency (mean and SD) and pulse width range (minimum to >250uS). These descriptive statistics were derived from raw values recorded by TLOG for each TENS treatment session. Medication classification and length of CLBP illness provide a clinical context.
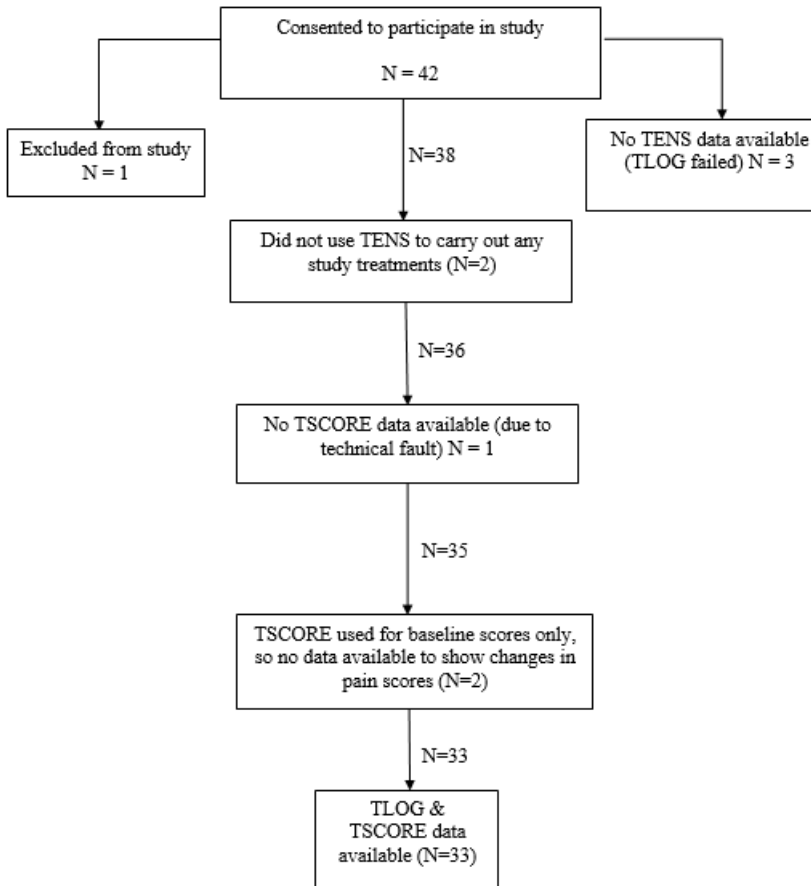
Fig. 2. Flow chart showing: TENS-use, TSCORE-use and participant attrition during the course of the study.
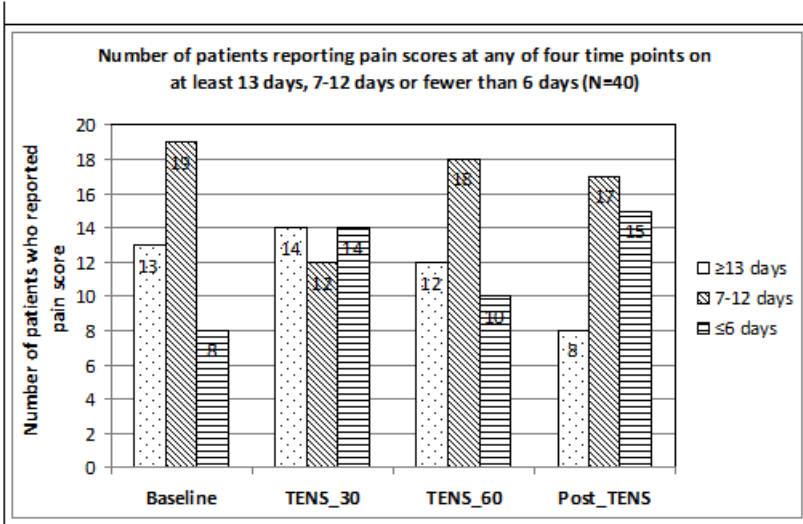
Fig. 3. Number of patients reporting pain scores at any of four time points before, during and after TENS on at least 13 days, 7-12 days or fewer than 6 days.
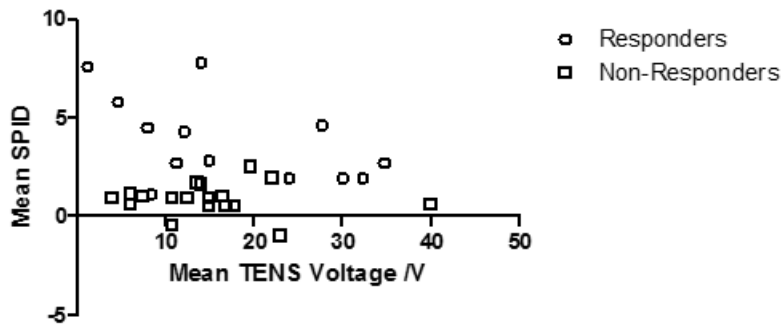
Fig 4. Comparison of Mean summed pain intensity difference (SPID) with respect to mean TENS voltage for responders and non-responders. (Values taken from Table 3)

It is interesting to note that some responders have a high mean SPID with a relatively low mean TENS voltage.