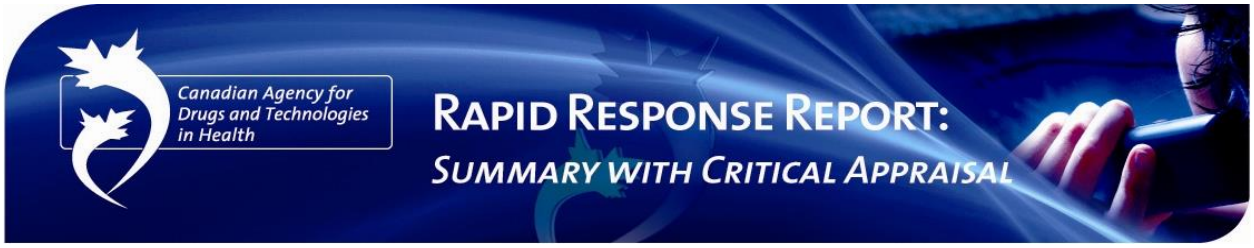

TITLE: Home Transcutaneous Electrical Nerve Stimulation for Chronic Pain: A Review of the Clinical Effectiveness

DATE: 09 December 2016

CONTEXT AND POLICY ISSUES

Chronic pain is one of the most common reasons for seeking medical care.[1] While definitions can vary, chronic pain can be considered "pain without biological value that has persisted beyond the normal time and despite the usual customary efforts to diagnose and treat the original condition and injury."[2] Generally, a minimum of six weeks or longer is considered beyond the normal time, although this definition can vary depending on the condition.[2] To manage chronic pain, a multi-faceted approach to treatment is often recommended in guidelines for management in order to achieve overall therapeutic goals.[2-5] In general, treatment modalities can include pharmacologic and nonpharmacologic approaches, with a combination of treatment modalities being recommended.[1]

Transcutaneous electrical nerve stimulation (TENS) is a nonpharmacologic or physical approach to the management of chronic pain. It involves stimulating the painful region with low-voltage electricity, applied to the skin.[2] Generally, four electrodes are placed around the painful area and 10-30 mA of electricity is delivered at a high or low frequency for 30 to 60 minutes once or twice daily.[2] Electrical stimulation is delivered through the intact skin, near the source of pain and activates nerves in the underlying area, producing a comfortable tingling sensation.[6] TENS is thought to alleviate pain through a 'gating' mechanism in the dorsal horn of the spinal cord which regulates incoming painful stimuli by means of small diameter afferent nerve fibres. Through stimulation of large diameter afferent nerve using TENS, the 'gate' in the dorsal horn can be 'closed' and the perception of pain reduced.[6]

TENS offers a non-invasive, nonpharmacologic option for the management of chronic pain. Traditionally TENS has been administered by a healthcare provider, such as a physiotherapist, in a clinic-based setting. As an alternate approach, TENS may also be applied in a home-based setting by the patient; however, it is unclear if efficacy in this setting is comparable to the clinic-based approach. Further, when delivered at home by the patient, there is potential for reduced efficacy due to issues with adherence to the treatment regimen and appropriate technique (e.g., placement of the electrodes). Moreover, there are different devices available that may produce different frequencies, waveform types, and wave amplitudes.[7]

This report will review evidence of clinical, cost and comparative effectiveness of home-use of TENS in patients with chronic musculoskeletal pain, osteoarthritis or diabetic neuropathy and existing evidence-based guidelines regarding the use of TENS in home-based settings.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of home transcutaneous electrical nerve stimulation (TENS) for patients with chronic pain?

2. What is the comparative clinical effectiveness of home TENS vs. pharmacological interventions for patients with chronic pain?

3. What is the cost-effectiveness of home TENS for patients with chronic pain?

4. What are the evidence-based guidelines regarding home use of TENS?

KEY FINDINGS

Two relevant randomized controlled trials (RCTs) and two relevant non-randomized studies were identified that assessed the clinical effectiveness of home TENS for chronic pain. These studies were inconclusive for the most part, producing mixed results and treatment effect estimates that were of questionable clinical relevance. No relevant literature was identified that assessed the comparative effectiveness home TENS for chronic pain versus pharmacological interventions, or the cost-effectiveness of home TENS use. According to guideline recommendations for the use of TENS (not specific to home use), TENS is not recommended for the management of osteoarthritis of the knee, chronic neck pain, or chronic low back pain, presumably in any delivery format. In contrast, two guidelines recommend the purchase of a home-based TENS to manage chronic pain syndrome and chronic low back pain if initial treatment in a clinic-based setting is effective and frequent use is anticipated, although the linkage to the evidence in this guideline was unclear.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011 and November 9, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations from the database and grey literature searches and selected studies for inclusion. In the first level of screening, titles and abstracts were reviewed and

potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with chronic musculoskeletal pain, osteoarthritis or diabetic neuropathy
Intervention	Home-use of transcutaneous electrical nerve stimulation (TENS)
Comparator	No treatment/sham treatment Pharmacological interventions
Outcomes	Clinical effectiveness (e.g. reduction in pain), harms, cost-effectiveness, evidence-based guidelines
Study Designs	Health technology assessments (HTA), systematic reviews (SR), meta-analyses (MA), randomized controlled trials (RCTs), non-RCTs, guidelines, economic evaluations

Exclusion Criteria

Studies that assessed TENS that was administered by a physiotherapist or other health care professional in a clinic-based setting were excluded from this Rapid Response which was focused on home-use of TENS. Guidance documents or consensus statements that did not include a description of the methodology used in their development, that were not clearly evidence-based, or did not make explicit recommendations were excluded.

Critical Appraisal of Individual Studies

The included randomized controlled trials (RCTs) and cohort studies were assessed with the respective SIGN50 Checklists for their designs.[5] Guidelines were assessed with the AGREE II instrument.[8] Summary scores were not calculated for the included literature; rather, the strengths and limitations of each included guideline or research study was described.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 411 citations were identified in the literature search. Following screening of titles and abstracts, 359 citations were excluded with 52 potentially relevant reports from the electronic search being retrieved for full-text review. Six potentially relevant publications were retrieved from the grey literature search. Of these 58 potentially relevant articles, 49 publications were excluded due to the incorrect population, intervention, outcome, language of the publication or design. Overall, five relevant evidence-based guidelines were included and four studies of clinical effectiveness. Two of the included guidelines made recommendations specific to TENS for home use. While the intervention of interest in this Rapid Response was TENS specifically for home use, three guidelines that recommended against its use without specifying a setting were included assuming that such statements could be interpreted to mean that TENS would not be recommended in any setting for that indication.[5,9,10] Appendix 1 describes the PRISMA flowchart of the study selection.

Summary of Study Characteristics

1. What is the clinical effectiveness of home transcutaneous electrical nerve stimulation (TENS) for patients with chronic pain?

Two RCTs[11,12] and two cohort studies[13,14] were identified in which the clinical effectiveness of home-based TENS was assessed relative to a standard or usual care condition for the management of chronic pain (Appendix 2, Table A1). One RCT was described as single-blind (likely the individual assessing outcomes), was conducted in the United States, and had a duration of three months.[11] Patients with osteoarthritis of the knee were randomized to receive treatment with a wearable TENS device or standard non-operative therapy (defined as self-directed exercise therapy and/or corticosteroid injections), with both groups being permitted to receive background pharmacotherapy. Key outcomes included pain reduction, functional improvements, health-related quality of life (HRQoL), and strength.

The second included RCT was an unblinded trial, carried out in the United Kingdom in patients with tennis elbow, the duration of which exceeded three months in approximately 43% of patients.[12] In this RCT, TENS, in addition to standard primary care management, was compared with standard primary care management alone (defined as advice on activity, self-management, and progressive exercises). The extent of pharmacotherapy use in either group was unclear. Key outcomes included pain, sick days and HRQoL.

The two cohort studies were based upon retrospective analysis of a Medicare claims database in the United States.[13,14] Both were performed using the same database, with one study capturing a more specific subset of patients. While one study included all patients who were identified as having low back pain (identified through coding in the database),[13] the other study included just those patients with low back pain without neurological involvement (again identified through coding).[14] Patients who received TENS were identified through having a claim for a TENS machine. As such, it was presumed that TENS was delivered in a home-based setting in these two studies.[13,14] One cohort study assessed drug costs and opioid use,[13] while the other assessed hospital and clinical visits, use of physical therapy and back surgery, as well as costs associated with these categories of healthcare utilization.[14]

2. What is the comparative clinical effectiveness of home TENS vs. pharmacological interventions for patients with chronic pain?

No relevant literature was identified that evaluated the comparative clinical effectiveness of home TENS compared with pharmacological interventions.

3. What is the cost-effectiveness of home TENS for patients with chronic pain?

No relevant literature was identified that evaluated the cost-effectiveness of home TENS for patients with chronic pain.

4. What are the evidence-based guidelines regarding home use of TENS?

The guideline characteristics, including the criteria used for the grading of recommendations and levels of evidence, are summarized in Table A2, Appendix 2.Two evidence-based guidelines, both from the State of Colorado, Division of Worker's Compensation in the United States, included recommendations specific to home use of TENS.[5,10] One of the two guidelines

was specific to back pain,[5] while the other addressed the management of chronic pain disorder.[10]

Three evidence-based guidelines that included recommendations against the use of TENS were included in this Rapid Response on the premise that the recommendation was applicable to any setting. Two guidelines were Canadian and produced recommendations for the management of low back pain[9] (from Alberta's Towards Optimized Practice group) and the chiropractic treatment of chronic neck pain (from the Canadian Chiropractic Association and the Federation Clinical Practice Guidelines Project).[15] The remaining guideline was produced by an international group (Osteoarthritis Research Society International) and focused on the non-surgical management of osteoarthritis of the knee.[16]

The criteria used to determine the rating of the level evidence and the strength of recommendation for the included guidelines is also summarized in Table A2, Appendix 2. The categorization differed between the guidelines.

Summary of Critical Appraisal

1. *What is the clinical effectiveness of home transcutaneous electrical nerve stimulation (TENS) for patients with chronic pain?*

The critical appraisal of the studies of clinical effectiveness is summarized in Table A3, Appendix 3. Overall, the RCTs that assessed the clinical effectiveness of home TENS were relatively weak in design in that they lacked blinding of the patients.[11,12] This is particularly problematic in that the outcomes assessed were generally subjective in nature, for example, pain or HRQoL. However, given that TENS creates a tingling sensation with the delivery of electricity through the skin, it may not be feasible to maintain blinding of this intervention. Allocation concealment was not described in one study, nor was the method of randomization and this study did not adhere to the intention to treat principle for statistical analysis.[11] One of the two RCTs included a power calculation to help ensure the study had an adequate sample size.[12]The use of background medications was permitted in both groups in one trial, but not the extent of use was not reported, making it difficult to ascertain of the two groups were treated equally. One study reported the adherence rate with TENS. According to predefined adherence criteria, less than one-half (47%) of the TENS group was adherent with their treatment regimen; however, the adherence rate in the primary care management only group was similar (41%).[12]There were potential generalizability issues in both RCTs, related to the exclusion criteria of the trials as patients with epilepsy,[11,12] diabetes with lower-extremity neuropathy,[11] and dermatological conditions[12] were excluded. While a range of important outcomes were reported in both studies, harms were not.

The cohort studies were based upon databases. Both studies used propensity score matching to help improve the baseline similarity between patients in the TENS and non-TENS groups.[13,14] The definitions used for low back pain and TENS were clearly specified in the paper; however, it was unclear if they had been previous validated. Given the data available, it was not possible to determine the dose of TENS, frequency of use or level of adherence to treatment in either study.[13,14] Further, any harms or adverse effects of TENS were not reported in the publications.[13,14]

2. What is the comparative clinical effectiveness of home TENS vs. pharmacological interventions for patients with chronic pain?

No relevant literature was identified that evaluated the comparative clinical effectiveness of home TENS compared with pharmacological interventions.

3. What is the cost-effectiveness of home TENS for patients with chronic pain?

No relevant literature was identified that evaluated the cost-effectiveness of home TENS for patients with chronic pain.

4. What are the evidence-based guidelines regarding home use of TENS?

The critical appraisal of the included guidelines is summarized in Table A4, Appendix 3. The included guidelines were methodologically rigorous in their development processes for the most part, with clearly stated objectives and target users of the guidelines.[5,9,10,15,16] It was reported that methodology of the AGREE collaboration was adhered to in two guidelines,[9,15] although from the details reported it was unclear if all steps of the AGREE methodology were performed (such as having a process in place for updating the guidelines or having the guideline externally reviewed as part of the development process).[15] Systematic literature searches to identify the relevant literature from electronic databases, hand searching and grey literature searches were reported.[5,9,10,15,16] However, one area in which there was a lack of clarity was in the process and criteria with which the relevant literature was screened into the guidelines for inclusion.[9,16]

Four of the included guidelines had multidisciplinary working groups responsible for formulating recommendations, with a broad range of health professions and other experts represented.[5,9,10,16] The guideline from the Canadian Chiropractic Association and the Federation Clinical Practice Guidelines Project, appeared to only have representation from chiropractors and occupational therapists.[15] Four of the included guidelines were unclear as to whether the views of patients or other end users were sought. [5,9,10,15] An exception to this was the guideline produced by the Osteoarthritis Research Society International[16] which included a patient advocate as part of the guidelines development group and posted the guideline for public feedback.

The process used by these groups to formulate recommendations, however, was sometimes unclear. The Towards Optimized Practice Guideline was developed from a systematic review of guidelines, supplemented by additional literature sources if needed for some topics.[9] It was unclear how the quality of the seed guidelines was considered in making overall recommendations; however, only guidelines that were considered to be of "good" quality were eligible for inclusion in the guideline development process.[9] Further, when making recommendations based upon the literature, the guidelines from the State of Colorado, Division of Worker's Compensation were unclear with respect to the linkage between the recommendations made and the evidence-base from which they were drawn. While recommendations were quite specific with respect to frequencies, duration and maximum treatment, it was not clear if these details were tied to the literature.[5,10]

Summary of Findings

1. What is the clinical effectiveness of home transcutaneous electrical nerve stimulation (TENS) for patients with chronic pain?

Summary of findings and conclusions from the included RCTs and cohort studies are found in Appendix 4, Table A5.

The RCTs that assessed TENS combined with standard care relative to standard care alone found statistical differences for some, but not all outcomes. Specifically, in patients with osteoarthritis of the knee statistical improvements were seen in the timed up and go test (an assessment of mobility) and passive range of motion (extension).[11] As well, the difference in improvements in the Knee Society Score between groups was statistical significant for the objective score (which considers alignment, joint motion, instability and symptoms), the physical component summary (PCS) of the SF-36 (a measure of the physical aspects of HRQoL), and Lower Extremity Functional Scale.[11] Differences in change between the TENS and usual care group on the 2-minute walk test, functional Knee Society Score (a which considers walking, standing and other activities), mental component score (MCS) of the SF-36 (a measure of the mental aspects of HRQoL) and pain did not differ statistically. The authors concluded while positive results were shown, larger randomized studies were required to assess the effects of TENS on OA of the knee.

In an RCT that assessed TENS in addition to primary care management relative to primary care management alone in patients with tennis elbow no difference was found in pain intensity (evaluated on a 10-point numeric rating scale) after six weeks, six months or 12 months of treatment.[12] As well, the proportion of patients who rated their tennis elbow as 'much better' did not differ statistically between groups at any of the three time points. HRQoL was assessed with the SF-12 and the EQ-5D and differences between groups at any of the time points were not statistically significant, with the exception of the SF-12 MCS at 12 months, which was 3.35 (95% confidence interval [CI]: 0.14 to 6.56) greater in the group that received TENS. The authors concluded that the addition of TENS to usual care did not improve outcomes.

In one of the two cohort studies that looked only at opioid use and drug costs, a lower proportion of the TENS group used opioids during the period of data capture (57.7% compared with 60.3%, $P < 0.0001$).[13] Related to this, the average opioid cost was lower ($169 for the TENS group compared with $192 for the non-TENS group). The average pharmacy cost for the TENS group was also lower ($2955 for the TENS group compared with $3104 for the non-TENS group). The authors concluded that TENS may allow physicians to be more aggressive in treating chronic low back pain since it is non-invasive and a non-narcotic.

In the second cohort study,[14] health care utilization and costs were assessed. A lower proportion of the TENS group had an emergency department visit (overall or pain-related) or inpatient hospital stay (overall or pain-related). Total healthcare costs ($17 957 for TENS compared with $17 986 for the non-TENS group, $P < 0.0001$) and costs related to physical therapy ($793 for TENS compared with $865 for the non-TENS group, $P < 0.0001$) and imaging ($244 for TENS compared with $373 for the non-TENS group, $P < 0.0001$) were lower for the TENS group, whereas there was no statistical difference in back surgery costs ($94 for TENS compared with $101 for the non-TENS group, $P = 0.31$). The authors concluded that TENS was associated with lower rates of utilization and costs, but the differences might not be clinically compelling.

2. What is the comparative clinical effectiveness of home TENS vs. pharmacological interventions for patients with chronic pain?

No relevant literature was identified that evaluated the comparative clinical effectiveness of home TENS compared with pharmacological interventions.

3. What is the cost-effectiveness of home TENS for patients with chronic pain?

No relevant literature was identified that evaluated the cost-effectiveness of home TENS for patients with chronic pain.

4. What are the evidence-based guidelines regarding home use of TENS?

Summary of guideline recommendations are found in Appendix 4, Table A6.

Two guidelines included recommendations specific to the home use of TENS, one in low back pain[5] and one in chronic pain disorder.[10] In low back pain, general recommendations are made with respect to the use of TENS in a clinic-based setting, delivered by a healthcare professional and it is then stated that "Consistent, measurable functional improvement must be documented prior to the purchase of a home unit."[5] Similarly, guidelines for chronic pain disorder include a statement that "A TENS home unit should be purchased if treatment is effective and frequent use is recommended."[10] This recommendation was made following a maximum of four treatments with TENS in clinic-based setting, delivered by a healthcare provider.

The remaining three guidelines did not support the use of TENS (presumably in any setting) for the treatment of low back pain,[9] chronic neck pain,[15] or osteoarthritis of the knee,[16] due to a lack of literature, inconclusive findings or inconsistent results.

Limitations

Overall, the literature that assessed the clinical effectiveness of TENS for home use was limited in quantity and quality. Two RCTs were identified in two specific conditions (osteoarthritis of the knee and tennis elbow). The study in osteoarthritis included few patients, which could potentially limit the generalizability depending on the representativeness of the samples.[11] Further, this study did not include a power calculation to determine if it had adequate statistical power.[11] The study in osteoarthritis was carried out in a single centre, which was a referral clinic for severe joint problems, which could limit the generalizability. Approximately 10% of the patients in the RCT in tennis elbow had a pain duration of less than one month, while an additional 49% had tennis elbow for one to three months. Thus, a portion of the patients enrolled in this trial may not be considered to have chronic pain. Other issues with these RCTs that potentially compromised their internal validity included a lack of reporting of the methods of allocation concealment and blinding,[11] and open-label assessment of subjective outcomes such as pain and HRQoL,[11,12] although the ability to blind an intervention such as TENS may not be possible given the sensation created by the delivery of electricity through the skin. The ability to assess the true effect of the intervention was also potentially compromised by a number of factors in the studies. Adherence with TENS problematic, with adherence rates of about 50%, and the use of background therapies (such as pain medications) as a co-intervention was permitted, but poorly reported.[11,12]

Two cohort studies provided some additional outcome data on opioid use, drug costs, healthcare utilization and healthcare costs, but these studies have important limitations.[13,14] There are issues with generalizability of the results of the two cohort studies given that they were carried out in the United States, where the healthcare system is structured differently. Presumably drivers of utilization and potential barriers to use may differ in that context relative to Canada. Further, the studies were performed using databases and could not capture important information about the dose and frequency of use of TENS and adherence with treatment recommendations. Moreover, the identification of patients with low back pain and users of TENS was through codes in a database. It was unclear if these definitions had been previously validated. Finally, the cohort studies cannot control for all known and any unknown confounders. As such, there is a potential for bias in the results.

Harms were not assessed in either of the RCTs or in the cohort studies, which leaves an evidence gap with respect to safety of TENS for home use. No literature was identified in which the clinical effectiveness of TENS for home use in diabetic neuropathy was identified. Neuropathy was an exclusion criteria in one of the RCTs included in this Rapid Response.[11]

While cost and healthcare utilization were assessed as outcomes in the two included cohort studies, no studies of true cost-effectiveness of home use of TENS were identified for chronic pain, nor were any studies of the comparative effectiveness of home use TENS relative to pharmacotherapy or other treatment approaches beyond what was considered to be standard care.

Guidelines specific to the home use of TENS were limited and were not identified for all of the chronic pain populations of interest (e.g., diabetic neuropathy) and it was assumed that those that recommended against the use of TENS were generalizable to any setting. However, it is unclear if this was the true intent of the guideline.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Two RCTs and two cohort studies assessed the clinical effectiveness of home use of TENS for chronic pain and produced inconclusive results overall. While improvements for some functional outcomes were noted in one RCT, within the same study no differences were found for other measures. Improvements in HRQoL and pain were minimal and statistically nonsignificant in both RCTs. Differences in healthcare utilization and costs associated with TENS use were of unclear clinical relevance in two cohort studies. Overall, the included literature that assessed the clinical effectiveness of home TENS in chronic pain has limitations with respect to internal validity and generalizability. Two guidelines that addressed the home use of TENS in low back pain and chronic pain disorder recommended purchase of a unit only if TENS was shown to be effective in clinic-based setting first. No evidence of the cost-effectiveness or clinical effectiveness of TENS was identified.

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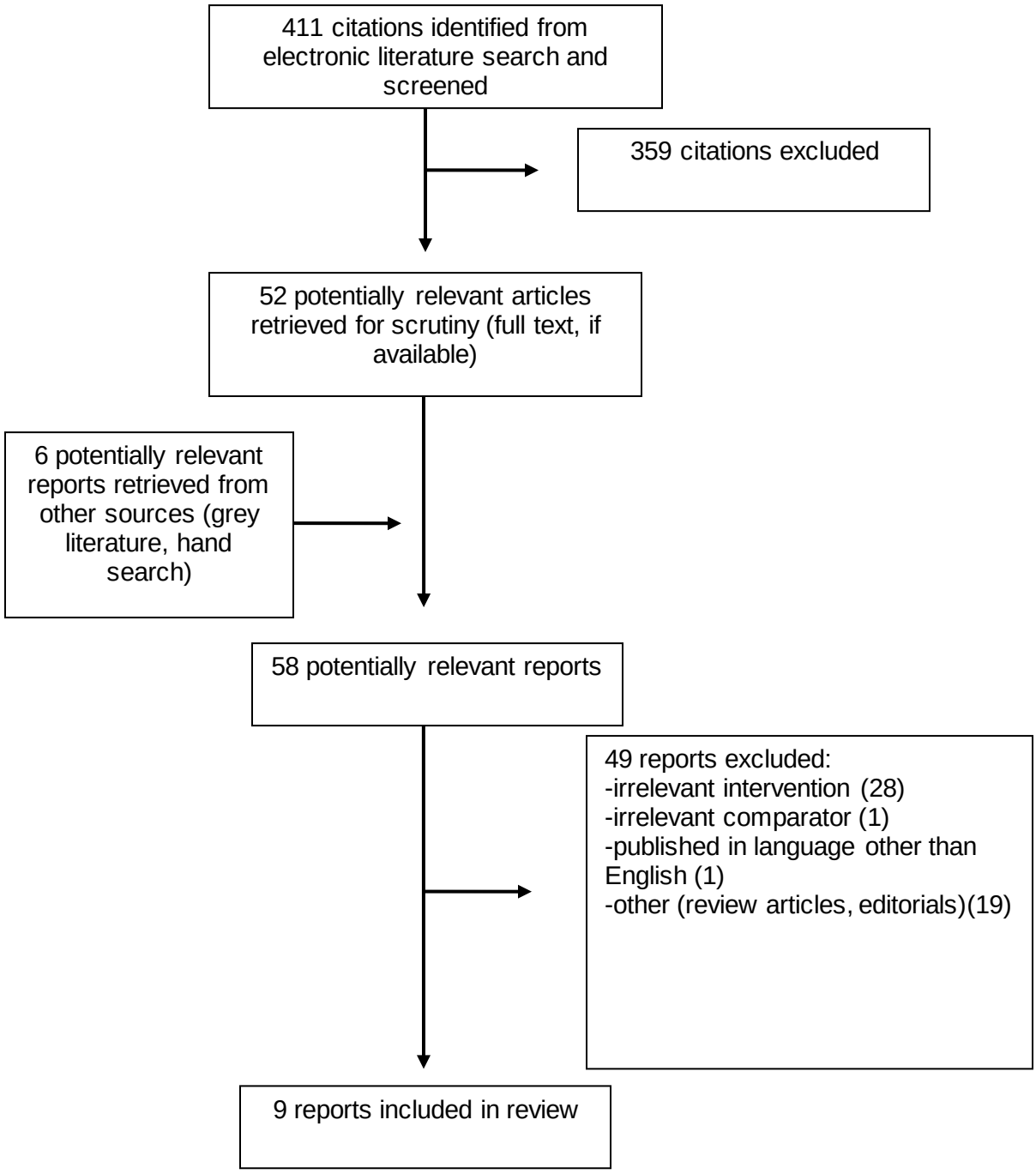
APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Study Design and duration	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
Randomized Controlled Trials					
Cherian et al., 2015[11] United States	Prospective, randomized single-blind trial 3 months	25 adults with osteoarthritis of the knee. 78% Female Average age: 54 (I) to 55 (C) years	TENS device housed in specialized wrap for the knee to permit wearing through activities except bathing or swimming. The TENS device delivered 12-second intervals of grouped pulses with rate and duration varying between each cycle. Low voltage current was used.	Standard nonoperative therapy with or without corticosteroid injections. Both groups could receive any pain medications such as NSAIDS and narcotics.	Pain reduction, subjective functional improvements (e.g., LEFS, objective and functional KSS), objective functional improvements (e.g., TUGT, 2 minute walk test), HRQoL (e.g., SF-36), isokinetic strength.
Chesterton et al., 2013[12] United Kingdom	Unblinded, randomized, controlled trial. 12 months	241 adults with tennis elbow. 45% Female Average Age: 48 years 43% had symptoms for more than three months	Primary care management plus patient controlled TENS. TENS machine with self-adhesive, reusable electrodes pads for use 45 minutes per day on days where pain persisted. TENS could be used more frequently if the patient wished. High frequency TENS was used. Duration of use was a minimum of six weeks.	Primary care management only: Information and advice about exercise, self-management, and activity.	Pain NRS, pain global rating scale, number of sick days, HRQoL (SF-12, EQ-5D)
Cohort Studies					
Pivec et al., 2015[13] United States	Retrospective cohort study based on claims data.	45 826 adult patients with CLBP	Code for a TENS device	No code for a TENS device, but received other therapy	Drug costs, opioid use

Table A1: Characteristics of Included Clinical Studies

First Author, Publication Year, Country, Study Name	Study Design and duration	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes
	Patients with CLBP who received TENS were propensity score matched to a group of patients with CLBP who did not receive TENS. TENS was identified through a database claim for a TENS machine. As such, it presumed that TENS was delivered as a home-based intervention. 12 months	Average age: 50.6 65% Female Excluded patients diagnosed with cancer or neurodegenerative disease.		including PT, opioids, back surgery or diagnostic imaging.	
Pivec et al., 2013[14] United States	Retrospective cohort study based on claims data. Patients with CLBP who received TENS were propensity score matched to a group of patients with CLBP who did not receive TENS. TENS was identified through a database claim for a TENS machine. As such, it presumed that TENS was delivered as a home-based intervention.	16 593 adult patients with CLBP without neurological involvement.*	Code for a TENS device	No code for a TENS device, but received other therapy including PT, opioids, back surgery or diagnostic imaging.	Hospital and clinic visits, physical therapy use, back surgery, costs

***** Patients in Pivec et al., 2013[14] are a subset of patients included in Pivec et al., 2015[13]

CLBP=Chronic lower back pain; C=Control; HRQoL=Health-related quality of life; I=Intervention; KSS=Knee Society Score; LEFS=Lower extremity function score; NSAID=Nonsteroidal anti-inflammatory; NRS= Numeric rating scale; SF= Short Form; TENS= Transcutaneous electrical nerve stimulation; TUGT=Timed up and go test; VAS=Visual analog scale

Table A2: Characteristics of Included Guidelines

Guideline Society or Collaboration, Country	Focus of Guideline	Strength of Recommendation	Level of Evidence
Towards Optimized Practice, 2015[9] Canada	Adults with low back pain	**"Do** • The Guideline Development Group (GDG) accepted the original recommendation, which provided a prescriptive direction to perform the action or used the term "effective" to describe it • The GDG supplemented a recommendation or created a new one, based on their collective professional opinion, which supported the action • A supplementary literature search found at least one systematic review presenting consistent evidence to support the action **Do not do** • The GDG accepted the original recommendation, which provided a prescriptive direction not to perform the action, used the term "ineffective" to describe it, or stated that the evidence does "not support" it • The GDG supplemented a recommendation or created a new one, based on their collective professional opinion, which did not support the action • A supplementary literature search found at least one systematic review presenting consistent evidence that did not support the action **Do not know** • The Guideline Development Group (GDG) accepted the original recommendation, which provided a prescriptive direction to perform the action or used the term "effective" to describe it • The GDG supplemented a recommendation or created a new one, based on their collective professional opinion, which supported the action	Systemic Review Randomized Control Trial Non-Randomized Comparative Study Case Series Guideline Expert Opinion

Table A2: Characteristics of Included Guidelines

Guideline Society or Collaboration, Country	Focus of Guideline	Strength of Recommendation	Level of Evidence
		• A supplementary literature search found at least one systematic review presenting consistent evidence to support the action"[9]p.25	
Canadian Chiropractic Association and the Federation Clinical Practice Guidelines Project, 2014[15] Canada	Adults with Chronic Neck Pain	**Strong** Consistent findings among ≥2 low-risk-of-bias controlled trials with no limiting factors **Moderate** Consistent findings among ≥ 2 low-risk-of-bias controlled trials with minor limiting factors or 1 low-risk-of-bias controlled trial with no limiting factors **Weak** 1 low-risk-of-bias controlled trial with limiting factors **Inconsistent** Unresolvable differences	
Low Back Pain; State of Colorado, Division of Worker's Compensation, 2014[5] United States	Adults with back pain	**"Consensus** means the judgment of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established." **"Some"** evidence means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect. **"Good"** evidence means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect. **"Strong"** evidence means the recommendation considered the availability of multiple relevant and	Stated as following GRADE methodology.

Table A2: Characteristics of Included Guidelines

Guideline Society or Collaboration, Country	Focus of Guideline	Strength of Recommendation	Level of Evidence
		high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect."[5]p.3-4	
Osteoarthritis Research Society International, 2014[16]	Non-surgical management of knee osteoarthritis	**Not Reported**	Quality of evidence: The methodological rigor of the highest level of evidence used. Meta-analyses and SRs were assigned a quality rating of "Good", "Fair", or "Poor" using the Assessment of Multiple Systematic Reviews Tool (AMSTAR). The Cochrane Risk of Bias Assessment Method was used to rate RCTs.
State of Colorado, Division of Worker's Compensation, 2011[10] United States	Chronic Pain Disorder	**"Consensus** means the judgment of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established." **"Some"** evidence means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect. **"Good"** evidence means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on	Stated as following GRADE methodology.

Table A2: Characteristics of Included Guidelines			
Guideline Society or Collaboration, Country	**Focus of Guideline**	**Strength of Recommendation**	**Level of Evidence**
		the intervention's effect. **"Strong"** evidence means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect."[10]p.3-4	

AMSTAR= Assessment of Multiple Systematic Reviews Tool; GDG=Guidelines development group; GRADE= Grading of Recommendations Assessment, Development and Evaluation; RCT=Randomized controlled trial

APPENDIX 3: Critical Appraisal of Included Publications

Table A3: Strengths and Limitations of Randomized Controlled Trials and Cohort Studies using the SIGN50 Checklists[5]

Strengths	Limitations
Cherian et al., 2015[11]	
• The research question is clear, appropriate and focused. • The outcome measures appear to be standard assessments. A wide range of outcomes were assessed, including pain, function and HRQoL, and range of motion. • Less than 10% of the study population was lost to follow-up.	• The trial is described as randomized, but the methods used for randomization and allocation concealment are not described. • While the trial was described as single-blind, it is unclear who was blinded to treatment allocation. Presumably, it was the individuals assessing the outcomes (other than PROs) but this was not stated. • Unblinded assessment of PROs is problematic given the subjective nature of these measures. This creates a potential for bias. • Background medications were permitted for pain control and the extent of use was not reported. Thus, it was unclear if both groups were treated equally other than the TENS intervention. • The statistical analysis was not based on the intention to treat principle. • The study was carried out at a specialized referral joint clinic. This might limit the generalizability. • Individuals with epilepsy or diabetes with lower-extremity neuropathy were excluded. Thus, the results of this study would not be generalizable to these groups. • Harms were not reported.
Chesterton et al., 2013[12]	
• The research question is clear, appropriate and focused. • The outcome measures appear to be standard assessments. A range of outcomes were assessed, including pain, HRQoL, and sick leave from work. • The study was carried out at multiple centres, which may improve generalizability. However, there was no analysis to determine if outcomes were consistent across centres. • Appropriate methods of randomization and allocation concealment were used. • Background therapies were permitted and appeared to be used equally between groups.	• The loss to follow-up was unbalanced between the groups, with more being lost from the primary care only group. • Seven patients in the primary care only group received TENS. • Unblinded assessment of PROs is problematic given the subjective nature of these measures. This creates a potential for bias. • Adherence with TENS was less than 50%. • Follow-up over the course of the study was via mail questionnaire. There was no reassessment in the clinic setting which could have provided the opportunity to reassess adherence and proper use. • Approximately 10% of the population with tennis elbow had a duration of less than one month, while another 49% had a duration of one to three months. Depending on the definition, these patients might not be considered to have chronic pain. This could limit the generalizability of the results. • Harms were not reported.
Pivec et al., 2015[13]	
• The research question was clear and focused (specifically on opioid use). • Propensity score matching was used to select two groups of patients that were similar with respect to a number of important characteristics. • As the study was based on a database, all selected individuals participated.	• Harms were not reported. • It would be possible for individuals to have used opioids that were not captured in the database if they were not billed through Medicaid. • The use of TENS was identified by a database claim for a TENS machine. However, the frequency of use, intensity and duration could not be ascertained from

Table A3: Strengths and Limitations of Randomized Controlled Trials and Cohort Studies using the SIGN50 Checklists[5]	
Strengths	**Limitations**
• Follow-up was complete as the study participants were selected based upon complete claims data. • The outcomes were clearly defined based upon database codes and outlined in the publication.	the database. • It was unclear if the definitions used to identify patients with LBP in the claims database had been previously validated. • The statistical reporting was poor, without confidence intervals and sometimes missing point estimates.
Pivec et al., 2013[14]	
• The research question was clear and focused (specifically on opioid use). • Propensity score matching was used to select two groups of patients that were similar with respect to a number of important characteristics. • As the study was based on a database, all selected individuals participated. • Follow-up was complete as the study participants were selected based upon complete claims data. • The outcomes were clearly defined based upon database codes and outlined in the publication.	• Harms were not reported. • It would be possible for individuals to have used opioids that were not captured in the database if they were not billed through Medicaid. • The use of TENS was identified by a database claim for a TENS machine. However, the frequency of use, intensity and duration could not be ascertained from the database. • It was unclear if the definitions used to identify patients with LBP in the claims database had been previously validated. • The statistical reporting was poor, without confidence intervals and sometimes missing point estimates.

HRQoL= Health-related quality of life; LBP=Low back pain; PROs= Patient reported outcomes; TENS= Transcutaneous electrical nerve stimulation

Table A4: Summary of Critical Appraisal Using AGREE II[8]		
Guideline Society or Collaboration, Country, Author and Year	**Strengths**	**Limitations**
Towards Optimized Practice, 2015[9] Canada	• The guideline development group included family physicians, specialist physicians, physiotherapists, occupational therapists, nurses, pharmacists, researchers, and psychologists. • The literature search was systematic and extensive. • The quality of included guidelines was assessed according to the AGREE tool (but not reported in the final guideline). • The level of evidence to support each recommendation was clear, but the underlying quality of that evidence was not reported. • Process for developing recommendations was reported in a separate publication.[17]	• The selection criteria for the seed guidelines were unclear. • Some of the seed guidelines were potentially out of date (published as early as 2003). • Unclear how guideline quality was considered in making the recommendation. • The underlying quality of the evidence to support the recommendations was not reported.
Canadian Chiropractic Association and the Federation Clinical Practice Guidelines Project, 2014[15]	• Guideline development committee used a process based upon the criteria of the Appraisal of Guidelines Research and Evaluation (AGREE) collaboration for literature searching, screening, review, analysis, and interpretation • Objective and target audience of guideline clearly stated as “a supportive tool for practitioners and for their patients.” The guideline was not intended to be used as a standard of care.	• Unclear if the development group included individuals from all relevant professionals (Chiropractors and Occupational Therapy appeared to be represented) • It was unclear if there was a mechanism for updating the guideline. • It was unclear if the guideline had been externally reviewed as part of

Table A4: Summary of Critical Appraisal Using AGREE II[8]		
Guideline Society or Collaboration, Country, Author and Year	**Strengths**	**Limitations**
	• The strengths and limitations of the available evidence were clearly summarized. • The criteria for selecting the evidence were clearly stated. • The link between the recommendations and the supporting evidence was clear. • The literature search appeared to be comprehensive, consisting of database searching and hand searching.	the development process.
Low Back Pain; State of Colorado, Division of Worker's Compensation, 2014[5] United States	• Used a standard process that follows the GRADE methodology. • Clearly states the objective, target population and user of the guidelines. • Very detailed and explicit recommendations for treatment. • Used systematic literature review methods to identify the relevant literature. • Explicitly stated that the studies were too heterogeneous to pool any data. • Assessed the quality of the included studies using the Cochrane Risk of Bias Tool.	• The recommendations in the guideline were not explicitly linked to the evidence.
Osteoarthritis Research Society International, 2014[16]	• The guideline had clearly stated objectives and the target users (practitioners internationally) was clear. • The methods used to identify the relevant literature were clear and included database and hand searches. • The guideline development group included orthopedic surgeons, physical therapists, a primary care practitioner, clinical guidelines methodologist, one physical therapy and rehabilitation specialist, and one patient advocate. • Conflict of interest and method of handling (refraining from voting) was clearly stated. • The methods and process used by the committee to arrive at the recommendations was clear (voting on appropriateness according to the RAND/UCLA Appropriateness Method). • Recommendations were clear with a clear link to the literature. • The guideline had been disseminated for public comment prior to finalization.	• The criteria for literature selection and inclusion were unclear. • The methods for data extraction and synthesis were not clearly described. • It did not appear that the guideline had a process for updating.
Chronic Pain Disorder; State of Colorado, Division of Worker's Compensation, 2011[10]	• Used a standard process that follows the GRADE methodology. • Clearly states the objective, target population and user of the guidelines. • Very detailed and explicit recommendations for treatment. • Used systematic literature review methods to identify the relevant literature.	• The recommendations in the guideline are not explicitly linked to the evidence.

Table A4: Summary of Critical Appraisal Using AGREE II[8]		
Guideline Society or Collaboration, Country, Author and Year	**Strengths**	**Limitations**
	• Explicitly stated that the studies were too heterogeneous to pool any data. • Assessed the quality of the included studies using the Cochrane Risk of Bias Tool.	

AGREE – Appraisal of Guidelines for Research and Evaluation; GRADE – Grading of Recommendations Assessment, Development and Evaluation; RCT – Randomized controlled trial; SIGN - Scottish Intercollegiate Guidelines Network; UCLA=University of California at Los Angeles

APPENDIX 4: Main Study Findings and Author's Conclusions

Table A5: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Cherian et al., 2015[11]	
Change in Timed up and go (Mean Seconds) TENS -7.2 SC 3.9 (p=0.003) **Change in 2-Minute Walk (Mean Feet)** TENS 75.0 SC 44.9 (p=0.36) **Change in Passive Range of Motion (Extension)** TENS 0.23 SC 5.6 (p=0.04) **Change in Knee Society Score (Functional)** TENS 18.8 SC 10.4 (p=0.31) **Change in Knee Society Score (Objective)** TENS 23.2 SC 7.3 (p=0.03) **Change in SF-36 (Mental)** TENS 4.1 SC 1.1 (p=0.56) **Change in SF-36 (Physical)** TENS 11.4 SC 1.7 (p=0.03) **Change in Pain VAS** TENS -2.6 SC -1.3 (p=0.18) **Change in Lower Extremity Functional Scale** TENS 20.8 SC 7.5 (p=0.04)	*"In conclusion, the use of TENS was shown to have positive results on the improvement of pain, subjective and objective functional outcomes, as well as QOL in patients who have a painful osteoarthritic knee. We attributed our finding to the ability of this novel TENS to be worn throughout most ADL without disruption. However, due our limitations in the sample size, larger, randomized, prospective studies are require to better quantify the effects of TENS on painful knee arthritis." P.326*
Chesterton et al., 2013[12]	
Mean (SD) Change in Pain Intensity on 10 Point NRS at 6 weeks Primary Care Plus TENS: 1.9 (2.5) Primary Care Only: 2.2 (2.9) P = 0.31 **Mean (SD) Change in Pain Intensity on 10 Point NRS at 6 months**	*"The results show that supplementing primary care management (information and advice on analgesia and exercise) with self-administered TENS does not provide additional clinical benefits."P.8*

Table A5: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Primary Care Plus TENS: 3.3 (2.8) Primary Care Only: 3.6 (3.0) P = 0.53 **Mean (SD) Change in Pain Intensity on 10 Point NRS at 12 months** Primary Care Plus TENS: 4.1 (2.6) Primary Care Only: 3.8 (3.0) P = 0.14 **Global Rating of Change as Much Better at 6 weeks – n (%)** Primary Care Plus TENS: 35 (29) Primary Care Only: 45 (38) OR (95% CI): 0.63 (0.38 to 1.04) **Global Rating of Change as Much Better at 6 months – n (%)** Primary Care Plus TENS: 75 (62) Primary Care Only: 71 (59) OR (95% CI): 1.13 (0.62 to 2.06) **Global Rating of Change as Much Better at 12 months – n (%)** Primary Care Plus TENS: 84 (96) Primary Care Only: 79 (66) OR (95% CI): 1.16 (0.60 to 2.25) **Mean Difference in SF-12 PCS*** 6 weeks -0.36 (95% CI: -2.90 to 2.18) 6 months -1.09 (95% CI: -4.22 to 2.03) 12 months -0.85 (95% CI: -3.94 to 2.24) **Mean Difference in SF-12 MCS*** 6 weeks 0.11 (95% CI: -2.46 to 2.68) 6 months 1.53 (95% CI: -1.81 to 4.87) 12 months 3.35 (95% CI: 0.14 to 6.56) **Mean Difference in EQ-5D*** 6 weeks -0.02 (95% CI: -0.09 to 0.05) 6 months -0.01 (95% CI: -0.08 to 0.05) 12 months 0.00 (95% CI: -0.06 to 0.06)	
Pivec et al., 2015[13]	
Any opioid use (%) TENS: 57.7% Non-TENS: 60.3% P < 0.0001 Average Opioid Costs per Patient TENS: $169 Non-TENS: **$**192 Average Pharmacy Costs per Patient TENS: $2955 Non-TENS: **$**3104	*"Since TENS is both non-invasive and a non-narcotic, it may potentially allow physicians to be more aggressive in treating CLBP patients."p.274*

Table A5: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Pivec et al., 2013[14]	
Any ED Visit (%) TENS: 26.9% Non-TENS: 28.2% P = 0.048 **Any Inpatient Hospital Stay (%)** TENS: 13.7% Non-TENS: 15.9% P < 0.0001 **Pain-related ED Visit (%)** TENS: 5.0% Non-TENS: 6.8% P < 0.0001 **Pain-related Any Inpatient Hospital Stay (%)** TENS: 4.9% Non-TENS: 66% P < 0.0001 **Total Resource Use Costs – Mean (SD)**** TENS: $17 986 (30 617) Non-TENS: **$**17 957 (25 711) P < 0.0001 **Physical Therapy Costs – Mean (SD)** TENS: $793 ($1 635) Non-TENS: $865 (1 594) P < 0.0001 **Imaging Costs – Mean (SD)** TENS: $244 ($756) Non-TENS: $373 ($910) P < 0.0001 **Back Surgery Costs – Mean (SD)** TENS: $94 ($960) Non-TENS: $101 (1142) P = 0.31	*"Compared with treatment without TENS, the authors' results demonstrate that TENS is associated with fewer inpatient, outpatient, physician office, emergency department, and physical therapy visits, less diagnostic imaging, and fewer episodes of back surgery and is less costly annually, although these savings may not be clinically compelling". p.928*

* A positive difference favours TENS

** Includes emergency department, inpatient hospital, outpatient hospital, physician office, durable medical equipment and pharmacy

CLBP=Chronic lower back pain; ED=Emergency department; LBP=Lower back pain; MCS= Mental component summary; NRS= Numeric rating scale; PCS=Physical component summary; SD=Standard deviation; SF= Short Form; TENS= Transcutaneous electrical nerve stimulation; VAS=Visual analog scale

Table A6: Summary of Recommendations by Source	
Guideline Society or Collaboration, Year	**Recommendations**
Towards Optimized Practice, 2015[9]	" There is insufficient evidence (no evidence from SRs) to recommend for or against the following interventions for chronic low back pain • Back belts, corsets, non-motorized traction, or over-the-counter TENS"p.21
Canadian Chiropractic Association and the Federation Clinical Practice Guidelines Project, 2014[15]	"Transcutaneous Nerve Stimulation/Multimodal—Chronic Neck Pain. There is insufficient evidence that supports a recommendation for transcutaneous nerve stimulation (TENS) for the treatment of chronic neck pain. This conclusion is based on 1 low-risk-of-bias study with more than 1 limiting factors." p.56
Low Back Pain; State of Colorado, Division of Worker's Compensation, 2014[5]	**"Transcutaneous Electrical Nerve Stimulation (TENS):** Interferential squared wave with microcurrent, usually with four channels. A generally accepted treatment. TENS should include at least one instructional session for proper application and home use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width, and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit. • Time to Produce Effect: Immediate. • Frequency: Variable. • Optimum Duration: 3 sessions. • Maximum Duration: 3 sessions. If beneficial, provide with home unit or purchase if effective." p.91
Osteoarthritis Research Society International, 2014[16]	**Transcutaneous electrical nerve stimulation (TENS)** "**Recommendation:** Uncertain: knee-only OA Not appropriate: multiple-joint OA **Rationale:** A 2009 SR found inconclusive results regarding the effect of TENS for pain relief in knee OA. Due to the low methodological quality and high heterogeneity of included trials, no effect size was reported as a primary result. The review found no evidence to suggest that TENS was unsafe. A recent RCT revealed no statistically significant difference for pain between TENS and a sham TENS procedure. **Quality assessment:** Level of evidence: SR of randomized or quasi-randomized clinical trials. Quality of evidence: Good."p.370
State of Colorado, Division of Worker's Compensation, 2011[10]	**"Electrical Stimulation (Unattended):** TENS - Electrical stimulation, once applied, requires minimal on-site supervision by the physical or nonphysical provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A TENS home unit should be purchased if treatment is effective and frequent use is recommended. • Time to Produce Effect: 2 to 4 treatments. • Frequency: Varies, depending upon indication, between 2 to 3 times per day to 1 time week. A home unit should be purchased if treatment is effective and frequent use is recommended. • Optimum and Maximum Duration: 4 treatments for clinic use."p.96

OA = Osteoarthritis; RCT =Randomized controlled trial; SR = Systematic review ; TENS = Transcutaneous electrical nerve stimulation