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Matching the perceived benefits of Transcutaneous Electrical Nerve Stimulation (TENS) for chronic musculoskeletal pain against Patient Reported Outcome Measures using the International Classification of Functioning, Disability and Health (ICF).

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Abstract

Background

There is no consensus regarding the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) for chronic musculoskeletal or low back pain. A review of previous trial methodology identified problems with treatment fidelity. Qualitative research with experienced TENS users identified specific contexts for TENS use, leading to individualised outcomes. There is little information available to guide the selection of Patient Reported Outcome Measures (PROMs) appropriate for TENS evaluation.

Objective

To determine the capability of previously used PROMs to capture the perceived benefits of TENS reported by secondary care Pain Clinic patients who successfully used TENS to manage chronic musculoskeletal pain.

Design

The World Health Organisation International Classification of Functioning, Disability and Health (ICF) was used to match the perceived benefits of TENS against previously used PROMS.

Methods

Semi-structured interviews conducted with nine patients (6 women) as well as three other qualitative datasets (88 patients in total) generated patient-reported benefits which were matched against previously used PROMs using the ICF.

Findings

There were 18 items in the final list of benefits, and none of the four functional outcome measures used in previous RCTs captured more than 8 of these 18 items. The data analysis complemented the inductive thematic analysis but could not replace it, indicating the value of both forms of analysis.

Conclusions

This study highlights a low level of match between outcome measures used in previous TENS studies, and the benefits perceived by experienced TENS users. This suggests that further work is required if the patient-reported benefits of TENS are to be evaluated.

Keywords

Transcutaneous electric nerve stimulation; Patient reported outcome measures; Pain clinics; Qualitative research; Musculoskeletal pain; Low back pain

Manuscript

Introduction

Transcutaneous electrical nerve stimulation (TENS) is a portable, inexpensive and low risk form of electrostimulation which has the potential to improve the quality of life of people who live with chronic musculoskeletal pain [1,2]. Whilst there is evidence to support the hypoalgesic effect of TENS from laboratory studies on healthy humans using experimental pain models [3-7], there is no consensus regarding its effectiveness for chronic musculoskeletal pain [8] or low back pain [9,10]. A review of the methodologies of randomised controlled trials (RCTs) for acute, chronic and cancer pain [11] identified significant problems with elements of implementation fidelity such as limited duration of TENS application, insufficient intensity and limited instruction in TENS use that could explain the lack of evidence of effectiveness. In addition to these methodological issues, Bennett *et al* [11] identified outcome assessment as a key issue which should be addressed to improve the quality of future research.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [12] recommended core patient reported outcome measures (PROMs) for chronic pain clinical trials, including the Brief Pain Inventory [13], the Multidimensional Pain Inventory [14] and the Short Form 36 [15]. The Roland and Morris Disability Questionnaire [16] was recommended as an additional disease-specific PROM for low back pain. PROMs can be judged against eight criteria [17] including validity, reliability, precision, interpretability, feasibility, acceptability, and responsiveness. The eighth criterion of 'appropriateness' describes the "match" of a measure to the "purpose and questions of a trial" [17]. One risk of a poorly matched PROM was highlighted by a clinical audit of long-term users of TENS [18] which indicated that improved sitting tolerance was one important reported benefit of TENS. None of these four IMMPACT-recommended measures include items related to sitting tolerance, so a possible benefit of TENS could be overlooked by these PROMs.

A study using semi-structured interviews explored the benefits reported by nine experienced TENS users with chronic musculoskeletal pain [19,20]. A thematic analysis [21] of these data indicated that pain relief, distraction from pain, and a reduction in the sensations associated with muscle tension/spasm were separate

direct benefits. These direct benefits led to a range of indirect benefits that were dependent upon the way that individuals chose to use their device, including medication reduction, enhanced function, psychological benefits and an enhanced ability to rest. This complex pattern of TENS use, including the number and variability of outcomes, number of behaviours required, and the degree of tailoring of the intervention suggested that it should be considered as a complex intervention [22]. The study also generated a wealth of data regarding the ways in which patients learned to use TENS in their day to day lives, including the problems associated with TENS and how users managed these problems [23]. These data can inform a process evaluation [24] for pragmatic TENS use, informing both clinical practice [25] as well as the design of studies focussed on determining TENS effectiveness.

The present article reports on a secondary analysis of these qualitative data and three other qualitative datasets: an audit [18], a focus group and a service evaluation (88 participants in total) [20] which were linked with the International Classification of Functioning, Disability and Health (ICF) [26]. The outcome of this matching exercise was then compared with PROMs used in previous TENS studies identified by Cochrane reviews [8,9]. The ICF is a taxonomy providing a standardised description of health and health-related states, the primary aim being to provide a standardised language and coding system to facilitate communication across disciplines and around the world. The ICF structure consists of two parts, each part consisting of two components. Part 1 provides two descriptive lists, body structures and body functions, grouped as one component, "Body Functions and Structures". The second component of Part 1 is a list of "Activities and Participation". Part 2 consists of two components: "Environmental Factors" influencing function and disability, and "Personal Factors", which are internal influences on function: the taxonomy for this component has not yet been developed. The ICF uses an alphanumeric coding system. Each component is coded with a different letter: ‘b’ represents body functions, ‘s’ represents body structures, ‘d’ represents activities and participation and ‘e’ represents environmental factors. Following this initial letter, a numerical code begins with a chapter number (one digit), with the option of adding three further digits to indicate more detailed levels of coding.

The ICF was used as a reference framework for this secondary analysis, primarily to facilitate the crossmatching of the data against PROMs [27] to assess the extent of the

match with the perceived benefits reported. The structure of the ICF also facilitated decisions about the amount of detail to preserve in the representation of the data. Using the ICF as a pre-existing code acted as a theoretical framework for deductive thematic analysis [28, 29] of the interview data: a form of methodological triangulation [30]. A number of overlapping concepts are used within outcome research, including health status, functional status, well-being, quality of life and health-related quality of life, which are often used synonymously: in contrast to this, the ICF provides a sharper focus on function [31], supporting the conceptual clarity of the data analysis.

Aim

The aim of this study was to determine the capability of commonly used outcome measures to capture the perceived benefits of TENS reported by secondary care Pain Clinic patients who successfully used TENS devices to help them to manage chronic musculoskeletal pain.

Method

Individual semi-structured interviews were used to generate the primary dataset. Open questions were asked about participants' patterns of TENS use, and their perceptions of the benefits. Data saturation occurred at nine participants [32]. Adult secondary care patients with chronic musculoskeletal pain (more than 3 months) self-reporting benefit from TENS were recruited by means of Pain Clinic waiting room posters in a city in southern England. This purposive sampling strategy [17] was selected to optimise the relevance of the data, which could inform research design for a future TENS evaluation in a Pain Clinic setting. Secondary care Pain Clinic patients may present with more than one pain problem: having more than one area of pain is a negative prognostic factor [33-35] therefore a decision was taken to include any patients with chronic musculoskeletal pain, rather than a narrower focus on one

regional pain. Patients with primary neuropathic pain (such as multiple sclerosis and peripheral neuropathy) and visceral pain were excluded as the natural history and pain mechanisms differ from musculoskeletal pain [36].

A small focus group (2 men, 2 women) had previously discussed these issues: these data were analysed using thematic analysis [21] to develop the discussion guide for the individual semi-structured interviews and these data formed a second dataset for the current study. The third dataset was an audit of 46 experienced TENS users [18] and the fourth was a service evaluation of 29 patients [20]. All datasets were generated from the same Pain Clinic.

Ethical issues

Approvals were 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 for the focus group and interviews: written informed consent was gained from participants. Data were anonymised at the point of transcription and pseudonyms are used for published extracts, modified to remove identifiable information to protect anonymity.

Data analysis using the ICF linking rules

Linking rules were developed [31] to guide the way in which concepts from different sources are mapped against the ICF and were intended primarily to guide the process of comparing different PROMs against the ICF. Limitations recognised by Cieza *et al* [31] were that the rules were primarily designed for linking the ICF with technical and clinical measures, health-status measures and interventions but that they may have other uses, such as linking patient statements in interviews to the ICF. They stated "additional applications may pose challenges which require new rules, or the redefinition and specification of existing rules" [31]. Some redefinition was required for the purposes of this study: the modified linking rules are presented in a simplified form in Table 1, for transparency.

Interview data preparation prior to linking

The interview data linked to the ICF were refined through five stages including the preparation of respondent validation summaries [30] before the linking took place: a summary is presented in Figure 1. The linking exercise was conducted using these respondent validation summaries rather than the original interview data. In cases of uncertainty regarding the coding, the interview transcript was re-examined before a coding decision was taken.

Linking of PROMs against the ICF

The Cochrane review of TENS for chronic low back pain [9] identified 47 potential studies, but only four RCTs met review entry criteria. One study presented in two publications [37,38] was conducted in a laboratory and only measured pain severity, so it was not useful to compare with the qualitative research findings. The PROMs used by the three remaining studies which were appropriate for this matching exercise were linked to the ICF using the updated linking rules [20]. These were the Low Back Outcome Score [39], the Oswestry Disability Index [40], the Roland and Morris Disability Questionnaire [16] and the Short Form 36 (SF-36) [15]. The studies identified for inclusion in the Cochrane review of chronic pain [8] did not capture any outcomes related to function or quality of life.

Findings

Interview data linked with ICF codes

This section first presents the tabulated perceived benefits from one interview (pseudonym Fran, Table 2) to illustrate the recording method used before presenting the integrated perceived benefits from all nine interviews. Each individual interview respondent validation summaries was coded separately, which facilitated a focus on individual differences, and allowed the individual transcript to be examined to assist with the resolution of coding difficulties. Coding issues are presented as footnotes, which act as a commentary about decisions taken during coding. This enhances the transparency of this stage of the data analysis, by allowing access to the detail of the coding process: all nine interviews have been published elsewhere [20].

Integrating coded data

Following the completion of the ICF linking exercise for each individual interview, the data with ICF codes were integrated into summary tables. Two strategies of integrating the coded data were explored: a fine-grained approach, maintaining detail, and a coarse-grained strategy which aimed to facilitate comparison with other data sources and outcome measures. Table 3 shows a fine-grained summary of the ICF body functions identified within the individual interviews. A coarse-grained strategy shown in Table 4 is used to integrate some of the codes which have similar meanings: data related to sleep were grouped together under the ICF code b134, 'sleep functions' and data related to muscle tension and spasm were grouped together under the ICF code b780, 'sensations related to muscles and movement functions'. The course-grained strategy is likely to be more useful in future research exploring the frequency of these perceived benefits within a wider population. Both of these tables indicate on the bottom two rows the number of ICF-linked perceived benefits within each interview, and a running total of ICF-linked benefits. These two rows provide evidence of the decreasing return of new ICF-linked benefits with each further interview, supporting the decision to stop interviewing. These tables facilitated a matching exercise with the other three datasets, and a final list of patient-reported benefits was developed.

Interview data linked with PROMs

The outcome of this matching exercise is presented in Table 5. There are 18 items in the final list of benefits: none of the four functional PROMs would capture more than 8 of these 18 items. The table also indicates that the PROMS include a significant number of items which do not match patient reported benefits, with the SF-36 having 86% of its items non-matching.

Discussion

This study has achieved its aim by conducting the deductive thematic analysis (using the ICF as a theoretical framework) resulting in a list of ICF codes that was crossmatched against three other qualitative datasets. This enhanced list of perceived benefits of TENS was crossmatched against PROMs used in previous TENS studies, highlighting a low level of match between these measures and the benefits perceived

by experienced TENS users. If the list is a reasonable representation of the benefits of TENS within a wider population, then this low degree of matching indicates that these PROMs are at risk of generating results which do not reflect the reality of TENS use. If this risk is considered metaphorically as a “sin of omission” then Table 5 provides a quantitative estimate of the magnitude of this “sin”. The number and percentage of items contained in each PROM which mismatched the list items is also shown in Table 5. This mismatch can be considered metaphorically as a “sin of commission”, which might risk overlooking the actual benefits of TENS, amongst the “noise” of items contained in PROMs which the qualitative data did not indicate were helped by TENS. A consequence of this for patients, clinicians and care providers is that trials using these PROMs may underestimate the efficacy of TENS. This suggests that further work is required to identify suitable outcomes if patient-reported benefits of TENS are to be the focus of an evaluation.

This form of crossmatching perceived benefits of a treatment against PROMS using the ICF may be novel, so we have included discussion of the methodological issues. Difficulties in the analysis using the ICF were recorded as footnotes [20] then summarised using thematic analysis [28], and are presented below. These issues do not undermine the use of the ICF, but they highlight important aspects of the data that the ICF does not represent.

Temporal aspects

Participants made reference to processes and to time, especially in relation to pain experience. For example, a flare-up of pain describes a prolonged exacerbation of pain, which influenced TENS use and the subsequent benefits. TENS was referred to as providing fast pain relief, and facilitating recovery. The ICF cannot code for these temporal aspects, as it does not code for the passage of time: it could be thought of as providing a "snapshot" view as opposed to a “film” representing processes unfolding over time. Temporal aspects were also referred to in relation to the use of TENS to reduce pain after activities, or to facilitate continued function if the pain increased before planned activity.

Experiential aspects

The ICF codes body structures and functions rather than lived experiences of those structures and functions. For example, the code for pain, b280 describes the ability of

the nervous system to process pain, highlighting the sensory rather than the emotional aspects of pain. In contrast, participants talked about the emotional aspects of pain and the role of TENS to enhance coping, with psychological benefits including acceptance and empowerment. These psychological aspects may be represented in the future by the ICF personal factors, but at present they do not have ICF codes. Participants also talked about TENS distracting them from pain, and this is not coded for by the ICF. The inductive thematic analysis offers a richer representation of the data than the ICF analysis alone, and can be used to supplement it in expanding the focus of TENS evaluation.

There were a number of references to a reduction in the use of other forms of pain relief including medication, a reduced requirement to sit to ease pain and a reduction in the requirement for a walking stick, but the ICF does not code for these benefits.

There were some issues with the precision of coding as the ICF may group several activities into one code, such as code d6403, using household appliances such as washing machines, irons and vacuum cleaners. The physical demands of using an iron and a vacuum cleaner are different, so some people with chronic pain may manage one but not another. A similar issue relates to the precision of coding for different types of paid employment: there is a risk of lost information if the code alone is relied upon, as TENS may not help with all kinds of work. Similarly, code d5701, 'managing diet and fitness', groups these two different ways of looking after one's health. No-one reported improved diet, so this imprecision was highlighted in Table 5 by placing the reference to diet in parentheses.

A specific strength in the method used in this study relates to the use of respondent validation summaries as a starting point for matching, rather than interview transcripts. In addition to their primary use, to allow participants to comment on their interview summaries to enhance validity [30] these summaries provided a precis of the interviews from which crossmatching could proceed. This reduced the work required in crossmatching each statement and facilitated the production of individual tables, providing a high degree of transparency to the data analysis [20].

Further work is required to establish the frequency of patient reported benefits related to strategic TENS use within a larger cohort of TENS users, to inform decision making regarding the selection of appropriate outcomes to capture the complex,

strategic use of TENS. Further qualitative work is needed to characterise the psychological benefits and also to determine how to evaluate the distraction from pain reported by some TENS users. A means of quantifying the reduction in the sensations associated with muscle tension/spasm will need to be established if this patient-reported direct benefit is to be evaluated. A treatment-specific approach to evaluating TENS, sensitive to the context of use, may be required before we can determine if the effects of TENS are due to a specific effect, over and above placebo.

Contribution of the Paper

- This study highlights a low level of match between patient reported outcome measures used in previous TENS studies, and the benefits perceived by experienced TENS users.
- There is no consensus regarding the effectiveness of TENS for chronic musculoskeletal pain or low back pain due to a lack of good quality studies.
- A treatment-specific approach to evaluating TENS as a complex intervention, and sensitive to the patient's context of use, may be required before we can determine whether the effects of TENS are due to a specific effect, over and above placebo.

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Conflict of Interest: There are no conflicts of interest.

Ethical Approval: Approvals were 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.

References

[1] Sluka, K. A., J. M. Bjordal, S. Marchand and B. A. Rakel. What Makes Transcutaneous Electrical Nerve Stimulation Work? Making Sense of the Mixed Results in the Clinical Literature. Physical Therapy. 2013;93(10): 1397-1402.

[2] Johnson, MI, Jones G. Transcutaneous electrical nerve stimulation: current status of evidence. Pain Management. 2016;7:4:1-4.

[3] Chesterton LS, Barlas P, Foster NE, Lundeberg T, Wright CC, Baxter GD. Sensory stimulation (TENS): effects of parameter manipulation on mechanical pain thresholds in healthy human subjects. Pain. 2002;99:253-62.

[4] Chesterton LS, Foster NE, Wright CC, Baxter GD, Barlas P. Effects of TENS frequency, intensity and stimulation site parameter manipulation on pressure pain thresholds in healthy human subjects. Pain. 2003;106:73-80.

[5] Moran F, Leonard T, Hawthorne S, Hughes CM, McCrum-Gardner E, Johnson MI, et al. Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity. The Journal of Pain. 2011;12:929-35.

[6] Chen CC, Johnson MI. Differential frequency effects of strong nonpainful transcutaneous electrical nerve stimulation on experimentally induced ischemic pain in healthy human participants. Clin J Pain. 2011;27:434-41.

[7] Choi JC, Kim J, Kang E, Lee JM, Cha J, Kim YJ, et al. Brain mechanisms of pain relief by transcutaneous electrical nerve stimulation: A functional magnetic resonance imaging study. Eur J Pain. 2015.

[8] Nnoaham Kelechi E, Jharna K. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database of Systematic Reviews 2008. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003222.pub3/abstract

[9] Khadilkar A, Odebiyi DO, Brosseau L, Wells GA. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database of Systematic Reviews. 2009. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003008.pub3/full

[10] National Institute for Health Care Excellence. Low back pain and sciatica in over 16s: assessment and management. NICE Guideline NG59. 2016. Available from: https://www.nice.org.uk/guidance/ng59

[11] 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;152:1226-32.

[12] Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005;113:9-19.

[13] Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore. 1994;23:129-38.

[14] Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain. 1985;23:345-56.

[15] Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical Care. 1992;30:473–83.

[16] Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low back pain. Spine. 1983;8:141-4.

[17] Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. 1998; 2(16). Health Technol Assess. 1998;2.

[18] Gladwell P, Bridson J. TENS Effectiveness: Have we been barking up the wrong RCT? Poster session presented at: International Association for the Study of Pain 11th World Congress on Pain. Sydney, Australia 2005. Available at: http://f1000.com/posters/browse/summary/1092879. Accessed 15 December 2018.

[19] Gladwell PW, Badlan K, Cramp F, Palmer S. Direct and Indirect Benefits Reported by Users of Transcutaneous Electrical Nerve Stimulation for Chronic Musculoskeletal

Pain: Qualitative Exploration Using Patient Interviews. Physical Therapy. 2015;95:1518-28.

[20] Gladwell P. Focusing outcome measurement for Transcutaneous Electrical Nerve Stimulation evaluation: incorporating the experiences of TENS users with chronic musculoskeletal pain [PhD thesis]. University of the West of England; 2013.

[21] Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006;3:77-101.

[22] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

[23] Gladwell PW, Badlan K, Cramp F, Palmer S. Problems, Solutions, and Strategies Reported by Users of TENS for Chronic Musculoskeletal Pain: A Qualitative Exploration Using Patient Interviews. Physical Therapy. 2016;96:1039-48.

[24] Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance2015.

[25] Hoeger Bement MK, St Marie BJ, Nordstrom TM, Christensen N, Mongoven JM, Koebner IJ, Fishman SM, Sluka KA. An interprofessional consensus of core competencies for prelicensure education in pain management: curriculum application for physical therapy. Phys Ther. 2014;94:451-65.

[26] World Health Organization. International Classification of Functioning, Disability and Health: ICF. Geneva: WHO; 2001.

[27] Sigl T, Cieza A, Brockow T, Chatterji S, Kostanjsek N, Stucki G. Content comparison of low back pain-specific measures based on the International Classification of Functioning, Disability and Health (ICF). The Clinical Journal of Pain. 2006;22:147-53.

[28] Boyatzis RE. Transforming qualitative information: thematic analysis and code development. Sage; 1998.

[29] Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006;3:77-101.

[30] Flick U. Managing quality in qualitative research. London: Sage; 2007.

[31] Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustün B, Stucki G. ICF linking rules: an update based on lessons learned. J Rehabil Med. 2005;37:212-8.

[32] Guest G, Bunce A, Johnson L. (2006) How Many Interviews Are Enough? An Experiment with Data Saturation and Variability. Field Methods. 2006;18(1):59-82.

[33] Croft, P. The epidemiology of pain: the more you have, the more you get. Annals of the Rheumatic Diseases. 1996:55;859-860

[34] Linton, S. J. and Halldén, K. Can We Screen for Problematic Back Pain? A Screening Questionnaire for Predicting Outcome in Acute and Subacute Back Pain. The Clinical Journal of Pain. 1998:14(3);209-215.

[35] Laisné, F., Lecomte, C. and Corbière, M. (2012) Biopsychosocial predictors of prognosis in musculoskeletal disorders: a systematic review of the literature. Disability and Rehabilitation. 2012:34(5);355-382.

[36] Sluka KA. Mechanisms and management of pain for the physical therapist. Seattle: IASP Press. 2009.

[37] Cheing GL, Hui-Chan CW. Repeated application of TENS produce cumulative effects on chronic clinical pain but not acute experimental pain in chronic low back patients. Proceedings of the 8th World Congress on Pain. 1996;8:85.

[38] Cheing GLY, Hui-Chan CWY. Transcutaneous electrical nerve stimulation: Nonparallel antinociceptive effects on chronic clinical pain and acute experimental pain. Archives of physical medicine and rehabilitation. 1999;80:305-12.

[39] Greenough CG, Fraser RD. Assessment of Outcome in Patients with Low-Back Pain. Spine. 1992;17:36-41.

[40] Fairbank J, Couper J, Davies J, O'Brien J. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy. 1980;66:271-3.

Figure 1. Schematic representation of the management of the individual interview data from the data generation stage through to the linking of the perceived benefits of Transcutaneous Electrical Nerve Stimulation (TENS) against the International Classification of Functioning, Disability and Health (ICF).

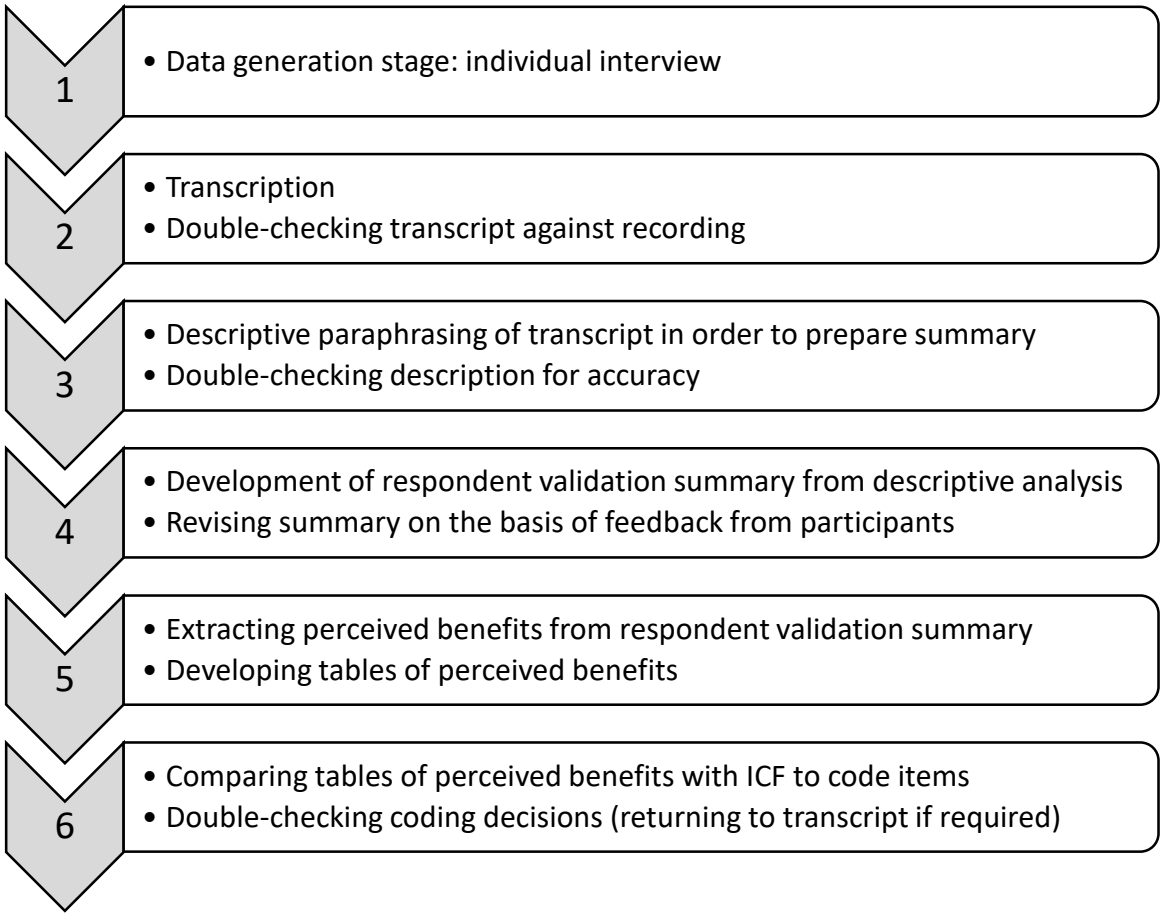

Table 1. Rules for the linking of health-status measures to the International Classification of Functioning, Disability and Health (ICF), presented alongside modifications to these rules developed specifically for matching the perceived benefits of Transcutaneous Electrical Nerve Stimulation (TENS) against the ICF. Modified from Cieza *et al* (2005).

Notation	Specific rules for health-status measures	Modified rules for comparing interview data with the ICF
a.	Before starting the process of linking health-status measures to the ICF categories, identify all meaningful concepts within each item of the health status measure under consideration.	Before starting the process of linking perceived benefits to the ICF categories, identify all meaningful concepts within the interview data.
b.	The response options of an item are linked if they contain meaningful concepts.	Not applicable.
c.	The interval of time to which the item refers such as "during the last week" is not linked to the ICF.	Not applicable.
d.	If a meaningful concept of an item is explained by examples, both the concept and the examples are linked. However, the ICF category to which the examples have been linked will be put within parentheses.	Not applicable.

Table 2. ICF coding of one participant's perceived benefits (pseudonym Fran).

If a segment of text from the respondent validation summary contains two benefits, the text shown in italics is the benefit encoded in that line.

Data from respondent validation summary	ICF detailed classification	ICF Code
It manages the *pain*, so that the pain is not immobilising.	Pain	b280
It manages the pain, so that the pain is *not immobilising*.	Not definable[1]	nd-ph
It allows *reduced medication* during the day, which reduces the side-effects.	Not definable[2]	nd-gh
It allows reduced medication during the day, which *reduces the side-effects*.	Consciousness functions[3]	b110
As a result of these reduced side-effects, she can *drive*, and go to social events.	Driving motorized vehicles	d4751
As a result of these reduced side-effects, she can drive, and *go to social events*.	Recreation and leisure	d920
It helps her to work full-time.	Full-time employment	d8502
It helps her cope with *uncomfortable seating*, which also helps with social events.	Not definable[4]	nd-e
It helps her *cope with* uncomfortable *seating*, which also helps with social events.	Maintaining a sitting position	d4153
It helps her cope with uncomfortable seating, which also helps with *social events*.	Recreation and leisure	d920
It helps with walking and *climbing stairs*, which also helps with social events.	Climbing	d4551
It helps with walking and climbing stairs, which also helps with *social events*.	Recreation and leisure	d920

[1] The ICF does not have a code for "being immobilised", instead it focuses upon muscle functions, or upon more specific activities. Therefore, this more global statement cannot be coded.
[2] The ICF has a code for drugs, e1101, as an environmental factor in chapter 1: products and technology. However, this code does not facilitate coding of a reduction in medication dose.
[3] Fran described the specific side-effects as "knocking her out", also including her speech and vision, balance and coordination. These side-effects made it impossible for her to drive or work. The specific problems described (speech, vision, balance and coordination) are not coded, as the ICF code for consciousness functions is an exclusion to these codes. That is to say, these problems were a consequence of the effect of the medication upon her consciousness functions, rather than an impairment of her visual system, balance system etc.
[4] This improvement in the ability to cope with uncomfortable seating is an example of the way in which improvement in an activity can lead to improvement in participation. However, there is not an ICF code relating to the seating itself, as an environmental factor. The perceived benefit of TENS in helping her to sit is coded in the line below as sitting, d4153.

Data from respondent validation summary	ICF detailed classification	ICF Code
It helps with activities like *shopping*, laundry and vacuuming.	Shopping	d6200
It helps with activities like shopping, *laundry* and vacuuming.	Doing housework[5]	d640
It helps with activities like shopping, laundry and *vacuuming*.	Using household appliances	d6403
It helps her do what able-bodied people do: it offers *normality*.	Not definable[6]	nd-gh
It helps to manage *flare-ups of pain*, together with increased medication and rest.	Not definable[7]	nd-b
Flare-ups of pain are *less frequent*, because of the combination of TENS and medication.	Not covered[8]	nc
It helped her to *accept* her pain, which in the first 18 months, before she used TENS, was more disabling.	Not definable[9]	pf
It works alongside relaxation techniques to help her to *recover* after she gets home from work.	Not definable[10]	nd-gh
It *empowers her, has offered more freedom*, and this has led to reduced isolation.	Not definable[11]	nd-mh
It empowers her, has offered more freedom, and this has led to reduced *isolation*.	Not covered[12]	nc-mh

[5] There is not an ICF code for the task of doing laundry using a washing machine. The closest codes are d6400: Washing and drying clothes and garments (this is only for clothes washed by hand, and dried in the air) or d6403: Using household appliances (this includes using all kinds of household appliances, such as washing machines, dryers, irons, vacuum cleaners and dishwashers). Fran does not specify whether she dries her clothes using a dryer, or a clothesline. This item cannot be coded as either d6400 or d6403. Therefore, it has been given a two-level code, d640 as the code which fits best, even though this is a less precise descriptor.

[6] "Normality" was considered as a psychological benefit of TENS, but there is not an equivalent ICF code.

[7] A flare-up of pain is qualitatively more complex than an increase in pain severity, so the ICF code for pain is not an adequate code for the experience of a flare-up.

[8] In addition to the issue discussed in footnote 6 above, the ICF does not have the facility to code for the frequency of events.

[9] "Acceptance" may be best categorised as a personal factor, and hence does not yet have an ICF code.

[10] "Recovery" indicates an improvement over time which is not solely about pain relief, so b280 as a code is insufficient.

[11] The benefits of freedom, and feeling empowered, are strongly interrelated and are psychological factors which may be categorised in the "personal factors" category of the ICF.

[12] There is not an ICF code relating to the experience of social isolation.

Table 3. ICF body functions identified in each respondent validation summary: fine grained strategy.

In this analysis, the maximum amount of detail is maintained by linking concepts to the most detailed ICF classification. The right-hand column indicates the number of cases reporting each ICF code. The bottom two rows indicate the number of items per case, and the number of new ICF codes identified in each subsequent interview.

ICF code	ICF descriptor	Fran	Irene	Brian	Jack	Claire	Naomi	Sally	Oliver	Moira	n
b110	Consciousness functions	✓									1
b134	Sleep functions		✓	✓			✓				3
b1341	Onset of sleep		✓		✓	✓	✓	✓	✓		6
b140	Attention functions						✓				1
b280	Pain	✓	✓	✓	✓	✓	✓	✓	✓		8
b780	Sensations related to muscles and movement functions		✓								1
b7800	Sensation of muscle stiffness						✓				1
b7801	Sensation of muscle spasm				✓	✓				✓	3
Number of items per case		2	4	2	3	3	5	2	2	1	
Number of new ICF codes		2	3	0	1	0	2	0	0	0	

Table 4. ICF body functions identified in each respondent validation summary: coarse grained strategy.

In this analysis, a coarse-grained strategy is used, using higher level ICF classifications. The right-hand column indicates the number of cases reporting each ICF code. The bottom two rows indicate the number of items per case, and the number of new ICF codes identified in each subsequent interview.

ICF code	ICF descriptor	Fran	Irene	Brian	Jack	Claire	Naomi	Sally	Oliver	Moira	n
b110	Consciousness functions	✓									1
b134	Sleep functions		✓	✓	✓	✓	✓	✓	✓		7
b140	Attention functions						✓				1
b280	Pain	✓	✓	✓	✓	✓	✓	✓	✓		8
b780	Sensations related to muscles and movement functions		✓		✓	✓	✓			✓	5
Number of items per case		2	3	2	3	3	4	2	2	1	
Number of new ICF codes		2	2	0	0	0	1	0	0	0	

Table 5. Matching of items in list of common benefits against the ICF codes linked with the Low Back Outcome Score (LBOS), the Oswestry Disability Index (ODI), the Roland and Morris Disability Questionnaire (RMDQ), and the SF-36.

ICF code	Perceived benefit/ICF descriptor	LBOS	ODI	RMDQ	SF-36
b134	Sleep functions	✓	✓		
b140	Attention functions				
b280	Pain	✓	✓	✓	✓
b780	Sensations related to muscles and movement functions				
d166	Reading				
d5701	Managing (diet and) fitness				
d4153	Maintaining a sitting position	✓	✓		
d4154	Maintaining a standing position		✓	✓	
d450	Walking	✓	✓	✓	✓
d4551	Climbing (stairs)			✓	✓
d470	Using transportation	✓	✓		
d6200	Shopping				
d640	Doing housework	✓			✓
d850	Remunerative employment	✓			✓
d920	Recreation and leisure				
Not coded	Distraction				
Not coded	Medication reduction	✓			
Not coded	Enhanced rest				
Number of items in each PROM matched against list items/Total no. items in list		8/18	6/18	4/18	5/18
Percentage of items in list captured by each PROM (rounded to the nearest integer)		44	33	22	28
Number of items in each PROM which **do not** match list items/Total no. items in PROM		5/13	6/12	20/24	31/36
Percentage of PROM items which **do not** match list items (rounded to the nearest integer)		38	50	83	86