Transcutaneous electrical nerve stimulation for acute pain (Review)

Walsh DM, Howe TE, Johnson MI, Moran F, Sluka KA

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[Intervention Review]

Transcutaneous electrical nerve stimulation for acute pain

Deirdre M Walsh[1], Tracey E Howe[2], Mark I Johnson[3], Fidelma Moran[1], Kathleen A Sluka[4]

[1]Health and Rehabilitation Sciences Research Institute and School of Health Sciences, University of Ulster, Newtownabbey, UK. [2]School of Health & Life Sciences, Glasgow Caledonian University, Glasgow, UK. [3]Faculty of Health and Social Sciences, Leeds Metropolitan University, Leeds, UK. [4]Graduate Program in Physical Therapy & Rehabilitation, University of Iowa, Iowa City, Iowa, USA

Contact address: Deirdre M Walsh, Health and Rehabilitation Sciences Research Institute and School of Health Sciences, University of Ulster, Shore Road, Newtownabbey, Co. Antrim, BT38 7PY, UK. dm.walsh@ulster.ac.uk.

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ABSTRACT

Background

This is an updated version of the original Cochrane review published in Issue 2, 2009. Transcutaneous Electrical Nerve Stimulation (TENS) is a non-pharmacological agent, based on delivering low voltage electrical currents to the skin. TENS is used for the treatment of a variety of pain conditions.

Objectives

To assess the analgesic effectiveness of TENS for acute pain in adults to see if it had any analgesic effect in its own right.

Search strategy

The following databases were searched: Cochrane Pain, Palliative and Supportive Care Group Specialised Register; the Cochrane Central Register of Controlled Trials, CENTRAL (in *The Cochrane Library*); MEDLINE; EMBASE; CINAHL; AMED; PEDro; OTseeker; OpenSIGLE; and, reference lists of included studies. The most recent search was undertaken on January 7th 2011.

Selection criteria

Randomised controlled trials (RCTs) of adults with acute pain (less than 12 weeks) were included if they examined TENS given as a sole treatment and assessed pain with subjective pain scales. Studies were eligible if they compared TENS to placebo TENS, no treatment controls, pharmacological interventions or non-pharmacological interventions. Studies on experimental pain, case reports, clinical observations, letters, abstracts or reviews were excluded. Studies on TENS and labour pain, pain due to dental procedures and primary dysmenorrhoea were excluded. Studies where TENS was given with another treatment as part of the formal study design were also excluded. No restrictions were made regarding language.

Data collection and analysis

Two review authors independently assessed study eligibility and extracted data. Data were extracted on the following: types of participants and pain condition, study design and methods, treatment parameters, adverse effects, and outcome measures. Study authors were contacted for additional information if necessary.

Main results

No new included studies were included in this update, however, two new studies are awaiting classification. Of 1775 studies identified in the search, 163 were identified as relevant. Of these, 145 were excluded; the vast majority of these were excluded due to TENS being given with another treatment. Six studies were categorised as awaiting classification as the information provided in the full text failed to clarify their eligibility. Twelve RCTs involving 919 participants at entry were included. The types of acute pain conditions included procedural pain, e.g. cervical laser treatment, venipuncture, screening flexible sigmoidoscopy and non-procedural pain, e.g. postpartum uterine contractions, rib fractures. It was not possible to perform a meta-analysis due to insufficient data.

Authors' conclusions

There are no changes to the conclusions since the original version of the review was published in issue 2, 2009. Due to insufficient extractable data in the studies included in this review, we are unable to make any definitive conclusions about the effectiveness of TENS as an isolated treatment for acute pain in adults.

PLAIN LANGUAGE SUMMARY

Effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) as a sole treatment for acute pain in adults

TENS is a form of electrical current that can be applied to the skin with the aim of providing pain relief. The objective of this review was to determine how effective TENS was in relieving acute pain in adults when applied as a sole treatment. The database searches identified 1775 studies; of these, 12 met the inclusion criteria for the review with a total of 919 participants. Analysis of the combined results of these 12 studies was not possible due to insufficient extractable data. There is insufficient evidence to draw any conclusions about the effectiveness of TENS for the treatment of acute pain in adults.

BACKGROUND

This review is an update of a previously published review in The Cochrane Database of Systematic Reviews (Issue 2, 2009) on 'Transcutaneous electrical nerve stimulation for acute pain'.

Description of the condition

Pain is described as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage' (Merskey 1994). Acute pain is typically defined as pain that has a duration of less than three months (Strong 2002). Current approaches to acute pain management include pharmacological agents (drugs) and a number of non-pharmacological agents, one of which is Transcutaneous Electrical Nerve Stimulation (TENS).

Description of the intervention

The clinical application of TENS involves the delivery of an electrical current typically from a small battery-operated device to the skin via surface electrodes. Natural forms of electricity (e.g. electrogenic fish) have been used as a method of pain relief since the Egyptian era.

How the intervention might work

A theoretical foundation for electroanalgesia (pain relief by electrical methods) was only established in 1965 through the publication of Melzack and Wall's pain gate theory (Melzack 1965). This theory proposed that a gate existed in the dorsal horn (part of the spinal cord) which could regulate the amount of incoming nociceptive traffic (painful stimuli) via small diameter afferent nerve fibres (fibres conducting impulses towards the brain). This gate could effectively be closed by a variety of other types of stimuli such as touch, pressure and electrical currents which activate the large diameter afferent fibres.

TENS is regarded as a relatively inexpensive, safe, non-invasive modality with few side effects that can be utilised to treat a variety of painful conditions (Johnson 2008; Walsh 1997). Technological advances have produced a wide range of stimulators with an even wider range of stimulation parameters for clinicians and

patients to choose from (e.g. frequency, pulse amplitude, pulse duration, electrode placement site). TENS interventions tend to be described according to technical characteristics as either high frequency, low intensity (conventional TENS) or low frequency, high intensity (acupuncture-like TENS, AL-TENS). This technical approach fails to specify the physiological intention of delivering TENS. In this regard, the physiological intention when administering conventional TENS is to activate selectively non-noxious afferent nerve fibres in the skin (Aβ-fibres) which is claimed to inhibit transmission of nociceptive information at the level of the spinal cord (i.e. segmental modulation) (Sluka 2003). In practice, Aβ nerve fibre activity is recognised by the user reporting strong electrical paraesthesia (pins and needles) beneath the electrodes. The physiological intention of AL-TENS is to generate a muscle twitch which is believed to increase activity in small diameter afferent nerve fibres in muscles (Aδ) leading to activation of descending pain inhibitory pathways. In practice, AL-TENS is achieved by administering low frequency and high intensity, but non painful, currents over muscles. Interestingly, experimental evidence to establish the roles of different afferent fibres in TENS outcome is inconclusive (Garrison 1994; Levin 1993; Radhakrishnan 2005). Recent work has indicated that different frequencies of TENS may act through different neurotransmitter systems. Sluka and colleagues conducted a series of animal studies that have shown that low frequency TENS-induced antihyperalgesia (decreased sensitivity to pain) is mediated by activation of serotonin and mu opioid receptors while high frequency TENS activates delta opioid receptors (Kalra 2001; Radhakrishnan 2003; Sluka 1999). However, evidence showing that TENS outcome in humans is frequency dependent is as yet inconclusive as demonstrated in a recent systematic review of experimental pain studies (Chen 2008).

Why it is important to do this review

TENS is used extensively for acute and chronic pain (DeSantana 2008). Previous Cochrane Reviews on TENS for specific chronic pain conditions have suggested that TENS is more effective than placebo TENS although definitive conclusions were sometimes hindered by methodological weaknesses in randomised controlled trials (RCTs) (Bennett 2011; Brosseau 2003; Johnson 2010; Rutjes 2009). An all-encompassing Cochrane Review on TENS for a variety of chronic pain conditions (i.e. pain greater than three months' duration) reported inconclusive results (Nnoaham 2008). However, recent meta-analyses on the effectiveness of TENS for chronic musculoskeletal pain (Johnson 2007) and for osteoarthritis of the knee (Rutjes 2009) demonstrated a significant effect on pain over placebo.

Systematic reviews on TENS for specific types of acute pain have reported that TENS was no better than controls for postoperative pain (Carroll 1996) and labour pain (Dowswell 2009). However, the findings of reviews of TENS for postoperative pain have been challenged because pain measures were taken when patients were allowed free access to analgesic medication. This compromises pain scores because patients in placebo control and TENS groups titrate analgesic medication to achieve effective pain relief, and therefore exhibit similar pain scores. Review authors also included studies that under-dosed TENS or used an inappropriate TENS technique, or both. A meta-analysis with subgroup analysis demonstrated a significantly better outcome for TENS when applied using adequate (optimal) stimulation techniques when compared to non adequate stimulation techniques (Bjordal 2003); optimal TENS techniques were defined as an intensity that was strong enough to generate a strong paraesthesia and electrodes applied at the site of the operative scar. To date, there has been no all encompassing systematic review on TENS for acute pain. A systematic review, which takes account of adequate TENS techniques, is necessary to assist clinicians and researchers to make informed decisions on the effectiveness of this modality for acute pain. TENS can be given either as a sole treatment, i.e. stand alone treatment, or combined with other interventions; this review will focus on TENS given as a sole treatment only to see if it had sufficient efficacy in its own right.

OBJECTIVES

Primary objective

To assess the analgesic effectiveness of TENS, as a sole treatment, for acute pain in adults.

Secondary objectives

To assess:

1. if TENS effectiveness is influenced by the type of TENS (i.e. conventional TENS versus AL-TENS);
2. if TENS effectiveness is influenced by the time of recording the outcome measure, i.e. if outcome is influenced by measurements taken when TENS is switched on (during TENS measurement) compared to when TENS has been turned off after the treatment (post-TENS measurement);
3. if TENS effectiveness is influenced by duration of TENS treatment;
4. if TENS effectiveness differs for different acute pain conditions; and,
5. the safety of TENS for the treatment of acute pain.

METHODS

Criteria for considering studies for this review

Types of studies

All prospective RCTs were included. Both cross-over and parallel study designs were acceptable. We excluded data from the following: studies that were non-randomised; studies of experimental pain; case reports; clinical observations; and, letters, abstracts, reviews (unless they provided additional information from published RCTs that met the criteria).

Types of participants

Study participants were required to be adults (i.e. 16 years and over) with a diagnosis of acute pain (less than 12 weeks) by any cause including injury or surgical intervention. Acute pain conditions included, but were not limited to, the following: back pain; angina; musculoskeletal pain; procedural pain; fractures; and, headache. Postpartum pain studies were included if the pain investigated was due to episiotomy or Caesarean section irrespective of the presence of uterine cramps. Studies including patients with pain due to uterine contractions (i.e. labour) alone were excluded as this was the subject of the protocol for another Cochrane Review at the time the protocol for the current review was written (Dowswell 2009). In addition, studies on electrical stimulation for dental procedures were excluded as this is a subject for a separate review. Studies including patients with acute pain due to primary dysmenorrhoea were also excluded as this condition has been covered by a previous Cochrane Review (Proctor 2002).

Types of interventions

Only studies which evaluated surface electrical nerve stimulation for the treatment of acute pain were included (i.e. transcutaneous as opposed to percutaneous electrical stimulation). Appropriate delivery of TENS was defined as follows:

1. A 'standard TENS device' was used which delivered biphasic or monophasic (type of waveform) pulsed electrical currents in the mA range. TENS had to be delivered using at least two surface electrodes. TENS delivered using single probes (i.e. TENS pens) were excluded. Neuromuscular electrical stimulation (NMES) devices and Interferential Current devices were excluded.
2. TENS was administered to produce a strong electrical paraesthesia that was felt by the patient. AL-TENS delivered at strong intensities to generate muscle twitches were included. Studies were excluded if the active TENS intervention was delivered at intensities reported to be 'barely perceptible', 'faint or 'mild'.
3. TENS was administered in an area of the body which was sensate (where pain is being felt) at either (a) the site of pain or (b) over nerve bundles proximal (near) to the site of pain. TENS delivered at acupuncture stimulation points was only included if the point was lying over nerve bundles proximal (near) to the site of pain. Any parameters of treatment meeting these criteria were considered as were any duration or frequency of treatment and either self-applied or therapist-applied treatments.

The interventions to be compared included the following:

- TENS versus placebo TENS (i.e. use of a sham TENS device). A sham TENS device was defined as a device similar to the one used in the active group but the output was modified in some way so that either no electrical current or a barely perceptible electrical current is delivered through the electrodes;
- TENS versus no treatment controls;
- TENS versus a pharmacological intervention;
- TENS versus a non-pharmacological intervention.

Studies were excluded if TENS was given in combination with any other treatment as part of the formal study design, e.g. analgesic medication, exercise.

Types of outcome measures

The outcome measures included for analysis were:

Primary outcomes

- standard subjective scales (e.g. visual analogue scales (VAS)) for pain intensity or pain relief, or both.

Secondary outcomes

- other measures of pain.

Adverse events associated with the intervention were recorded. Information was also sought on the level of compliance with the intervention, the magnitude and duration of effect.

Search methods for identification of studies

Please see the Pain, Palliative and Supportive Care Review Group search strategy (Thomas 2011).

Electronic searches

To identify studies for inclusion in this review, detailed search strategies were developed for each electronic database searched. These were based on the search strategy developed for MEDLINE but revised appropriately for each database. The search strategy combined the subject specific search with phase one and two of the Cochrane Sensitive Search Strategy for RCTs (as published in Appendix 5b in the Cochrane Handbook for Systematic Reviews of Interventions version 4.2.5, Higgins 2005). The subject specific search used a combination of MeSH (upper case) and free text (lower case) terms based on the MEDLINE search strategy via

OVID which can be seen in Appendix 1. The search attempted to identify all relevant studies irrespective of language. Non-English papers were assessed and translated when necessary. Other search strategies are presented in the appendices (Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; and Appendix 9).

The search was run for the original review on 8th August 2008 and subsequent searches were run on 7th January 2011. The following databases were searched:

- Cochrane Pain, Palliative and Supportive Care Group Specialised Register (4^{th} August 2008; as data are captured in CENTRAL, this database was not included in the 2011 update search);
- Cochrane Central Register of Controlled Trials, CENTRAL (*The Cochrane Library* Issue 1, 2011);
- MEDLINE (1950 to 7th January 2011);
- EMBASE (1980 to 7th January 2011);
- CINAHL (1982 to 27th December 2010);
- AMED (1985 to 7th January 2011);
- PEDro (www.pedro.org.au) accessed 7th January 2011);
- OTseeker (www.otseeker.com) accessed 7th January 2011); and,
- OpenSIGLE (http://opensigle.inist.fr) accessed 7th January 2011.

Searching other resources

Reference lists of all included studies, key textbooks, and previous systematic reviews were searched for additional studies.

Data collection and analysis

Selection of studies

From the title, abstract, and descriptors, pairs of review authors independently reviewed the results of the literature searches to identify potentially relevant studies for full review. Disagreements were resolved by consensus. Review authors were not blinded from authors' names, institutions, journal name or study results at this stage or any stage of the review. From the full text, studies that met the selection criteria were selected for inclusion. Additional information or clarification was sought from the primary author if incompletely reported.

Data extraction and management

Pairs of review authors independently extracted data using a customised data extraction tool tested prior to use. Disagreement was resolved by consensus or by consulting with a third review author. Authors of studies were contacted where there was incomplete reporting of data. Data were extracted on the following:

Study participants

Age, gender, condition, inclusion/exclusion criteria, number of participants randomised, number of and reasons for withdrawals or dropouts.

Study

Design and location, methods of sequence generation and allocation concealment, blinding, intention-to-treat or per protocol analysis, outcome measures for pain, and results of statistical analysis.

Interventions used

Where TENS was applied and by whom, stimulation parameters (frequency, waveform, pulse amplitude/intensity, pulse duration), electrode details, treatment time and frequency, and adverse effects.

Assessment of risk of bias in included studies

We originally intended to assess the methodological quality of studies using the scale devised by Jadad 1996 as detailed in the protocol. However, with the launch of RevMan 5 in 2008, it was decided to use the Cochrane Collaboration's tool for assessing risk of bias as described in chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 (Higgins 2011). Two review authors independently assessed the following: sequence generation, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data, and other sources of bias (funding). Disagreement was resolved by consensus or by consulting with a third review author.

Measures of treatment effect

Where available and appropriate, quantitative data for the outcomes listed in the inclusion criteria are presented. For each study, relative risk and 95% confidence intervals (CI) were calculated for dichotomous outcomes. For continuous outcomes reported using the same scale, weighted mean differences (WMD) and 95% CIs were calculated. Where results for continuous outcomes were presented on different scales, standardised mean differences (SMD) and 95% CIs were calculated. It was planned to calculate the number-needed-to-treat-to-benefit (NNT) for treatment effect.

Dealing with missing data

In cases of missing data due to withdrawals or dropouts, only the data analysed in the study were used for analysis in this review.

Assessment of heterogeneity

It was intended that where appropriate, results of comparable groups of studies would be pooled using the fixed-effect model and 95% CIs calculated. Heterogeneity between comparable studies would be tested using a standard chi-squared test and considered statistically significant at a P value less than 0.1, after due consideration of the value of I squared. Any evidence of heterogeneity would be investigated to determine if there were obvious differences in the studies that were likely causes of the heterogeneity. If the heterogeneity was regarded as likely to have serious effects on the validity of the results, then the data would not be combined. Where there was significant heterogeneity, we intended to view the results of the random-effects model and present these when appropriate.

Subgroup analysis and investigation of heterogeneity

Where the data allowed, we also planned separate outcome analyses to test the following null hypotheses:

1. there is no difference in analgesia between AL-TENS (visible phasic muscle contractions) and conventional TENS (no visible muscle contraction);
2. there is no difference in analgesia if the outcome measure is recorded during TENS application;
3. there is no difference in analgesia between different TENS treatment durations; and,
4. there is no difference in analgesia between different acute pain condition

Sensitivity analysis

We planned to undertake sensitivity analyses to investigate the effects of allocation concealment, methodological quality and intention-to-treat (ITT) analysis.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search

No new included studies were included in this update; however, two new studies are awaiting classification (Gregorini 2010; Rajpurohit 2010). The authors of these two studies were contacted to clarify their eligibility based on our inclusion criteria (Rajpurohit 2010: if the study involved only acute pain; Gregorini 2010: if other treatment was given in addition to TENS). Of the 1775 studies retrieved from the literature searches, 163 were considered relevant: 145 were excluded because TENS was given in combination with another treatment (n = 113) or TENS was not delivered appropriately for acute pain based on our inclusion criteria (n = 32). Twelve studies were included and six were put into the 'Studies awaiting classification' category. The included studies, excluded studies and studies awaiting classification will be discussed separately below.

Included studies

A summary of the included studies is provided under the headings below; all were published in English. Further details can be found in the 'Characteristics of included studies' table.

Participants

In the 12 included studies (Cheing 2005; Coyne 1995; Crompton 1992; De Angelis 2003; Hansson 1983; Hruby 2006; Limoges 2004; Liu 1985; Olsen 2007; Oncel 2002; Ordog 1987; Roche 1985), there were 919 participants at entry. Two studies did not indicate the sex of participants (Ordog 1987; Roche 1985) and one did not provide details on age (Ordog 1987). Of those studies that provided these details, there were 308 males and 465 females with an age range of 11 to 81 years. Two studies had a mixed population of adults and children (Cheing 2005; Oncel 2002), therefore pain outcome data were not analysed in these studies. Three studies included only females (Crompton 1992; De Angelis 2003; Olsen 2007) while the remaining were mixed gender studies.

Five studies investigated the effect of TENS on procedural pain: procedures included cervical laser treatment (Crompton 1992), office hysteroscopy (De Angelis 2003), screening flexible sigmoidoscopy (Limoges 2004), flexible cystoscopy (Hruby 2006) and venipuncture (Coyne 1995). The remaining studies were on haemophiliac pain (Roche 1985), acute trauma such as sprains or fractures (Ordog 1987), postpartum uterine contractions (Olsen 2007), acute orofacial pain (Hansson 1983), post thoracotomy (Liu 1985), rib fractures (Oncel 2002), and neuropathic pain (Cheing 2005).

Setting

Studies took place in Europe (two in the UK, two in Sweden, one in Turkey, one in Italy), North America (four in the USA), and Asia (one in China, one in Hong Kong). Eleven studies were conducted in a hospital or specialised clinic with participants in one of these studies continuing to use TENS at home after discharge (Oncel 2002). In one study, participants received TENS instruction in hospital but only used it at home (Ordog 1987).

Design

All included RCTs used a parallel group design.

Sample sizes

The number of participants randomised to each treatment group ranged from eight (Olsen 2007; Roche 1985) to 71 (De Angelis 2003). Seven studies had at least 20 participants in each of the treatment groups (Crompton 1992; De Angelis 2003; Hansson 1983; Hruby 2006; Limoges 2004; Oncel 2002; Ordog 1987). Interestingly, only one study performed a prospective sample size calculation to determine the appropriate number of participants required (Crompton 1992). Olsen 2007 reported that they based their sample size on results from previous studies in the area but did not provide *a priori* power analysis details; they performed a *post hoc* power analysis on the data they collected and concluded that the numbers they recruited (n = 13 and 8 in the two groups) were adequate. None of the other studies gave reasons for the number of participants recruited.

TENS device and application

All included studies placed electrodes at the painful site except Roche 1985 who placed electrodes over the sensory nerve supplying the painful area or close to the area of bleed in their sample of haemophiliacs. Ten of the 12 included studies used two electrodes (single channel). Crompton 1992 used four electrodes over the anterior abdominal wall (painful area) and two over the sacrum for pain experienced during cervical laser treatment. Limoges 2004 placed two electrodes over the abdomen (painful area) and two electrodes parallel to the spinal cord at L1-S3 level for screening flexible sigmoidoscopy pain. The majority of the included studies used rubber/silicone electrodes with gel or self-adhesive electrodes and one used metal electrodes (Ordog 1987). Five studies did not provide full details of the type, size, number of electrodes used (Crompton 1992; De Angelis 2003; Hruby 2006; Liu 1985; Ordog 1987).

In terms of the magnitude of the electrical current, one study (Limoges 2004) described the pulse amplitude (i.e. mA value), eight described the intensity (i.e. subjective description of the applied current, Cheing 2005; Coyne 1995; Crompton 1992; De Angelis 2003; Hansson 1983; Oncel 2002; Ordog 1987; Roche 1985) and three described both (Hruby 2006; Liu 1985; Olsen 2007). Two studies applied the stimulus at a fixed pulse amplitude (30 mA, Limoges 2004; 50 mA in the high pulse amplitude TENS group and 10 to 15 mA in the low pulse amplitude TENS group, Olsen 2007). A range of subjective descriptions were used for intensity such as: tingling non-painful sensation from stimulated area (high frequency TENS group) or non-painful muscular contractions in stimulated area (low frequency TENS group, Hansson 1983); strong but tolerable tingling (Cheing 2005); subjective level of comfort (Liu 1985); highest level that did not make participants uncomfortable (Oncel 2002); definite but comfortable perception with no muscle activation (Roche 1985); or, below pain threshold (Coyne 1995). De Angelis 2003 used the term 'tickle' to describe the level of intensity. This is an unusual term but may be due to translation of a foreign language. Four studies indicated that the pulse amplitude was adjusted during treatment (Coyne 1995; De Angelis 2003; Hansson 1983; Hruby 2006) while this information was unclear or not provided in the remaining studies.

The majority of studies employed a high electrical pulse frequency during TENS, ranging from 51 Hz (mean frequency for the control group who received low pulse amplitude TENS in Liu 1985) to 160 Hz (Coyne 1995). Two studies employed a train of pulses delivered at a low frequency (Hansson 1983; Roche 1985). Pulse duration ranged between 50 μs (Oncel 2002) and 210 μs (Crompton 1992) with one study detailing a pulse duration range of 310 to 400 μs on the strength duration mode they used (Coyne 1995). Ordog 1987 did not specify frequency or pulse duration settings. All 12 studies provided details of the model and/or manufacturer of the TENS device used with only two studies using a device from the same manufacturer (Hansson 1983 and Olsen 2007). There was a wide variation in the number of treatments and individual treatment times across the studies. Single TENS treatments were applied in seven of the 12 included studies (Coyne 1995; Crompton 1992; De Angelis 2003; Hansson 1983; Hruby 2006; Limoges 2004; Roche 1985) while the other studies gave multiple treatments. In the five procedural pain studies, three did not specify a treatment duration (Crompton 1992; De Angelis 2003; Hruby 2006); in those that did, it varied from five to 32 minutes (Coyne 1995; Limoges 2004). In Oncel's study (Oncel 2002), participants continued to use the TENS device at home for two days post discharge while in Ordog's study (Ordog 1987) they received a demonstration of TENS use in the hospital but then used it at home themselves. In the non-procedural pain studies, the treatment duration varied from one minute (Olsen 2007) to the TENS being worn as often as required (Ordog 1987). In terms of compliance with TENS, only two studies involved TENS being self-applied at home where compliance could be assessed (Oncel 2002; Ordog 1987). Ordog 1987 reported that the mean length of use of TENS was three days and that none of the participants in their study was using the TENS at their one month follow up. Oncel 2002 did not provide any information on compliance with TENS.

Comparison groups

Nine studies used a placebo group, four used no treatment controls, three used a pharmacological intervention and two used a non-pharmacological intervention as comparison groups to active TENS. Placebo TENS was delivered in nine studies; eight of these used a sham device that was similar to the active TENS device but it had no batteries, the internal circuit was disconnected, or the device was not switched on (Cheing 2005; Coyne 1995; Hansson

1983; Hruby 2006; Limoges 2004; Oncel 2002; Ordog 1987; Roche 1985). Liu 1985 applied a low pulse amplitude stimulus (fixed at 2.5 mA) in their comparison group as they felt this was more effective than a no stimulus placebo; for the purposes of this review, this was treated as a placebo group although the authors called it a control group. Interestingly, only three of the placebo TENS studies included TENS naïve participants. Coyne 1995 specified 'no previous TENS exposure' as an inclusion criterion and Cheing 2005 had 'people who had received any TENS' as an exclusion criterion. Ordog 1987 indicated in their methodology that none of their participants had used TENS previously. Finally, Olsen's participants were also TENS naive but this study did not include a placebo group (Olsen 2007).

A control group was used in four studies. De Angelis 2003, Hruby 2006 and Coyne 1995 used a no treatment control group whereas Limoges' control group received only verbal encouragement (Limoges 2004).

Three studies used a pharmacological intervention as a comparison group: local anaesthetic (lignocaine with octopressin, Crompton 1992); non-steroidal anti-inflammatory drug (NSAID) (naproxen sodium, Oncel 2002) and Tylenol (Ordog 1987). Hansson 1983 and Olsen 2007 both used a non-pharmacological intervention (TENS) as their comparison groups. Olsen 2007 compared high (50 mA) and low (10 to 15 mA) pulse amplitude TENS groups only in their study. Hansson 1983 compared conventional TENS (100 Hz) to AL-TENS (2 Hz trains with 71 Hz internal frequency).

Adverse effects

Adverse effects were not reported in four studies (Cheing 2005; Coyne 1995; Crompton 1992; Liu 1985). In the remaining eight studies, three reported there were no adverse effects (Oncel 2002; Ordog 1987; Roche 1985). Five studies reported a range of adverse effects. De Angelis 2003 reported nausea (8.5% of TENS group; 11.3% of control group, sample size of 71 per group); shoulder pain (3% of TENS group; 0% of control group); bradycardia 0% of TENS group; 2.8% of control group); and, dizziness (8.5% of TENS group; 10% of control group) but did not specifically link these effects to TENS. Twenty nine out of 30 participants in the TENS group and 6/30 participants in the placebo TENS group reported pain, burning, tingling at the electrode site (Limoges 2004). Two out of 48 active TENS participants could not tolerate TENS and 1/49 placebo participants reported severe abdominal pain several hours after the flexible cystoscopy procedure (Hruby 2006). TENS was discontinued in 1/13 participants in the high pulse amplitude TENS group in Olsen's study due to reported discomfort during stimulation (Olsen 2007). Most participants in the low frequency TENS group in Hansson's study (sample size of 20) found the muscle twitches uncomfortable (Hansson 1983).

Outcomes

All of the included studies used standard pain scales/questionnaires to record pain intensity (VAS; numerical rating scale, NRS; McGill pain questionnaire, MPQ; verbal scale). Additional outcome measures included a measure of discomfort of the TENS treatment using a five-point verbal scale (Olsen 2007); time in minutes until first report of pain reduction and maximum pain reduction (Hansson 1983); overall impression with TENS using a four-point categorical scale (Liu 1985); and, a questionnaire on their experience of TENS, i.e. if participants found it comfortable, unpleasant, helpful, frightening, soothing or pain relieving (Crompton 1992).

Only one study measured pain intensity whilst TENS was switched on and generating an electrical paraesthesia (Hruby 2006). De Angelis 2003 and Limoges 2004 recorded the pain their participants experienced during a painful procedure after the procedure was finished. Crompton 1992 measured pain post procedure but it is unclear if the participants were asked to record the pain experienced during the procedure rather than at that time. The remaining studies recorded pain pre every individual TENS treatment (Cheing 2005), pre and post the individual TENS treatments (presumably immediately post treatment but not indicated, Coyne 1995; Hansson 1983; Liu 1985; Olsen 2007; Roche 1985).

In terms of assessing the duration of the TENS effect, three studies recorded pain for more than three days: Liu 1985 recorded postoperative pain for ten days; Cheing 2005 recorded pain on days one, four, seven and 11; and, Ordog 1987 recorded pain pre TENS, after two days of treatment, and finally, one month post injury.

With regard to data analysis of these outcomes, Crompton 1992 reported they used intention-to-treat analysis and Coyne 1995 used per protocol analysis. Two of the remaining studies indicated they used neither type of analysis (Oncel 2002; Roche 1985) and eight studies did not provide any details.

Excluded studies

One hundred and forty-five studies were excluded from the review. See table of 'Characteristics of excluded studies' for reasons for excluding 32 of these studies, e.g. a standard TENS device was not used or the applied intensity was deemed too low based on our inclusion criteria. A further 113 studies were excluded on the basis that TENS was given in combination with another treatment as part of the formal study design; of these, 70 were postoperative pain studies. Due to the number of studies in this category, they have been listed separately (Table 1). In the majority of these studies, TENS was given with analgesic medication but some provided TENS in conjunction with non-pharmacological interventions, e.g. TENS given as part of a physiotherapy package of treatment.

Studies awaiting classification

Six studies are awaiting classification. Four were written in English (Ekblom 1987; Gregorini 2010; Hsueh 1997; Rajpurohit

2010) and two in Portuguese that required translation (de Paiva Tosato 2007; Salvador 2005). The authors of these six studies were contacted by e-mail to clarify their eligibility based on three of our inclusion criteria (if the study involved acute pain, if it was a randomised study, or if other treatment was given in addition to TENS). However, no response was obtained. A summary of these studies is in the table 'Characteristics of studies awaiting classification'.

Risk of bias in included studies

The 'Risk of bias' table provides details of how and why the included studies were judged on the following items: allocation; blinding; incomplete outcome data; and, sources of funding bias. Figure 1 provides a summary of overall risk of bias in the 12 studies as high, low or unclear. Figure 2 provides details of the judgments about each methodological quality item for each study.

Figure 1. Methodological quality graph: review authors' judgments about each methodological quality item presented as percentages across all included studies.

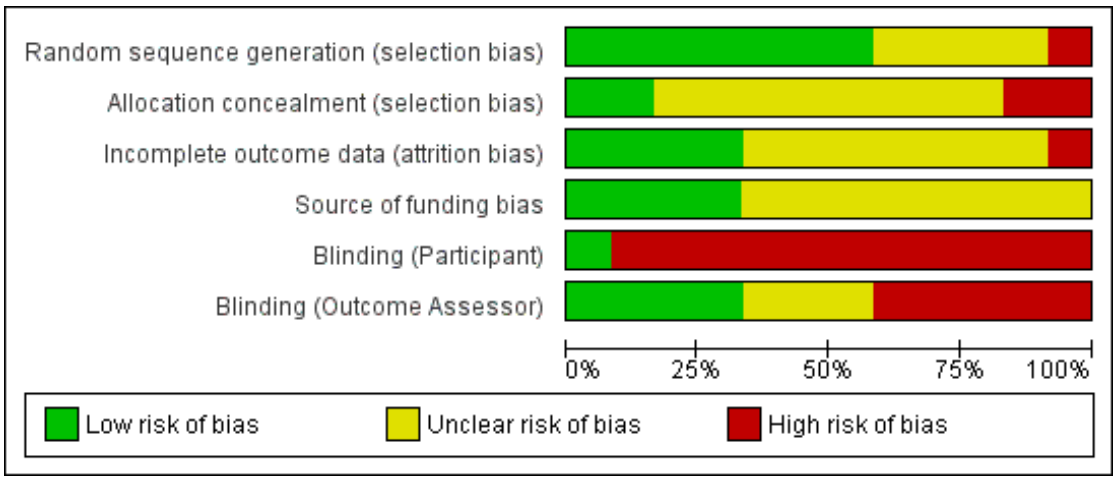
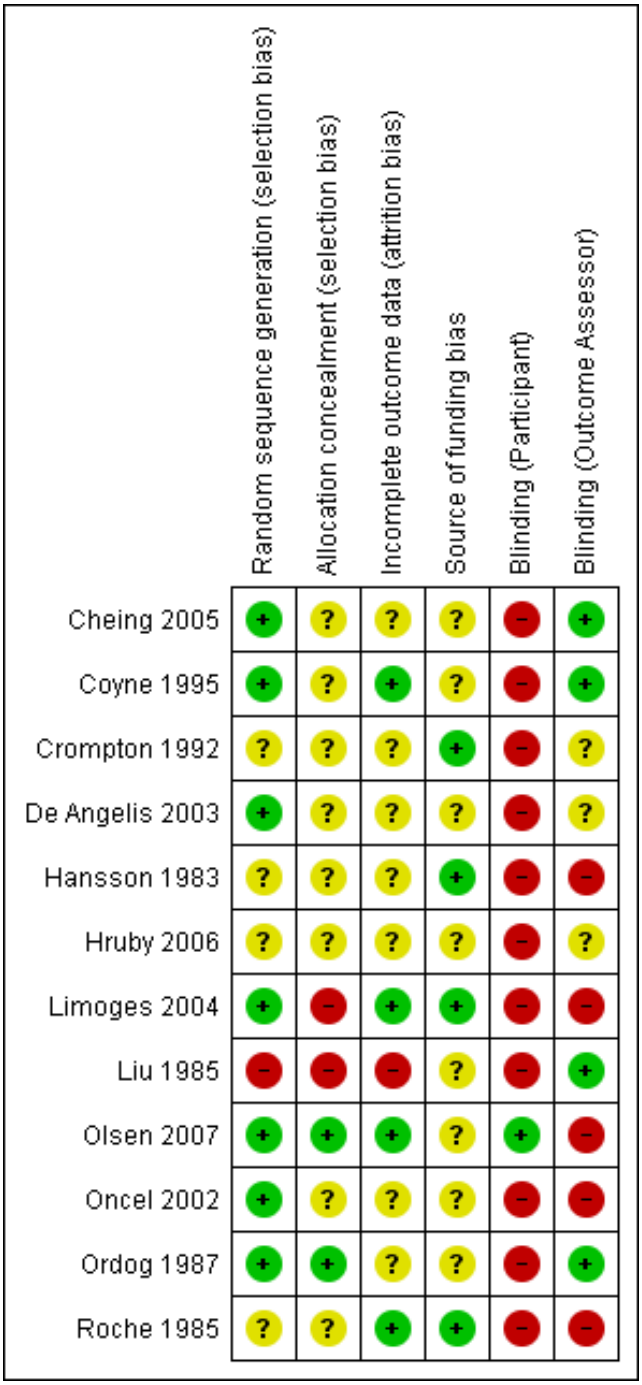


Figure 2. Methodological quality summary: review authors' judgments about each methodological quality item for each included study.



Allocation

Sequence generation was deemed to be adequate in seven studies (Coyne 1995; Cheing 2005; De Angelis 2003; Limoges 2004; Olsen 2007; Oncel 2002; Ordog 1987), and unclear or inadequate in the other five studies. Only three of these studies used a computer generated list for sequence generation (De Angelis 2003; Olsen 2007; Oncel 2002). This is an optimal method for preventing selection bias. Ordog 1987 adopted an unusual method of mixing the active and sham TENS units together and releasing the decoding process when all units were returned to the researcher after the study was completed. Other methods of adequate allocation sequence generation included using a randomisation table (Coyne 1995). The remaining studies were rated as either inadequate (dividing participants alternatively into groups, Liu 1985) or unclear in their methods of sequence generation (Crompton 1992; Hansson 1983; Hruby 2006; Roche 1985).

Only two studies had adequate allocation concealment (Olsen 2007; Ordog 1987). Olsen 2007 was the only study to transfer allocation to a series of pre-sealed opaque envelopes. Ordog's unusual but effective method of concealment was to reveal which of the TENS units were active or sham only after they were returned to the researcher when the study was completed (Ordog 1987). Details of how allocation was concealed were unclear in the majority of studies (Cheing 2005; Coyne 1995; Crompton 1992; De Angelis 2003; Hansson 1983; Hruby 2006; Oncel 2002; Roche 1985) and deemed inadequate in two (Limoges 2004; Liu 1985).

Blinding

Blinding of both the participant and the outcome assessor was assessed in the included studies.

Participant blinding

It is inherently impossible to successfully blind participants to an electrical current as it generates a sensory experience, therefore the majority of studies (11) were judged to have inadequate participant blinding methods. Olsen's study (Olsen 2007) only had two active TENS groups as a comparison; as there was no placebo group and participants were TENS naive, this study was judged to be adequate in terms of blinding. The other authors must be given credit as they made additional efforts to conceal allocation. Three of the placebo group studies specified that participants were TENS naïve (Cheing 2005; Coyne 1995; Ordog 1987). Eight studies used a sham TENS device that was similar to the active TENS device but delivered no current (Cheing 2005; Coyne 1995; Hansson 1983; Hruby 2006; Limoges 2004; Oncel 2002; Ordog 1987; Roche 1985) or a very low pulse amplitude current (Liu 1985). In addition, some studies told participants they may or may not feel a sensation during the treatment (Cheing 2005; Limoges 2004; Oncel 2002; Roche 1985) or that some people may not experience the stimulation (Hansson 1983). Liu 1985 told all participants how TENS worked to control pain and what they should expect from TENS after their operation while Ordog 1987 stated that their placebo TENS group was not told that the functioning units can produce a mild electrical shock by turning up the unit.

Assessor blinding

In four studies, the person who recorded the outcomes was blind to group allocation (Cheing 2005; Coyne 1995; Liu 1985; Ordog 1987). Oncel's study (Oncel 2002) did not have all of the assessors blinded. The pain scores were recorded by one of the authors and several nurses; the author was not blind to group allocation but the nurses were. Four studies did not have blinded assessors: Hansson 1983; Limoges 2004; Olsen 2007; Roche 1985. The remaining studies (Crompton 1992; De Angelis 2003; Hruby 2006) did not provide sufficient details regarding assessor blinding.

Follow up and exclusions

Limoges 2004 and Roche 1985 reported that there were no dropouts in their studies. Coyne 1995 dropped ten participants post randomisation as they did not meet blood donor criteria. Participants should have been screened for inclusion/exclusion criteria first before randomisation. This flaw in their study design may have affected the study outcome. Crompton 1992 gave details of two exclusions (one participant failed to record a pain score and another found the cervical laser treatment uncomfortable) but there were no details of what group they belonged to. Olsen 2007 reported one participant dropped out due to discomfort of stimulation (high pulse amplitude TENS group). Oncel 2002 reported that eight participants were excluded due to complications and were replaced. The reasons for these exclusions were provided (seven had respiratory distress during the hospitalisation period - three had hemothorax and four had pneumothorax; one had hemothorax post discharge) but the authors did not indicate to which groups they belonged to. Liu 1985 reported the number of participants that data were recorded from on each postoperative day but did not give specific reasons for incomplete data. The following studies did not provide details on if there were any incomplete data: Cheing 2005; De Angelis 2003; Hansson 1983; Hruby 2006; Ordog 1987.

Other potential sources of bias

Four studies acknowledged sources of funding: loan of units from a TENS manufacturer (Crompton 1992); TENS unit provided by a

TENS manufacturer and university project grant (Limoges 2004); research foundation (Hansson 1983); and, a research council grant (Roche 1985). None of these sources were thought to introduce a bias.

Effects of interventions

Primary objective

The primary objective of this review was to assess the analgesic effectiveness of TENS, as a sole treatment, for acute pain in adults. It was not possible to extract data from six studies for the following reasons: data presented as median and interquartile (IQ) range (Crompton 1992); unable to extract data from paper (Coyne 1995); we were uncertain if the data presented were standard deviations (De Angelis 2003; Hruby 2006); and, mixed age groups (i.e. participants under 16 years included (Cheing 2005; Oncel 2002). The following authors were contacted in an attempt to obtain the data: Crompton 1992 (responded but unable to provide data as mean and SD); Coyne 1995 (responded but unable to provide data); Hruby 2006 and De Angelis 2003 (no response). There were insufficient extractable data in the remaining six included studies to allow meta-analysis of any comparisons outlined in the sections below. The results of these six studies are summarised below under the headings of the four types of comparisons.

TENS versus placebo TENS

Five studies compared active TENS to placebo TENS but they all used different outcomes making it impossible to pool these data. It is important to note that Liu 1985 uses the term 'Control group' even though they delivered a fixed low pulse amplitude (2.5 mA) TENS treatment to these participants as a form of placebo. Pain relief was recorded using VAS, NRS, pain rating index (PRI) and a categorical scale. Statistically significant differences were observed for only one of these measures (VAS) in one study.

Hansson 1983 reported the numbers of participants who experienced > 50% pain relief post treatment using a VAS. Neither high nor low frequency TENS was significantly different (P = 0.18) from placebo TENS: relative risk (RR) 1.59 (95% CI 0.40 to 6.34) and RR 2.25 (95% CI 0.59 to 8.52). Roche 1985 showed no significant difference (P = 0.09) between active and placebo groups in the number of participants that showed > 50% pain relief post treatment on a PRI, RR 2.86 (95% CI 0.84 to 9.71). It is interesting to note that these authors reported a significant difference in their paper (P < 0.02) but RevMan 5 analysis did not.

In the Limoges 2004 study, no significant differences (P = 0.29) between active and placebo groups were found in pain intensity during the procedure (NRS), WMD -0.27 units (95% CI -0.77 to 0.23). Immediately post treatment, Liu 1985 did not show any significance (P = 0.1) between active and placebo groups using VAS for pain intensity, WMD -1.53 cm (95% CI -3.37 to 0.31). Using the same outcome measure, Ordog 1987 showed a significant decrease (P = 0.0007) in VAS pain intensity in the TENS group compared to placebo after two days of treatment, WMD -2.44 cm (95% CI -3.85 to -1.03).

Liu 1985 asked participants to use a categorical scale to rate their overall impression with TENS. The numbers of participants that rated TENS as excellent/good was not significantly different (P = 0.47) between active and placebo groups, RR 1.29 (95% CI 0.65 to 2.54).

TENS versus *no* treatment control

Only one of the six studies eligible for meta-analysis compared TENS with no treatment control. Limoges 2004 (90 participants) used an NRS to measure pain during screening flexible sigmoidoscopy. In this study, there was no significant difference (P = 0.36) between TENS and no treatment control groups, WMD -0.23 points (95% CI -0.72 to 0.26).

TENS versus a pharmacological intervention

One of the six studies (Ordog 1987) used a pharmacological intervention but combined it with TENS (TENS plus Tylenol group) so there was no direct comparison of TENS alone versus Tylenol.

TENS versus a non-pharmacological intervention

Two studies included two different TENS groups as comparisons. Olsen 2007 (21 participants) compared TENS delivered at high pulse amplitude (50 mA) and low pulse amplitude (10 to 15 mA) at a frequency of 80 Hz. Hansson 1983 (62 participants) compared conventional TENS (100 Hz, intensity of two to three times perception threshold) versus AL-TENS (2 Hz pulse train, intensity of three to five times perception threshold). Pain relief was recorded using a VAS and a verbal scale for level of discomfort of the TENS treatment itself. Statistically significant differences were observed in both of these measures in one of the studies.

Conventional TENS versus AL-TENS

In Hansson's study (Hansson 1983), there was no significant difference (P = 0.38) in the number of participants who reported more than 50% pain relief post treatment (using VAS) between high and low frequency TENS, RR 0.71 (95% CI 0.32 to 1.54).

High pulse amplitude TENS versus low pulse amplitude TENS

Olsen 2007 showed significant pain relief post treatment using VAS (P = 0.0001) for high pulse amplitude TENS, WMD -2.70 cm (95% CI -4.08 to -1.32). In contrast, a significantly (P = 0.04) higher number of participants reported severe/worst possible

discomfort with low pulse amplitude TENS compared to high pulse amplitude TENS, odds ratio (OR) 0.04 (95% CI 0.00 to 0.90).

Secondary objectives

It was not possible to perform any planned subgroup analysis for any of the secondary objectives due to limited extractable data. There was only one study that compared conventional TENS to AL-TENS. As described above, Hansson 1983 showed no significant differences. Due to insufficient data, we were unable to determine if TENS effectiveness was influenced by the time of recording the outcome measure, i.e. during TENS measurement compared to post TENS measurement. Similarly, the limited number of included studies did not provide sufficient data to compare the duration of TENS treatment or comparisons for different acute pain conditions. In terms of safety of TENS, only five studies reported adverse effects and these were limited to a small number of participants. The majority of these effects were related to what participants felt under the electrodes (pain, burning, tingling) with some participants finding the muscle twitches during low frequency TENS uncomfortable.

DISCUSSION

Summary of main results

This systematic review examined the effectiveness of TENS as a sole intervention for the treatment of acute pain in adults. No new included studies were included in this update, however, two new studies are awaiting classification. Out of 155 studies identified in the original search, 12 RCTs involving 919 participants at entry met the inclusion criteria. We were only able to extract data from six of the 12 included studies (total of 339 participants at entry): Hansson 1983; Limoges 2004; Liu 1985; Olsen 2007; Ordog 1987; Roche 1985. It was not possible to perform a meta-analysis due to the limited data available. Of the six studies that we could extract data from, the findings were as follows: only one out of five studies that compared TENS to placebo TENS showed a statistically significant superior effect of active TENS; one study compared TENS to a no treatment control with no significant difference reported; one study compared conventional TENS to AL-TENS and showed no significant difference; and, one study demonstrated significant pain relief for high pulse amplitude TENS compared to low pulse amplitude TENS. Five out of the 12 studies reported a range of adverse effects that were primarily related to sensations experienced at the electrode site or the muscle contractions associated with low frequency TENS. The methodological quality of the studies varied considerably in the 12 included studies. Using the risk of bias assessment, sequence generation was judged to be adequate in seven studies, allocation concealment was adequate in two studies and only four had adequate assessor blinding.

Overall completeness and applicability of evidence

We categorised the 12 included studies into procedural and non-procedural pain. The range of acute pain conditions included in this review was limited by the inclusion/exclusion criteria. The greatest number of excluded studies were on postoperative pain as they gave analgesic medication in addition to TENS for pain management. These studies were excluded on the basis that addition of another treatment would compromise pain relief measures making it impossible to ascertain the contribution of TENS. The effect of TENS in combination with other treatments for acute pain is the subject for another systematic review. All studies were in the English language with the majority of them (ten) based in either Europe or North America. Only one study described the use of TENS by the participants solely at home (Ordog 1987). As TENS can easily be self-applied for most conditions, this limits the evidence for comparison of self-applied versus therapist-applied TENS.

The range of outcome measures used provided limited data that could be extracted from the included studies which made it impossible to combine outcomes in a meta-analysis. Furthermore, the lack of standardisation of when the outcome measures were recorded limits the interpretation of the results. Both experimental pain and clinical studies suggest that maximum pain relief is obtained while TENS is switched on (Johnson 1991; Johnson 1999; Tong 2007). Thus the timing of pain measurement is crucial, particularly for procedural pain; some included studies measured pain post procedure but asked participants to record 'during procedure' pain thus relying on recall (De Angelis 2003; Limoges 2004). Pain intensity was measured during TENS application in only one study (Hruby 2006), the remainder used pre-post measurements. As TENS has been shown to have maximum pain relieving effects during application, it is therefore important to record pain outcome whilst it is being applied. Furthermore, only three studies continued to record the effect of TENS on pain outcome for more than a few days (Cheing 2005; Liu 1985; Ordog 1987), thus limiting any conclusions regarding the duration of effect of TENS on acute pain.

The reporting of TENS treatments showed wide variations across the 12 studies. Several studies failed to report full details of the TENS parameters used or technique of application, thus making replication impossible. In terms of comparing different TENS parameters, one study compared conventional and AL-TENS with no significant differences reported (Hansson 1983) and one study reported significant pain relief for high versus low pulse amplitude (Olsen 2007). This finding is consistent with recent experimental pain studies that indicated high pulse amplitude (irrespec-

tive of the applied frequency) is the key parameter for effective TENS applications (Aarskog 2007; Chen 2008; Claydon 2008). Furthermore, Bjordal's meta-analysis of TENS for postoperative pain (Bjordal 2003) highlighted the relevance of optimal (strong or maximal non-painful) intensity levels for pain relief in this clinical population.

Quality of the evidence

The 12 included studies involved 919 participants at entry. Unfortunately the data extracted did not provide sufficient evidence regarding the effectiveness of TENS as a sole treatment for acute pain. Overall, the methodological quality of the evidence was poor. The key methodological weaknesses were inadequate methods or lack of information on: allocation concealment; blinding of the outcome assessors; incomplete outcome data; and, method of analysis (per protocol or intention to treat). Despite attempts to obtain information from authors, we were unable to extract data from six studies.

Of the twelve included studies, the sample sizes ranged from eight to 71 per group and only one did a prospective sample size calculation (Crompton 1992). Olsen 2007 did a *post hoc* power analysis on their data and concluded they had a sufficient sample size. Inadequate power has obvious implications on study outcome and is a serious issue that needs to be addressed in RCTS on TENS.

In terms of blinding, none of the included studies assessed the success of blinding. This issue was recently highlighted by Hrobjartsson 2007 who analysed a random sample of 1599 blinded RCTs indexed in CENTRAL and reported that only 2% reported tests for the success of blinding. TENS naïvety is an important inclusion criteria in studies attempting to blind participants. However, only four of the studies in the review indicated that participants were TENS naïve. Although blinding of electrical stimulation devices is inherently impossible, investigators should make every attempt to blind participants by using a sham TENS device. Typical sham devices used by the studies in this review had no electrical output although one (Liu 1985) used a low pulse amplitude (2.5 mA) as they felt this was more appropriate. Rakel 2010 recently developed and tested a new sham TENS device that allowed the clinician applying TENS to be completely blinded to the application of TENS. The sham TENS device delivered a current for 30 seconds, then the current slowly ramped off for another 15 seconds. This output allowed the clinician to set the pulse amplitude without knowing if the unit was an active or sham device. Thus, the method of delivery of treatment by the clinician was identical to each participant.

Potential biases in the review process

Review authors were not blinded from authors' names, institutions, journal name or study results at any stage of the review. However, pairs of review authors undertook each stage of the review process independently and the outcomes were compared. Data were extractable for only six of the 12 eligible studies and this may bias the conclusions of this review.

AUTHORS' CONCLUSIONS

Implications for practice

No new included studies were included in this update, however, two new studies are awaiting classification. There are no changes to the conclusions since the original version of the review published in issue 2, 2009. Conclusions about the effectiveness of TENS as a sole treatment for acute pain are impossible to make due to the limited data available. There was incomplete reporting of treatment regimes by many of studies in this review making the interpretation of analysis or even replication impossible.

Implications for research

Further adequately powered research studies are required to provide a comprehensive assessment of the role of TENS as a sole treatment in acute pain management. The Consolidated Standards of Reporting Trials (CONSORT) statement has been revised for non-pharmacologic treatments (Boutron 2008); this should be adopted to ensure better reporting of all aspects of study design and subsequent reporting. In particular, appropriate sequence generation and allocation concealment methods should be used and reported. Sample size calculations should be performed to determine appropriate participant numbers. Complete details of the TENS application should be provided to allow subgroup analysis between studies. The selection of appropriate TENS parameters, in particular a strong but comfortable intensity should be performed. A clear description of missing data and how they are analysed is required. Outcome assessor blinding should be adopted as a key element of future study design. Blinding of participants is accepted as a challenge in TENS studies but should be addressed nevertheless. Finally, future studies should adopt a common policy of reporting means and standard deviations for continuous data to enable data extraction for subsequent meta-analysis.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cheing 2005

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: clinical diagnosis of hypersensitive hands due to peripheral nerve injuries, 19. Groups: TENS Group, 10; Placebo Group, 9.
Participants	Demographics: n = 19, mean 35 yrs, range 15-58 yrs, 16 M/3 F. TENS Group, 32 +/- 11 yrs; Placebo Group, 38 +/- 13 yrs (mean +/- SD). Setting: outpatients. Inclusion: people who complained of hypersensitive hands within or adjacent to the site of the injury, and who were able to complete the VAS independently. Exclusion: people who had general manifestations of pain as seen in causalgia or shoulder-hand syndrome; people who had received any TENS or undergone a desensitization programme 1 month prior to the study; cardiac pacemaker or who had experienced sensory loss in their hands prior to the study. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: presume by clinician. Waveform: square pulses. Frequency: 100 Hz. Pulse duration: 200 μs. Pulse amplitude/Intensity: adjusted to produce a tingling sensation that was strong but tolerable. Placebo Group: procedures identical to those for TENS group, except that a sham unit was used. Internal circuit of the sham TENS unit disconnected but the indicator lamp lit when unit switched on. All participants told that they might or might not feel a tingling sensation during Rx. Electrodes: 2 rectangular carbon rubber electrodes with gel, 2 cm x 3 cm, anode applied directly over the hypersensitive area and cathode placed proximally along the distribution of the same peripheral nerve. Duration and frequency of Rx: 20 mins, 10 Rxs. Device/manufacturer: 120Z TENS unit (ITO, Tokyo). Adverse effects: not detailed.
Outcomes	Pain outcome: pain intensity using VAS for a brush-evoked stimulus with a toothbrush. Recorded before Rx on days 1, 4, 7 and 11. Intention to treat/per protocol analysis: not detailed. Statistical analysis: no evaluable data for this review as mixed age population (adults and children). Significantly lower pain scores were found in the TENS group than in the Placebo group by Day 7 and Day 11. Both groups demonstrated significant decreases in VAS scores across treatment sessions.
Notes	Abbreviation: Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Cheing 2005 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Subjects were matched by age, history of developing hypersensitivity and baseline VAS scores, and then randomly assigned into either the TENS (n =10) or placebo group (n = 9) by drawing lots.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'All subjects were blind to group allocation. The placebo group had received no active treatment (just placebo TENS) throughout the study. The treatment procedures for the placebo group were identical to those for the real TENS group, except that a sham unit was used. The appearance of the sham unit was identical to that of a real TENS unit, but the internal circuit of the sham TENS unit was disconnected. When the machine was switched on, there was no output of current, but the indicator lamp lit up. All subjects were told that they might or might not feel a tingling sensation during the treatment.' 'People who had received any TENS' was an exclusion criteria.
Blinding (Outcome Assessor)	Low risk	'The blinded assessor repeatedly practiced applying the same brushing force on a digital balance prior to the study.'

Coyne 1995

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: procedural IV needlestick pain in blood donors, 71. Groups: TENS Group, 19; Placebo TENS Group, 21; Control Group, 21, these are numbers after 10 participants were dropped due to not meeting Virginia Blood Service criteria for blood donation.
Participants	Demographics: n = 71 randomised, 26 M/35 F post dropout. TENS Group, 36 yrs; Placebo TENS Group, 37 yrs; Control Group, 35 yrs (mean). Setting: blood donor clinic. Inclusion: blood donors meeting Virginia Blood Service criteria for donation; previous IV insertion; no previous TENS exposure; upper extremity exposure for electrode placement; appropriate consent obtained; having venipuncture to the right or left antecubital site. Exclusion: not detailed. Withdrawals/dropouts: 10 participants were dropped as they did not meet the Virginia Blood Service criteria for blood donation.
Interventions	Where applied: in clinic. Applied by: clinician. Waveform: balanced and biphasic. Frequency: 160 pulses/s. Pulse duration: 310-400 μs on the strength-duration mode. Pulse amplitude/Intensity: below the participant's pain threshold, adjusted during stimulation to maintain this level. Placebo TENS Group: TENS unit without batteries. Control Group: no treatment. Electrodes: 4 carbon electrodes, 4 cm, applied at site of venipuncture in a square fashion. Duration and frequency of Rx: min 12 mins and max 32 mins, 1 Rx. Device/manufacturer: Maxima III TENS unit. Adverse effects: not detailed.
Outcomes	Pain outcome: pain assessed by a subjective and an affective VAS. Recorded pre IV insertion, after Rx, and at end of needle insertion phase. Intention to treat/per protocol analysis: per protocol. Statistical analysis: no evaluable data for this review as unable to extract data from paper. No significant difference among groups for sensory or affective VAS scores.
Notes	Abbreviation: IV- intravenous; Rx- treatment; VAS- visual analogue scale.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'It was a convenient sample of 71 volunteer donors from the Virginia Blood Service who were randomized into one of the following three groups.' Author response 'a randomization table was

Coyne 1995 (*Continued*)

		how the participants were selected as participants arrived and consented to the study.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	'However, ten subjects were dropped because they did not meet the Virginia Blood Service criteria for blood donation (i.e. low haemoglobin).'
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'No previous TENS exposure' was an inclusion criteria. Author responded 'both were blinded' to the question 'who was blinded, was it the patient and person recording VAS?' Author response 'TENS unit without batteries were the sham'. Control group received no treatment so these participants could not be blinded.
Blinding (Outcome Assessor)	Low risk	Author responded 'both were blinded' to the question 'who was blinded, was it the patient and person recording VAS?'

Crompton 1992

Methods	Type of study: randomised, controlled, parallel design. Condition and number of participants randomised: women undergoing cervical laser treatment, 100. Groups: TENS Group, 34; Local Anaesthetic Group, 35; TENS and Local Anaesthetic Group, 29. NB 10 more participants recruited than initially intended as researchers lost count of number recruited and failed to stop the trial.
Participants	Demographics: n = 100, all F. TENS Group, 31.8 +/- 9 yrs; Local Anaesthetic Group, 32.6 +/- 9 yrs; TENS and Local Anaesthetic Group, 30.1 +/- 8 yrs (mean+/-SD). Setting: colposcopy unit. Inclusion: colposcopic diagnosis of cervical intra-epithelial neoplasia. Exclusion: past history of treatment for CIN; other cervical surgery or pelvic inflammatory disease; postmenopausal women; cardiac pacemakers. Withdrawals/dropouts: 1 woman excluded as she failed to record pain score. Another found treatment too uncomfortable so direct local infiltration was added.

Crompton 1992 (*Continued*)

Interventions	Where applied: in hospital. Applied by: clinician. Waveform: not detailed. Frequency: 80 Hz. Pulse duration: 210 μs. Pulse amplitude/Intensity: activated by participants under instruction, told to increase it until it became uncomfortable. Electrodes: 4, conductive silicone polymer electrodes and gel, size not detailed. 2 applied anteriorly to abdominal wall just above symphysis pubis, and 1 on each side of sacrum. Duration and frequency of Rx: participants given approx 20 min to experiment with TENS until they were called into another room for laser treatment. Duration of TENS during laser treatment not detailed, 1 Rx. Device/manufacturer: Microtens (Neen Pain Management, UK). Adverse effects: not detailed.
Outcomes	Pain outcome: pain assessed by a VAS after the procedure. After procedure, participants asked to complete questionnaire on TENS, one question was 'did they find TENS pain relieving?'. Intention to treat/per protocol analysis: intention to treat. Statistical analysis: no evaluable data for this review as data presented as medians and IQ ranges. Median pain score for TENS Group was significantly higher than that for local anaesthetic. Combining TENS with local anaesthesia did not further reduce the median pain score. 51 women who used TENS completed questionnaire: of the coherent responses 75% thought it was pain relieving.
Notes	Abbreviation: CIN- cervical intra-epithelial neoplasia; IQ- interquartile; Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'Suitable subjects were then allocated to one of the following three groups according to a block randomized code.' It is unclear how this code was generated.
Allocation concealment (selection bias)	Unclear risk	'The block randomization code was held by one investigator who then allocated treatment. The nurses, clerical officers responsible for the computerized appointments, and the laser surgeon did not have access to this code.' It is unclear how this code was kept concealed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	'One woman was excluded because she failed to record pain score. Another

Crompton 1992 (*Continued*)

		found the treatment too uncomfortable and therefore direct local infiltration was added.' No indication what group these individuals were randomised to. 'Fifty-one women who used TENS completed the questionnaire. Six responses were incoherent and nine women claimed the treatment was not painful and they did not need to turn the TENS on.' No indication what group these individuals were randomised to.
Source of funding bias	Low risk	'We are indebted to Roy Sherlock of Neen Pain Management Systems (Old Pharmacy Yard, Church Street, Dereham, Norfolk NR16 1DJ) for lending us the TENS units.'
Blinding (Participant)	High risk	'As it is impossible to conceal the use of TENS from the attendants a sham instrument was not used in group 3.' Groups were: TENS Group; Local Anaesthetic Group; TENS and Local Anaesthetic Group. There was no Placebo Group.
Blinding (Outcome Assessor)	Unclear risk	No details provided.

De Angelis 2003

Methods	Type of study: randomised, controlled, parallel design. Condition and number of participants randomised: participants undergoing office hysteroscopy, 142. Groups: TENS Group, 71; Control Group, 71.
Participants	Demographics: n = 142, all F. TENS Group, 47.9 +/- 10 yrs; Control Group, 50 +/- 10 yrs (mean +/- SD). Setting: gynaecological endoscopy centre. Inclusion: outpatient hysteroscopy. Exclusion: not detailed. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: clinician. Waveform: symmetric rectangular biphasic waveform. Frequency: 100 pulses/s. Pulse duration: 100 μs. Pulse amplitude/Intensity: device set at basal level of stimulation, participant felt mild

De Angelis 2003 (*Continued*)

	tickle in area between electrodes. Participant instructed when she felt pain to gently press plus switch once or several times. If feeling was unpleasant she could reduce amplitude by pressing minus switch until discomfort disappeared. Control Group: no TENS applied. Electrodes: 2, type and size not detailed, on abdomen in middle of line joining iliac spine and pubic tubercle. Duration and frequency of Rx: during procedure, 1 Rx. Device/manufacturer: Freelady TENS, Life Care, Tiberias, Israel. Adverse effects: nausea, shoulder pain and dizziness reported in both groups, not specifically linked to TENS.
Outcomes	Pain outcome: pain experienced during procedure assessed by VAS, after procedure. For TENS group, pain at basal level of stimulation was compared with pain felt after participant increased amplitude at least once. Intention to treat/per protocol analysis: not detailed. Statistical analysis: no evaluable data for this review as unclear if SD data are presented. Significantly lower pain experienced during procedure by TENS Group vs Control group. Within TENS group, pain at basal level of stimulation vs after participants had increased amplitude at least once was significantly higher. Pelvic pain evaluated 5 mins after examination - significant reduction in TENS group vs Control group.
Notes	Abbreviation: Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'A randomized, computer-generated list was used to divide the subjects into two equal groups (A and B) of 71 patients.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. No details provided. Groups were TENS group and no treatment Control group. There was no Placebo group. As the Control group received no treatment, these participants could not be blinded.

De Angelis 2003 (*Continued*)

Blinding (Outcome Assessor)	Unclear risk	No details provided.

Hansson 1983

Methods	Type of study: randomised, placebo-controlled, parallel design. Condition and number of participants randomised: acute oro-facial pain, 62. Groups: HF TENS Group, 22; LF TENS Group, 20; Placebo TENS Group, 20.
Participants	Demographics: n = 62, 19-54 yrs, 26 M/36 F. Setting: emergency clinic for dental surgery. Inclusion: acute oro-facial pain. Exclusion: not detailed. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in clinic. Applied by: presume by clinician. Waveform: monopolar square wave pulses. Frequency: HF Group, 100 Hz; LF Group, 2 Hz, 71 Hz pulse train with total duration of 84 ms delivered at 2 /sec. Pulse duration: 0.2 ms. Pulse amplitude/Intensity: HF, adjusted to 2-3 times perception threshold to produce a tingling non-painful sensation from the stimulated area. Output adjusted during TENS in order to maintain a constant tingling sensation. LF, adjusted to 3-5 times perception threshold which produced non-painful muscular contractions in the stimulated area. Placebo TENS Group: same as for other TENS groups except no batteries in units and participants told some people may not experience the stimulation. Electrodes: 2, 2 cm x 3 cm conducting rubber, skin overlying painful area. Duration and frequency of Rx: 30 min, 1 Rx. Device/manufacturer: CEFAR SIII, Lund, Sweden. Adverse effects: most participants found the muscle twitches produced by low frequency TENS uncomfortable.
Outcomes	Pain outcome: 5-graded verbal scale for pain intensity before Rx. VAS for pain intensity before and after Rx. During Rx pain rated continuously using a graphic rating scale-consistent results obtained with both methods. Time until first report of subjective pain reduction and maximal pain reduction recorded. Intention to treat/per protocol analysis: not detailed. Statistical analysis: HF TENS: 7/22 reported pain reduction > 50%, includes 2 who had total pain reduction. LF TENS: 9/20 reported pain reduction > 50%, includes 2 who had total pain reduction. Placebo TENS: 8/20 reported some degree of pain relief, includes 2 who had pain reduction >50%. In the two active TENS groups, approx 80% reported a reduction of pain within less than 5 mins after onset of stimulation.
Notes	Abbreviation: HF- high frequency; LF- low frequency; Rx- treatment; VAS- visual analogue scale.

Risk of bias

Hansson 1983 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'The patients were assigned randomly to one of the three groups.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Source of funding bias	Low risk	'This work has been supported by grants from Magnus Bergwalls Stiftelse.' This is a research foundation.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'For practical reasons a double-blind technique could not be used.' For the Placebo TENS group - 'Twenty patients received in all ways, except two, the same treatment as the two groups receiving TENS. One difference was that the TENS stimulators used were not equipped with batteries; and the other difference was that these patients were told that some people may not experience the stimulation.' The exclusion criteria were not provided so we do not know if participants had to be TENS naïve.
Blinding (Outcome Assessor)	High risk	Study appears to be designed as single blind (i.e. participants blind).

Hruby 2006

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: participants undergoing flexible cystoscopy, 148. Groups: Active TENS Group, 48; Placebo TENS Group, 49; Control Group, 51.
Participants	Demographics: n = 148, 108 M/40 F. Active TENS Group, 62.23 yrs; Placebo TENS Group, 61.53 yrs; Control Group, 60.98 yrs (? mean). Setting: office-based. Inclusion: flexible cystoscopy for surveillance of transitional cell carcinoma; voiding symptoms; hematuria, or stent removal. Exclusion: participants with a neobladder; cystoscopy with biopsy or with dilation of strictures; participants taking chronic analgesics or with pain syndromes; and participants who required post procedure catheterization.

Hruby 2006 (*Continued*)

	Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: clinician. Waveform: symmetric rectangular biphasic. Frequency: 100 pulses/s. Pulse duration: 180 μs. Pulse amplitude/Intensity: at the initial settings, the participant typically felt a slight tickle at the site of the electrodes. The tickling sensation is greater than the sensory threshold but less than the pain threshold. The starting point for pulse amplitude was 20 mA. During flexible cystoscopy, participants were able to change the amplitude on the TENS device at will. Placebo TENS Group: unit identical to active unit but without any nerve stimulation. Control Group: no analgesia. Electrodes: 2, type and size not detailed, each electrode was placed halfway along an imaginary line drawn from the ASIS to pubis. Duration and frequency of Rx: duration not detailed, 1 Rx. Device/manufacturer: Prometheus Group, Dover, NH. Adverse effects: 2 participants in the Active TENS group could not tolerate the TENS unit as the amplitude was gradually increased to the starting point of 20 mA; 1 participant in the Placebo TENS group reported severe abdominal pain several hours after the procedure.
Outcomes	Pain outcome: VAS, 30 seconds and 1 min into the procedure, 5 mins after procedure finished. Intention to treat/per protocol analysis: not detailed. Statistical analysis: no evaluable data for this review as unclear if SD data are presented. No significant changes in VAS between groups at each of the 3 time points.
Notes	Abbreviation: ASIS-anterior superior iliac spine; Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'A total of 148 patients were prospectively randomized into one of three groups.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. Text says it was a double-blind study but

Hruby 2006 (*Continued*)

		no details provided - assume they intended to blind the participants. The Placebo TENS group was described as 'a control group with a placebo TENS unit (unit identical to active unit but without any nerve stimulation)'. The inclusion/exclusion criteria did not state that participants had to be TENS naïve. Control group received no treatment so these participants could not be blinded.
Blinding (Outcome Assessor)	Unclear risk	Text says it was a double-blind study but no details provided if the outcome assessor was blinded.

Limoges 2004

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: participants undergoing screening flexible sigmoidoscopy, 90. Groups: TENS Group, 30; Placebo TENS Group, 30; Control Group, 30.
Participants	Demographics: n = 90, 51 M/39 F. TENS Group, 57.18 +/- 7.787 yrs; Placebo TENS Group, 55.97 +/- 5.411 yrs; Control Group, 58.6 +/- 9.073 yrs (mean +/- SD). Setting: SFS speciality clinic. Inclusion: over 50 yrs; presenting for screening flexible sigmoidoscopy. Exclusion: cardiac pacemakers; automated implanted cardiac defibrillators; pre procedural skin irritation at electrode placement site; pre procedural sedation or analgesia. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in clinic. Applied by: clinician. Waveform: biphasic waveform and asymmetric pulse pattern. Frequency: 100 Hz. Pulse duration: 190 μs. Pulse amplitude/Intensity: 30 mA, setting chosen after progressively increasing amplitude and testing tolerability of each level on volunteers. Same intensity used for all participants. Placebo TENS Group: unit same as active group, attached to participant but not turned on. All participants told they may or may not feel tingling sensation at electrode site. Control Group: received only verbal encouragement. Electrodes: 4 self-adhesive, 2 x 5 inch rectangular, 2 on left upper and lower quadrants of abdomen and 2 parallel to spinal cord at L1-S3 level. Duration and frequency of Rx: varied 5-15 mins, 1 Rx. Device/manufacturer: Empi EPIX VT TENS. Adverse effects: 29 participants in TENS group and 6 participants in Placebo TENS group reported pain/burning/tingling at electrode site.

Outcomes	Pain outcome: pain experienced during procedure assessed by a NRS of 1-5 for pain intensity after procedure finished. Intention to treat/per protocol analysis: not detailed. Statistical analysis: no significant difference between groups for pain experienced during the procedure.
Notes	Abbreviation: NRS- numerical rating scale; Rx- treatment; SFS- screening flexible sigmoidoscopy; SD- standard deviation.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Author response 'Randomization was done by drawing numbers out of a hat. We picked a number out of the hat after the patient arrived and consented to participate'.
Allocation concealment (selection bias)	High risk	Author response 'Randomization was done by drawing numbers out of a hat. We picked a number out of the hat after the patient arrived and consented to participate'.
Incomplete outcome data (attrition bias) All outcomes	Low risk	'Ninety subjects were enrolled and completed the study.'
Source of funding bias	Low risk	'Funding for this study was provided by the Innovative Pilot Project Grant Program at the University of California Davis Medical Center. The TENS unit was provided by EMPI, Inc.'
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'Subjects in the sham TENS group were connected to the TENS unit exactly the same as subjects in the TENS group. The research assistant manipulated the programming buttons on the TENS unit exactly as with the TENS group, but without actually turning the TENS units on beforehand. This step was performed in an effort to maintain blinding of both the endoscopist and subject. Subjects in the control group received only verbal encouragement.' The inclusion/exclusion criteria did not state that participants had to be TENS

Limoges 2004 (*Continued*)

		naïve. Control group received no active treatment so these participants could not be blinded.
Blinding (Outcome Assessor)	High risk	Author response re the placebo TENS group 'the TENS unit was attached to the subject but never turned on by the RA (I and the subject were blinded to this)'. 'My RA administered the questionnaires.'

Liu 1985

Methods	Type of study: randomised, double blind, controlled, parallel design. Condition and number of participants randomised: post thoracotomy, 30. Groups: TENS Group, 15; Control Group, 15.
Participants	Demographics: n = 30, 18-72 yrs, 22 M/8 F. TENS Group, 51.73 yrs; Control Group, 52.73 yrs (mean). Setting: hospital. Inclusion: post thoracotomy. Exclusion: participants who had cardiac surgery. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: clinician. Waveform: not detailed. Frequency: mean was 75.75 Hz for TENS Group, 51 Hz for Control Group. Pulse duration: 0.1 ms. Pulse amplitude/Intensity: set at a subjective level of comfort, not adjusted during treatment, mean pulse amplitude was 7.33 mA for TENS Group. Control Group: TENS applied at fixed pulse amplitude of 2.5 mA. All participants told how TENS worked to control pain and what to expect from TENS after surgery. Electrodes: 2 carbon rubber and gel, size not detailed, placed on most painful area along incision wound. Duration and frequency of Rx: 20 min, daily treatment from 1^{st} postop day until pain disappeared or participant discharged or Rx rejected by participant. Device/manufacturer: HRS Neuro-Pulse Model HME-12. Adverse effects: not detailed.
Outcomes	Pain outcome: overall impression with TENS rated using 4 categories, after TENS discontinued. Pain rated using a 0 to 10 scale before and after each TENS Rx. Recorded daily (for 10 days) until pain disappeared, or patient discharged or treatment rejected by the patient. Intention to treat/per protocol analysis: not detailed. Statistical analysis: significant alleviation of pain after TENS every day in the TENS group. No significant change in the Control group except on days 4 and 6. Significant difference between groups for post TENS pain scores on days 2/5/6/7/8.

Liu 1985 (*Continued*)

Notes	Abbreviation: Rx- treatment; VAS- visual analogue scale.	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Author response - 'The patients were enrolled to the study consecutively before the surgery, divided into experimental and control groups alternatively'. 'Males and females were counted separately.'
Allocation concealment (selection bias)	High risk	See under randomisation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Table 2 gives pain scores on days 1-10. The table details the number of participants from whom data were recorded on each day - shows a decline as the days progress. The text says that stimulation was given everyday from first postop day until pain disappeared, or the participant was discharged or the treatment was rejected by the participant. Table shows data collected for all participants (n=15/group) for days 1 and 2 only. Figure 1 shows number of participants in each group that continued with TENS for each postop day. Specific reasons for each participant not recording pain scores was not given.
Source of funding bias	Unclear risk	No funding source detailed.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. Author response 'The study design was double blinded. The patients and I (the evaluator) were blinded. All patients were explained how TENS worked to control pain and what the patient should expect from TENS after operation'. The Control group received low intensity TENS. The exclusion criteria were not provided so we do not know if participants had to be TENS naïve.

Liu 1985 (*Continued*)

Blinding (Outcome Assessor)	Low risk	Author response 'The study design was double blinded. The patients and I (the evaluator) were blinded'.

Olsen 2007

Methods	Type of study: randomised, controlled, parallel design. Condition and number of participants randomised: newly delivered women with pain from postpartum uterine contractions, 21. Groups: HI TENS Group, 13; LI TENS Group, 8.
Participants	Demographics: n = 21, all F, 31 yrs (mean). HI TENS Group, 31 +/- 4.2 yrs; LI TENS Group, 31 +/- 4.8 yrs (mean+/-SD). Setting: Department of Obstetrics and Gynecology. Inclusion: newly delivered healthy women; well integrated in the Swedish language with uncomplicated vaginal delivery; painful postpartum uterine contractions that required pain relief. Exclusion: systemic disorders; abnormal pregnancy; operative delivery; other treatments for the pain should not have been initiated. Withdrawals/dropouts: 1 in HI TENS group dropped out due to discomfort of stimulation.
Interventions	Where applied: in hospital. Applied by: clinician. Waveform: not detailed. Frequency: 80 Hz. Pulse duration: 0.2 ms. Pulse amplitude/Intensity: HI, set at 50 mA. LI, set at just above the sensory threshold (10-15 mA). Electrodes: 2 carbon rubber and gel, 53x34 mm, placed on the lower part of the abdomen, bilaterally over the uterus. Duration and frequency of Rx: 1 minute, 1 Rx repeated twice if no effect occurred. Device/manufacturer: Cefar AB, Lund, Sweden. Adverse effects: no adverse effects except for discomfort during stimulation were recorded.
Outcomes	Pain outcome: measurement of discomfort on a 5-point verbal scale, before and after Rx. VAS for present pain intensity, before and after Rx. Discomfort of Rx recorded on a 5-point verbal scale. Intention to treat/per protocol analysis: not detailed. Statistical analysis: median decrease in VAS pain ratings before and after treatment was larger in the HI TENS group than in the LI TENS group. Post Rx, women in the HI TENS group had less pain from the uterine contractions than the women in the LI TENS group. HI TENS group experienced significantly less discomfort from uterine contractions after treatment compared with the LI TENS group. Discomfort from TENS itself was significantly greater in HI group than in LI group.
Notes	Abbreviation: HI- high intensity; LI- low intensity; Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Olsen 2007 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'After informed written consent, the women were randomized to either high-intensity (HI) or low intensity (LI) high-frequency (80 Hz) TENS. The allocation sequence was determined before the study by a research assistant using a computer generated random table.'
Allocation concealment (selection bias)	Low risk	'Groups were coded and the allocation transferred to a series of pre-sealed opaque envelopes.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	'One patient in the HI TENS group dropped out from the study immediately after commencing TENS treatment because of discomfort of the stimulation.'
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	Low risk	Study described as single-blind. Groups were high-intensity (HI) or low intensity (LI) high-frequency (80 Hz) TENS. There was no Placebo TENS group. 'Before treatment the women were informed that they might experience pain or discomfort from the electrical stimulation.' Author response 'it was the participants who were blinded to the treatment'. Author response 'The patients had no previous experience of TENS'.
Blinding (Outcome Assessor)	High risk	Study was designed as single blind.

Oncel 2002

Methods	Type of study: randomised, placebo-controlled, parallel design. Condition and number of participants randomised: minor rib fractures, 100. Groups: NSAID Group, 25; TENS Group, 25; NSAID and Placebo TENS Group, 25; Placebo Tablets Group, 25.
Participants	Demographics: n = 100, 11-81 yrs, 41 F/59 M, 40 +/- 16 yrs (mean +/- SD). NSAID Group, 35 +/- 19 yrs; TENS Group, 44 +/- 15 yrs; NSAID and Placebo TENS Group, 41 +/- 14 yrs; Placebo Tablets Group, 40 +/- 16 yrs. Setting: hospital emergency service.

Oncel 2002 (*Continued*)

	Inclusion: minor rib fractures. Exclusion: 1^{st} or 2^{nd} rib fracture; more than 3 rib fractures or flail chest; requiring hospitalisation for cranial or abdominal trauma; patient refusal; undergoing any kind of surgery (including tube thoracostomy); cardiac or psychiatric illness; < 10 yrs; history of gastrointestinal bleeding or ulcer or other contraindications for NSAIDS; being pregnant. Withdrawals/dropouts: 8 participants were excluded because of complications and they were replaced. 7 had respiratory distress during the hospitalisation period; 3 had hemothorax and 4 had pneumothorax. All were treated with tube thoracostomy. Right hemothorax was diagnosed on the eighth patient the day after he had been discharged. He was re-hospitalized and underwent a tube thoracostomy procedure.
Interventions	Where applied: in hospital and at home. Applied by: clinician in hospital and by participant at home. Waveform: not detailed. Frequency: 80 Hz. Pulse duration: 50 μs. Pulse amplitude/Intensity: Participants asked to turn up to the highest level that did not make them uncomfortable. Placebo TENS Group: TENS unit without batteries and no sign on unit that showed it was on. Participants in the TENS and NSAID and Inactive TENS group told they might or might not feel a sensation of tingling. Electrodes: 2 or 4 carbon rubber electrodes with adhesive gel, 3.4 x 4.2 cm, placed on both sides of fractures along lines of intercostal nerves. Duration and frequency of Rx: 30 mins, 6 Rxs. Two treatments in hospital: within 2 hrs after admission and 12 hrs later. On discharge, home TENS twice a day for 2 days. Device/manufacturer: Dual channel TENS, Biotens Inc Istanbul, Turkey. Adverse effects: no complications seen during study.
Outcomes	Pain outcome: pain assessed by 0-10 scoring system. Recorded when hospitalised -pre Rx, next day before they were discharged (after 2 phases of Rx) and third day after therapy had ended. Intention to treat/per protocol analysis: no. Statistical analysis: no evaluable data for this review as mixed age population (adults and children). Day 0 - no significant difference between groups. Day 1-pain in Placebo group significantly higher than other groups. Pain in TENS group significantly less than NSAID and NSAID and Inactive TENS groups. Day 3-pain in TENS group significantly less than all other groups and no significant difference between these 3 groups. All participants except the Placebo group had significantly less pain on days 1 and 3 than day 0. In the Placebo group, pain was significantly less on day 3 than 0 but no difference between pain levels on day 0 and 1.
Notes	Abbreviation: NSAID- non-steroidal anti-inflammatory drug; Rx- treatment; SD- standard deviation.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Oncel 2002 (*Continued*)

Random sequence generation (selection bias)	Low risk	'One hundred consecutive patients admitted to Kartal Education and Research Hospital Emergency Service, were randomized into four groups.' Author response 'A computerized randomization protocol had been received prior to the beginning of the study, and the randomization of the patients was done accordingly'.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	'Eight patients were excluded because of complications and they were replaced. Seven had respiratory distress during the hospitalisation period; three had hemothorax and four had pneumothorax. All were treated with tube thoracostomy. Right hemothorax was diagnosed on the eighth patient the day after he had been discharged. He was re-hospitalized and underwent a tube thoracostomy procedure.' No indication what group these individuals were randomised to.
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'These patients were told that they might or might not feel a sensation of tingling, and this instruction was carefully standardized. The same blinded nurses performed two phases of TENS therapy during the hospitalization period and instructed the patients how to use the machine at home. These nurses were told that every patient would be treated with active TENS units and that they were not to know about the content of the study. Inactive TENS units were out of battery and there were no signs on the machines that showed they were 'on'.' Author response 'As mentioned in the paper, the patients were completely unaware that the cases in the control group would not feel a sensation, and both the patients and the nurses assumed that all cases would

Oncel 2002 (*Continued*)

		have a TENS treatment.' The inclusion/exclusion criteria did not state that participants had to be TENS naïve.
Blinding (Outcome Assessor)	High risk	Author response 'The pain scores were recorded by one of the authors (HY) or by educated nurses. The nurses were blinded to the randomization but the author was not'. Not all of the outcome assessors were blind to group allocation.

Ordog 1987

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: acute trauma outpatients, 100. Groups: Functioning TENS Group, 25; Placebo TENS Group, 25; Functioning TENS plus Tylenol, 25; Placebo TENS plus Tylenol, 25.
Participants	Demographics: n = 100, age/gender not detailed. Setting: outpatients. Inclusion: acute trauma outpatients. Exclusion: < 21 yrs; hx cardiac disease or pacemaker; insufficient aptitude or personality for operation of apparatus; allergies to acetaminophen or codeine; pregnancy. Withdrawals/dropouts: not detailed.
Interventions	Where applied: at home by participant. Applied by: participant. Waveform: not detailed. Frequency: not detailed. Pulse duration: not detailed. Pulse amplitude/Intensity: instructed to adjust energy knob to level at which pain disappeared or until they felt a mild electric shock from the unit. Placebo TENS Group: unit appeared like active but no electrical current transmitted to the skin. It produced the slight hum and vibration that active unit produced. Participants were not told that the functioning units could produce a mild electrical shock by turning up the unit. Electrodes: 2 metal electrodes and a disposable sterile skin pad, size not detailed. Applied over area of injury or as close to it as practical. Duration and frequency of Rx: could be worn at all times or as often as required for pain control. Device/manufacturer: disposable TENS-PAC unit measures ½ x 3 x 4 inches. Dow Corning, Arlington, Tennessee. Adverse effects: no complications and no side effects except a mild tingling sensation at higher output levels, 20% of participants reported this effect.

Ordog 1987 (*Continued*)

Outcomes	Pain outcome: 11 point VAS for pain intensity, administered pre Rx, after two days of Rx, and a month after initial injury. Intention to treat/per protocol analysis: not detailed. Statistical analysis: statistically significant reduction in pain severity in functioning TENS vs placebo group at day 2, not at 1 month. No significant difference between functioning TENS unit and Tylenol group when either the subjective levels of pain versus time or pre-Rx and post-Rx pain levels at 2 days and 1 month were compared. Mean length of use of TENS in all groups was 3 days versus a mean of 5 days for the oral analgesics in the 2 Tylenol groups.
Notes	Abbreviation: Rx- treatment; VAS- visual analogue scale.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'One hundred consecutive consenting acute trauma outpatients seen by the researcher were randomly assigned to four pain treatment groups. Randomization of the TENS-PAC units was achieved by mixing the two boxes of 50 functioning and 50 placebo units together. A decoding process was released when all of the TENS-PAC units were returned after the study was completed. All of the units were returned to the researcher following the study to determine which units the patient had and also to assure their function.'
Allocation concealment (selection bias)	Low risk	'A decoding process was released when all of the TENS-PAC units were returned after the study was completed. All of the units were returned to the researcher following the study to determine which units the patient had and also to assure their function.'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Source of funding bias	Unclear risk	No details provided.
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. 'In the study, 50% of the patients received a functioning TENS-PAC, and the other 50% received a 'placebo' unit, which appeared and operated in all ways similar to the functioning unit except that no elec-

Ordog 1987 (*Continued*)

		trical current was transmitted to the skin. This 'placebo' unit was originally a functioning TENS-PAC, but in this unit, an internal wire that supplied the electrical current to the skin was cut. The TENS-PAC produces a slight hum and vibration that the 'placebo' unit also produced. The 'placebo' units were prepared by an independent source, and neither the researcher nor the patient was able to identify which unit was given until the study was completed. The possibility that the patients might have figured out whether they had the placebo units seems remote, as patients were not told that the functioning units can produce a mild electrical shock by turning up the unit. As none of the patients had used TENS previously, it is unlikely that they would have known that an electrical shock could be produced only by the functioning units.'
Blinding (Outcome Assessor)	Low risk	'The 'placebo' units were prepared by an independent source, and neither the researcher nor the patient was able to identify which unit was given until the study was completed.'

Roche 1985

Methods	Type of study: randomised, placebo-controlled, parallel design. Condition and number of participants randomised: haemophiliac participants, 36. Groups: Active TENS Group, 28; Placebo TENS Group, 8.
Participants	Demographics: n = 36, 35 +/- 12 yrs (mean +/- ?SD), gender not detailed. Setting: specialised outpatient clinic at hospital. Inclusion: haemophiliac participants suffering from unilateral haemorrhage into a joint. Exclusion: participants attending for dental care or for treatment to haemorrhage in the region of the face, abdomen or cranium. Withdrawals/dropouts: none.
Interventions	Where applied: in hospital. Applied by: clinician. Waveform: square wave pulses. Frequency: internal pulse frequency of trains was 100 Hz and repetition rate of trains was 5 Hz. In initial stage of study, trains of pulses rather than continuous TENS reported by participants as being more tolerable, consequently this form of TENS was adopted throughout the study.

Roche 1985 (*Continued*)

	Pulse duration: 1 ms pulses, 100 ms train duration. Pulse amplitude/Intensity: raised to a level of definite but comfortable perception with no presence of muscle activation. Placebo TENS Group: as for active group but no stimulation applied. Participants informed that a very high frequency of stimulation was being used which they might or might not feel. Electrodes: 2 or 4, flexible carbon electrodes layered with electrode gel, 2x2 cm, over the major sensory nerves supplying affected area or as close as possible to area of bleed. Duration and frequency of Rx: 25 min, 1 Rx. Device/manufacturer: Digitimer Ltd, Model DS2. Adverse effects: none.
Outcomes	Pain outcome: MPQ (PRI, PPI, group scores for each category) before and after Rx for current pain. Intention to treat/per protocol analysis: no. Statistical analysis: over 71% of participants receiving TENS reported changes in MPQ scores which represented pain relief >50%. Only 2 placebo participants (25%) reported this amount of pain relief. The difference between participants reporting at least 50% relief was significantly different between groups using PRI and PPI. 9 TENS participants reported > 80% pain relief, 4 of these reported 100% pain relief. 2 placebo participants reported > 50% pain relief, neither reported 100%. Pre Rx PRI data divided into mild-medium (PRI score of 0-25) and medium-severe (PRI score of 26-50) based on highest recorded PRI score of 50. For TENS participants, difference between these 2 groups of scores was not significant.
Notes	Abbreviation: MPQ- McGill pain questionnaire; PPI- present pain index; PRI- pain rating index; Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'The subjects were randomly assigned to one of two groups.'
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Author response 'No' to my question 'Were there any dropouts/withdrawals?'.
Source of funding bias	Low risk	'The research was supported by a grant from The British Medical Research Council (Grant No. 0979/723/N) awarded to K. Gijsbers.'
Blinding (Participant)	High risk	It is impossible to adequately blind participants who receive electrical stimulation. Author response 'The study was single blind. The same researcher took measures

Roche 1985 (*Continued*)

		and applied TENS. Specific TENS settings were screened from participants'. 'The same apparatus and electrodes were used for the placebo group, but no stimulation was applied. These subjects were informed that a very high frequency of stimulation was being used which they might or might not feel.' The exclusion criteria were not provided so we do not know if participants had to be TENS naïve.
Blinding (Outcome Assessor)	High risk	Author response 'The study was single blind. The same researcher took measures and applied TENS. Specific TENS settings were screened from participants'.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Akhmadeeva 2010	RCT but chronic pain.
Andersen 2009a	RCT but not a standard TENS device.
Andersen 2009b	RCT but not a standard TENS device.
Barbarisi 2010	RCT but chronic pain.
Barker 2006	RCT but intensity too low.
Baskurt 2006	RCT but chronic pain.
Bertalanffy 2005	RCT but intensity too low.
Chee 1986	RCT but microcurrent used.
Coletta 1988	RCT but intensity too low.
Dogu 2009	RCT but chronic pain.
Durmus 2009	RCT but chronic pain.
Ekblom 1985	RCT but TENS delivered at distal acupuncture point.

(*Continued*)

Fengler 2007	RCT but microcurrent used/chronic condition.
Gul 2009	RCT but chronic pain.
Herman 1994	RCT but not a standard TENS device.
Izadpanah 2005	RCT but needle electrode used/not standard TENS device.
Korkmaz 2010	RCT but chronic pain.
Lang 2007	RCT but intensity too low.
Lee 1997	RCT but not a standard TENS device.
Leo 1986	RCT but mixed acute and chronic pain.
Mora 2006	RCT but intensity too low.
Murina 2008	RCT but chronic pain.
Pope 1994	RCT but not acute pain.
Reichstein 2005	RCT but H-wave device used.
Solomon 1985	RCT but not a standard TENS device.
Stratton 2009	RCT but chronic pain.
Sunshine 1996	RCT but APS therapy used/chronic condition.
Taskaynatan 2007	RCT but IFT used.
Tsai 2010	RCT but chronic pain.
Tulgar 1991a	RCT but chronic conditions included.
Tulgar 1991b	RCT but chronic conditions included.
Wang 2009	RCT but chronic pain.

Characteristics of studies awaiting assessment *[ordered by study ID]*

de Paiva Tosato 2007

Methods	Type of study: randomised, controlled, parallel design. Condition and number of participants randomised: temporomandibular pain (? acute pain), 20. Groups: Massage Group, 10; TENS Group, 10.
Participants	Demographics: n = 20, 22-46 yrs, 31.75 +/- 8.71 (mean+/-SD), all F. Setting: not detailed. Inclusion: signs and symptoms of temporomandibular disorders; females. Exclusion: no temporomandibular pain; males; dental problems; systemic disease; patients having other treatment (dental treatment, physiotherapy, medication). Withdrawals/dropouts: not detailed.
Interventions	Where applied: not detailed. Applied by: not detailed. Waveform: not detailed. Frequency: not detailed. Pulse duration: not detailed. Pulse amplitude/Intensity: participants told the sensation should be pleasant and were told to report whenever the intensity of the current decreased. Electrodes: not detailed. Placed over masseter muscle, anterior portion of temporal muscle. Duration and frequency of Rx: 30 min, 1 Rx. Device/manufacturer: Quark. Adverse effects: not detailed.
Outcomes	Pain outcome: VAS for pain intensity, before and after Rx. Intention to treat/per protocol analysis: not detailed. Statistical analysis: statistically significant reduction in VAS scores post Rx in both groups.
Notes	Abbreviation: Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Ekblom 1987

Methods	Type of study: ? randomised, placebo-controlled, parallel design. Condition and number of participants randomised: acute pain from teeth or surrounding tissues, 40. Groups: 100 Hz Vibration Group, 8; Placebo Vibration Group, 5; 2 Hz TENS Group, 11; 100 Hz TENS Group, 11; Placebo TENS Group, 5.
Participants	Demographics: n = 40, 20-58 yrs, 23 M/17 F. Setting: emergency clinic for dental and oral surgery. Inclusion: acute pain from teeth and/or surrounding tissues. Exclusion: not detailed. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in clinic. Applied by: presume by clinician. Waveform: monopolar square wave pulses. Frequency: HF Group, 100 Hz; LF Group, 71 Hz pulse train (duration 84 ms) delivered at 2 Hz. Pulse duration: 0.2 ms.

Ekblom 1987 (*Continued*)

	Pulse amplitude/Intensity: HF set to produce a tingling sensation. LF set to produce prominent muscular contractions. Placebo TENS Group: electrodes applied to skin but no stimulation transmitted. Participants informed that some people might not experience the stimulation. Electrodes: 2, 3 cmx3 cm conducting rubber, skin overlying painful area, anode distal. Duration and frequency of Rx: 30 min, 1 Rx. Device/manufacturer: not detailed. Adverse effects: not detailed.
Outcomes	Pain outcome: VAS and 5 level verbal scale for pain intensity, before and after Rx. Heat pain threshold recorded before, during and after Rx. Intention to treat/per protocol analysis: not detailed. Statistical analysis: no active stimulation was superior to the others re number of participants reporting pain reduction; placebo significantly less effective than active stimulation. No significant effects of Rx on heat pain threshold.
Notes	Abbreviation: HF- high frequency; LF- low frequency; Rx- treatment; VAS- visual analogue scale.

Gregorini 2010

Methods	Type of study: randomised, placebo-controlled, parallel design. Condition and number of participants randomised: postoperative period of cardiac surgery, 25. Groups: Placebo Group, 12; TENS Group, 13.
Participants	Demographics: n = 25, 59.9 ± 10.3 yrs (mean+/- ?SD), 18 M/7 F. Setting: inpatient. Inclusion: patients aged between 35-80 years who had undergone elective cardiac surgery via longitudinal median sternotomy. Exclusion: patients with pacemaker; pregnant women; cognitive or intellectual impairment; absence of pain in the postoperative period; sensitivity disorders; and patients undergoing any type of analgesia in the eight-hour period preceding the beginning of the protocol. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: participant. Waveform: not detailed. Frequency: 80 Hz. Pulse duration: 150 μs. Pulse amplitude/Intensity: participants adjusted the intensity of stimulation at the point at which they felt a strong, although yet comfortable, prickling sensation, and were told to reduce the intensity if they felt uncomfortable. Electrodes: 2 pairs of adhesive electrodes, 10 x 3.5 cm. Placed one on each side of the surgical wound in the subclavian region. Duration and frequency of Rx: 4 hrs, 1 Rx. Device/manufacturer: TENS Device, KLD, Amparo, São Paulo, Brazil. Adverse effects: not detailed.
Outcomes	Pain outcome: numerical VAS for pain intensity at rest and with cough, before and after Rx. Intention to treat/per protocol analysis: not detailed. Statistical analysis: TENS significantly reduced pain in the postoperative period.

Notes	Abbreviation: Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Hsueh 1997

Methods	Type of study: randomised, double blind, placebo-controlled, parallel design. Condition and number of participants randomised: myofascial trigger points of upper trapezius muscle (? acute pain) , 60. Groups: Placebo Group, 18; ENS Group, 20; EMS therapy, 22.
Participants	Demographics: n = 60, 44.4 +/- 13.9 yrs (mean +/- ?SD), 25 M/35 F. Placebo Group, 41.4 +/- 13.0 yrs; ENS Group, 42.7 +/- 13.8 yrs; EMS therapy, 44.4 +/- 14.5 yrs (mean+/-?SD). Setting: outpatient clinic at hospital. Inclusion: myofascial trigger points in one side of upper trapezius muscles. Exclusion: < 18 yrs or > 80 yrs; acute or serious illness; mental retardation; neurologic deficits involving the investigated upper limb; advanced osteopathic or arthropathic disorder of the cervical spine or the shoulder of the investigated side; participants should have had no therapy, such as physical therapy or injection therapy, within the last 2 months on MTrPs selected for this study. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in clinic. Applied by: presume by clinician. Waveform: not detailed. Frequency: 60 Hz. Pulse duration: not detailed. Pulse amplitude/Intensity: at a level that the participant could feel but was not strong enough to induce muscle contraction. Placebo Group: participant told that a certain type of therapy would be given to treat MTrPs, but was not told what treatment was to be given. Electrodes were applied on the upper trapezius muscle as in other groups, 0 mA current intensity. Electrodes: 2, type and number not detailed, negative electrode placed on MTrP of upper trapezius muscle and positive one on its acromial tendon insertional site. Duration and frequency of Rx: 20 min, 1 Rx. Device/manufacturer: not detailed. Adverse effects: not detailed.
Outcomes	Pain outcome: VAS for pain intensity, before and after Rx. PT of MTrP of the upper trapezius muscle before and after Rx. Intention to treat/per protocol analysis: not detailed. Statistical analysis: improvement in PI and PT was significantly greater in the ENS Group than the other 2 groups.
Notes	ENS- electrical nerve stimulation; EMS- electrical muscle stimulation; MTrPs- myofascial trigger points; PI- pain intensity; PT- pain threshold; Rx- treatment; SD- standard deviation; VAS- visual analogue scale.

Rajpurohit 2010

Methods	Type of study: randomised, controlled, parallel design. Condition and number of participants randomised: bruxism with masticatory muscle pain (? acute pain), 60. Groups: MENS, 30; TENS Group, 30.
Participants	Demographics: n = 60, age not detailed, 36 M/24 F. Setting: physiotherapy department in a hospital. Inclusion: clinical diagnosis of bruxism; muscle tenderness over masseter muscle; early morning temporomandibular joint stiffness and pain; duration of pain more than three weeks; and, age ranged from 19 to 60 years. Exclusion: wearing any removable restoration; treated with analgesic and antiinflammatory drugs; having muscle pain without bruxism; presence of any tumour or cancer around jaws or infection. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in hospital. Applied by: not detailed. Waveform: not detailed. Frequency: 50 Hz. Pulse duration: 0.5 ms. Pulse amplitude/Intensity: intensity was as per the participant's tolerance. Electrodes: carbon electrodes, number not detailed, 40 x 54 mm^2. Placed over the affected side of masseter muscle. Duration and frequency of Rx: 20 minutes, 1 Rx daily for 7 days. Device/manufacturer: not detailed. Adverse effects: not detailed.
Outcomes	Pain outcome: VAS for pain intensity, pre TENS and post TENS at the end of the seventh day of treatment. Tenderness by using digital pressometer of 2 KgF, pre TENS and post TENS at the end of the seventh day of treatment. Intention to treat/per protocol analysis: not detailed. Statistical analysis: statistically significant pain relief and decrease in tenderness in MENS group compared to TENS group.
Notes	Abbreviation: MENS- microcurrent electrical nerve stimulation; Rx- treatment; VAS- visual analogue scale.

Salvador 2005

Methods	Type of study: ? randomised, blinded, controlled, parallel design. Condition and number of participants randomised: acute low back pain, 28. Groups: Muscle Energy Technique Group, 14; TENS Group, 14.
Participants	Demographics: n = 28, age not detailed, all M. Setting: clinic. Inclusion: acute low back pain (constant pain present for no more than 3 weeks); shortening of at least one of the muscle groups assessed; no treatment (physiotherapy or tablets) in the last 2 weeks for the low back pain. Exclusion: chronic low back pain; rheumatological problems (arthritis, osteoporosis); no muscle shortening; positive Valsalva. Withdrawals/dropouts: not detailed.
Interventions	Where applied: in clinic. Applied by: clinician. Waveform: not detailed. Frequency: not detailed.

Salvador 2005 (*Continued*)

	Pulse duration: not detailed. Pulse amplitude/Intensity: not detailed. Electrodes: not detailed. Duration and frequency of Rx: 5 min, 1 Rx. Device/manufacturer: Quark. Adverse effects: not detailed.
Outcomes	Pain outcome: VAS for pain intensity, before and after Rx. Intention to treat/per protocol analysis: not detailed. Statistical analysis: significant reduction in pain intensity after treatment in TENS group when compared to Muscle Energy Technique group.
Notes	Rx- treatment; VAS- visual analogue scale.

DATA AND ANALYSES

Comparison 1. TENS versus placebo TENS

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 VAS >50% pain relief post treatment	1	62	Risk Ratio (M-H, Fixed, 95% CI)	1.92 [0.74, 4.98]
2 Pain rating index >50% pain relief post treatment	1	36	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.84, 9.71]
3 VAS for pain intensity after two days of treatment	1	50	Mean Difference (IV, Fixed, 95% CI)	-2.44 [-3.85, -1.03]
4 Numerical rating scale for pain intensity during procedure	1	60	Mean Difference (IV, Fixed, 95% CI)	-0.27 [-0.77, 0.23]
5 Overall impression with TENS (excellent/good rating)	1	30	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.65, 2.54]
6 VAS for pain intensity post treatment	1	30	Mean Difference (IV, Fixed, 95% CI)	-1.53 [-3.37, 0.31]

Comparison 2. TENS versus no treatment control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Numerical rating scale for pain intensity during procedure	1	60	Mean Difference (IV, Fixed, 95% CI)	-0.23 [-0.72, 0.26]

Comparison 3. High pulse amplitude TENS versus low pulse amplitude TENS

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Measure of discomfort (severe/worst possible discomfort rating)	1	20	Odds Ratio (M-H, Fixed, 95% CI)	0.04 [0.00, 0.90]
2 VAS for pain intensity post treatment	1	20	Mean Difference (IV, Fixed, 95% CI)	-2.7 [-4.08, -1.32]

Comparison 4. Conventional TENS versus AL-TENS

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 VAS >50% pain relief post treatment	1	42	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.32, 1.54]

Analysis 1.1. Comparison 1 TENS versus placebo TENS, Outcome 1 VAS >50% pain relief post treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

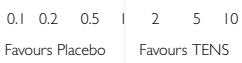
Outcome: 1 VAS >50% pain relief post treatment

Study or subgroup	TENS n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Hansson 1983	9/20	2/10		49.2 %	2.25 [0.59, 8.52]
Hansson 1983	7/22	2/10		50.8 %	1.59 [0.40, 6.34]
Total (95% CI)	**42**	**20**		**100.0 %**	**1.92 [0.74, 4.98]**

Total events: 16 (TENS), 4 (Placebo)

Heterogeneity: $Chi^2 = 0.13$, df = 1 (P = 0.72); $I^2 = 0.0\%$

Test for overall effect: Z = 1.33 (P = 0.18)



Analysis 1.2. Comparison 1 TENS versus placebo TENS, Outcome 2 Pain rating index >50% pain relief post treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

Outcome: 2 Pain rating index >50% pain relief post treatment

Study or subgroup	Favours placebo TENS n/N	Placebo TENS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Roche 1985	20/28	2/8		100.0 %	2.86 [0.84, 9.71]
Total (95% CI)	**28**	**8**		**100.0 %**	**2.86 [0.84, 9.71]**

Total events: 20 (Favours placebo TENS), 2 (Placebo TENS)

Heterogeneity: not applicable

Test for overall effect: Z = 1.68 (P = 0.092)

Analysis 1.3. Comparison 1 TENS versus placebo TENS, Outcome 3 VAS for pain intensity after two days of treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

Outcome: 3 VAS for pain intensity after two days of treatment

Study or subgroup	TENS N	Mean(SD)[cm]	Placebo TENS N	Mean(SD)[cm]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Ordog 1987	25	3.04 (2.6)	25	5.48 (2.5)		100.0 %	-2.44 [-3.85, -1.03]
Total (95% CI)	**25**		**25**			**100.0 %**	**-2.44 [-3.85, -1.03]**

Heterogeneity: not applicable

Test for overall effect: Z = 3.38 (P = 0.00072)

Analysis 1.4. Comparison 1 TENS versus placebo TENS, Outcome 4 Numerical rating scale for pain intensity during procedure.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

Outcome: 4 Numerical rating scale for pain intensity during procedure

Study or subgroup	TENS N	Mean(SD)[unit]	Placebo TENS N	Mean(SD)[unit]	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Limoges 2004	30	2 (0.947)	30	2.27 (1.015)		100.0 %	-0.27 [-0.77, 0.23]
Total (95% CI)	**30**		**30**			**100.0 %**	**-0.27 [-0.77, 0.23]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.07 (P = 0.29)

Analysis 1.5. Comparison 1 TENS versus placebo TENS, Outcome 5 Overall impression with TENS (excellent/good rating).

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

Outcome: 5 Overall impression with TENS (excellent/good rating)

Study or subgroup	Favours Placebo n/N	Favours TENS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Liu 1985	9/15	7/15		100.0 %	1.29 [0.65, 2.54]
Total (95% CI)	**15**	**15**		**100.0 %**	**1.29 [0.65, 2.54]**

Total events: 9 (Favours Placebo), 7 (Favours TENS)

Heterogeneity: not applicable

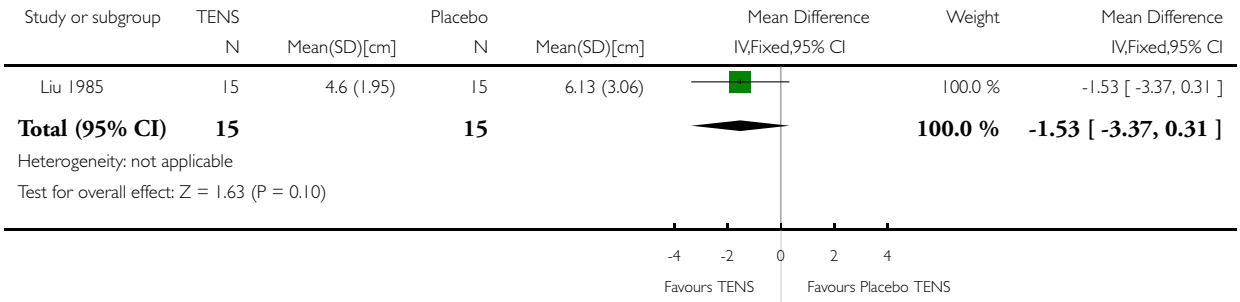
Test for overall effect: Z = 0.72 (P = 0.47)

Analysis 1.6. Comparison 1 TENS versus placebo TENS, Outcome 6 VAS for pain intensity post treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 1 TENS versus placebo TENS

Outcome: 6 VAS for pain intensity post treatment

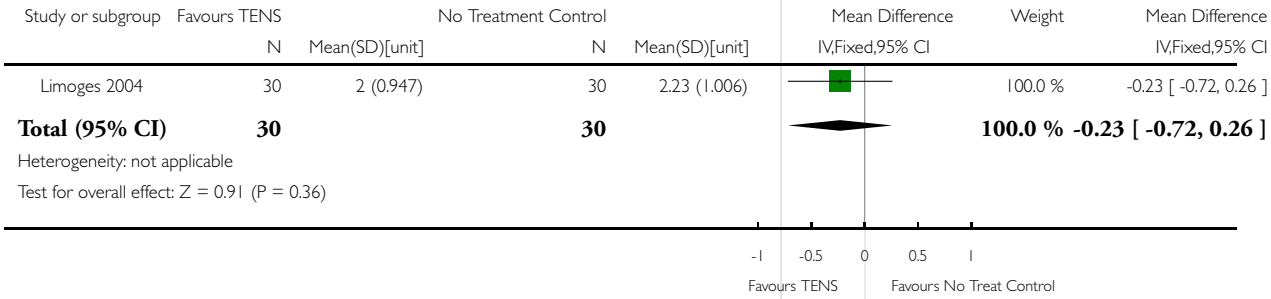


Analysis 2.1. Comparison 2 TENS versus no treatment control, Outcome 1 Numerical rating scale for pain intensity during procedure.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 2 TENS versus no treatment control

Outcome: 1 Numerical rating scale for pain intensity during procedure

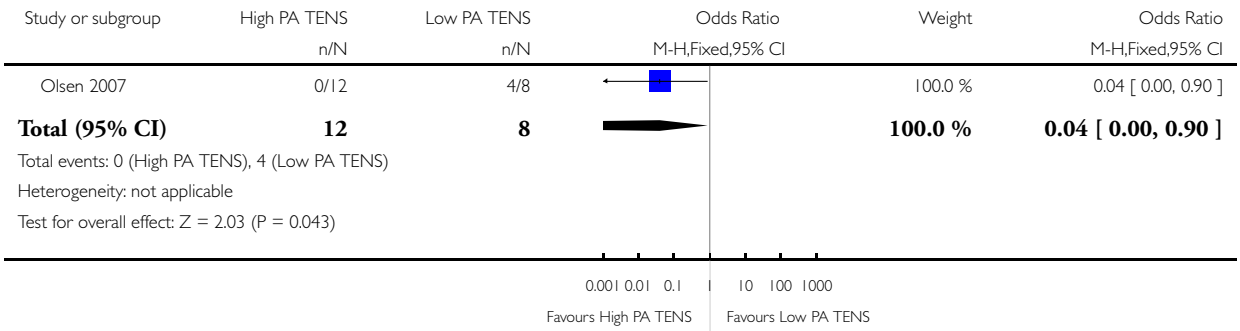


Analysis 3.1. Comparison 3 High pulse amplitude TENS versus low pulse amplitude TENS, Outcome 1 Measure of discomfort (severe/worst possible discomfort rating).

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 3 High pulse amplitude TENS versus low pulse amplitude TENS

Outcome: 1 Measure of discomfort (severe/worst possible discomfort rating)

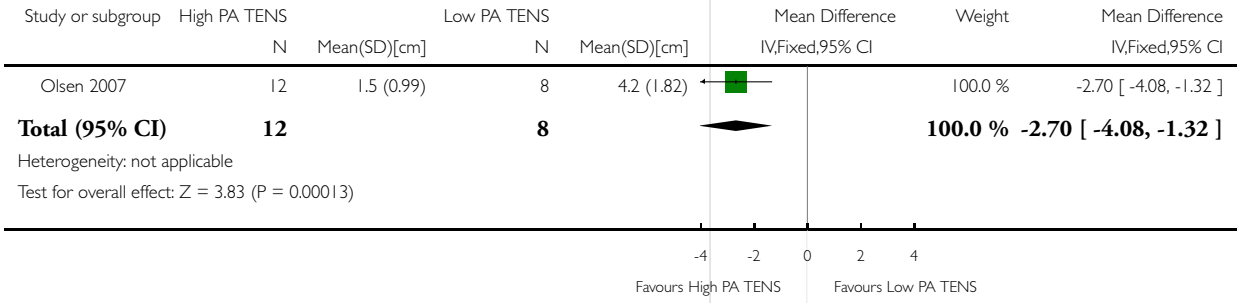


Analysis 3.2. Comparison 3 High pulse amplitude TENS versus low pulse amplitude TENS, Outcome 2 VAS for pain intensity post treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 3 High pulse amplitude TENS versus low pulse amplitude TENS

Outcome: 2 VAS for pain intensity post treatment



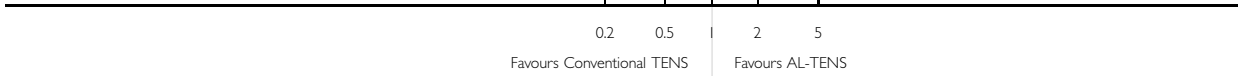
Analysis 4.1. Comparison 4 Conventional TENS versus AL-TENS, Outcome 1 VAS >50% pain relief post treatment.

Review: Transcutaneous electrical nerve stimulation for acute pain

Comparison: 4 Conventional TENS versus AL-TENS

Outcome: 1 VAS >50% pain relief post treatment

Study or subgroup	Conventional TENS n/N	AL-TENS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Hansson 1983	7/22	9/20		100.0 %	0.71 [0.32, 1.54]
Total (95% CI)	**22**	**20**		**100.0 %**	**0.71 [0.32, 1.54]**
Total events: 7 (Conventional TENS), 9 (AL-TENS)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.87 (P = 0.38)					



APPENDICES

Appendix 1. Ovid MEDLINE search strategy

1. exp Pain/
2. Pain Measurement/
3. Pain Threshold/
4. Pain Clinics/
5. Myofascial Pain Syndromes/
6. Hyperalgesia/
7. exp Headache Disorders/
8. (toothache$ or tooth-ache$ or ear-ache$ or earache$ or sciatic$ or neuralgi$ or migraine$ or headache$ or neuralgi$ or cephalalgi$ or metatarsalgia$ or bursitis or hyperalg$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
9. pain$.ti.
10. pain$.ab.
11. exp Angina Pectoris/
12. angina.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
13. Metatarsalgia/
14. or/1-13
15. exp Transcutaneous Electric Nerve Stimulation/
16. “TENS”.ti.
17. “TENS”.ab.
18. “TNS”.ti.
19. “TNS”.ab.
20. “ENS”.ti.
21. “ENS”.ab.

22. ("transcutaneous electric$ nerve stimulation" or "transcutaneous nerve stimulation").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
23. ("electric$ nerve stimulation" or "electrostimulation therap$" or "electro-stimulation therap$").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
24. ("electric$ nerve therap$" or electroanalgesi$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
25. transcutaneous electric$ stimulation.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
26. TES.ti,ab.
27. or/15-26
28. 14 and 27
29. RANDOMIZED CONTROLLED TRIAL.pt.
30. CONTROLLED CLINICAL TRIAL.pt.
31. RANDOMIZED CONTROLLED TRIALS.sh.
32. RANDOM ALLOCATION.sh.
33. DOUBLE BLIND METHOD.sh.
34. SINGLE BLIND METHOD.sh.
35. or/29-34
36. (ANIMALS not HUMAN).sh.
37. 35 not 36
38. CLINICAL TRIAL.pt.
39. exp CLINICAL TRIALS/
40. (clin$ adj25 trial$).ti,ab.
41. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
42. PLACEBOS.sh.
43. placebo$.ti,ab.
44. random$.ti,ab.
45. RESEARCH DESIGN.sh.
46. or/38-45
47. 46 not 36
48. 47 not 37
49. 37 or 48
50. 28 and 49

Appendix 2. Ovid AMED search strategy

1. exp Pain/
2. Pain measurement/
3. Pain threshold/
4. PAIN CLINICS.mp.
5. Myofascial pain syndromes/
6. Hyperalgesia/
7. exp Headache/
8. (toothache$ or tooth-ache$ or ear-ache$ or earache$ or sciatic$ or neuralgi$ or migraine$ or headache$ or neuralgi$ or cephalalgi$ or metatarsalgia$ or bursitis or hyperalg$).mp. [mp=title, subject heading word, abstract, instrumentation]
9. pain$.ti.
10. pain$.ab.
11. exp angina pectoris/
12. angina.mp. [mp=title, subject heading word, abstract, instrumentation]
13. Metatarsalgia/
14. or/1-13
15. exp Transcutaneous electric nerve stimulation/

16. “TENS”.ti.
17. “TENS”.ab.
18. “TNS”.ti.
19. “TNS”.ab.
20. “ENS”.ti.
21. “ENS”.ab.
22. (“transcutaneous electric$ nerve stimulation” or “transcutaneous nerve stimulation”).mp. [mp=title, subject heading word, abstract, instrumentation]
23. (“electric$ nerve stimulation” or “electrostimulation therap$” or “electro-stimulation therap$”).mp. [mp=title, subject heading word, abstract, instrumentation]
24. (“electric$ nerve therap$” or electroanalgesi$).mp. [mp=title, subject heading word, abstract, instrumentation]
25. transcutaneous electric$ stimulation.mp. [mp=title, subject heading word, abstract, instrumentation]
26. TES.ti,ab.
27. or/15-26
28. 14 and 27
29. RANDOMIZED CONTROLLED TRIAL.pt.
30. CONTROLLED CLINICAL TRIAL.pt.
31. RANDOMIZED CONTROLLED TRIALS.sh.
32. RANDOM ALLOCATION.sh.
33. DOUBLE BLIND METHOD.sh.
34. “single blind method”.mp. [mp=title, subject heading word, abstract, instrumentation]
35. or/29-34
36. (ANIMALS not HUMANS).sh.
37. 35 not 36
38. CLINICAL TRIAL.pt.
39. exp CLINICAL TRIALS/
40. (clin$ adj25 trial$).ti,ab.
41. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
42. PLACEBOS.sh.
43. placebo$.ti,ab.
44. random$.ti,ab.
45. RESEARCH DESIGN.sh.
46. or/38-45
47. 46 not 36
48. 47 not 37
49. 37 or 48
50. 28 and 49

Appendix 3. EBSCO CINAHL search strategy

1 exp PAIN/
2 PAIN MEASUREMENT/
3 PAIN CLINICS/
4 MYOFASCIAL PAIN SYNDROMES/
5 HYPERALGESIA/
6 exp HEADACHE/
7 (toothache* OR tooth-ache* OR ear-ache* OR earache* OR sciatic* OR neuralgi* OR migraine* OR headache* OR neuralgi* OR cephalalgi* OR metatarsalgia* OR bursitis OR hyperalg*).ti,ab
8 pain*.ti,ab
9 exp ANGINA PECTORIS/
10 angina.ti,ab
11 PAIN THRESHOLD/

12 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11
13 exp TRANSCUTANEOUS ELECTRIC NERVE STIMULATION/
14 (TENS OR TNS OR ENS).ti,ab
15 (transcutaneous AND stimulation).ti,ab
16 TES.ti,ab
17 ((electric* AND stimulation) OR electrostimulation OR electro-stimulation).ti,ab
18 ((electric* nerve therap*) OR electroanalgesi*).ti,ab
19 13 OR 14 OR 15 OR 16 OR 17 OR 18
20 12 AND 19
21 RANDOM ASSIGNMENT/
22 SINGLE-BLIND STUDIES/
23 DOUBLE-BLIND STUDIES/
24 TRIPLE-BLIND STUDIES/
25 CROSSOVER DESIGN/
26 FACTORIAL DESIGN/
27 ((multicentre OR multicenter OR multi-centre OR multi-center) AND stud*).ti,ab
28 random*.ti,ab
29 (latin AND square).ti,ab
30 (cross-over OR crossover).ti,ab
31 PLACEBOS/
32 placebo*.ti,ab
33 ((singl* OR doubl* OR trebl* OR tripl*) AND (blind* OR mask*)).ti,ab
34 exp CLINICAL TRIALS/
35 (clin* AND trial*).ti,ab
36 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35
37 20 AND 36

Appendix 4. Ovid EMBASE search strategy

1. exp PAIN/
2. Pain Assessment/
3. Pain Threshold/
4. Pain Clinic/
5. Myofascial Pain/
6. HYPERALGESIA/
7. exp "Headache and Facial Pain"/
8. (toothache$ or tooth-ache$ or ear-ache$ or earache$ or sciatic$ or neuralgi$ or migraine$ or headache$ or neuralgi$ or cephalalgi$ or metatarsalgia$ or bursitis or hyperalg$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
9. pain$.ti.
10. pain$.ab.
11. exp Angina Pectoris/
12. angina.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
13. METATARSALGIA/
14. or/1-13
15. exp Transcutaneous Nerve Stimulation/
16. "TENS".ti.
17. "TENS".ab.
18. "TNS".ti.
19. "TNS".ab.
20. "ENS".ti.

21. "ENS".ab.
22. ("transcutaneous electric$ nerve stimulation" or "transcutaneous nerve stimulation").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
23. ("electric$ nerve stimulation" or "electrostimulation therap$" or "electro-stimulation therap$").mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
24. ("electric$ nerve therap$" or electroanalgesi$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
25. transcutaneous electric$ stimulation.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
26. TES.ti,ab.
27. or/15-26
28. 14 and 27
29. random$.ti,ab.
30. factorial$.ti,ab.
31. (crossover$ or cross over$ or cross-over$).ti,ab.
32. placebo$.ti,ab.
33. (doubl$ adj blind$).ti,ab.
34. (singl$ adj blind$).ti,ab.
35. assign$.ti,ab.
36. allocat$.ti,ab.
37. volunteer$.ti,ab.
38. CROSSOVER PROCEDURE.sh.
39. DOUBLE-BLIND PROCEDURE.sh.
40. RANDOMIZED CONTROLLED TRIAL.sh.
41. SINGLE BLIND PROCEDURE.sh.
42. or/29-41
43. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
44. HUMAN/
45. 44 and 43
46. 43 not 45
47. 42 not 46
48. 28 and 47

Appendix 5. CENTRAL (*The Cochrane Library*) search strategy

1. MeSH descriptor Pain explode all trees in MeSH products
2. MeSH descriptor Pain Measurement, this term only in MeSH products
3. MeSH descriptor Pain Threshold, this term only in MeSH products
4. MeSH descriptor Pain Clinics, this term only in MeSH products
5. MeSH descriptor Myofascial Pain Syndromes, this term only in MeSH products
6. MeSH descriptor Hyperalgesia, this term only in MeSH products
7. MeSH descriptor Headache Disorders explode all trees in MeSH products
8. (Toothache* or tooth-ache* or ear-ache* or earache* or sciatic* or neuralgi* or migrain* or headache* or neuralgi* or cephalalgia or metatarsalgia* or bursitis or hyperalg*) in All Fields in all products
9. pain* in Record Title in all products
10. pain* in Abstract in all products
11. MeSH descriptor Angina Pectoris explode all trees in MeSH products
12. angina in All Fields in all products
13. MeSH descriptor Metatarsalgia, this term only in MeSH products
14. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
15. MeSH descriptor Transcutaneous Electric Nerve Stimulation explode all trees in MeSH products
16. "TENS" in Record Title in all products

17. “TENS” in Abstract in all products
18. “TNS” in Record Title in all products
19. “TNS” in Abstract in all products
20. “ENS” in Record Title in all products
21. “ENS” in Abstract in all products
22. (transcutaneous next electric* next nerve next stimulation or “transcutaneous nerve stimulation”) in All Fields in all products
23. (“electric* nerve stimulation” or “electrostimulation therap*”) in All Fields in all products
24. (“electric* nerve therap*” or electroanalgesi*) in All Fields in all products
25. “TES” in Record Title in all products
26. “TES” in Abstract in all products
27. (transcutaneous next electric* next stimulation) in All Fields in all products
28. (#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27)
29. (#14 AND #28)

Appendix 6. PEDro search strategy

Abstract & Title:“electrical stimulation” pain
Therapy: electrotherapies, heat and cold
Problem: pain
Method: Clinical Trial
Note: check “match all search terms”

Appendix 7. OTseeker search strategy

Keywords: electrical stimulation
Methods: clinical trial

Appendix 8. OpenSIGLE search strategy

((pain OR toothache* OR tooth-ache* OR ear-ache* OR earache* OR sciatic* OR neuralgi* OR migraine* OR headache* OR neuralgi* OR cephalalgi* OR metatarsalgia* OR bursitis OR hyperalg* OR myofascial OR angina*) AND (transcutaneous electric nerve stimulation OR tens OR tns OR ens OR transcutaneous electric* OR transcutaneous nerve stimulation OR electric* nerve stimulation OR electrostimulation therap* OR electro-stimulation therap* OR electro-stimulation OR electrostimulation OR electric* nerve therap* OR electroanalgesi*))

Appendix 9. Cochrane Pain, Palliative and Supportive Care Group specialised register search strategy

((pain* or hyperalgesi* or headache* or migrain* or toothache or “tooth ache*” or earache or “ear ache*” or sciatic* or neuralgi* or cephalgi* or metatarsalg* or bursitis or angina) AND (“transcutaneous electric* nerve stimulation” or “transcutaneous nerve stimulation” or “electric* nerve stimulation” or “electrostimulation therap*” or electroanalgesi* or TENS))

WHAT'S NEW

Last assessed as up-to-date: 14 June 2011.

Date	Event	Description
7 January 2011	New search has been performed	Updated search done in January 2011. No new included studies but two new studies are awaiting classification (Gregorini 2010; Rajpurohit 2010) and an additional 12 studies were assessed and excluded from this review (Akhmadeeva 2010; Andersen 2009a; Andersen 2009b; Barbarisi 2010; Dogu 2009; Durmus 2009; Gul 2009; Korkmaz 2010; Murina 2008; Stratton 2009; Tsai 2010; Wang 2009). A further 17 studies were excluded as TENS was given with another treatment (see Table 1).

Table 1. Studies excluded as TENS given in combination with other treatments

Akyuz G, Kayhan O, Babacan A, Gener FA. Transcutaneous electrical nerve stimulation (TENS) in the treatment of postoperative pain and prevention of paralytic ileus. Clinical Rehabilitation, 1993, 7, 3, 218-21.
Ali J, Yaffe CS, Serrette C. The effect of transcutaneous electric nerve stimulation on postoperative pain and pulmonary function. Surgery, 1981, 89, 4, 507-12.
Alm WA, Gold ML, Weil LS. Evaluation of transcutaneous electrical nerve stimulation (TENS) in podiatric surgery. Journal of the American Podiatry Association, 1979, 69, 9, 537-42.
Anderson AF, Lipscomb AB. Analysis of rehabilitation techniques after anterior cruciate reconstruction. American Journal of Sports Medicine, 1989, 17, 2, 154-60.
Angulo DL, Colwell CWJr. Use of postoperative TENS and continuous passive motion following total knee replacement. The Journal of Orthopaedic and Sports Physical Therapy, 1990, 11, 12, 599-604.
Ardic F, Sarhus M, Topuz O. Comparison of two different techniques of electrotherapy on myofascial pain. Journal of Back and Musculoskeletal Rehabilitation, 2002, 16, 1, 11-6.
Arena M, Savoca G, Lednyiczky G. Percutaneous paravertebral infiltration of O2-O3, bioresonance magnetotherapy, transcutaneous electrical nerve stimulation and psychosomatic postural rehabilitation in the treatment of degenerative joint disease of the lumbar spine with functional insufficiency of the vertebral motor unit. International Journal of Ozone Therapy, 2008, 7, 1, 29-36.
Avraham F, Aviv S, Ya'akobi P, Faran H, Fisher Z, Goldman Y, Neeman G, et al. The efficacy of treatment of different intervention programs for patellofemoral pain syndrome-a single blinded randomized clinical trial. Pilot study. The Scientific World Journal, 2007, 7, 1256-62.
Baker SB, Wong CC, Wong PC, Jenkins LC. Transcutaneous electrostimulation in the management of postoperative pain: initial report. Canadian Anaesthetists' Society Journal, 1980, 27, 2, 150-5.
Bayindir O, Paker T, Akpinar B, Erenturk S, Askin D, Aytac A. Use of transcutaneous electrical nerve stimulation in the control of postoperative chest pain after cardiac surgery. Journal of Cardiothoracic and Vascular Anesthesia, 1991, 5, 6, 589-91.

Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

Bennett MI, Johnson MI, Brown SR, Radford H, Brown JM, Searle RD. Feasibility study of transcutaneous electrical nerve stimulation (TENS) for cancer bone pain. Journal of Pain, 2010, 11, 4, 351-9.
Benedetti F, Amanzio M, Casadio C, Cavallo A, Cianci R, Giobbe R, et al. Control of postoperative pain by transcutaneous electrical nerve stimulation after thoracic operations. Annals of Thoracic Surgery, 1997, 63, 3, 773-776.
Bicer A, Ozisik S, Aksik SC, Erdogan C. Comparison of local corticosteroid injection and conventional physical therapy in management of the painful shoulder. Turkiye Klinikleri Tip Bilimleri Dergisi, 2005, 25, 4, 506-12.
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Celik D, Akyuz G, Yeldan I. Comparison of the effects of two different exercise programs on pain in subacromial impingement syndrome. Acta Orthopaedica Et Traumatologica Turcica, 2009, 43, 6, 504-9.
Chen L, Tang J, White PF, Sloninsky A, Wender RH, Naruse R, et al. The effect of location of transcutaneous electrical nerve stimulation on postoperative opioid analgesic requirement: acupoint versus nonacupoint stimulation. Anesthesia & Analgesia, 1998, 87, 5, 1129-34.
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Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

de la Rocha AG, Chambers K. Pain amelioration after thoracotomy: a prospective, randomized study. Annals of Thoracic Surgery, 1984, 37, 3, 239-42.
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Domaille M, Reeves B. TENS and pain control after coronary artery bypass surgery. Physiotherapy (London), 1997, 83, 10, 510-6.
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Emmiler M, Solak O, Kocogullari C, Dundar U, Ayva E, Ela Y, Cekirdekci A, Kavuncu V. Control of acute postoperative pain by transcutaneous electrical nerve stimulation after open cardiac operations: a randomized placebo-controlled prospective study. Heart Surgery Forum, 2008, 11, 5, E300-3.
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Ferraz FS, Moreira CMC. Electroanalgesia with TENS in postoperative of cardiac surgery [Portuguese]. Fisioterapia em Movimento, 2009, 22, 1, 133-9.
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Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

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Hazneci B, Tan AK, Ozdem T, Dincer K, Kalyon TA. The effects of transcutaneous electroneurostimulation and ultrasound in the treatment of reflex sympathetic dystrophy syndrome. Ftr - Turkiye Fiziksel Tip Ve Rehabilitasyon Dergisi, 2005, 51, 3, 83-9.
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Jensen JE, Conn RR, Hazelrigg G, Hewett JE. The use of transcutaneous neural stimulation and isokinetic testing in arthroscopic knee surgery. American Journal of Sports Medicine, 1985, 13, 1, 27-33.
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Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

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Klin B, Uretzky G, Magora F. Transcutaneous electrical nerve stimulation (TENS) after open heart surgery. The Journal of Cardiovascular Surgery (Torino), 1984, 25, 5, 445-448.
Kruger LR, Van der Linden WJ, Cleaton-Jones PE. Transcutaneous electrical nerve stimulation in the treatment of myofascial pain dysfunction. South African Journal of Surgery, 1998, 36, 1, 35-8.
Laitinen J, Nuutinen L. Failure of transcutaneous electrical nerve stimulation and indomethacin to reduce opiate requirement following cholecystectomy. Acta Anaesthesiologica Scandinavica, 1991, 35, 8, 700-5.
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Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

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Quinton DN, Sloan JP, Theakstone J. Transcutaneous electrical nerve stimulation in acute hand infections. Journal of Hand Surgery - British Volume, 1987, 12 B, 2, 267-8.
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Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

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Shehab D, Adham N. Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain. Physiotherapy Canada, 2000, 52, 3, 208-10, 214.
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Tascioglu F, Dalkiran I, Oner C. The efficacy of low-level laser in the treatment of subacromial impingement syndrome due to partial rupture of the supraspinatus tendon. Turkiye Fiziksel Tip Ve Rehabilitasyon Dergisi, 2003, 49, 6, 18-22.

Table 1. Studies excluded as TENS given in combination with other treatments (*Continued*)

Taspinar S, Sahin F, Ercalik C, Kuran B, Barkut K, Celik M, et al. Comparison of the efficacy of corticosteroid injection, night splint and physiotherapy in diabetic carpal tunnel syndrome. Turkiye Fiziksel Tip Ve Rehabilitasyon Dergisi, 2007, 53, 2, 54-60.
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Walker RH, Morris BA, Angulo DL, Schneider J, Colwell Jr CW. Postoperative use of continuous passive motion, transcutaneous electrical nerve stimulation, and continuous cooling pad following total knee arthroplasty. Journal of Arthroplasty, 1991, 6, 2, 151-6.
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Wang WC, George SL, Wilimas JA. Transcutaneous electrical nerve stimulation treatment of sickle cell pain crises. Acta Haematologica, 1988, 80, 2, 99-102.
Warfield CA, Stein JM, Frank HA. The effect of transcutaneous electrical nerve stimulation on pain after thoracotomy. Annals of Thoracic Surgery, 1985, 39, 5, 462-5.
Yip YB, Tse HM, Wu KK. An experimental study comparing the effects of combined transcutaneous acupoint electrical stimulation and electromagnetic millimetre waves for spinal pain in Hong Kong. Complementary Therapies in Clinical Practice, 2007, 13, 1, 4-14.

Please note that in the above studies there may have been other reasons for exclusion in addition to the fact that TENS was used in combination with other treatments.

HISTORY

Protocol first published: Issue 3, 2006

Review first published: Issue 2, 2009

Date	Event	Description
1 May 2008	Amended	Protocol converted to new review format

CONTRIBUTIONS OF AUTHORS

DW was responsible for co-ordinating the development of the review and is its guarantor. The main database searches were conducted by DW. FM joined the review team for this update. All authors participated in the screening of studies against eligibility criteria, data extraction, interpretation of the data, formulation of the results and their clinical interpretation. All authors developed and commented on the drafts of the review.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- University of Ulster, UK.
- Glasgow Caledonian University, UK.
- Leeds Metropolitan University, UK.
- University of Iowa, USA.

External sources

- Cochrane Fellowship (DW), Research and Development Office, Northern Ireland, UK.
- Strategic Priority Grant, Department for Employment and Learning, Northern Ireland, UK.
- Scottish Funding Council, UK.
- Chief Scientist Office Scotland, UK.
- NHS Education for Scotland, UK.
- Scottish Executive Health Department, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

It was decided to use the Cochrane Collaboration's new tool for assessing risk of bias to ascertain the methodological quality of studies instead of Jadad's scale as this is now the Cochrane Collaboration's recommended tool for all Cochrane reviews. We were unable to test for heterogeneity or perform subgroup or sensitivity analyses due to lack of suitable data. Studies were excluded if TENS was given in combination with any other treatment, pharmacological or non-pharmacological. A list of the studies excluded for this reason is provided in Table 1.

INDEX TERMS

Medical Subject Headings (MeSH)

Acute Disease; Pain [*therapy]; Randomized Controlled Trials as Topic; Transcutaneous Electric Nerve Stimulation [*methods]

MeSH check words

Humans