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Problems, Solutions, and Strategies Reported by Users of Transcutaneous Electrical Nerve Stimulation for Chronic Musculoskeletal Pain: Qualitative Exploration Using Patient Interviews

Peter William Gladwell, Kathryn Badlan, Fiona Cramp, Shea Palmer

Background. Transcutaneous electrical nerve stimulation (TENS) could offer a non-drug form of pain relief, but there is no consensus regarding its effectiveness for chronic musculoskeletal pain or chronic low back pain. A recent review of previous trial methods identified significant problems with low treatment fidelity. There is little information available to inform the development of a pragmatic implementation design for a TENS evaluation.

Objectives. The aim of this study was to explore the experiences of patients who were receiving secondary care in a pain clinic and who had expertise in using TENS to 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. Semistructured interviews were conducted 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 patients learned to address a range of problems in order to optimize TENS use. Patients may need to personalize the positioning of electrodes and the TENS settings and to readjust them over time. Patients learned to use TENS in a strategic manner, and the outcomes of each strategy varied.

Conclusions. The findings indicated that a pragmatic TENS evaluation may need to incorporate a learning phase to allow patients to optimize this complex pattern of TENS usage, and evaluation may need to be sensitive to the outcomes of strategic use. These findings also have implications for clinical practice.

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Transcutaneous electrical nerve stimulation (TENS) is a portable, inexpensive, and low risk form of electrostimulation that has the potential to improve the quality of life of people who live with chronic musculoskeletal pain.^{1,2} Although there is evidence to support the hypoalgesic effect of TENS from laboratory studies on healthy humans using experimentally induced pain models,³⁻⁷ there is no consensus regarding its effectiveness for chronic musculoskeletal pain⁸ or chronic low back pain.⁹ A recent review of the methods of TENS randomized controlled trials (RCTs) for acute, chronic, and cancer pain¹⁰ identified significant problems with elements of implementation fidelity, such as limited duration of TENS application, insufficient stimulation, and limited instruction in TENS use, that could explain the negative findings of some trials. The assessment of implementation fidelity of TENS RCTs conducted by Bennett et al¹⁰ used the conceptual framework developed by Carroll et al,¹¹ which is composed of 2 major elements: adherence and moderating factors. *Adherence* is defined as “how far those responsible for delivering an intervention actually adhere to the intervention as it is outlined by its designers”¹¹ and includes the subcategories of treatment content, coverage, frequency, and duration. Moderators are factors that influence the degree of fidelity with which an intervention is implemented and include intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness to a treatment program.

There is potential for confusion around terminology: adherence also has been defined as “the extent to which a person’s behaviour corresponds with the agreed recommendations from a health-care provider.”¹² The terms “adherence” and “compliance” have been used in recent TENS research¹³ to indicate the extent to which a research participant adheres to a TENS study protocol. It should be noted that the equivalent term used by Carroll et al¹¹ is “participant responsiveness.”

Evaluations of TENS should be rigorously designed to provide reliable information

about the utility of TENS, over and above any nonspecific (eg, placebo) effects. The design of a study exploring effectiveness (ie, the impact of TENS when used in everyday life)¹⁴ should have an implementation design that optimizes the pragmatic use of TENS. However, 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 a study might use, as evidenced by variations in protocols of recent TENS trials.^{15,16} Although there is some evidence regarding the effectiveness of different settings for chronic pain,¹⁷ there may also be a tension between the preference of patients for different settings¹⁸ and the tendency for studies to opt for fixed settings. As a foundation for an implementation design, it would be helpful to have knowledge of the pragmatic approach developed by experienced TENS users to optimize the benefits in daily life. This knowledge could inform decisions about TENS protocols and any associated patient education to enhance any potential benefits of TENS and minimize any obstacles to use. Limited knowledge had previously been generated by a questionnaire-based audit,¹⁹ which suggested that the benefits of TENS could be divided into 2 categories: (1) benefits associated with pain relief (eg, use during pain exacerbations to relieve early morning stiffness and associated pain or to reduce medication use) and (2) benefits associated with assisting specific functions (eg, prolonged sitting, such as at a theatre or other social events; traveling; housework; prolonged standing). However a literature search showed no published qualitative studies which explored these issues in depth.²⁰

A qualitative study using semistructured interviews was designed to explore the benefits reported by experienced TENS users with chronic musculoskeletal pain.^{20,21} The findings indicated that pain relief, distraction from pain, and a reduction in the sensations associated with muscle tension or spasm should be considered as separate outcomes. These 3 direct benefits led to a wide range of indirect benefits dependent on patient decision making, including medication reduction, enhanced function, psycho-

logical benefits, and enhanced ability to rest. The complex pattern of TENS usage suggested that TENS could be considered as a complex intervention because of the number and variability of outcomes, the number of behaviors required, and the degree of tailoring of the intervention required.²² The study also generated a wealth of data regarding the ways in which patients learned to use TENS in their daily lives, including the problems associated with TENS and how users managed these problems: these data can inform a process evaluation²³ for pragmatic TENS use and are presented in this article. The current literature could inform the design of studies focused on determining TENS effectiveness and inform clinical practice.²⁴

The aim of the investigation was to explore the various uses of TENS devices reported by patients receiving secondary care in a pain clinic who successfully used them to manage chronic musculoskeletal pain.

Method

Individual semistructured interviews were used to generate data. Open questions were asked about participants’ patterns of TENS use and their perceptions of the benefits. A small focus group (2 men, 2 women) had previously discussed these issues. The focus group data were analyzed using thematic analysis²⁵ to develop the discussion guide²⁰ for the individual semistructured interviews. Data saturation occurred at 9 participants.^{20,21}

Recruitment, Inclusion, and Exclusion Criteria

Adult patients in secondary care with chronic musculoskeletal pain were recruited by means of pain clinic waiting room posters in a city in southern England. This purposive sampling strategy²⁶ was selected to optimize the relevance of the data, which could inform research design for a future TENS evaluation in a pain clinic setting. Patients receiving secondary care in a pain clinic may present more than one pain problem: having more than one area of pain is a negative prognostic factor.²⁷⁻²⁹ Therefore, a decision was made to include any patients with chronic musculoskeletal pain,

rather than having a narrower focus on one regional pain. Patients with primary neuropathic pain (eg, multiple sclerosis, peripheral neuropathy) and visceral pain were excluded, as the natural history and pain mechanisms differ from those of musculoskeletal pain.³⁰

Ethical Issues

Recruitment by waiting room posters rather than approaching patients directly facilitated consent. Informed consent was gained, and data were de-identified at the point of transcription. Pseudonyms were used for published data extracts, which were modified to remove identifiable information, protecting anonymity.

Managing Quality

Quality criteria for realist qualitative research^{31,32} were used as benchmarks to ensure that a comprehensive, high-quality process was followed. The ways in which this research met these quality criteria have been published elsewhere.²⁰ The criteria included the choice of appropriate and sensitive methods; contextualization of the research and 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.³³

Data Analysis

Thematic analysis²⁵ was selected as the primary data analysis method. The 6 phases of thematic analysis recommended by Braun and Clarke²⁵ are: becoming familiar with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report. The first author (P.W.G.) conducted and transcribed the interviews using a spreadsheet for data management. Thematic analysis was used to prepare summaries that were posted to the relevant participants so that they could offer feedback for respondent validation.³⁴ The summaries produced for the respondent validation exercise satisfied the need for a level

Table 1.

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 Managed 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

1 review,²⁵ which involved checking whether the themes worked in relation to the coded extracts.

A key methodological challenge was how to integrate the ideographic complexity of individual experiences into a meaningful, nomothetic summary that could inform future population-based evaluations of TENS without losing sensitivity to the complex data from which the analysis was 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 whether the themes worked in relation to the entire data set: a level 2 review.²⁵ This process was managed by tabulating the different themes identified in each case and looking for the presence or absence of data relating to these themes in other cases.²⁰ The apparent absence of data in a specific interview relating to a theme identified in other interviews triggered a review of the relevant transcript to identify any data relevant to the theme or for 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 was congruent with Yin's multiple case study method,³⁵ although Yin described

the group-level thematic analysis as "drawing cross-case conclusions."³⁵ The thematic analysis was undertaken by the first author and monitored for quality and rigor by the other authors in a series of meetings. The resulting analysis was cross-matched against 4 other less complex qualitative data sets, 3 of which were generated as part of the same research program.²⁰

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 9 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 1. Only 2 participants had a single, uncomplicated regional musculoskeletal pain problem, which supported 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. Three of the 9 respondent validation summaries were returned with helpful comments and clarifications. The comparison with 4 other less-detailed qualitative data sets identified one other relevant subtheme.²¹

Participant pseudonyms shown in Table 1 are used in this article and in an earlier article²⁰ to allow readers to follow the case-level analysis where required. Accounts of the practicalities of TENS

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Table 2.

Summary of Problems With Transcutaneous Electrical Nerve Stimulation (TENS) Use Reported by Experienced TENS Users

Problem Subtheme	Problem	Description of Problem	Consequences
Connectivity	Pad adhesion	Tendency for the pads to peel off the skin with movement, influenced by skin type, body hair, and perspiration (eg, in summer)	TENS not used for activities involving larger movements unless problem overcome with additional tape or strapping
	Wires	Disconnection, especially with larger range of movement (eg, bending) Wires dangling: can catch on external objects	Some users were put off using TENS at times, depending on their activity plans and the severity of the pain
Fitting the TENS device	Reaching to fit the pads	Difficulty in reaching the painful part (reported as a problem for 2 users with low back pain)	Assistance sometimes required to fit pads; if not available, users may be deterred from use
	Clothing	Difficulty of undressing to fit the pads	TENS used less often
Availability	Portability and accessibility	Bulky to carry (eg, in a bag, in case of need)	May not be used away from home
		May be difficult to access at home (eg, on different floor of house)	May not be used when it otherwise would be of benefit
Sensation and settings	Sensation of TENS and the controls	Sensation could be irritating or unhelpful for certain pain sensations	User would experiment with settings and pad positions but may not be successful
		Replacement TENS devices provided sensations that were either too weak or the wrong kind of sensation	At times, users were using suboptimal devices, as they could not find effective replacements for older, broken devices
Visibility	Device or wires are visible to other people	Other people might comment on the TENS device	Users might decide not to wear TENS device in public or would try to conceal it

use in everyday life generated by the interviews were detailed and extensive, so data extracts are used sparingly, but further data extracts are presented elsewhere,^{20,21} in addition to the full respondent validation summaries.²⁰

The analysis indicated that participants learned to address a range of problems in order to optimize TENS use. Experienced TENS users may need to personalize the positioning of electrodes and the TENS settings and to readjust them over time. Patients learned to use TENS in a strategic manner, and the outcomes of each strategy varied. There were limits to the benefits of TENS use that related to the problems with use and to the choices the participants made about engaging with different activities.

Main Theme: Problems With TENS Use

A wide range of problems associated with TENS use was reported. These problems provided some explanation for the choices which patients make about the use or non-use of TENS in different situations. The problems are summarized in Table 2, and the text below indicates the decisions that users made to manage or avoid these problems.

Subtheme: problems with connectivity. The subtheme drew together data describing the difficulties associated with maintaining a connection between the TENS device and the lead, the lead and the pads, and the pads with the skin.

The main problem reported with the pads was the tendency for them to loosen from the skin as the user moved. This was not a universal problem, and some data related it to the users' skin type and body hair. Loosening of the pads also related to the area of the body treated: the knee was reported as a particular problem, especially in association with larger leg movements. As a result, some participants chose not to use TENS for management of leg pain if they wanted to engage in activities requiring larger leg movements (eg, climbing steep stairs). This problem was overcome by one user (Brian) by using a knee support over the pads.

Another problem with connectivity was a tendency of the pads to slide, especially in hot weather, probably due to perspiration. This problem was cited by Fran as limiting the benefits of TENS for gardening because it was normally done in

warm weather, and the larger movements involved in gardening also caused the pads to lift.

The 2 connectivity issues reported with the leads were disconnection, especially with larger movements when the pads were attached to the legs, and the leads catching on external objects. These problems deterred some participants (eg, Oliver, Claire) from using TENS at times, depending on their plans for activity and the severity of the pain.

Subtheme: problems with fitting TENS. The 2 problems reported with fitting the device were difficulty in reaching the painful area to place the pads and undressing to fit the device. Two users with low back pain (Jack and Oliver) required help at times to fit the pads. Oliver explained:

You really do need somebody to help you; it's all right if it's the front of your body, but it isn't, it's my back, so consequently you do need that extra help from somebody to get it on and get it on in the right place.

Undressing to fit the TENS pads deterred Naomi from using TENS, particularly if it

involved placing the pads on her knee. This was cited as a particular obstacle if she was already engaged in an activity, in which case she would tend to take medication instead of fitting TENS, as medication was more convenient.

Subtheme: problems with availability. This theme included reports of practical obstacles to the use of TENS, which meant that participants did not use TENS when they might because the TENS was not available. To illustrate this point, some users compared the portability and, therefore, availability of medication and the relative difficulties with the portability of the TENS device. Naomi did not always want to carry a bag large enough for the TENS device while not in use, so it was not always available when needed. Jack did not want to carry the extra weight of the TENS device. Jack also preferred to wear loose-fitting, comfortable trousers, which did not have a firm waistband to which the TENS could be securely clipped.

Accessibility within the home could also be a problem, particularly if the TENS device was on a different floor of the house or temporarily mislaid among other possessions. Oliver would keep the TENS device in a drawer, thus not be prompted by the visibility of the TENS to use it, so his wife would prompt him to use it if he complained about pain. At times, Sally also required prompting from a family member to use the TENS device, and she reported difficulty in finding her TENS device within the home. Of note, both Oliver and Sally were intermittent TENS users: they experienced daily pain but used TENS only when pain was more intrusive. They reported significant periods of time between these episodes of increased pain when they did not use TENS.

Subtheme: problems with TENS sensation and settings. This theme drew together data relating to a range of problems associated with the sensation of the TENS stimulation and the controls. Some users complained that the sensation was irritating at times. For 2 users (Moirra, Naomi), this irritability was dependent on the quality of the pain, and using TENS with the wrong kind of pain

could aggravate the pain. Naomi also had identified a tendency to become irritated with the sensation if the TENS had been used on the same settings, in the same area and for too long. She would resolve this problem by changing the settings or moving the pads.

Two users (Brian, Sally) referred to difficulties in choosing a replacement TENS device, as they produced sensations that were either too weak to be effective or the wrong kind of sensation. These comments are relevant for TENS evaluation, as there may be variability of sensation among TENS devices. Sally had a strong preference for a particular TENS sensation and complained about the difficulty involved in shopping for a replacement device because the packaging may not clearly indicate the available settings.

Claire found the timing mechanism on her TENS machine to be limiting, especially as she used the device to help her to sleep. She had noticed a tendency to wake up when the stimulation came to an end, and she thought that a machine without a timer might not have this disadvantage.

Subtheme: problems with the visibility of TENS. Moirra reported a problem with using TENS in public because of a concern about its visibility and what other people might think or that they would ask questions. This problem did not always deter her from using TENS in public situations. This was not a universal problem; for example, Fran talked about her ability to conceal the device under her clothing.

The diverse range of problems outlined in this section affected some users more than others. There was a clear interaction among these problems, the benefits that were possible, and the strategies of use chosen (see below). Some users explained how they had learned to overcome a particular problem, and this information is presented in the next section.

Main Theme: Learning to Use TENS

The interviews contained a large amount of data relating to the practicalities of

TENS use, including the use of different settings, different pad positions, and a diverse set of ideas relating to the optimization of TENS use that were more difficult to subcategorize. Taken together, the data indicated that TENS is not a simple intervention that can be quickly taught and then evaluated in daily use. Rather, the accounts of the participants suggested that TENS requires a period of learning to minimize problems and to optimize benefits. Relevant data were analyzed for the purpose of developing a patient information sheet, which has since been published.³⁶

Subtheme: changing the settings. All but 2 of the participants reported changing the settings to optimize the benefits. The participants' reasons for changing the settings are detailed in Box 1.

Box 1. Experienced Transcutaneous Electrical Nerve Stimulation (TENS) Users Reported the Benefits of Changing TENS Settings
<ul style="list-style-type: none">• Some settings worked better when the pain was more severe.• Some settings felt better on one area of pain than another.• Changing the settings from time to time stopped them getting used to one sensation.• An intermittent setting could be used for a longer treatment than a constant setting.• The sensation fades after a while, and increasing the intensity helped to make the TENS effective again.

Naomi explained the process and value of varying the settings:

So I'll vary that (the intensity) according to how much it hurts, um, then I've also got the option of, um, changing the wavelength of it and also the spacing of that, so I'll use, I'll sort of change those depending on, yeah, just depending on how it hurts, and it's a matter of just kind of fiddling and finding out (what) works particularly at that time.

The data indicated the value of adjusting the settings (intensity, pulse duration and pulse rate, and burst/modulated option) to suit the individual, the pain severity, the area to be treated, and the strategy of use (see below). Only one

participant had not experimented, as the participant described receiving prescriptive advice from a therapist about the best settings to use. Another participant used to experiment but reported stopping this experimentation after being given prescriptive advice from a therapist about the best settings.

Subtheme: pad positioning. Each person had his or her own particular methods, and some participants reported the need to be flexible and adapt these methods as their pain experience varied. The different approaches to pad positioning described by users are presented in Box 2. A range of options were represented, and flexibility in pad position was a key theme. This protocol contrasts with the protocols of some clinical trials, which have been prescriptive in their advice regarding pad positioning.¹⁵

Box 2. Experienced Transcutaneous Electrical Nerve Stimulation Users Described Different Options for Pad Positioning

- Two pads, one either side of the pain
- One pad over an area of pain, with a second pad nearby
- Four pads surrounding the area of the pain
- To treat 2 pain problems, use one pair of pads to treat each pain at the same time. Alternatively, treat each area in turn.
- For back or neck pain that is worse on one side of the body than the other, place 2 pads on the more painful side.
- For back pain and leg pain, place 2 pads on the back and another 2 pads in a line down the leg where the pain is experienced.

A range of suggestions were generated when participants were asked to suggest “top tips” for new TENS users. Experimentation, with an aim of increasing confidence in use and overcoming problems, was encouraged. A learning process regarding the settings was described by some participants, 2 of whom (Fran, Jack) had used a diary to log their experiences.

Main Theme: Strategies of TENS Use

The data analysis exploring the reasons why TENS was used in particular situa-

tions indicated a relationship between the context of TENS use and the specific strategy used. Contextual factors included the pain severity, the quality of the pain, and the activity plans of the TENS user. Four strategies were identified from the interviews, and a detailed comparison with the other qualitative data sets²⁰ identified a fifth strategy (ie, to manage morning stiffness). Each strategy had different outcomes.

Subtheme: strategic use at rest.

Transcutaneous electrical nerve stimulation may be used while resting, either in a pain-contingent manner after activities that have increased the pain or preemptively before activities that are then facilitated because of prior TENS use at rest. Problems with connectivity did not interfere with use when resting, so this was an available strategy for those participants with significant connectivity problems (eg, Jack, Claire). Claire was asked specifically about the timing of use:

Interviewer: Are there particular times that you might use the TENS machine?

Claire: Usually, sort of later on in the evening and stuff, like when I'm in bed.

Interviewer: And why is that the case, that it's the evenings?

Claire: Probably because I'm lying down, so it's easier. If I'm moving around, it can come unstuck, so it's easier just to do it in the one place.

This strategy may have been linked with other pain management strategies, such as the use of relaxation methods, or distractions, such as music or watching television. A specific example of TENS use at rest was before sleep to reduce pain-related insomnia. Outcomes included help with symptoms, enhanced rest, and enhanced function after rest.

Subtheme: strategic use during specific activities.

Transcutaneous electrical nerve stimulation was used to help with the symptoms associated with specific activities (eg, sitting, walking), with the aim of enhancing function. This could have been a pre-emptive strategy, with TENS being fitted before the activity started (eg, Fran, Irene, Moira, Oliver,

Claire). Fran explained that she would choose specific settings while sitting:

I was able to enjoy the concert, and I was sat in a very, very uncomfortable chair, you know, but the TENS enabled me to see it.

For this participant and others, benefits of using TENS were significant, including help with symptoms and enhanced specific function. Problems with connectivity, accessibility, and portability sometimes interfered with use during certain activities, limiting the extent of the benefit.

Subtheme: strategic use during general activities.

This strategy involved wearing the TENS unit during everyday activities (rather than at rest or just for specific activities) and was used when increased pain might interfere with a range of daily activities. Problems with connectivity, accessibility, and portability sometimes interfered with use, so it was not a strategy that all users could utilize, but users who were able to overcome these problems might use TENS for much of the day (eg, Oliver, Naomi, Fran). Oliver explained:

It's a tool I use alongside the medication to help me function when the back is playing, to remove that pain, or help take my mind off the pain, to enable me to carry on working, really, and you know, functioning day-to-day.

Patient-reported outcomes from this strategy included help with symptoms and enhanced general function. This strategy might have led to an uplift in general function or was a strategy used when pain was more intrusive to minimize incapacity.

Subtheme: strategic use during a severe pain flare-up.

Using a TENS unit during a flare-up of pain was valuable in helping to reduce symptoms and to mitigate incapacity. This strategy provided help with symptoms that may have been modest in extent but still valued. For example, Sally completed a 100-mm visual analog scale during her interview, which indicated a 16% reduction in pain severity during a flare-up. Users indicated

that TENS may have mitigated a reduction in function associated with a flare-up (eg, Fran, Oliver, Sally, Jack). Jack explained:

If, you know, 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.

Outcomes of TENS use included help with symptoms and a mitigation of the extent of pain-related incapacity during a flare-up (rather than an increase in function).

Subtheme: strategic use to manage morning stiffness. This strategy was the deliberate use of TENS in the morning to help regain mobility caused by morning stiffness and any associated increase in pain. This strategy was identified from cross-matching against 2 other qualitative data sets, so a transcribed quotation is not available to support this strategy.

Main Theme: Individual Limits of TENS Benefits

This theme related to the limits that participants reported regarding the benefits gained from TENS use. There were 3 subthemes: tasks and activities that participants cannot achieve despite using TENS, activities that remain limited despite using TENS, and symptoms that were not helped by TENS. The limits emerged from an interaction of factors relating to the individual participants, their pain problem, their attitudes and beliefs regarding their pain, their ways of using TENS, and any problems that they encountered with use. As limits were individual and depended on the context of TENS use, the case-level analysis was used to understand this main theme.

A useful framework within which to understand the functional limits of TENS use was to consider the activities and tasks that an individual living with chronic pain could normally achieve, those they found difficult to do because of pain, and those not achieved at that time. Although a detailed functional analysis was not planned as part of the interviews, there were sufficient data in most

Table 3. Tasks and Activities Not Achieved by the Interview Participants Despite the Use of Transcutaneous Electrical Nerve Stimulation (TENS)

Participant	Tasks and Activities Not Achieved Despite the Benefits of TENS
Fran	Fran referred to some unspecified activities not undertaken
Irene	Physical aspects of work, longer walks, sports
Brian	Longer walks, paid employment
Jack	Longer walks, paid employment
Claire	"Moving around more": not specified
Naomi	Sports
Sally	Not applicable: Sally did not use TENS for function
Oliver	Sports (eg, badminton, lifting, gardening)
Moira	Longer walks; cycling over 15-min duration

interviews to indicate some activities that could be categorized as tasks and activities that cannot be achieved; these tasks and activities are shown in Table 3. This list indicated that there were limits to the ability of TENS to influence functional goals, as these activities were not achieved despite the benefits of TENS.

The lack of impact of TENS on these activities was explained using 3 categories: (1) the type or quality of pain associated with the activity was not helped by TENS, (2) the severity of the pain that might be associated with or provoked after the activity was experienced as a deterrent to engaging with that level of activity, and (3) there was concern that engaging in the activity might have aggravated the condition causing the pain (ie, caused physical harm).

Evidence of the first category has been presented in a related article,²¹ where Irene described the TENS as being unhelpful for shooting pains, which were more severe, and associated with faster movement.

The second category, severe pain associated with the activity, was indicated by Fran in this extract:

Interviewer: There's a good range of activities there that you use it for, and that helps in all sorts of areas of life. Are there areas where you've found it hasn't helped? Are there areas where you've found the TENS machine hasn't given you that edge?

Fran: Um, that's really difficult, because I do limit myself, because I've worked so long with it now, um, I've become quite a routine person, um, I do get criticized by my family that I don't experiment enough, I don't push myself enough, but I think that's fear, because you do get comfortable in things that you know that TENS is going to work with.

An example of the third category, concern about harm, was provided by Oliver in the following extract. Oliver did not participate in sports, gardening, or decorating because he was concerned that it would worsen his underlying condition:

No, my wife is the gardener. So I don't tend to do physical stuff, decorating or whatever, if I can avoid it, because it's not good for me.

Oliver expanded on the issue about activities that were "not good" in this data extract:

It helps me function from a day-to-day point of view, contributing toward easing pain, definitely, but does it, it doesn't then say okay, well, now I can start laying the garden or picking up paving stones because you're not going to do that anyway, unless you're stupid, because you're going to compound the underlying problem, because it's not curing that, it's, it's a pain reliever, or assistance to pain reliever, not a cure of the underlying problem. And that

underlying problem, whether it's hurting or not, is still there.

The issues explored in this section could relate to fear of increased pain or fear of physical harm: fear avoidance is associated with increased disability.³⁷

In addition to those activities that were not managed despite TENS, a number of participants reported that TENS was less helpful for certain "difficult to manage" activities because of the extent or type of movement involved. This difficulty was partly related to problems with connectivity, with pads peeling off with bending activities (Fran), and when doing jobs around the home (Jack) and to leads becoming disconnected when pads were used to treat knee pain when more mobile (Fran and Naomi). One participant (Moirá) found that TENS did not help her to manage dressing or undressing because the leads complicated the process. Two participants (Fran and Oliver) did not use TENS to help with sleep because the leads would be a problem when they turned over in bed. These issues are qualitatively different from the list of activities that were not engaged in due to lack of help from TENS. These issues were related to the specific movements and postures involved in the activities that the participant was doing, which were not facilitated by TENS use because the problems associated with TENS use interfered with its potential benefits.

Discussion

This research has generated novel findings regarding the problems associated with TENS use and the different strategies that experienced TENS users utilized to optimize the benefit from TENS. Taken together, the findings indicated that TENS is not a simple intervention that can be quickly taught and then evaluated in daily use. Rather, the accounts of the participants suggested that TENS use requires a period of learning to minimize problems and to optimize benefits. There was sufficient evidence that TENS should be considered as a complex intervention.²²

If the strategic use of TENS identified in this study is important for other TENS users, it follows that an evaluation should

be designed to capture what patients use TENS to do, rather than being treated as passive recipients of a treatment prescription that they are expected to adhere to. This type of adherence (participant responsiveness)¹¹ has been debated in relation to medication prescription, where it is synonymous with compliance, defined as "the extent to which a patient's behaviour matches the prescriber's advice."^{38(p115)} Both of these terms were considered to indicate passivity on the part of the patient by Broekmans et al,³⁸ who preferred the term "concordance" used by the Royal Pharmaceutical Society of Great Britain³⁹ to describe the outcome of shared decision making between the patient and the prescriber. There is a risk that a research protocol that calls for a high level of compliance to a fixed protocol (treating TENS as a simple intervention) may inadvertently offset the "benefit to problem ratio" for individuals. Such a trial would have weak ecological validity, if indeed a flexible approach is necessary to optimize TENS benefits. In clinical practice, there may be a risk that a prescriptive clinician expecting patient adherence to his or her advice may have worse outcomes than a clinician willing to use shared decision making⁴⁰⁻⁴² to establish optimal concordance. This issue could be explored by developing a comparative trial of prescriptive versus strategic use. Although it is recognized that patients would prefer shared decision making,⁴³ it should be recognized that achieving this aim is not straightforward,⁴⁴ and it is possible that a clinical tool to foreground shared decision making in the provision of TENS may be helpful.

The findings indicated the value of a flexible approach to pad positioning and choice of settings, including appropriate stimulation intensity, that converges with recently published work highlighting the importance of these factors.^{45,46} This article deliberately uses the word "settings" rather than "parameters," as it was the word used by participants and indicated the active role of patients in varying the settings to optimize the benefits.

An exploration of the strengths and weaknesses of this research has been presented in the related article,²¹ but a specific methodological issue arose in the data analysis relating to this article. The analysis of problems summarized in Table 2 provided a typology but did not indicate the impact of a specific problem on any one participant or the consequences for the participant's use of TENS. The way in which problems could interact with the context of use and strategies of use to influence TENS benefits was complex, as it was influenced by a TENS user's management of specific problems. The limited descriptive and explanatory power of thematic analysis was evident here: it was helpful to develop a taxonomy or typology, but not necessarily useful to explore complex processes, interactions, and experiences.²⁵ To go beyond the thematic analysis, information about a particular problem was incorporated with contextual information about the individual users, the behavior of their pain, their functional difficulties, their goals, their other pain management strategies to explain their use of TENS, and their perceived benefits. This limitation of the thematic analysis in presenting contextualized TENS use was balanced out in this research by the case-level analysis that provided examples of specific problems that were contextualized to demonstrate their impact for individuals and their interaction with other factors.

This exploration of the problems, solutions, and strategies reported by users of TENS for chronic musculoskeletal pain signposts some future research directions. First, the information generated from this research could act as a foundation for an implementation design for a TENS evaluation, including a detailed patient education package as a moderating factor to adherence.¹¹ This education package would require initial evaluation before it is used more widely in a TENS evaluation. Second, the strategic use of TENS warrants further investigation, particularly to assess the frequency of strategic use within a wider population of TENS users. This investigation should incorporate cognitive interviewing⁴⁷ to ensure that the definitions of strategic use have face validity with patients. It

also should facilitate the detection of any further strategies that patients might report. Third, the potential for strategic TENS use to generate different outcomes in different contexts should be evaluated using an approach that explores the relationships among context, mechanism, and outcome, such as realist evaluation.⁴⁸ This approach may require the development of a TENS-specific outcome measure.

The data relating to the problems associated with TENS and the limits of TENS benefits indicated that TENS may be more helpful for less dynamic activities, such as sitting and walking, and less helpful for dynamic activities, such as bending and sports. If this knowledge is generalizable across a wider population of patients with chronic pain, it has the potential to inform TENS evaluation and clinical practice.²² For evaluation, it could inform both patient selection and outcome measure selection. It may be more informative to include patients who have difficulty with sedentary activities (eg, sitting tolerance) in an evaluation. Additionally, it may be more informative to select outcome measures that do not include dynamic activities to improve content validity. Therefore, if TENS is more likely to help some functions than others, a treatment-specific functional outcome measure may be more sensitive than a generic functional outcome measure, reducing the signal-to-noise ratio. In clinical practice, it could guide decision making regarding the likely value of TENS as a treatment for pain-related incapacity, depending on the functional difficulties faced by the individual patient.

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Problems, Solutions, and Strategies Reported by Users of Transcutaneous Electrical Nerve Stimulation for Chronic Musculoskeletal Pain: Qualitative Exploration Using Patient Interviews

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