Direct and Indirect Benefits Reported by Users of Transcutaneous Electrical Nerve Stimulation for Chronic Musculoskeletal Pain: Qualitative Exploration Using Patient Interviews

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Background. There is no consensus regarding the effectiveness of transcutaneous electrical nerve stimulation (TENS) for management of chronic musculoskeletal pain or chronic low back pain. A recent review of previous trial methodology identified significant problems with low treatment fidelity. There is little information available to guide selection of patient-reported outcome measures appropriate for TENS evaluation.

Objectives. The purpose of this study was to explore the experiences of patients at a secondary care pain clinic who successfully used TENS to help manage chronic musculoskeletal pain. These key informants were selected because they had the potential to generate knowledge that could inform research design and clinical practice.

Design. A qualitative method using individual semistructured interviews with open questions was selected for its capacity to generate rich data.

Methods. A mini focus group informed the development of a discussion guide for semistructured interviews with 9 patients (6 women, 3 men). Thematic analysis was used as the primary data analysis method, and this analysis was enhanced by a case-level analysis of the context and processes of TENS use of each individual.

Results. Data analysis indicated that distraction from pain and a reduction in the sensations associated with muscle tension or spasm should be considered as separate outcomes from pain relief. These direct benefits led to a wide range of indirect benefits dependent on patient decision making, including medication reduction, enhanced function, psychological benefits, and enhanced ability to rest.

Conclusions. The findings indicate that evaluating TENS using a unidimensional pain scale is likely to overlook potential benefits. The complex pattern of TENS usage, as well as multiple direct and indirect outcomes, indicates that TENS could be considered as a complex intervention.

Transcutaneous electrical nerve stimulation (TENS) research has been published over several decades, but there is still no consensus regarding its effectiveness for chronic musculoskeletal pain[1] or chronic low back pain.[2] A recent review of the methods of TENS trials for acute, chronic, and cancer pain[3] identified significant problems with low treatment fidelity, such as limited instruction in TENS use, limited duration of TENS application, and insufficient stimulation. These problems with low fidelity have the potential to explain the negative findings of some randomized controlled trials (RCTs).

The assessment of implementation fidelity of TENS RCTs conducted by Bennett et al[3] used the conceptual framework developed by Carroll et al[4] to guide data extraction and analysis. This framework, represented in Table 1, is composed of 2 major elements: adherence and moderating factors. There is a lack of consensus about the optimal timing and duration of TENS sessions and the TENS settings (eg, pulse duration and frequency) that should be adhered to, as evidenced by variations in protocols of recent TENS trials.[5,6] There is also tension between the preference of patients for different settings[7] and the tendency of individual trials to opt for fixed settings. The risk is that evaluators may adhere to a specific fixed TENS protocol, which may only suit a proportion of trial participants, rather than using a flexible approach, which may be preferable for a higher proportion of participants.

Table 1.
Conceptual Framework for Implementation Fidelity Developed by Carroll et al,[4] Including Definitions of the Elements of the Framework[a]

Elements	Subcategories	Definition
Adherence: how far those responsible for delivering an intervention actually adhere to the intervention as it is outlined by its designers	Content	The active ingredients of the intervention
	Coverage	Whether all of the people who should be participating in or receiving the benefits of an intervention actually do so
	Frequency	How often intervention takes place
	Duration	How long intervention lasts
Moderators: factors that influence the degree of fidelity with which an intervention is implemented	Intervention complexity	Number of processes/stages involved and their specificity
	Facilitation strategies	Support strategies that may optimize and standardize implementation fidelity
	Quality of delivery	A manner of delivery appropriate to achieving the intended outcome
	Participant responsiveness	Acceptability of an intervention to a participant and his or her engagement with it
Identification of essential components	Explored using a sensitivity analysis/component analysis. Not an integral part of implementation fidelity.	

[a] Adapted with permission from: Carroll C, Patterson M, Wood S. et al. A conceptual framework for implementation fidelity. *Implement Sci.* 2007;2:40.

In addition to methodological issues, such as ensuring adequate treatment, Bennett et al[3] identified adequate outcome assessment as a key issue that should be addressed to improve the quality of future research. Patient-report outcome measures (PROMs) can be judged against a range of 8 criteria,[8] including reliability, validity, and responsiveness. A further criterion of "appropriateness" describes the "match" of a measure to the "purpose and questions of a trial."[8] The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)[9] recommended core outcome measures for chronic pain clinical trials, including the use of disease-specific outcome measures where available, together with the Brief Pain Inventory,[10] the Multidimensional Pain Inventory,[11] and the 36-Item Short-Form Health Survey (SF-36).[12] The Roland-Morris Disability Questionnaire[13] was recommended as a disease-specific outcome measure for low back pain. The risk of a poorly matched outcome measure was highlighted by a clinical audit of long-term users of TENS,[14] which indicated that improved sitting tolerance was one important reported benefit of TENS. None of these 4 IMMPACT-recommended outcome measures include items related to sitting tolerance.

A literature search for studies reporting patient experience of TENS use showed no evidence of any detailed qualitative research that had the potential to inform the choice of an appropriate PROM for TENS or to inform the development of a protocol for the delivery of TENS within a trial.[15] Therefore, an inductive research strategy[16] was used to iden-

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- **eFigure:** Process Involved in Naomi's Use of TENS to Facilitate Cogntive Activities: One of the Psychological Benefits Reported by TENS Users

tify and describe the patterns of perceived benefits of TENS for experienced users, who acted as key informants to generate knowledge about the use of TENS and its outcomes. Induction is a research strategy designed to explore and describe a phenomenon and to identify patterns (regularities). Inductive research is not intended to "prove" its findings, or to test them. The findings of inductive research may then be used for theory development, but this is not a necessary feature of this research strategy.

The aim of the investigation was to explore the benefits reported by patients at a secondary care pain clinic who successfully used TENS devices to help them to manage chronic musculoskeletal pain. These key informants were selected because they have the potential to generate detailed knowledge to inform clinical practice and research design.

Method

Individual semistructured interviews were selected for their capacity to generate rich data.[17] Open questions were asked about participants' patterns of TENS use and their perceptions of the benefits. A small focus group (2 men, 2 women) discussed these issues, and these data were analyzed using thematic analysis[18] to develop the discussion guide for the individual semistructured interviews. Interviews were conducted until there was evidence of increasing data saturation.[15,19]

Recruitment and Inclusion and Exclusion Criteria

Adult patients receiving secondary care for chronic musculoskeletal pain were recruited by means of pain clinic waiting room posters in a city in southern England. This purposive sampling strategy[20] was selected to optimize the relevance of the data, which could inform PROM selection for a future TENS evaluation in a pain clinic setting. These patients may present more than one regional pain problem, and having more than one area of pain is a negative prognostic factor.[21–23] Therefore, a decision was made to include any patients with chronic musculoskeletal pain rather than a narrower focus on one regional pain problem. Patients with primary neuropathic pain (eg, due to multiple sclerosis or peripheral neuropathy) and visceral pain were excluded, as the natural history and pain mechanisms differ from those of musculoskeletal pain.

Ethical Issues

Approval for the study was received from the National Research Ethics Service (Frenchay REC reference 08/H0107/9), the relevant UK National Health Service Research and Development department, and the Faculty of Health & Life Sciences Ethics Sub-Committee of the University of the West of England, Bristol. Informed consent was obtained, and data were anonymized at the point of transcription. Pseudonyms are used for published data extracts, which have been modified to remove identifiable information, protecting anonymity.

Managing Quality

Quality criteria for realist qualitative research[24,25] were used as benchmarks to ensure that a comprehensive, high-quality process was followed. The ways in which this research met these criteria have been published elsewhere.[15] The criteria include the choice of appropriate and sensitive methods, contextualization of the research and the connection to an existing body of knowledge, transparency of the method of data generation, theoretical justification of the participant selection, use of systematic data collection and analysis methods, respondent validation, management of reflexivity, and transparency of the discussion. These criteria are compatible with those of the Qualitative Research Guidelines Project.[26]

Data Analysis

Thematic analysis[18] was selected as the primary data analysis method because of its systematic approach to deriving categories from the data, using a flexible but clearly delineated method that is independent from pre-existing theoretical frameworks and thus remains flexible in its use. The 6 phases of thematic analysis recommended by Braun and Clarke[18] are: (1) becoming familiar with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. The first author (P.W.G.) conducted and transcribed the interviews, then used thematic analysis to prepare summaries, which were posted to the relevant participants so that they could offer feedback for respondent validation.[27] The summaries produced for respondent validation satisfied the need for a level 1 review,[18] which involved checking if the themes worked in relation to the coded extracts.

A key methodological challenge inherent in this research was how to integrate information about individuals into a meaningful, nomothetic summary that can inform future population-based evaluations of TENS without losing sensitivity to the ideographic complexity of the individual experiences from which the data were generated. This challenge was addressed, in part, by the respondent validation summaries, which acted as a case-level analysis of the context and processes of TENS use for each individual. The combination of these different summaries into a thematic analysis for the group involved checking if the themes work in relation to the entire data set: a level 2 review.[18] This review was managed by tabulating

Table 2.
Regional Pain Problems Treated Using Transcutaneous Electrical Nerve Stimulation (TENS) and Self-Reported Years of TENS Use for Each Anonymized Participant

Participant (Pseudonym)	Sex	Regional Pain Treated Using TENS	TENS Use (y)
Fran	Female	Low back and knee pain	8
Irene	Female	Low back pain	>1
Brian	Male	Knee pain	>10
Jack	Male	Low back and neck pain	10
Claire	Female	Thoracic and low back pain	4–5
Naomi	Female	Knee, hip, and low back pain	11
Sally	Female	Low back pain	6–7
Moira	Female	Low back, hip, and elbow pain	13–14
Oliver	Male	Low back and leg pain	20

the different themes identified in each case and looking for the presence or absence of data relating to these themes in other cases. The apparent absence of data in a specific interview relating to a theme identified in other interviews triggered a further analysis of the relevant transcript to identify any data relevant to the theme or any explanation as to why this theme was not represented in this particular case. The case-level analysis, therefore, supplemented the thematic analysis, facilitating a more complex analysis of the data. The preparation of the respondent validation summaries before conducting the group-level thematic analysis is congruent with Yin's multiple case study method,[28] although Yin described the group-level thematic analysis as "drawing cross-case conclusions." The thematic analysis was undertaken by the first author and monitored for quality and rigor by the other authors. The resulting analysis was compared with 4 other less detailed qualitative data sets, 3 of which were generated as part of the same research program.[15]

Results

All participants were white British and spoke English as a first language. Nine individual interviews were conducted between April 2009 and January 2010. The participants (6 women, 3 men) varied in age between 28 and 54 years, with an even distribution of participants across this age range. The areas of the body treated and years of TENS use are shown in Table 2. Only 2 participants had a single, uncomplicated regional musculoskeletal pain problem, which supports the decision regarding inclusion of patients with multiple pain problems and enhances the transferability of the findings for future research in a pain clinic setting. The participants reported a combined experience of approximately 83 to 86+ years of TENS use. Three of the 9 respondent validation summaries were returned with helpful comments and clarifications. The resulting analysis was compared with 4 other less detailed qualitative data sets, and no other relevant themes were identified.[15] Extensive data relating to the ways of using TENS, including strategic use, also were generated by this research.[15]

Table 3.
Matrix Representing Subthemes of Direct and Indirect Perceived Benefits of Transcutaneous Electrical Nerve Stimulation (TENS), Indicating the Presence of Relevant Data in Each Interview[a]

	Direct Benefits			Indirect Benefits			
Participant Pseudonym	Pain Relief	Distraction From Pain	Muscle Spasm/ Tension	Medication Reduction	Enhanced Rest	Psychological Benefits	Help With Function
Fran	√	×	n/a	√	√	√	√
Irene	√	?	√	×	√	?	√
Brian	√	√	n/a	√	?	?	√
Jack	√	?	√	×	√	√	√
Claire	√	√	√	√	√	?	√
Naomi	√	√	√	×	×	√	√
Sally	√	√	×	×	×	√	×
Oliver	√	√	×	?	?	?	√
Moira	×	√	√	×	×	√	√

[a] √=data clearly indicated the presence of this benefit, ×=data clearly indicated the absence of this benefit, n/a=not applicable for this participant, ?=insufficient data to conclude if this benefit was present or absent.

Direct Benefits

Data relating to the perceived benefits of TENS were organized into 2 themes by separating the direct benefits (eg, help with symptoms) from the indirect benefits (eg, help with function), which were a consequence. Three subthemes were developed to represent the direct benefits of TENS: (1) pain relief, (2) distraction from pain, and (3) reduced sensation of muscle tension and spasm. Table 3 represents the distribution of the direct and indirect benefits across the data set, indicating that there was evidence of all of the themes and subthemes within the first 3 interviews. This retrospective analysis of data saturation[19] suggests that further interviews were not required, although the subsequent interviews provided further examples of each subtheme, which were helpful in the data analysis stage because the subthemes were easier to identify if a number of examples were present.[29]

Direct benefit subtheme 1: pain relief. Eight of the 9 participants reported pain relief as a result of TENS use, as shown in Table 3. The following data extract illustrates the difference between pain relief as a direct benefit and the indirect benefits:

> It doesn't take the pain away, total. What it does, it makes it manageable . . . there's a big difference between managed pain and chronic pain. Chronic pain just totally immobilizes you, whereas managed pain gives you some normality. You are able to continue with your life, and I think . . . from a pain perspective, as I have already said, it empowers me, the TENS enables me, to have that control over my disability. (Fran)

Managed pain is contrasted by Fran with "chronic pain," used here as a lay term to mean severe pain. The "managed pain" is equivalent in meaning to pain relief as a direct benefit of TENS, whereas the benefits of mobility, continuing with life, normality, and control are reported as consequences of the managed pain and so were developed into themes as indirect benefits.

There was evidence from the case-level analysis that TENS helped with some types of pain quality more than others. In particular, pain of a sharp and shooting nature associated with faster or larger movements was reported as being helped less by TENS than constant pain, limiting the indirect benefits of TENS for some activities:

> I think it would be too much an activity . . . when you're doing a sport . . . because I play a lot of (a ball sport), so it would be when you are batting or throwing, those jerky movements, I don't think it would really work. (Irene)

The case-level analysis indicated that experiences of the participants of TENS use during a pain flare-up differed to some extent. Two participants (Oliver and Claire) reported that TENS was of lesser value as the pain escalated. However, they would still persist with its use, in addition to other pain relief methods, to gain any possible benefit, however slight. Other participants (Fran, Jack, Naomi, and Sally) routinely used TENS to help during flare-ups of pain, with more benefit. For example, Jack reported having used TENS for flare-ups:

> If . . . I am doubled up, if I can't get out of the chair, nothing cures it, nothing. But this thing I can aim at the dead spot, and it will move it, and make things a lot easier for me.

Direct benefit subtheme 2: distraction from pain. Several participants suggested that the TENS sensation provided a helpful distraction from pain. During the thematic analysis, it was important to decide whether this distraction should be classified as a direct benefit of TENS use or to consider it only as a hypothetical mechanism of TENS action leading to the direct benefit of pain relief. This issue was explored by examining the actual words used by participants. For example, Claire described both distraction and pain relief operating separately:

> It's quite good for the distraction thing apart from anything else, just sort of having the impulses sort of takes your mind off the pain. But I think it does help with the pain as well.

Naomi explained her experience, saying that she would:

> . . .turn it up to kind of cover, so it kind of covers up the pain.

This "covering up" of the pain did not depend on her being consciously aware of a sensation at all times. This finding suggests that distraction at a conscious level is not the only mechanism of operation. Naomi explained the process this way:

> Yeah, . . .it's almost that it numbs that area so that you don't notice it particularly, and if you change it, then you notice it. So . . . if you notice that . . . if you find that actually you're starting to feel the pain, then perhaps turn it up, and then you would notice it again, but again it would fade as well, then it would just fade again.

Oliver and Brian both suggested that distraction from the pain was a benefit of TENS use, but both also reported a reduction in pain. In contrast, Moira perceived the benefit of TENS only as a distraction from the pain, rather than pain relief as such:

> It distracts, disguises . . . changes the pain for a while. You get some time off from the pain if you get it right.
>
> What the TENS machine does is change my ability to cope with it. Or my ability to . . . put it further to the

> back of my mind so that I can then go about my business.

Of note, Moira reported that the distraction (or disguising) benefit of TENS relieved her continuous pain more than other types of pain such as shooting pain, which could be more severe at times. The case-level analysis, therefore, informed the thematic analysis and confirmed that distraction should be considered as a direct benefit of TENS use.

Direct benefit subtheme 3: reduced sensation of muscle tension and spasm. A reduction in the sensation of muscle tension and spasm was reported by several participants. This benefit may represent a physiological change in the behavior of the muscles or an altered perception of the muscles, or both. From these interview data alone, we can conclude only that TENS influenced the perception of muscle tension and spasm, which is concordant with the World Health Organization *International Classification of Functioning, Disability and Health*[30] code b780, described as "sensations of muscle stiffness and tightness of muscles, muscle spasm or constriction, and heaviness of muscles." The following data extract provides a clear indication of the link between this direct benefit and the indirect benefit of increased function:

> Because I feel they were all knotted . . . they were all knotted up, so with this machine, I feel that it's sort of made them a bit more open and relaxed to allow me to move a bit more freely. (Irene)

In summary, the case-level and thematic analysis of the data indicated that the influence of TENS on symptoms experienced by patients with chronic musculoskeletal pain is unlikely to be captured by the use of a unidimensional pain scale, and a more complex assessment is likely to be required.

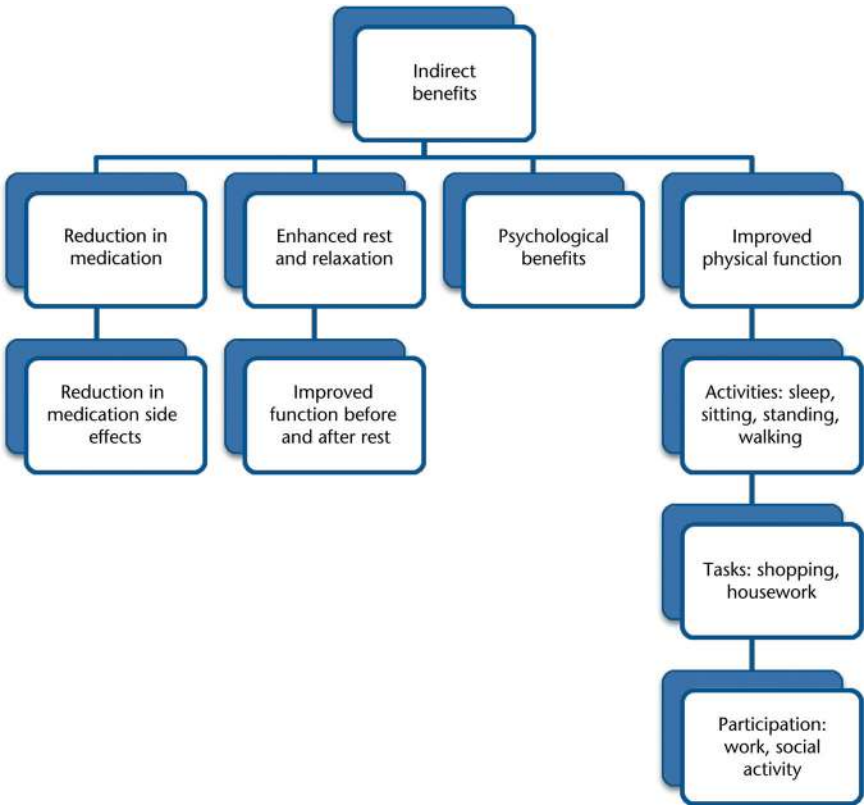

Figure 1.
Representation of the main theme of the indirect benefits of transcutaneous electrical nerve stimulation, showing the subthemes.

Indirect Benefits

The defining feature of an indirect benefit is that it is consequent upon the direct benefits of TENS, whether that involved a reduction in pain intensity, distraction from pain, reduction in the sensation of muscle tension and spasm, or a combination of or all 3 of these benefits. An overview of all of the indirect benefits is shown in Figure 1.

Indirect benefit subtheme 1: reduction in medication. The case-level analysis indicated that the 3 participants who reported a reduction in medication as an indirect benefit of TENS all experienced difficulties with medication, which increased the importance of this perceived benefit. In contrast, the other 6 participants used TENS as an adjunct to pain medication: they chose to use TENS when medication was insufficiently helpful. For Fran, pain medication caused significant sedation, which meant that she had been unable to drive and unable to work before first using TENS, as she explained:

> If I wasn't able to use the TENS in between, I would have to use those other 2 tablets. . . . I wouldn't be able to drive, I'd be dangerous, because it's very much like being outside your body . . . it affects my speech, it affects my vision . . . my coordination, my balance, everything. It's tremendous.

The use of TENS offered Fran significant pain relief, which she indicated on a 100-mm visual analog scale (VAS) as a reduction from 80 mm to 50 mm. This pain reduction allowed

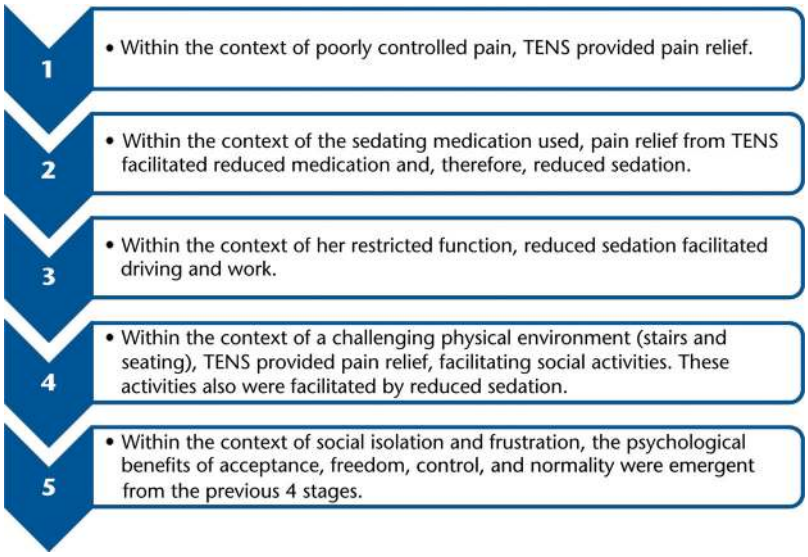

Figure 2.
Representation of Fran's perceived benefits of transcutaneous electrical nerve stimulation (TENS), illustrating the reduction in medication as a stepwise, contextualized process linking direct and indirect benefits of TENS use across several domains.

her to reduce her medication dose to a level where she could drive, function at work, and socialize. These indirect benefits are shown in Figure 2 as deriving from the direct benefits of TENS use within a context of poorly controlled pain and medication associated with side effects. The contexts of further indirect benefits reported by Fran are shown in Figure 2 and are described below.

Indirect benefit subtheme 2: enhanced rest. This subtheme is developed from 5 accounts of TENS being used to enhance the benefits of a planned rest period. This use is associated with a common pain management strategy known as "pacing" or "activity management," which involves a planned alternation of physical and sedentary activities, sometimes linked with a change of posture (eg, lying down).[31,32] These periods of planned rest typically form part of a daily routine. Preemptive rest may be used in this way to facilitate activity that follows the rest period, as referred to in the extracts below. These periods of planned rest are different from those times when rest is used because pain and associated symptoms have escalated to a level where an individual feels unable to remain active, commonly known as a "flare-up" of pain. Irene mentioned using TENS while sitting to relax her back muscles so that she could carry on with activity later in the day:

> No, I wouldn't say it helped me sit, because I would sit down to use it, to make it, to make me, to make . . . I don't know what it does, but to sort of relax the muscles, to enable me to then carry on with the rest of the day.

The case-level analysis indicates that this use of TENS to enhance recuperative rest can be conceptualized as a mechanism operating within a specific context, as detailed in Figure 3.

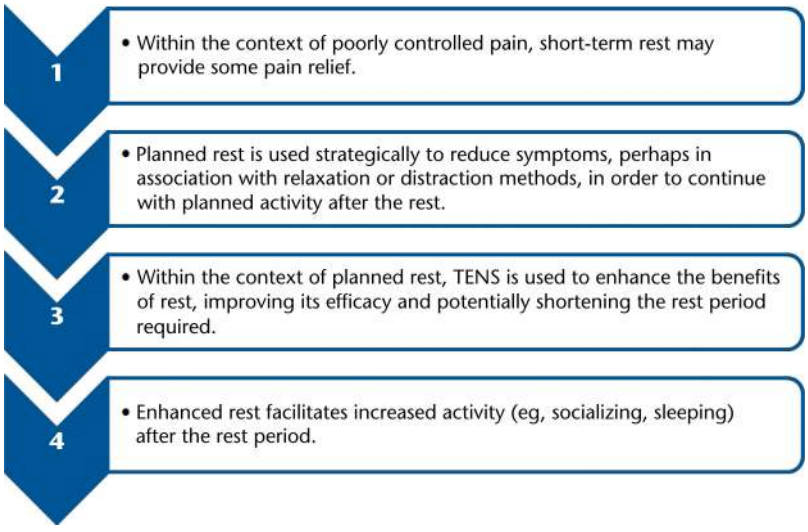

Figure 3.
Processes involved in the use of transcutaneous electrical nerve stimulation (TENS) to enhance planned rest, leading to potential benefits after the rest period.

Indirect benefit subtheme 3: psychological benefits. Although this subtheme is constructed from data relating to the perceived benefits of TENS use that fall within the psychological domain, it should be noted that the psychological domain is diverse, and the perceived benefits reported relate only to a subset of psychological functions. One of the clearest examples of a psychological benefit from TENS use was the improvement in concentration reported by Naomi:

> Yeah, you're not in so much pain, so you can then concentrate on something else, you can actually, kind of, you can read a book, which takes

> your mind off the fact that you're in pain . . . you can go and do something else, it's the bit that you're not conscious of it all the time, of how much pain you're in, so yeah . . . it does, it works on a lot of different levels.

There is case-level evidence here of a process involving different stages, which are represented in the eFigure (available at ptjournal.apta.org). The direct benefit (pain relief) facilitates an indirect benefit (improved concentration), which facilitates Naomi's ability to read, leading to further pain relief via a distraction mechanism.

Sally made reference to the psychological benefits of TENS use indirectly by describing the emotional suffering that she experienced during a pain flare-up:

> Yeah, they're awful. Those days I've just, I have said I would rather not be there on my bad days 'cause they are just awful. They are horrible.

The modest pain relief that she reported helped to ameliorate this suffering. Sally completed the pain VAS, indicating pain severity of 100 mm during a flare-up (the anchor described as "pain as bad as possible"); she indicated a reduction in pain severity to 84 mm as a result of TENS use. This 16% pain reduction falls into the 10% to 20% pain reduction indicated by IMMPACT[33] as a minimal clinically important difference: for Sally, it is clearly enough of a difference for the use of TENS to be worthwhile.

Fran described the psychological challenges in the early days of her pain and the importance of TENS in helping her to make a transition toward control and acceptance. This transition included physical and psychological elements:

> Psychologically, it's really hard when you're first diagnosed with something . . . or even prior to being diagnosed . . . you're suffering, really really bad pain . . . . I've found that when that's happened to me, the adjustment with coming to terms with the pain, chronic pain may never ever be cured, all right . . . the most that you could hope for is for it to be managed, or maintained . . . . That transition is very very tough to take, and I . . . was pumped with loads and loads of drugs, to begin with . . . and my quality of life was zero, until I started experimenting with the TENS, and it's through that, that I got that control, and I was able to do that transition psychologically. So it's not only the physical [effects], it's the psychological effects it has on you as well, but I think you've got to understand what the TENS does: it's not going to cure your pain, it enables it to be managed. (Fran)

In summary, this subtheme brings together case-level data related to improved concentration, reduced suffering, acceptance, control, and empowerment. This is an important but heterogeneous group of perceived benefits.

Indirect benefit subtheme 4: function. The case-level analysis of the influence of TENS use on daily function indicated complexity. Some participants indicated an increase in function as a result of TENS use, whereas others used TENS to help them to sustain their usual level of function when it might be threatened by an increase in pain. An additional complication to the analysis of the functional benefits was the extent to which specific activities were helped or whether the benefits were generalized to most day-to-day activities. A clear example of the latter case was provided by Oliver, who reported help with general function when his pain was worse. He tended not to use TENS when his pain was less intrusive because of the problems associated with use. When asked if there were any activities that TENS does not help with, Oliver explained:

> I don't see, because the whole thing is, I keep saying, about day-to-day function, you know, function, just existing day-to-day, working and so on when it flares up, so the answer to that is probably "no," because it contributes towards that. There's nothing else that I can think of, well, sticking the TENS on doesn't help with me boiling an egg . . . well, it probably does, because I've got to stand up (laughs), so it's all to do with the overall picture, the day-to-day, just doing your day-to-day stuff.

In contrast, some users reported that TENS would be used to facilitate increased levels of specific activities, such as sitting, standing, and walking. Increases in these specific activities led to improved involvement with tasks such as shopping and housework and participation in work and social activities. A case-level example of this indirect benefit was provided in a data extract from Fran, represented in Figure 2, which indicated that TENS could increase sitting tolerance, especially in uncomfortable chairs, which facilitated attendance at social events, leading to a reduction in social isolation:

> If you've actually got chronic pain in your back, . . . just sitting or climbing the stairs or just standing even for short periods of time can be excruciating. Now, if you've actually got your TENS on, and you can fiddle around with it to get the pulses very inconspicuously, it enables you to do things that able-bodied people are able to do with the least discomfort . . . because not all cinemas, all seating areas, are specifically made for you, whereas in my home and even in my work environment, I've got special chairs. I can't afford that luxury when I go out socializing, so I've got a choice really: I either use my TENS . . . so I can be as able as everyone else, or I don't use my TENS, and I become isolated, so it's given me more freedom.

Sleep was reported as an indirect benefit of TENS. Using TENS before falling asleep can be thought of as a special case of using TENS to enhance rest, with the aim of reducing sleep latency, but several users also reported that they would sleep with the TENS machine switched on, as Brian explained:

> Yeah, sometimes it will be on solid for 2 days. I know because I've got to try and go to sleep with it on as well, so if I can't go to sleep, I will put the TENS on and go to sleep.

Case-level analysis indicated that this was not a universal benefit and may be negated by the user's tendency to move around at night and any consequent difficulty in keeping the pads and leads in place.

Improved ability to read also was reported as an indirect functional benefit of TENS, as shown in the eFigure. It is possible that the reduced interference of pain with cognitive capacity as a result of TENS use might lead to improvements in other cognitive activities, but such improvements were not spontaneously reported by participants.

In summary, TENS use could be directed toward improvements in function or maintaining function. Function involving dynamic movements such as sports, reaching, and heavy lifting was notable by their absence.

Discussion

These interviews with experienced TENS users provided a wealth of interconnected information about the use and benefits of TENS, which has potential to guide clinical practice and research. For research purposes, the data analysis indicated that the perceived benefits of distraction from pain and a reduced sensation of muscle spasm or tension as direct benefits should be considered separately from pain relief. It also indicated that some types of pain experience, such as shooting pain, may be helped less by TENS than more constant, background pain, and this finding indicates the need for a more focused evaluation. A specific evaluation of the effect of TENS on the experience of a pain flare-up also may be needed. For clinical and research purposes, explaining these separate types of benefit to novice TENS users may encourage them to experiment with TENS use to explore and optimize these different direct benefits. Knowledge derived from this inductive study, therefore, can inform the delivery of care, which is concordant with the interprofessional consensus of core competencies for prelicensure education in pain management.[34] In particular, this study informs collaborative approaches to decision making, the diversity of treatment options, the importance of patient autonomy, and flexibility in care.[34]

The findings indicate the need for outcome measures specific to TENS, and further research will be needed to develop and evaluate these tools. Only one study that used a PROM for muscle spasm was identified in the literature. Warke et al[35] conducted an RCT of TENS for patients with multiple sclerosis and low back pain. They used a VAS to collect data about participants' reports of muscle spasm intensity and found that high-frequency TENS produced a greater reduction in spasm than low-frequency TENS or placebo TENS. It would be possible to use a similar scale in an evaluation of TENS to identify the frequency and extent to which patients report this benefit. Some developmental work, however, may be required before this scale is adopted. First, a VAS for spasm is likely to be vulnerable to the same difficulties with completion that some patients have with a pain VAS,[36,37] so a numerical rating scale may be more acceptable to patients. Second, different descriptions of the muscle sensations were used by participants, and it is necessary to ensure that patients understand the meanings of any words used. For example, an item relating to "muscle tension" may not be endorsed by a patient who perceives that he or she has "muscle spasm." Another descriptor was "knotted muscles," which again may be perceived as different from tension and spasm by some patients. Cognitive interviewing would be required to develop the relevant items, to explore patient face validity, and to consider scaling issues.

If distraction from pain is a frequent and significant direct benefit of TENS use, its measurement may be challenging for researchers, as the method of measuring distraction should not depend on contemporaneous self-report because of the risk of introducing an observer effect. Put simply, asking a TENS user how much the TENS is currently distracting him or her from pain is likely to diminish the effect it aims to measure. There appears to be no evidence of a pre-existing measure for distraction suitable for this purpose, so a TENS-specific PROM will need to be developed.

The psychological benefits of improved concentration, reduced suffering, acceptance, control, and empowerment were identified in the analysis. Although it is clear that these participants link each of these psychological benefits to their use of TENS, there was little evidence that the benefits might be particular to TENS compared with any other effective pain treatment. However, it is notable that none of the psychological benefits would be captured by the outcome measures recommended by IMMPACT.[9]

A complex pattern of functional benefits was reported, reflecting the

choices that participants made about using TENS to achieve different outcomes in different contexts (eg, at rest, during activities, during a flare-up). This contextualized use leads to complexity of implementation and outcomes, indicating that TENS could be considered as a complex intervention.[38] This flexible approach to TENS use is not concordant with a fixed TENS protocol for clinical practice or for research purposes. An appropriate functional PROM that is treatment-specific may need to be developed to ensure that it is sensitive to the different outcomes achieved by TENS users in different contexts. The findings also indicated the value of a flexible approach to pad positioning and choice of settings, including appropriate stimulation intensity,[15] that converges with recently published work highlighting the importance of these factors.[39,40]

A particular strength of this research derives from the semistructured interviews, which encouraged users to express a wide range of experiences that other research methods may not have facilitated. The extensive experience of the participants contributes to the credibility of the data. The primary author (P.W.G.) has extensive clinical experience working with patients who use TENS for chronic pain management, which facilitated both the interviews and the data analysis. The limitations of interviews are that they would be an inefficient method to gain evidence about rare benefits of TENS, they cannot estimate the frequency or size of benefits within a wider population, and they cannot separate any specific effects from nonspecific effects. It should be acknowledged that the interview participants' ages and ethnic background represent a subset of the wider population of TENS users. However, the interview data can focus future efforts to collect quantitative data about the frequencies of these benefits within a wider population of patients. The data also have informed the development of a patient information sheet,[41] which has incorporated expert patient experiences and can inform clinical practice as well as research design.

All authors provided concept/idea/research design. Dr Gladwell, Dr Cramp, Mrs Badlan, and Professor Palmer provided writing. Dr Gladwell provided data collection, participants, and institutional liaisons. All authors provided project management. Mrs Badlan, Dr Cramp, and Professor Palmer provided consultation (including review of manuscript before submission).

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