Transcutaneous electrical nerve stimulation (TENS) for chronic pain (Review)

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[Intervention Review]

Transcutaneous electrical nerve stimulation (TENS) for chronic pain

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ABSTRACT

Background

Transcutaneous electrical nerve stimulation (TENS) is a popular pain treatment modality but its effectiveness in chronic pain management is unknown. This review is an update of the original Cochrane review published in Issue 3, 2001.

Objectives

To evaluate the effectiveness of TENS in chronic pain.

Search strategy

The Cochrane Library, EMBASE, MEDLINE and CINAHL were searched. Reference lists from retrieved reports and reviews were examined. Date of the most recent search: April 2008.

Selection criteria

RCTs were eligible if they compared active TENS versus sham TENS controls; active TENS versus 'no treatment' controls; or active TENS versus active TENS controls (e.g. High Frequency TENS (HFTENS) versus Low Frequency TENS (LFTENS)). Studies of chronic pain for three months or more which included subjective outcome measures for pain intensity or relief were eligible for evaluation. No restrictions were made to language or sample size. Abstracts, letters, or unpublished studies, and studies of TENS in angina, headache, migraine, dysmenorrhoea and cancer-related pain were excluded.

Data collection and analysis

Data were extracted and summarised on the following items: patients and details of pain condition, treatments, study duration, design, methods, subjective pain outcome measures, methodological quality, results for pain outcome measures and adverse effects, and conclusions by authors of the studies. Extracted data and methodological quality of studies were confirmed by the review authors.

Main results

Of 124 studies identified from the searches, 99 did not fulfil pre-defined entry criteria. Twenty-five RCTs involving 1281 participants were evaluated. Included studies varied in design, analgesic outcomes, chronic pain conditions, TENS treatments and methodological quality. The reporting of methods and results for analgesic outcomes were inconsistent across studies and generally poor. Meta-analysis was not possible. Overall in 13 of 22 inactive control studies, there was a positive analgesic outcome in favour of active TENS treatments.

For multiple dose treatment comparison studies, eight of fifteen were considered to be in favour of the active TENS treatments. Seven of the nine active controlled studies found no difference in analgesic efficacy between High Frequency (HF) TENS and Low Frequency (LF) TENS.

Authors' conclusions

Since the last version of this review, new relevant studies have not provided additional information to change the conclusions. Published literature on the subject lacks the methodological rigour or robust reporting needed to make confident assessments of the role of TENS in chronic pain management. Large multi-centre RCTs of TENS in chronic pain are still needed.

PLAIN LANGUAGE SUMMARY

Effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) alone in the management of chronic pain

Despite the widespread use of TENS machines, the analgesic effectiveness of TENS still remains uncertain. This has mainly been due to inadequate methodology and reporting in earlier studies but more recent studies of TENS for chronic pain fail to offer necessary improvements in methodological rigour to define the place of TENS in chronic pain management with any certitude. The search process identified 124 studies; 25 met the inclusion criteria for evaluation in this review but there were insufficient extractable data to make meta-analysis possible. New studies of rigorous design and adequate size are needed before any evidence-based recommendations can be made for patients or health professionals.

BACKGROUND

This review is an update of a previously published review in The Cochrane Database of Systematic Reviews (Issue 3, 2001) on 'Transcutaneous electrical nerve stimulation (TENS) for chronic pain'.

Transcutaneous electrical nerve stimulation (TENS) is the application of electrical stimulation of varying frequency, intensity and pulse duration to the skin for pain relief (Sluka 2003). Different TENS modalities use varying combinations of frequency and intensity settings on the device to elicit pain relief. TENS is generally believed to be a safe non-invasive intervention which may produce significant analgesia in many patients with moderate predictable pain associated with a range of conditions (Rushton 2002). It is used in a variety of clinical settings to treat diverse acute and chronic pain conditions, and although clinical studies of its long-term efficacy have yielded variable results, it has become popular with both patients and health professionals of different disciplines, including physiotherapists, midwives, nurses and doctors.

The clinical application of TENS today evolved from Shealy's developmental work on neuro-modulation techniques in the 1960s (Shealy 1967) which is underpinned by the 'gate control theory' (Melzack 1965). It is thought that pain may be alleviated by using peripheral stimulation, such as rubbing, vibration, heat or cold, or, as in the case of TENS, electrical stimulation directly over the area of pain. This peripheral stimulation induces electrical activity which inhibits the brain's perception of pain. The 'gate control theory' is based on the principle that there is a gateway in the dorsal horn of the spinal cord, which somehow controls or regulates the flow of pain messages that are then sent to (ascending) and from (descending) higher levels of the brain for central processing, thus reducing the perception of pain. Other postulated mechanisms of the pain relief mediated by TENS include the promotion of endorphin release in the brain (Sluka 2003) and local dilatation of blood vessels in injured tissue (Chen 2007).

TENS is widely used in pain clinics in the UK where it is often considered as a first line intervention in the management of various chronic pain conditions. One survey of 1912 participants treated at a single pain clinic (Davies 1997) reported that about 58% of 379 participants benefited from TENS when it was tried as the first line treatment. An earlier survey by the same authors (Davies 1994) suggested that 10% of participants with neuropathic pain had tried TENS before referral to a pain clinic.

TENS is also a popular treatment amongst physiotherapists in England (Paxton 1980; Pope 1995). A report published by the

UK's Audit Commission in 1997 (Audit Comm 1997) recommended careful consideration of the use of TENS as its effectiveness was not proven. The Commission's conclusions were based on the lack of strong supportive evidence from the published systematic reviews on TENS that were available at that time, and also the negative findings of reviews in labour and postoperative pain (Carroll 1996; Carroll 1997a; Carroll 1997b). Systematic reviews have now been published on the effectiveness of TENS in various acute and chronic pain settings, but the conclusions of some may be unreliable as they have based their findings on evidence from both randomised and non-randomised trials (Gadsby 1997b; Reeve 1996; Simkin 1989).

Randomised trials are the gold standard in clinical trials of efficacy and non-randomised trials have been associated with increased estimates of treatment effects of up to 40% above those which use random allocation (Schulz 1995). We are not aware of any published systematic reviews which have evaluated the analgesic effectiveness of TENS in chronic pain using only published RCTs, and by making direct comparisons between active TENS (actual stimulation) and sham TENS (placebo) treatments. In postoperative pain, non-randomised trials of TENS have been associated with the reporting of significantly enhanced treatment effects, when compared to the randomised trials (Carroll 1996). In labour pain, again using only the published RCTs to make direct comparisons between active TENS and sham TENS treatments, no differences could be found in favour of active TENS for any of the analgesic outcomes (Carroll 1997a; Carroll 1997b).

Blinding is another important issue for studies of TENS and has been the topic of debate (Deyo 1990). High frequency TENS is often delivered at intensities (low) associated with buzzing or paraesthesia, or both, over the area of stimulation, and low frequency TENS (LFTENS) and acupuncture-like TENS (ALTENS*)* are often delivered at intensities (high) associated with muscle contractions, or a sharp 'flicking' sensation (Sluka 2003). These sensations make true double blinding of TENS extremely difficult, if not impossible. Trials that are not double-blind are likely to overestimate estimates of treatment effects by as much as 20% (Carroll 1997b; Schulz 1995).

Treatment group size is another important methodological consideration. Some review authors exclude studies where less than ten participants have been randomly allocated to study treatments, on the grounds that such studies lack the necessary power to detect statistically significant differences between treatments (L'Abbé 1987; Moore 1998). Mathematical modelling has been applied in recent analgesic studies which use subjective pain outcome measures, to examine the impact of study treatment group size when estimating the statistical significance and clinical relevance of treatment effects and bias (Moore 1998). A sample size much larger than 40 participants per treatment group may be needed to establish clinically relevant superiority for an analgesic intervention over placebo (Moore 1998).

Although the cost of TENS to health organisations and individuals may be difficult to calculate because of the varying costs of the devices, leads, electrodes, adhesive agents and batteries, long term use of TENS in chronic pain may have cost benefits for health services if it is effective. If the clinical effect of TENS in chronic pain is no more than that of a placebo effect, then it would be difficult to justify the continued use of TENS. However, if it is shown to be more than a placebo effect, and if it is safe, TENS should be made more accessible to patients with chronic pain and could be utilised more widely in primary care, before referral to specialist pain clinics.

The aim of updating this Cochrane review was to determine the effectiveness of TENS in chronic pain.

OBJECTIVES

To evaluate the analgesic effectiveness and safety of TENS for the treatment of chronic pain.

METHODS

Criteria for considering studies for this review

Types of studies

Studies were included if they were full journal publications of one or more RCTs in which the analgesic effects of repeated or continuous use of TENS was studied in patients with chronic pain. Chronic pain was defined as pain of at least three months duration. Studies were excluded if:

- the author(s) did not state that the interventions had been randomly allocated;
- the method of randomisation was inadequate (i.e. sequential, 'quasi', pseudo, or alternate allocation); or
- they were abstracts, letters and review articles.

We did not actively seek unpublished studies, and did not contact manufacturers of TENS machines.

Types of participants

Trials investigating a study population of adult participants (aged 18 years and over) with chronic pain of at least three months duration were considered for this review. Studies where TENS was used under experimental pain conditions were excluded. Participants with chronic pain conditions associated with acute episodes, such as angina, tension-type headache, migraine and dysmenorrhoea were not considered in this review. Participants with chronic pain

of cancer origin were also not considered in this review. Reviews of the effectiveness of TENS in acute pain (Walsh 2008) and cancer-related pain (Oxberry 2008) are available from the Cochrane Database of Systematic Reviews.

Types of interventions

Studies were included if they were RCTs that evaluated the analgesic effectiveness of TENS in chronic pain. Three types of studies were eligible for evaluation in this review. Studies that included one or more direct treatment comparisons of active TENS treatments were eligible if participants were allocated randomly to receive:

- active TENS stimulation versus sham TENS controls; or
- active TENS stimulation versus 'no treatment' controls; or
- active TENS stimulation versus another form of active TENS stimulation [i.e. Low Frequency TENS (LFTENS) versus High Frequency TENS (HFTENS)].

HFTENS was defined as stimulation at a frequency of > 10 Hz. LFTENS was defined as stimulation at a frequency of < 10 Hz. Sham TENS was defined as a treatment group which used an identical TENS device to that of the active treatment group, but which was modified so that it was incapable of producing an electric current.

Studies that did not use a conventional battery-operated portable TENS device, with two or more standard electrodes that were directly applied to the skin were not considered in this review. Studies were not included if they compared TENS in combination with another intervention, for example, TENS used in combination with laser therapy or an oral analgesic.

Types of outcome measures

The primary outcome measures for this review were subjective assessments of pain intensity or pain relief obtained through direct questioning of individual participants before and after administration of the study treatments. These measures included:

- visual analogue scale (VAS) scores for pain intensity or pain relief;
- categorical scores for pain intensity or pain relief; or
- end of treatment global ratings of treatment efficacy as made by the study participants.

Studies which did not include subjective measures of either pain intensity, or pain relief as part of the overall assessment of efficacy before and after treatment with TENS were excluded. Investigator ratings of pain or treatment efficacy, where participants were not directly questioned about their pain, or asked to give a direct response as part of the study treatment evaluation, were not considered valid. Dichotomous data, approximating to 50% improvement, were extracted from each study for analysis (McQuay 1996). The hierarchy of approximate measures was:

- patient global judgement of treatment efficacy (good/excellent);
- patient rating of pain intensity (no pain/slight pain, or 50% improvement), or pain relief (good/excellent); or
- any improvement or marked improvement.

Search methods for identification of studies

Studies were sought of RCTs for TENS in chronic pain. A number of different electronic databases were searched to identify eligible published studies, including *The Cochrane Library* (online version 2007), MEDLINE (1966 to 2008), CINAHL (1982 to 2008) and EMBASE (1980 to 2008). Each database was searched for all years. The search of all databases was run for the original review in December 1999 and a subsequent search was run for the update in April 2008.

A sensitive search strategy for identifying RCTs (Dickersin 1994) was used in combination with the Cochrane Pain, Palliative and Supportive Care Group strategy for identifying pain studies. Both search strategies were then used in combination with free-text words (in lower cases) and MESH terms (in upper cases) to identify TENS - this search strategy can be seen in Appendix 1. Additional studies were identified from the reference lists of retrieved studies, review articles and textbooks.

Data collection and analysis

Data extraction

Information about the pain condition, the site of pain, the number of participants, study design and duration of treatments was extracted from each study. The type of TENS equipment, its settings, the method and frequency of its use and placement of electrodes were also extracted. Control group(s) design and the use of TENS in these controls were similarly noted. Pain outcomes, overall findings and conclusions were noted for each study, together with any adverse effect information. A judgement was made by the review authors as to whether the overall conclusion of each study was positive or negative for the analgesic effectiveness of TENS. A study was considered positive if there was at least one statistically significant difference reported between active TENS and sham TENS treatment in the original study for at least one of the analgesic outcome measures. Studies that were judged as having a positive result had to have used appropriate statistical tests: for example tests had to be two-sided to be considered valid. Post-hoc sub-group analysis in the original studies was not considered in our assessment of overall effectiveness.

Statistical analysis

We planned to use dichotomous data from the analgesic outcomes (see previous section on 'Types of outcome measures') to derive the number-needed-to-treat-to-benefit (NNT) and the relative benefit (RB) for active TENS compared with controls (Cook 1995). With regard to the safety of TENS treatment, we intended to use information on adverse events, where reported, to calculate the number-needed-to-treat-to-harm (NNH) and the relative risk (RR). Unfortunately, there were insufficient extractable data in the 25 included studies to make meta-analysis possible. Quantitative data analysis was not considered feasible or appropriate, and therefore the results are presented descriptively and qualitatively.

RESULTS

Description of studies

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

One hundred and twenty-four studies of TENS were retrieved and considered for inclusion in this review and 25 of these were included (1281 participants).

Excluded studies

Ninety-nine of the studies were excluded as they did not meet the criteria for inclusion. The reasons for exclusion are given in the 'Characteristics of excluded studies' table. Common reasons were that studies were not of randomised trials that directly compared either conventional and sham TENS or two forms of conventional TENS (e.g. LFTENS and HFTENS). In addition, some excluded studies used flawed methods of randomisation, assessed TENS in combination with other analgesic treatments or assessed an unconventional form of portable TENS (e.g. electro-auroscope, Re-box device, Codetron or roller TENS device). Other excluded studies did not use subjective pain outcomes and did not study chronic pain of more than three months duration.

One study we excluded from this review (Jeans 1979) is described as a randomised trial in a Cochrane Review which evaluated TENS for back pain (Gadsby 1997b). We contacted the review authors who confirmed that the study, Jeans 1979, had not used random allocation and had been included in error.

Although the authors of another report (Bloodworth 2004) stated that it was a randomised study of stochastic versus conventional TENS, six study settings (all possible combinations of two electrode positions and three TENS unit setting), were randomly assigned to each of the 13 participants in the study. The study appeared to have been more a trial of TENS electrode position and TENS unit setting than a genuine randomised trial of conventional and stochastic TENS.

Another study (Mannheimer 1978) did not provide sufficient extractable information about the TENS device, study interventions, research methods and design to be included, and the study was excluded on methodological grounds.

Three of the excluded studies were dual publications (Fargas-Babjak 1989; Lehmann 1983; Thorsteinsson 1978).

Marchand 1993 reported that they used a 'pseudo-randomisation' method to allocate participants to treatments of HFTENS, sham TENS and no treatment controls. The study authors did not provide the reader with further information on their method of randomisation, and a consensus meeting decided to exclude this study on the grounds of inadequate method of randomisation.

Included studies

Six new studies have been added to this updated review, having met the criteria for inclusion (Al-Smadi 2003; Cheing 2003; Köke 2004; Ng 2003; Oosterhof 2006; Warke 2006).

Altogether, twenty-four studies of 25 RCTs met the study inclusion criteria for the review (Abelson 1983; Al-Smadi 2003; Ballegaard 1985; Cheing 2003; Grimmer 1992; Hsueh 1997; Jensen 1991; Köke 2004; Kumar 1997; Lewis 1994; Lewis 1984; Mannheimer 1979; Moore 1997; Møystad 1990a; Møystad 1990b; Nash 1990; Ng 2003; Oosterhof 2006; Smith 1983; Taylor 1981; Thorsteinsson 1978; Tulgar 1991a; Tulgar 1991b; Vinterberg 1978; Warke 2006).

Ballegaard 1985 provided details on two studies of TENS together in one published report. These two studies involved participants with chronic pancreatitis. Only one of the two studies described in the report used random treatment allocation (study two Ballegaard 1985) and was eligible for evaluation in this review.

The study undertaken by Kumar 1997 assessed TENS in patients who had experienced diabetic neuropathy symptoms for at least two months. Although this time the scale was less than our three-month limit for chronic pain, Kumar's results indicated that the cohort of participants had experienced symptoms of diabetic neuropathy for considerably longer than two months, so we considered it reasonable to include this study.

Møystad's study provided data on two RCTs involving the same cohort of participants. The two studies (Møystad 1990a; Møystad 1990b) are evaluated separately in this review.

Tulgar reported on the findings from both a pilot study and a long-term main study of TENS in the same issue of the journal, Pain (Tulgar 1991a; Tulgar 1991b). These are analysed as two separate studies in this review although it was not clear whether the long term study (Tulgar 1991b (n = 14) involved the same participant cohort that took part in the earlier pilot study (Tulgar 1991a (n = 27). For the purpose of this review we assessed the data as if they were from different cohorts of participants.

Data from these 25 studies were extracted and are summarised in the 'Characteristics of included studies' table and in Appendix 2;

Appendix 3; Appendix 4; and Appendix 5.

Study participants

The 25 included RCTs were published between 1978 and 2006. These studies involved 1281 participants with various chronic pain conditions of more than three months duration. (Readers should note that thirteen participants from an initial cohort of 19 participants in one study (Møystad 1990a) were randomised into a second randomised controlled trial (RCT) of TENS which was described in the same report (Møystad 1990b) giving an actual total of 1275 individual participants who were randomly allocated to receive study treatments. The number of participants reported in this review hereafter will refer to the number of participants who were randomised per study, unless otherwise stated).

TENS was studied in a variety of different chronic pain conditions including: rheumatoid arthritis with wrist pain (Abelson 1983; Mannheimer 1979; Vinterberg 1978) and temporomandibular joint dysfunction (Møystad 1990a; Møystad 1990b); multiple sclerosis with back pain (Al-Smadi 2003; Moore 1997; Warke 2006); osteoarthritis with knee pain (Cheing 2003; Grimmer 1992; Jensen 1991; Lewis 1994; Lewis 1984; Ng 2003; Smith 1983; Taylor 1981); neuropathy (Kumar 1997; Nash 1990; Tulgar 1991a; Tulgar 1991b); diverse chronic pain conditions (Köke 2004; Oosterhof 2006; Thorsteinsson 1978); pancreatitis (Ballegaard 1985) and myofascial trigger points (Hsueh 1997).

All included studies involved adult male and female participants. No studies were found which assessed TENS treatment for children with chronic pain. None of the 25 included studies involved participants with cancer-related pain.

Treatment group size

The number of participants randomised per treatment (as opposed to the number of participants available to be included in the data analysis according to the original published study) ranged from twelve (Taylor 1981) to 200 (Nash 1990). Eleven of the 25 studies (44%) had treatment group sizes of more than 20 (Cheing 2003; Hsueh 1997; Köke 2004; Lewis 1994; Lewis 1984; Moore 1997; Nash 1990; Oosterhof 2006; Thorsteinsson 1978; Tulgar 1991a; Warke 2006).

TENS device, application and use

Thirteen different types of TENS devices were used across the 25 included RCTs. Five studies did not provide any information on the name, manufacturer, or TENS device used (Hsueh 1997; Mannheimer 1979; Nash 1990; Tulgar 1991a; Tulgar 1991b). A purpose built device was made for use in the studies by Tulgar 1991a and Tulgar 1991b.

The method of TENS application varied considerably in terms of the parameters used, site of stimulation, frequency of use and duration of treatment across the different studies. The total number of TENS treatments in each study was also extremely variable; one to 168 treatment periods of stimulation per participant.

Fifteen studies looked at the effectiveness of TENS following investigator-administered single dose (Grimmer 1992; Hsueh 1997; Köke 2004; Mannheimer 1979; Møystad 1990a; Møystad 1990b; Ng 2003; Tulgar 1991a; Tulgar 1991b; Vinterberg 1978), repeated single dose (Abelson 1983; Smith 1983) or multiple dose (Al-Smadi 2003; Cheing 2003; Thorsteinsson 1978) treatments, with each stimulation period lasting ten to sixty minutes. TENS stimulation was self-administered in the other ten included studies (Ballegaard 1985; Jensen 1991; Kumar 1997; Lewis 1994; Lewis 1984; Moore 1997; Nash 1990; Oosterhof 2006; Taylor 1981; Warke 2006).

Three studies evaluated the analgesic effects following repeated single doses of stimulation with TENS, with daily or weekly treatment sessions lasting 20 to 30 minutes (Abelson 1983; Jensen 1991; Smith 1983). Other investigators studied the longer-term effects of patient administered TENS (Kumar 1997; Lewis 1994; Lewis 1984; Taylor 1981; Warke 2006). The total duration of TENS treatments varied between the studies from 20 minutes for one single treatment to up to 168 hours given as 30 to 60 minutes' stimulation per treatment, over two periods of two weeks separated by a one week washout period.

Most of the studies reported that they used two pairs of silicone or rubber electrodes which were either self-adhesive, or applied directly to the skin with special conductive gel and tape. Seven of the studies did not provide a general description of, or the type and number of electrodes used (Abelson 1983; Hsueh 1997; Lewis 1984; Nash 1990; Thorsteinsson 1978; Tulgar 1991a; Tulgar 1991b).

There was considerable variation in the site of stimulation and electrode placement reported across the different studies. Some investigators reported that the electrodes were placed directly over the site of pain (Abelson 1983; Al-Smadi 2003; Hsueh 1997; Köke 2004; Mannheimer 1979; Oosterhof 2006; Taylor 1981; Vinterberg 1978; Warke 2006). Others stimulated traditional acupuncture points (Ballegaard 1985; Grimmer 1992; Jensen 1991; Kumar 1997; Lewis 1994; Lewis 1984). Two studies did not specify the site of electrode placement in their study (Moore 1997; Nash 1990). Other studies (Cheing 2003; Ng 2003; Møystad 1990a; Møystad 1990b; Smith 1983; Thorsteinsson 1978) applied TENS stimulation to acupuncture points and trigger points directly involved in the area of pain.

Study sponsorship

None of the studies appeared to have been funded, either in total or in part, by the manufacturers of TENS devices, although four studies made an overt statement that the TENS devices had been provided by a named TENS manufacturer (Kumar 1997; Moore 1997; Taylor 1981; Thorsteinsson 1978). In two studies, the source of funding was not stated (Cheing 2003; Köke 2004).

Three of the studies seemed to have been supported financially by research grants (Ballegaard 1985; Lewis 1994; Ng 2003) and four through charitable organisations (Abelson 1983; Al-Smadi 2003; Oosterhof 2006; Warke 2006). Two studies appeared to have been carried out as part of research work submitted for higher degrees (Thorsteinsson 1978; Grimmer 1992).

Country of origin and language of publication

All but one of the included studies were published in English although trials were carried out in centres in Australia, Canada, China, Denmark, Hong Kong, New Zealand, Norway, The Netherlands, USA and UK. The only non-English language paper was published in Danish (Vinterberg 1978). Two studies (Tulgar 1991a; Tulgar 1991b) recruited participants from one centre in the UK and one centre in Turkey.

Risk of bias in included studies

Each study was independently scored for inclusion and quality using the Oxford Quality scale (Jadad 1996a) by the lead review author and at least one other review author (co-author). Studies which were described as randomised were given one point, and a further point if the method of randomisation was given and was appropriate (use of random number tables, for instance). Where randomisation was inappropriate (alternate allocation, for instance) the study was excluded. Studies which described the number of drop-outs and the reasons for withdrawal were given one point. Where there was disagreement between members of the review team, consensus was attained by discussion (Jadad 1996b).

The 25 included RCTs used parallel group, cross-over and partial cross-over designs, and were of varying methodological quality and treatment group size. Quality scores according to criteria defined in Jadad 1996a ranged from one to three (mean 1.9; median 2) with three of the studies (Köke 2004; Nash 1990; Smith 1983) achieving the maximum score of three. Nine of the studies achieved the maximum score of two for randomisation (i.e. they described the method of randomisation and this was considered adequate) (Al-Smadi 2003; Grimmer 1992; Köke 2004; Nash 1990; Ng 2003; Oosterhof 2006; Smith 1983; Vinterberg 1978; Warke 2006). Study authors of the other 16 studies did not provide information on the method of randomisation.

While there was no prior hypothesis that TENS cannot adequately be blinded, it was determined that (despite the considerable efforts of researchers documented in some studies) adequate blinding was impossible. Consequently no study was given any points for blinding, even if described as 'double-blind' (Grimmer 1992; Lewis 1994; Vinterberg 1978) or if blinded observers were used. Thus an included study could have a maximum score of three and a minimum score of one. Single-blinding was achieved in different ways and included the use of independent assessors (who were not involved with the randomisation, or the application of the TENS device or electrodes), the use of identical TENS device with no current, or the use of inactive machines for sham stimulation treatments.

Effects of interventions

There were insufficient extractable data in the 25 included studies to make meta-analysis possible. Quantitative data analysis was not considered feasible or appropriate, and therefore the results are presented descriptively and qualitatively.

Nine out of the 25 included studies adequately described their randomisation methods (Al-Smadi 2003; Grimmer 1992; Köke 2004; Nash 1990; Ng 2003; Oosterhof 2006; Smith 1983; Vinterberg 1978; Warke 2006). Although the authors of most studies described their efforts at ensuring blinding, it is doubtful that TENS trials can be genuinely blinded. Only in five of the included studies (Al-Smadi 2003; Kumar 1997; Köke 2004; Smith 1983; Warke 2006) was TENS used for at least four weeks and only in six studies (Köke 2004; Lewis 1994; Lewis 1984; Moore 1997; Oosterhof 2006; Warke 2006) was it applied for at least ten hours each week. Thus, two of the twenty-five studies (Köke 2004; Warke 2006) stood out from the rest in terms of appropriate randomisation and duration of TENS application. These studies recruited 180 (Köke 2004) and 90 (Warke 2006) participants.

Analgesic outcomes

Most studies used more than one analgesic outcome measure. All studies included at least one measure of pain intensity prior to administration of the study treatments (i.e. baseline pain). Post treatment evaluations, however, were made at varying time points after treatment, depending on the total duration of the study period.

A variety of different outcome measures were used across the different studies. Outcomes included subjective measures of both pain intensity and pain relief. The most commonly used analgesic outcome measure was the ten centimetre horizontal VAS for pain intensity. This was used in 16 of the 25 studies (Abelson 1983; Al-Smadi 2003; Ballegaard 1985; Cheing 2003; Grimmer 1992; Hsueh 1997; Köke 2004; Møystad 1990a; Møystad 1990b; Moore 1997; Nash 1990; Oosterhof 2006; Tulgar 1991a; Tulgar 1991b; Vinterberg 1978; Warke 2006). One author used a non-standard version of the VAS (Grimmer 1992). Other studies reported the use of numerical rating scales, categorical verbal rating or Likert type scales to measure pain intensity pre and post treatment (Kumar 1997; Jensen 1991; Ng 2003; Taylor 1981). In the study undertaken by Thorsteinsson 1977, it was not clear whether participants were asked directly about their subjective experience of pain before and after treatment, due to inadequate reporting.

Analgesic efficacy

Given the clinical and methodological heterogeneity between the different studies in terms of the variation in the use of TENS, sites of stimulation, study design, treatment duration, and the inability to extract sufficient dichotomous outcome data from the studies, pooling of data with meta-analysis was considered inappropriate. Quantitative analysis under these circumstances could result in misleading conclusions on the effectiveness of TENS in chronic pain. For the same reasons, we considered other quantitative analyses such as the calculation of NNT and NNH inappropriate in this review.

Study interventions

The included studies of TENS fell into two categories:
1. The 'inactive' treatment control studies in which active stimulation of TENS was directly compared to:

- Disabled/inactive TENS device (sham TENS); or
- 'No treatment' controls.

2. The 'active' treatment control studies in which active TENS stimulation was compared directly to:

- Active TENS (different forms of stimulation of TENS i.e. HFTENS versus LFTENS, or Acupuncture-like TENS).

1. Active TENS versus Sham TENS controls

Seventeen inactive treatment control studies made direct comparisons between active TENS and sham TENS treatments (Abelson 1983; Al-Smadi 2003; Cheing 2003; Grimmer 1992; Hsueh 1997; Kumar 1997; Lewis 1994; Lewis 1984; Moore 1997; Møystad 1990a; Møystad 1990b; Oosterhof 2006; Smith 1983; Taylor 1981; Thorsteinsson 1978; Vinterberg 1978; Warke 2006). In one study of patients with osteoarthritis of the knee, the outcomes of TENS and electro-acupuncture were compared to general education on osteoarthritic knee care in a 'no treatment' control group (Ng 2003).
Sham TENS stimulation controls were achieved by using identical TENS devices which had been modified in some way so that there was no electric current. (No studies reported the use of dead batteries as a method of achieving sham TENS stimulation). In one of these 17 studies (Lewis 1984), study participants were given an oral placebo tablet in addition to receiving the sham TENS device. This was done to maintain blinding, as a third treatment group of oral Naproxen was also compared to active TENS stimulation in this RCT. (This third treatment group (Naproxen) is not evaluated as part of this review).
Studies in the inactive treatment control category involved two distinct forms of stimulation: HFTENS and LFTENS (see Types of Interventions above). Two studies did not adequately define the stimulation frequency that they used in their study (Thorsteinsson 1978; Taylor 1981). In Thorsteinsson 1978, active TENS was considered to be more effective than sham TENS controls for the analgesic outcomes at during and immediately after stimulation. In Taylor 1981 there was a difference for the analgesic outcome at the two-week assessments between active TENS and the sham TENS treatment.
The summarised results for the analgesic outcomes for the 17 sham TENS control studies are shown in Appendix 2 (Abelson 1983; Al-Smadi 2003; Cheing 2003; Grimmer 1992; Hsueh 1997; Kumar 1997; Lewis 1994; Lewis 1984; Moore 1997; Møystad 1990a; Møystad 1990b; Oosterhof 2006; Smith 1983; Taylor 1981; Thorsteinsson 1978; Vinterberg 1978; Warke 2006). Treatments were judged to be either positive (+VE) or negative (-VE) in terms of their analgesic effectiveness compared to sham TENS treatments if data were available for evaluation from assessments at the following time points: immediately after the study treatment, for assessments done between 24 hours and one week, one and four weeks, one to six months, and for long-term follow up of at least six months. If no data were available for assessments at these time points this is shown in the table as NA (NA = data not available).
Appendix 2 shows that 22 different treatments were compared to sham TENS, or no TENS treatment controls. Of these, seven treatments (Grimmer 1992 [HF]; Grimmer 1992 [LF Burst]; Hsueh 1997 [HF]; Hsueh 1997[LF]; Møystad 1990a; Møystad 1990b; Vinterberg 1978) were single dose (SD) evaluations of TENS and fifteen (Abelson 1983; Al-Smadi 2003[HF]; Al-Smadi 2003[LF]; Cheing 2003; Kumar 1997; Lewis 1994; Lewis 1984; Moore 1997; Ng 2003; Oosterhof 2006; Smith 1983; Taylor 1981; Thorsteinsson 1978; Warke 2006[HF]; Warke 2006[LF]) were multiple dose treatment comparisons. Of the seven single dose treatment comparisons, five (Grimmer 1992[LF Burst]; Hsueh 1997[HF]; Hsueh 1997[LF]; Møystad 1990a; Vinterberg 1978) reported a positive analgesic effect in favour of the active TENS treatment, for at least one of the post-treatment assessments. Two did not detect any difference at any time point (Grimmer 1992 [HF]; Møystad 1990b). For the multiple dose treatment comparisons, eight reported a positive analgesic effect in favour of the active TENS treatment for at least one of the post treatment assessments (Abelson 1983; Cheing 2003; Kumar 1997; Lewis 1994; Ng 2003; Oosterhof 2006; Smith 1983; Thorsteinsson 1978). Four studies provided long-term analgesic efficacy data (Al-Smadi 2003; Smith 1983; Thorsteinsson 1978; Warke 2006). One of those studies (Smith 1983) reported an improvement with active TENS treatment at the one-to-four week post treatment evaluation, and the other three failed to find any difference 2.5 months (Al-Smadi 2003) and more than six months after treatment (Thorsteinsson 1978; Warke 2006).
Twelve studies made direct comparisons between HFTENS and sham TENS controls (Abelson 1983; Al-Smadi 2003; Cheing 2003; Grimmer 1992; Hsueh 1997; Lewis 1994; Moore 1997; Møystad 1990a; Oosterhof 2006; Smith 1983; Vinterberg 1978; Warke 2006). Two of those studies compared both HFTENS and

LFTENS to sham TENS controls (Al-Smadi 2003 and Warke 2006). See Appendix 3 for details of the four studies (Grimmer 1992; Hsueh 1997; Møystad 1990a; Vinterberg 1978) of single dose evaluations of HFTENS and eight evaluations (Abelson 1983; Al-Smadi 2003; Cheing 2003; Lewis 1994; Moore 1997; Oosterhof 2006; Smith 1983; Warke 2006) of multiple dose TENS.

Eight studies made direct comparisons between LFTENS and sham TENS controls (Al-Smadi 2003; Grimmer 1992; Hsueh 1997; Kumar 1997; Lewis 1984; Møystad 1990b; Ng 2003; Warke 2006). The results for the analgesic outcomes for these studies are summarised in Appendix 4. Three (Grimmer 1992; Hsueh 1997; Møystad 1990b) of the eight studies shown in Appendix 4 were single dose evaluations of LFTENS.

2. TENS versus Active TENS controls

Seven of the 25 included RCTs made direct comparisons of at least two different forms of active TENS stimulation in chronic pain. Summarised extracted information from studies involving 477 participants is shown in the 'Characteristics of included studies' table (Ballegaard 1985; Jensen 1991; Köke 2004; Mannheimer 1979; Nash 1990; Tulgar 1991a; Tulgar 1991b). Two of the seven active controlled studies made direct comparisons of conventional HFTENS and LFTENS, or ALTENS (Jensen 1991; Mannheimer 1979). The Mannheimer 1979 study included a third treatment comparison of train TENS, defined as high frequency, brief impulse, train stimulation at 3-70 Hz, duration of 80 msec, with a repetition rate of 3 Hz. Both of these studies failed to detect any statistically significant differences between HFTENS and LFTENS. One study compared HFTENS and a combination type high frequency high intensity TENS to active TENS controls in which participants were free to use TENS as they preferred (Köke 2004). The study found no differences in effectiveness for the three types of TENS. Ballegaard 1985 stimulated four different forms of acupuncture points, two inside and two outside Chinese Meridian zones, in participants with chronic pancreatic pain. No statistically significant differences were detected between the four sites of stimulation for the main pain outcome measures. Nash 1990 compared four types of TENS in a study involving 200 participants with various chronic pain conditions. Again, no statistically significant differences were detected between the study treatments, which were HF continuous TENS, HF pulsed TENS, LF continuous TENS and LF pulsed TENS.

The only study reporting any differences between different forms of stimulation for the analgesic outcomes was the single dose pilot study by Tulgar 1991a. This study used a cross-over design, and the authors reported a marked improvement in pain immediately after ten minutes of stimulation with HFTENS and train TENS, but not for LFTENS. Although formal statistical tests may have been used, this information was not reported. In their main study (Tulgar 1991b) the study authors could not find any differences in analgesic efficacy between HFTENS, burst train TENS or frequency modulated TENS. Eight of the 14 participants continued with TENS after completing the single dose cross-over study, using the stimulation frequency of their choice.

HFTENS versus LFTENS

Nine studies made direct comparisons between HFTENS and LFTENS (Al-Smadi 2003; Grimmer 1992; Hsueh 1997; Jensen 1991; Mannheimer 1979; Nash 1990; Tulgar 1991a; Tulgar 1991b; Warke 2006). Details of these studies are given in Appendix 5. Seven of these studies did not detect any differences between the analgesic outcomes of HFTENS and LFTENS (Al-Smadi 2003; Grimmer 1992; Hsueh 1997; Jensen 1991; Nash 1990; Tulgar 1991b; Warke 2006). One of the nine studies reported a difference in favour of HFTENS (Mannheimer 1979) and another reported a difference in favour of LFTENS (Tulgar 1991a). Five of the nine studies were single dose direct treatment comparisons of HFTENS and LFTENS (Grimmer 1992; Hsueh 1997; Mannheimer 1979; Tulgar 1991a; Tulgar 1991b) and four were multiple dose studies (Al-Smadi 2003; Jensen 1991; Nash 1990; Warke 2006).

Adverse effects

The methods used to detect or report adverse effects, or both, from the different study treatments were detailed in the methods section of only one of the studies (Köke 2004). In that study, one of the primary outcome variables was patients' global assessment of overall result, described by the authors as an index of a patient's assessment of efficacy versus side effects. This study presented dichotomous data for skin irritation, adherence problems of electrodes and difficulty attaching electrodes but found no difference in the occurrence of these effects between the groups. Three studies reported dichotomous data on adverse effects attributed to TENS in their results or discussion. One participant treated with HFTENS (Smith 1983) reported a skin rash, and another reported a burning sensation over the electrode site when treated with LFTENS (Kumar 1997). In addition, two studies mentioned the presence of skin irritation in some patients treated with HFTENS and low frequency ALTENS, but the authors did not specify how many patients were affected (Abelson 1983; Nash 1990). One study reported adverse effects that were attributed to drug toxicity rather than to TENS (Lewis 1984). Three other studies made a clear statement that none of the participants experienced any adverse effects from the study treatments (Moore 1997; Thorsteinsson 1978; Vinterberg 1978).

DISCUSSION

This review found that there is no good evidence for or against the effectiveness of TENS alone in the management of chronic

pain. Out of 124 studies identified in the original search, 25 RCTs involving 1281 participants met the inclusion criteria. Only a few of the included studies were rated of good methodological quality, having performed well on randomisation and description of loss to follow-up. The overall reporting of the methods, TENS treatments, and results for the different analgesic outcomes in the primary studies, was not only generally inadequate but widely different from one study to the other. Overall, of 12 studies that compared HFTENS to sham TENS, eight showed active treatment to be superior to sham and of eight studies that compared LFTENS to sham TENS, four showed active treatment to be superior. Nine studies compared HFTENS and LFTENS and in only two of those was there an overall difference in effectiveness.

In updating the original Cochrane review, six new studies have been added to the 19 studies in the original review. These six studies involved a total of 510 participants (age range 15 to 180) most of whom had either knee pain with osteoarthritis or low back pain with multiple sclerosis (Al-Smadi 2003; Cheing 2003; Köke 2004; Ng 2003; Oosterhof 2006; Warke 2006). Active TENS was compared to sham TENS in four of the studies (Al-Smadi 2003; Cheing 2003; Oosterhof 2006; Warke 2006); to active TENS in one study (Köke 2004), and to 'no treatment' in another study (Ng 2003). The duration of TENS treatment in the six studies ranged from one to six weeks and TENS was administered for one to 81 hours each week in a total of eight to 168 sessions. Four of the six studies used HFTENS (Al-Smadi 2003; Cheing 2003; Oosterhof 2006; Warke 2006), two of them finding no benefit of TENS over sham TENS in chronic pain relief (Al-Smadi 2003; Warke 2006). Of the three studies of LFTENS, two similarly found no benefit of TENS over sham TENS (Al-Smadi 2003; Warke 2006) and one concluded that TENS was superior to 'no treatment' with respect to chronic pain relief (Ng 2003). Some of the six studies were only of marginally better quality than earlier studies included in the review.

Although investigators may have, over the years, become more consistent in explicitly describing the characteristics and settings of TENS devices they use in trials, accruing studies apparently fail to replicate these parameters in a manner that facilitates pooling of results. Consequently, any pooling of analgesic outcome data for meta-analytical purposes is, as in this review, often not possible. Although most of the later reports in the review used standardised outcome measures like pre- and post-TENS scores on the VAS, these studies were not only inconsistent in their judgement of the efficacy of TENS in chronic pain, but were also too few both in numbers and pooled sample size to strongly define the direction of impact of TENS on chronic pain.

Eight of the 25 included studies in this review evaluated the effectiveness of single-dose stimulation with TENS (Grimmer 1992; Hsueh 1997; Mannheimer 1979; Møystad 1990a; Møystad 1990b; Tulgar 1991a; Tulgar 1991b; Vinterberg 1978). Although single dose studies are extremely useful and important in certain contexts (e.g. in acute post-operative pain) their relevance when evaluating the effectiveness of TENS in chronic pain has to be questioned. Many chronic pain experts believe that 30 to 40 minutes of stimulation twice a day for at least one month may be necessary to achieve significant pain relief (Cheing 2003). However, the stimulation duration in all eight single dose studies ranged from 15 to 30 mins, with the exception of Vinterberg 1978 where stimulation lasted 60 minutes. The duration of treatment was less than four weeks in about 80% of the studies, and in 70% of the trials stimulation occurred less than ten hours per week, with 60% of the participants having less than ten sessions of TENS. This may explain why some of the studies failed to detect any differences between active TENS and sham TENS controls.

Although this review does not find evidence to support the use of TENS alone in chronic pain management, the lack of evidence of effect is clearly different from evidence of lack of effect. Even if the effect of TENS on chronic pain is, in future studies, proven to be a weak one, its potential to augment the effect of other pain treatment modalities should be explored. For example, TENS and acupuncture may be individually effective for low back pain but show even better improvement in combination (Chao 2007). Furthermore, it has been suggested that the mixed frequency modes of TENS have a synergistic effect with exogenously administered opioids in post-operative patients (Hamza 1999). However, the synergistic effects of TENS with medications or other physical therapies are not only clearly beyond the scope of this review, but are poorly understood. Therefore large well designed studies will be needed to firmly establish the medication- or other treatment-sparing effects of TENS, particularly in chronic pain.

Thirteen out of 22 treatment comparisons of TENS and sham TENS concluded that TENS had a positive effect on chronic pain at one point or another. In pain studies, the proportion of participants who, on placebo, experience 50% of maximum possible pain relief can vary very widely, if only because of the small size of the studies (Moore 1998). However, a placebo controlled trial may not adequately demonstrate the presence or otherwise of the effect of placebo per se, as the supposed placebo effect may have been due to regression to the mean or a natural improvement in the course of the pain. A persuasive demonstration of the presence and quantity of any effect of placebo would require comparison of active treatment to both placebo and 'no treatment' groups. Where this has been done in systematic reviews, it has shown no difference between placebo and 'no treatment', except a small effect of placebo when pain is measured as a continuous outcome in pain trials (Hróbjartsson 2004). Although this small effect might have been relevant here, only one of the included studies (Ng 2003) assessed pain in a 'no treatment' group. Furthermore, it did not include a placebo TENS group and did not assess pain measured on a continuous scale.

Therefore, despite the fact that almost 60% of the treatment comparisons in this review judge TENS to have had an overall positive

effect on pain, they do not offer reliable evidence of the presence or quantity of any effect of placebo. The appropriate investigation of effects of placebo may be determined by the rigour of research design - appropriate controls enabling separation of such effects from natural history and regression to the mean, large sample sizes to capture small effects, and understanding such effects from patients' perspectives (Conboy 2006). Previous trials of TENS in chronic pain have clearly lacked such methodological rigour and future study designs will have to take this need into account.

Finally, the manufacturers of TENS equipment are under no obligation to monitor the efficacy or safety of their devices after the point of sale, or to carry out customer satisfaction surveys. It may be beneficial to consider:

- international licensing and regulation of TENS equipment;
- whether manufacturers claims of the benefits of TENS should be supported by evidence from high quality RCTs;
- whether TENS should be prescribed (patients can purchase a device over the counter from most large chemists, or directly from the manufacturer);
- whether monitoring of the long-term effectiveness of TENS devices should be undertaken; and
- if the equipment does not meet the expectations of the purchaser, the device is simply no longer used.

It is unfortunate that even more recent studies neither offer enough in terms of methodological rigour nor large sample size to define the effectiveness of TENS in chronic pain with any certitude. It is therefore hoped that future new trials of TENS for chronic pain will robustly address these issues in order to enable this review to be updated with data that will provide useful information for both clinicians and patients in the future.

the more recent studies in this review enrolled less than forty participants. In addition, most of the newer studies offered little more than the earlier ones in terms of methodological rigour. Given the resources allocated to TENS for the treatment of chronic pain in many countries, this situation should be urgently addressed.

If such large RCTs were set up in the UK, specialist nurses who run TENS out-patient clinics could be used to recruit patients into the study at a local level; ten such centres would be able to recruit the necessary number of patients for a meaningful study (ideally incorporating about 200 participants). TENS machine manufacturers could be asked to provide the TENS devices for use in the trials. An ideal design for a multi-centre study would be a parallel, or cross-over group design, although it should be borne in mind that cross-over designs may yield less conservative effect estimates than parallel arm trials (Lathyris 2007). Methods for analgesic intervention studies were developed in the 1950's, and the methodological requirements for such studies have recently been well described by others (McQuay 1998; Max 1991). Patients could be randomly allocated to receive either active TENS or a 'no treatment' control, or active TENS versus normal care. The optimal individualised TENS treatment could be determined by using a study run-in period during which time patients were given a trial of TENS over a two to six week period. Patients would be free to adjust the stimulator until they found the parameters that gave them optimum pain relief. They could then continue with the stimulation settings of choice during the study. Once the patients found optimum stimulation parameters, they would be reassessed in the outpatient clinic on a regular basis (e.g. one, three, six, nine, 12 months and then yearly) using the treatment plan suggested by Thompson 1998. Patients would be asked to keep a pain diary, daily before going to bed, for the duration of the study. Outcomes should include prospective subjective measures of pain intensity and pain relief, and patient diaries could be used in the context of this study.

AUTHORS' CONCLUSIONS

Implications for practice

Since the last version of this review, none of the new included studies have provided additional information to change the original conclusions. The methodological and reporting inadequacies of the primary studies included in this review mean that it is not possible to provide useful evidence-based information for the use of TENS for chronic pain.

Implications for research

Although the need has been long recognized to carry out large and well-designed RCTs examining the effectiveness of TENS, half of

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Abelson 1983

Methods	Study design: Parallel group Active TENS versus sham TENS Subjective pain outcome measures: VAS pain intensity (0-100) on rest & grip. Assessments pre & immediately after treatment (timing of assessment not stated). Blinding: Single blind, observer unaware of treatment allocation, red light active for both treatments TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 32 (32) Pain condition: Rheumatoid arthritis, wrist
Interventions	Treatment groups: 1. HFTENS (n=16) 2. sham TENS (n=16) TENS frequency (HF=>10 Hz; LF= <10 Hz): HFTENS 70Hz TENS intensity (threshold): Not stated Electrodes: Not described Stimulation site: Directly over area of pain (dorsal & ventral aspect of wrist) Treatment frequency and duration: Three single weekly treatments (in hospital) of 15 mins continual stimulation Total no of TENS sessions/treatments: 3 Total active stimulation time (TENS dose): 45 mins (15 mins/week) Device/Manufacturer: Cyrax Mark II
Outcomes	Authors' judgement on effectiveness: Positive (immediate post treatment) No short or long term data Reviewers' judgement on effectiveness: Same as above Dichotomous outcomes available for pain? No
Notes	Results presented as means & SD. Statistically significant differences reported in favour of active TENS (pre post treatment assessments) for all 3 treatments for pain on rest & grip. NSD for sham TENS Adverse effects: Skin irritation in some patients Dichotomous data available for adverse effects: No QS = 1 (1,0,0)

Abelson 1983 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Al-Smadi 2003

Methods	Study design: Randomised Controlled Trial Subjective pain outcome measures: Pain assessed with VAS, Leeds MS QoL questionnaire, SF-36 at 1, 6 and 10 wks Blinding: Double blind TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 15 Pain condition: Low back pain due to multiple sclerosis for at least three months
Interventions	Treatment groups: Low frequency TENS, high frequency TENS and placebo TENS TENS frequency (HF=>10 Hz; LF= <10 Hz): High (110 Hz) and Low (4 Hz) TENS intensity (threshold): Not stated Electrodes: 2 self-adhering PALS neuron-stimulation electrodes (13 x 5 cm) Stimulation site: Target was lumbar and sacral nerve roots, with centre of electrodes aligned with centre of the pain Treatment frequency and duration: 45 minutes thrice a week for 6 weeks Total no of TENS sessions/treatments: 18 sessions Total active stimulation time (TENS dose): 2.25 hours/week Device/Manufacturer: 12 0Z TENS unit /ITO, Tokyo, Japan
Outcomes	Authors' judgement on effectiveness: No statistically significant difference on all instruments. Reviewers' judgement on effectiveness: Same Dichotomous outcomes available for pain? No
Notes	Results presented as: Change in mean VAS scores for pain Adverse effects: none reported Dichotomous data available for adverse effects: N/A QS = 2 (2, 0, 0)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Ballegaard 1985

Methods	Study design: Active TENS versus Active TENS control Crossover, with 1 week run in period at start of study Subjective pain outcome measures: VAS PI, analgesic intake, patient treatment preference. Assessment pre treatment, daily pain ratings four times a day, clinic assessment 1,2,3 weeks Blinding: Patients were able to distinguish between different treatments but unable to determine which treatment was active. TENS administered by: Patient
Participants	No. of patients randomised (analysed): 16 (13) Pain condition: Pancreatitis
Interventions	Treatment groups: 1. HF AL TENS (segmental bladder meridian) (n=13) 2. control stimulation point a (outside bladder meridian area) (n=13) 3. control stimulation point (urinary bladder 11 (Dhazu)(n=13) TENS frequency (HF=>10 Hz LF= <10 Hz): 100-2 Hz TENS intensity (threshold): Sub initially, followed by supra Electrodes: Pair carbon rubber electrodes, left in situ for 1 week Stimulation site: Acupuncture points (different for each of the 3 treatments) Treatment frequency and duration: 30 minutes stimulation as required by patient until pain subsided for 1 week Total no of TENS sessions/treatments: Not reported Total active stimulation time (TENS dose): Not reported Device/Manufacturer: El pha 500 (Biometer International Ltd, Odense, Denmark)
Outcomes	Authors' judgement on effectiveness: NSD between treatments for VASPI, analgesic intake. Total Number of Stimulations with treatment A was significantly less than treatment B or C. Treatment preference: A 5/14, B 2/14, C 0 /14c, no preference 6/14 Reviewers' judgement on effectiveness: Negative Dichotomous outcomes available for pain? Yes
Notes	All patients entered an All patients entered an acupuncture trial before trial of TENS. 7/13 patient continued to use TENS every day 8-17 months after completion of trial. Results presented as medians Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Ballegaard 1985 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Cheing 2003

Methods	Study design: Randomised controlled study Subjective pain outcome measures: Pre-treatment and post treatment VAS scores for pain Blinding: Single blind TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 38 Pain condition: 50-80 yr old people with pain due to osteoarthritis of the knee for 2-7 yrs
Interventions	Treatment groups: TENS of three durations (20, 40, 60 mins) and Placebo TENS for 60 mins TENS frequency (HF=>10 Hz ; LF= <10 Hz): High (100Hz) TENS intensity (threshold): Not stated Electrodes: Four rubber electrodes (2 x 3 cm) placed with aqueous gel Stimulation site: Acupuncture points around the knee Treatment frequency and duration: 5 days a week for 2 consecutive weeks Total no of TENS sessions/treatments: 10 Total active stimulation time (TENS dose): 1.67 - 5 hours/week depending on group Device/Manufacturer: TENS model 12 0Z/ITO, Tokyo, Japan
Outcomes	Authors' judgement on effectiveness: TENS of any of the studied durations produced significantly lower VAS scores than placebo as early as the fifth day, maintained at 2 week follow-up. Reviewers' judgement on effectiveness: Same as authors' Dichotomous outcomes available for pain? No. Only present percentage reduction in VAS scores after treatment.
Notes	Results presented as: Percentage reduction in VAS score for pain using each modality Adverse effects: None reported Dichotomous data available for adverse effects: N/A QS = 2 (1, 0, 1)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Grimmer 1992

Methods	Study design: Parallel group Active TENS versus sham TENS Subjective pain outcome measures: Vertical VAS pain intensity (10 cm. Duration of relief. Assessments pre, immediately post treatment, 24 hrs Blinding: Described as double-blind. Subjects had no prior experience of TENS. Non- functioning leads. Assessments done by independent observer TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 60 (60) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. HFTENS (n=20) 2. LFTENS (strong burst) (n=20) 3. sham TENS (n=20) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 80 Hz LFTENS (burst) 80 Hz-3 Hz TENS intensity (threshold): Supra Sub Electrodes: 4 carbon rubber silicone electrodes, 2 x 3 cm Stimulation site: Acupuncture points Treatment frequency and duration: One single 30 minute stimulation Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 30 mins Device/Manufacturer: Medtronic Neuromod Selectra
Outcomes	Authors' judgement on effectiveness: Negative: immediate post treatment HF & LF Positive: short term 24 hrs for LF Burst Negative: short term for HF No long term data Reviewers' judgement on effectiveness: Same as above Dichotomous outcomes available for pain? No
Notes	All 3 groups given different instruction on sensation from TENS device. No statistically significant differences for pain immediately post treatment, but significant difference in stiffness for both burst & HF at 24 hours. Length of relief for burst only Adverse effects: Not stated Dichotomous data available for adverse effects: No

Grimmer 1992 (*Continued*)

	QS = 2 (2,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Hsueh 1997

Methods	Study design: Parallel group Active TENS versus sham TENS Subjective pain outcome measures: VAS pain intensity; pain pressure threshold; range of movement. Assessments pre and 20 mins post treatment Blinding: Observer blind to treatment allocation. Sham device set to zero amplitude TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 60 (60) Pain condition: Unilateral myofascial trigger points, upper trapezius muscle
Interventions	Treatment groups: 1. HFTENS - electromuscle stimulation (n=22) 2. LFTENS - electrical nerve stimulation (n=20) 3. Sham stimulation (n=18) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 60 Hz LFTENS 10 Hz TENS intensity (threshold): Sub Supra Electrodes: Not described Stimulation site: Directly over area of pain (trapezius muscles) Treatment frequency and duration: One single 20 minute stimulation Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 20 mins Device/Manufacturer: Not described. Possibly 2 different devices for ENS and EMS
Outcomes	Authors' judgement on effectiveness: Positive for ENS, pain intensity and pain threshold compared to sham stimulation. Positive for EMS compared to sham stimulation and ENS for pain intensity Reviewers' judgement on effectiveness: Positive: immediately post treatment for ENS and EMS compared to sham stimulation No long term data available

Hsueh 1997 (*Continued*)

	Dichotomous outcomes available for pain? No
Notes	Patients with mild and moderate pain include, therefore flawed single dose treatment design. Method of randomisation not given. Duration of pain <3 months, but mean duration of pain fulfilled inclusion criteria Adverse effects: Not stated Dichotomous data available for adverse effects: No QS = 1 (1,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Jensen 1991

Methods	Study design: Active TENS versus Active TENS control Parallel group, with 1 week no treatment run in phase, 2 weeks active treatment phase Subjective pain outcome measures: 4 point pain intensity on rest & movement (severe, moderate, mild, none) for typical pain over previous 24 hrs, analgesic consumption, overall reduction in pain (yes/no). Assessments pre and 1 week post treatment Blinding: No attempt to blind investigators to study treatments TENS administered by: Patient
Participants	No. of patients randomised (analysed): 20 (20) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. LF TENS (n=10) 2. HF TENS (n=10) TENS frequency (HF=>10 Hz LF= <10 Hz): LFTENS 2 Hz HTENS 80 Hz TENS intensity (threshold): Sub (gradual increase to maximum tolerated, not painful with or without muscle contraction) Electrodes: 2 pairs 3 x 4 cm, applied with electrode gel. Applied by investigators Stimulation site: 4 different acupuncture points around knee Treatment frequency and duration: One single 30 min treatment per day for 5 days in second week of study Total no of TENS sessions/treatments: 5

Jensen 1991 (*Continued*)

	Total active stimulation time (TENS dose): 5 x 30 minutes total 2.5 hours Device/Manufacturer: Elpha 500 (Biometer International Ltd, Odense, Denmark)
Outcomes	Authors' judgement on effectiveness: Negative No statistically significant differences found between study treatments. Statistically significant difference reported week 1 and week 3 for both treatments Reviewers' judgement on effectiveness: Negative Dichotomous outcomes available for pain? No
Notes	Study treatments not clearly reported, total stimulation in study difficult to define. Few data given in results section, one sided P values only. One sided statistical tests only used, not 2 sided tests. Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 1 (1,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Kumar 1997

Methods	Study design: Partial crossover Active TENS versus sham TENS Subjective pain outcome measures: 5 point pain intensity (0-5); VAS improvement in symptoms at follow up; assessments pre treatment, 1 week & at end of study at 4 weeks Blinding: Described as single blind TENS administered by: Patient
Participants	No. of patients randomised (analysed): 31 (31) Pain condition: Diabetic neuropathy
Interventions	Treatment groups: 1. LFTENS (n=18) 2. sham TENS (n=13) TENS frequency (HF=>10 Hz LF= <10 Hz): LFTENS 2-70Hz TENS intensity (threshold): Supra & Sub

Kumar 1997 (*Continued*)

	Electrodes: 4 self adhesive electrodes Stimulation site: Specific areas of leg (above patella, medial & lateral, neck of fibula, vastus lateralis) Treatment frequency and duration: 30 minute stimulation once a day over 4 weeks Total no of TENS sessions/treatments: 28 Total active stimulation time (TENS dose): 14 hours (3.5 hours per week) Device/Manufacturer: H-Wave (Electronic Waveform, Waveform California)
Outcomes	Authors' judgement on effectiveness: Positive (short term) Positive (1 month) Reviewers' judgement on effectiveness: Positive: 1 month No long term data available Dichotomous outcomes available for pain? Patients with any improvement (change of at least 1 category) TENS: 15/18 (83%) improved Sham TENS: 5/13 (38%) improved
Notes	Improvement at 1 month reported Adverse effects: LFTENS 1/18 burning sensation over electrode site Sham TENS 0/13 Dichotomous data available for adverse effects: LFTENS 1/18 QS = 1 (1,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Köke 2004

Methods	Study design: Randomised cross-over controlled trial Subjective pain outcome measures: Patient's assessment of pain reduction measured on VAS at 6 months follow up. Blinding: Single TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 180 (149) Pain condition: chronic pain (> 6 months)
Interventions	Treatment groups: High frequency. TENS vs. High freq/high int. TENS vs. Control TENS TENS frequency (HF=>10 Hz LF= <10 Hz): High (80 Hz) for intervention groups and low (30 Hz) for control group TENS intensity (threshold): Variable Electrodes: self-adhering reusable electrodes type PALS Platinum 895220 (5 x 5 sq.cm)

Köke 2004 (*Continued*)

	Stimulation site: Determined by painful area and region of the peripheral nerve innervating the area Treatment frequency and duration:. TENS 4-6 times a day for 1-hr periods (High freq/low int); 4-6 times a day for 30 min periods (high freq/high int); Total no of TENS sessions/treatments: 112-168 sessions per patient Total active stimulation time (TENS dose): 14- 42 hours/week Device/Manufacturer: Two TENS devices - TWIN-STAR/Van Lent Systems, B.V. Netherlands and TEN-Stem/Schwa Medico Netherlands.
Outcomes	Authors' judgment on effectiveness: No significant difference in size of effect b/w groups Reviewers' judgement on effectiveness: Agree with author Dichotomous outcomes available for pain? No
Notes	Results presented as: Mean pain reduction as measured by the VAS Adverse effects:Skin irritation causing 4 participants to withdraw Dichotomous data available for adverse effects: Yes QS = 3 (2, 0, 1)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Lewis 1984

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: Global rating; VAS pain relief; pain index, Piper (electronic) pain intensity scale Assessments pre & post (end 3 weeks). Daily VAS pain relief Blinding: Adapters used to block current at end of leads TENS administered by: Patient
Participants	No. of patients randomised (analysed): 36 (28) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. HFTENS + oral placebo (n=29) 2. sham TENS + oral placebo (n=29) 3. naproxen + sham TENS (n=29) TENS frequency (HF=>10 Hz LF= <10 Hz):

Lewis 1984 (*Continued*)

	HFTENS 70Hz TENS intensity (threshold): Supra Electrodes: Not described Stimulation site: Acupuncture points Treatment frequency and duration: 30-60 minutes stimulation, minimum of 3 times a day for 3 weeks per treatment Total no of TENS sessions/treatments: 63 (minimum) Total active stimulation time (TENS dose): 31.5-63 hours 105-22 hours per week 90-180 minutes per day Device/Manufacturer: 3 M Tenscare dual
Outcomes	Authors' judgement on effectiveness: No immediate data Negative: short term (3 weeks) No long term data Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? Complicated to extract Patients views on whether treatment was effective TENS: 15/28 (54%) Sham TENS: 10/28 (36%) Continue with treatment after study 7/29 (24%) sham TENS: 4/29 (14%)
Notes	Authors attribute high placebo response on lack of statistically significant differences between treatments Adverse effects: Drug related (oral placebo)toxicity TENS: 4 Sham TENS: 0 Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Lewis 1994

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: VAS pain relief; duration of relief; patient opinion. Assessments daily diary & weekly Blinding: Reported as being double blind. No current, broken lead at jack plug, red indicator light functioning TENS administered by: Patient
Participants	No. of patients randomised (analysed): 30 (29) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. HFTENS (n=29) 2. sham TENS (n=29) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 70Hz TENS intensity (threshold): Not stated Electrodes: 4 silicone rubber electrodes Stimulation site: Classical knee acupuncture points Treatment frequency and duration: 30-60 minutes stimulation, 3 times a day, over 3 weeks Total no of TENS sessions/treatments: 63 Total active stimulation time (TENS dose): 31.5-63 hours 105-22 hours per week 90-180 minutes per day Device/Manufacturer: RDG Tiger Pulse
Outcomes	Authors' judgement on effectiveness: No data for immediate post treatment Positive: short term 3 weeks No long term data Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? Pain relief >50% at 3 weeks TENS:13/28 (46%) Sham TENS:12/28 (43%) Continue with treatment after study TENS: 12/28 (43%) sham TENS: 4/28 (14%)
Notes	Authors question long term efficacy & placebo response. Significant differences reported at 3 weeks in favour of active treatment (pain relief) Adverse effects: Not stated Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Lewis 1994 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Mannheimer 1979

Methods	Study design: Active TENS versus Active TENS control Crossover, single treatment of stimulation Subjective pain outcome measures: Pain relief 4 step scale (1-5) immediately after treatment, duration of pain relief. Assessments pre and immediately post treatment Blinding: Not documented TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 20 (20) Pain condition: Wrist pain, rheumatoid arthritis
Interventions	Treatment groups: 1. HFTENS (n=20) 2. LFTENS (n-20) 3. train TENS (n=20) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 70Hz LFTENS 3 Hz Train TENS 3-70Hz TENS intensity (threshold): Supra (initially, titrated to sub) Electrodes: 1 pair electrodes, 9 cm2 Stimulation site: Area of pain (volar and dorsal side of wrist) Treatment frequency and duration: 10 minutes, single treatment Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 10 mins Device/Manufacturer: Not reported
Outcomes	Authors' judgement on effectiveness: Immediately post treatment: LFTENS was less effective than both HFTENS and train TENS marked Improvement in pain (change from baseline score of at least 2 categories on 1-5 scale) HF 18/20 LF 14/20 train 5/20 Reviewers' judgement on effectiveness: LFTENS was less effective than HFTENS and LFtrainTENS Dichotomous outcomes available for pain? Yes

Mannheimer 1979 (*Continued*)

Notes	No information on TENS device given. Experimental pain model. Dichotomous data given, but this does not necessarily approximate to 50% improvement. Patients may not all have had moderate pain on rest at baseline, scoring methods not clearly defined. No statistical tests used Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 1 (1,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Moore 1997

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: 5 point present pain intensity; VAS pain intensity; VAS pain relief; treatment preference; analgesic consumption. Assessments pre & immediately after treatment Blinding: Light active TENS administered by: patient
Participants	No. of patients randomised (analysed): 28 (24) Pain condition: Chronic back pain
Interventions	Treatment groups: 1. HFTENS (n=28) 2. sham TENS (n=28) 3. NMES (n=28) 4. NMES + TENS(n=28) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 100Hz TENS intensity (threshold): Supra Electrodes: 4 rectangular re-usable (2 per channel) Stimulation site: Not stated Treatment frequency and duration: 5 hours stimulation per day for 2 days Total no of TENS sessions/treatments: 2 Total active stimulation time (TENS dose): 10 hours Device/Manufacturer: Device not stated but supplier - Vision Quest
Outcomes	Authors' judgement on effectiveness: Negative: immediately post treatment No short or long term outcomes

Moore 1997 (*Continued*)

	Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? Continue with treatment TENS: 2/24 (8%) sham TENS: 2/24 (8%)
Notes	Results presented as means & SD Adverse effects: Reported as none Dichotomous data available for adverse effects: 0/24 QS = 2 (1,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Møystad 1990a

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: VAS pain intensity on rest & movement. Assessments pre & hourly up to 1 day after treatment Blinding: Independent observer, blind to treatments, no current TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 19 (19) Pain condition: Rheumatic arthritis with TMJ dysfunction
Interventions	Treatment groups: 1. HFTENS (n=19) 2. sham TENS (n=19) Report of 2 trials (same patients) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 100HZ TENS intensity (threshold): 1. Supra 2. Supra Electrodes: 2 rubber electrodes, covered with gel & attached to skin with tape Stimulation site: Pain area (HF) Acupuncture points (LF AL) Treatment frequency and duration: One single 30 minute stimulation Total no of TENS sessions/treatments: 1

Møystad 1990a (*Continued*)

	Total active stimulation time (TENS dose): 30 mins Device/Manufacturer: Kone Elpha 500
Outcomes	Authors' judgement on effectiveness: Positive: immediately post treatment No short or long term outcomes Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? No
Notes	HF TENS significant more effective than Sham TENS, pain on movement. No extractable data Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Møystad 1990b

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: VAS pain intensity on rest & movement. Assessments pre & hourly up to 1 day after treatment Blinding: Independent observer, blind to treatments, no current TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 13 (13) Pain condition: Rheumatic arthritis with TMJ dysfunction
Interventions	Treatment groups: 1. HFTENS (n=19) 2. sham TENS (n=19) Report of 2 trials (same patients) TENS frequency (HF=>10 Hz LF= <10 Hz): LFTENS 2 Hz TENS intensity (threshold): 1. Supra 2. Supra Electrodes: 2 rubber electrodes, covered with gel & attached to skin with tape Stimulation site:

Møystad 1990b (*Continued*)

	Pain area (HF) Acupuncture points (LF AL) Treatment frequency and duration: One single 30 minute stimulation Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 30 mins Device/Manufacturer: Kone Elpha 500
Outcomes	Authors' judgement on effectiveness: Negative: immediately post treatment No short or long term outcomes Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? No
Notes	HF TENS significant more effective than Sham TENS, pain on movement. No extractable data Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Nash 1990

Methods	Study design: Active TENS versus Active TENS control Parallel group, multiple dose Subjective pain outcome measures: 10 cm VAS pain intensity, treatment efficacy taken as 50% reduction in baseline pain. Assessments pre and post treatment at 1, 6, 12, 4 months Blinding: Described as being blind, identical pre-set device, with adjustable amplitude switch, and on/off switch TENS administered by: Patient
Participants	No. of patients randomised (analysed): 200 (200) Pain condition: Various nociceptive and neuropathic chronic pain conditions
Interventions	Treatment groups: 1. LFTENS continuous (n=50) 2. LFTENS pulsed (n=50) 3. HFTENS continuous (n=50) 4. HF TENS pulsed (n=50)

	TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 100Hz LFTENS 10 Hz HFPulsed 100Hz plus 2.3 Hz LFPulsed 10 Hz plus 2.3 Hz TENS intensity (threshold): supra (titrated to maximum level tolerated by patients) Electrodes: Not reported Stimulation site: Not reported Treatment frequency and duration: Up to 2 years, or a time period that it was clear treatment had benefited/ not benefited patient Total no of TENS sessions/treatments: Not reported Total active stimulation time (TENS dose): Not reported Device/Manufacturer: Not reported
Outcomes	Authors' judgement on effectiveness: Long term (1 year): No statistically significant differences between the 4 treatments overall Patients achieving 50% reduction in pain: LF pulsed: 11/50 LF cont: 13/50 combined LF: 24/100 HF pulsed: 19/50 HF cont: 12/50 combined HF: 31/100 Reviewers' judgement on effectiveness: All forms of stimulation effective, but no statistically significant differences found between the 4 TENS treatments Dichotomous outcomes available for pain? Yes
Notes	Little information given on electrodes and site of stimulation, use of TENS. Data presented as number of patient improved and odds ratios. No overall statistically differences between the different treatments. % benefiting at 1 year: 37% continual TENS 35% pulsed TENS 24% LFTENS 47% HFTENS possible faster onset of relief with HFTENS compared to LFTENS Adverse effects: Occasional skin rash in some patients. Marked muscle spasm with Pulsed HFTENS Dichotomous data available for adverse effects: No QS = 3 (2,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Ng 2003

Methods	Study design: Randomised Controlled Trial Subjective pain outcome measures: Numerical Rating Scale of pain assessed at 3 points - prior to 1st treatment, after 8 sessions of treatment and 2 weeks after last treatment Blinding: Single TENS administered by - investigator
Participants	No. of patients randomised (analysed): 24 Pain condition: Knee pain from osteoarthritis
Interventions	Treatment groups: Electro acupuncture vs. TENS vs. no treatment control TENS frequency (HF=>10 Hz; LF= <10 Hz): Low (2 Hz) TENS intensity (threshold): Not stated Electrodes: 50 x 35 sq.mm electrodes Stimulation site: Acupuncture points over knee Treatment frequency and duration: 20 mins of TENS stimulation Total no of TENS sessions/treatments: 8 sessions Total active stimulation time (TENS dose): 1.33 hours/week Device/Manufacturer: dual channel TENS model 12 0Z/ITO Co. Ltd, Tokyo, Japan
Outcomes	Authors' judgement on effectiveness: TENS produced pain reduction after 8 sessions of treatment and at 2 weeks after last session. No pain reduction achieved with control Reviewers' judgement on effectiveness: Agree with author Dichotomous outcomes available for pain? No
Notes	Results presented as: reduction in mean NRS of pain post treatment and at 2 weeks presented as percentages Adverse effects: None reported Dichotomous data available for adverse effects: N/A QS = 2 (2, 0, 0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Oosterhof 2006

Methods	Study design: Randomised Controlled Trial Subjective pain outcome measures: Pre-treatment and post-treatment VAS scores for pain. Blinding: Double TENS administered by: Patient
Participants	No. of patients randomised (analysed): 163 Pain condition: Chronic Pain of benign origin

Oosterhof 2006 (*Continued*)

Interventions	Treatment groups: TENS and sham TENS. TENS frequency (HF=>10 Hz; LF= <10 Hz): High (80 Hz) TENS intensity (threshold): Both high and low Electrodes: Disposable 5 x 6.4 cm self-adhering electrodes. Stimulation site: Electrodes applied over superficial cutaneous nerves in the painful segment Treatment frequency and duration: Average of 10-11.5 hours each day for 7 days Total no of TENS sessions/treatments: Not stated Total active stimulation time (TENS dose): 68.6-81.2 hours/week Device/Manufacturer: ELPHA II 1000/Danmeter A/S, Denmark
Outcomes	Authors' judgement on effectiveness: No difference in pain intensity between TENS and sham TENS groups Reviewers' judgement on effectiveness: Same as author's Dichotomous outcomes available for pain? Yes - proportion of patients achieving pain relief
Notes	Results presented as: Mean proportion of relief in pain intensity from TENS and sham TENS in groups willing or not willing to continue treatment. Authors do not however define what 'pain relief' means. Adverse effects: None Dichotomous data available for adverse effects: N/A QS = 2 (2, 0, 0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Smith 1983

Methods	Study design: Parallel Active TENS versus sham TENS Subjective pain outcome measures: 7 point pain intensity; analgesic intake; 7 point sleep scale; pain relief . Assessments pre, during & immediately after treatment, up to 2 hours. Weekly Assessments & daily patient diary Blinding: Broken electrode connection at jack point, flashing light TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 32 (30) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. HFTENS (n=15) 2. sham TENS (n=15) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 3-50 Hz

Smith 1983 (*Continued*)

	TENS intensity (threshold): Supra Electrodes: LCE TEC pads applied with electrode jelly Stimulation site: Tender points or acupuncture points Treatment frequency and duration: 20 mins stimulation, 8 times in 4 weeks Total no of TENS sessions/treatments: 8 Total active stimulation time (TENS dose): 160 mins Device/Manufacturer: RDG Tiger Pulse
Outcomes	Authors' judgement on effectiveness: Positive: immediately post treatment Positive: long term (4 & 8 weeks Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? 50% relief immediately post treatment TENS: 13/15 (87%) Sham TENS 13/15 (87%) 50% relief at 4 weeks TENS: 10/15 (67%) Sham TENS 4/15 (27%) 50% relief at 8 weeks TENS: 7/15 (46%) Sham TENS 4/15 (27%)
Notes	Dichotomous data available. Statistical tests not described Adverse effects: Skin irritation in 1 patient Dichotomous data available for adverse effects: No QS = 3 (2,0,1)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Taylor 1981

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: Global Pain Rating scale; 5 point change in pain; pain relief; ambulation; analgesic intake; (non standard) analgesic intake. Assessments pre & at end of 2 week treatment period Blinding: No current, broken leads TENS administered by: Patient
Participants	No. of patients randomised (analysed): 12 (10) Pain condition: Osteoarthritis knee
Interventions	Treatment groups: 1. *TENS (n=10) 2. sham TENS (n=10) TENS frequency (HF=>10 Hz; LF= <10 Hz): Not stated TENS intensity (threshold): Supra Electrodes: 4 Stimulation site: Pain area Treatment frequency and duration: 30-60 mins stimulation over 2 weeks, as required (some patients used continual stimulation) Total no of TENS sessions/treatments: Stimulation on a per patient basis if & when required Total active stimulation time (TENS dose): Stimulation on a per patient basis if & when required Device/Manufacturer: Gatron dual
Outcomes	Authors' judgement on effectiveness: No data immediate post treatment Positive: Short term 2 weeks (improved yes/ no) Negative: Long term Reviewers' judgement on effectiveness: As above Dichotomous outcomes available for pain? Change in pain subjective score at 2 weeks >50% TENS: 1/10 (10%) sham TENS: 1/10 (10%) 1/10 using TENS at 1 year
Notes	Positive short term, not for all outcomes though. Dichotomous data available, but none standard scoring methods Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1

Risk of bias

Item	Authors' judgement	Description

Taylor 1981 (*Continued*)

Allocation concealment?	Unclear	D - Not used

Thorsteinsson 1978

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: Physicians ratings of pain relief (complete, partial, none, aggravation of pain). Assessments pre, during & immediately post treatment. Follow up at 3 & 6 months after completion of study Blinding: Only supervisor was aware of treatment allocation. No current TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 107 (93) Pain condition: Chronic pain
Interventions	Treatment groups: 1. *TENS (n=93) 2. sham TENS (n=93) TENS frequency (HF=>10 Hz; LF= <10 Hz): Not stated TENS intensity (threshold): Not stated Electrodes: Not described Stimulation site: 3 different sites (area of pain, related nerve, non related nerve) Treatment frequency and duration: 20 mins stimulation, 3 times over 3 days (different site each day) Total no of TENS sessions/treatments: 3 Total active stimulation time (TENS dose): 60 mins Device/Manufacturer: Stimtech EPC, Stimulation Technology Co
Outcomes	Authors' judgement on effectiveness: Negative: during & immediately post treatment Negative: short term Negative: long term Reviewers' judgement on effectiveness: Positive: during & immediately post treatment Positive: short term Negative: long term Dichotomous outcomes available for pain? Treatment preference during stimulation over site of pain TENS: 31/93 (33%) Sham 10/93 (11%) Treatment preference after stimulation TENS: 27/93 (29%) Sham 8/93 (9%) Other dichotomous data also available

Thorsteinsson 1978 (*Continued*)

Notes	Dichotomous data available. Decline in use of TENS long term. Physician rating of patient response. Not clear whether active TENS was HF or LF Adverse effects: Reported as none Dichotomous data available for adverse effects: 0/93 QS = 2 (1,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Tulgar 1991a

Methods	Study design: Active TENS versus Active TENS control Pilot study, crossover (possible partial crossover only), single dose, followed by open supervised treatment with preferred stimulation mode after study, for 3 months Subjective pain outcome measures: VAS pain intensity. Treatment efficacy measured as % improvement in VAS pain intensity. Duration of pain relief, treatment preference. Assessments pre and at maximum of 5 minutes post stimulation. Blinding: Patients described as being blind to study treatments TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 27 (27) Pain condition: Various nociceptive and neuropathic chronic pain conditions 27 (27)
Interventions	Treatment groups: 1. HFTENS (?) 2. Burst TRAIN TENS (n=14) 3. Frequency modulated (n=?) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 70Hz Burst TRAIN TENS 100Hz/2 Hz (100Hz twice/second over 90 msec) Frequency modulated 70Hz/1 Hz (90-55 Hz over 90 msec) TENS intensity (threshold): Individually titrated Electrodes: Not reported Stimulation site: Optimum place for pain relief Treatment frequency and duration: 30 mins Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 30 minutes (for each of the 3 study treatments with TENS) Device/Manufacturer: Purpose built device

Tulgar 1991a (*Continued*)

Outcomes	Authors' judgement on effectiveness: 25/27 patients benefited overall from treatment. Patients preferred frequency modulated stimulation and burst stimulation to HFTENS Reviewers' judgement on effectiveness: Burst and HFTENS more effective than LF and continuous TENS Dichotomous outcomes available for pain? No
Notes	More patients preferred other 2 treatments to HFTENS. Not possible to derive dichotomous data Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Tulgar 1991b

Methods	Study design: Active TENS versus Active TENS control Crossover, single dose, followed by open supervised treatment with preferred stimulation mode after study, for 3 months Subjective pain outcome measures: VAS pain intensity. Treatment efficacy measured as % improvement in VAS pain intensity. Duration of pain relief, treatment preference. Assessments pre and at maximum of 5 minutes post stimulation. Blinding: Patients described as being blind to study treatments TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 14 (14) Pain condition: Various nociceptive and neuropathic chronic pain conditions
Interventions	Treatment groups: 1. HFTENS (n=14) 2. Burst Train TENS (n=14) 3. HFTENS + pulsed (n=14) 4. LFTENS + pulsed (n=14) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 70Hz Burst Train TENS 90 Hz-50 Hz, (repeated 1.3 times/second) HFTENS + pulsed 70Hz-55 Hz (every 90 seconds) LFTENS + pulsed 60 to 20 Hz over 90 seconds TENS intensity (threshold): Individually titrated

Tulgar 1991b (*Continued*)

	Electrodes: Not reported Stimulation site: Optimum place for pain relief Treatment frequency and duration: 20 minute treatments of stimulation Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 20 minutes (for each of the 4 study treatments with TENS) Device/Manufacturer: Purpose built device
Outcomes	Authors' judgement on effectiveness: NSD between treatments immediately after treatment Reviewers' judgement on effectiveness: Burst Train and HF TENS more effective than LF and continuous TENS Dichotomous outcomes available for pain? No
Notes	8/14 Patients who continued to respond after treatment were given stimulation of choice in a open fashion for up to 3 months. 1.8 were reported to benefit long term(at least 50% relief) Adverse effects: Not reported Dichotomous data available for adverse effects: No QS = 2 (1,0,1)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Vinterberg 1978

Methods	Study design: Crossover Active TENS versus sham TENS Subjective pain outcome measures: VAS pain intensity on rest. Assessments pre & post treatment Blinding: Described as double-blind because device produced stimulation that could not be felt TENS administered by: Investigator
Participants	No. of patients randomised (analysed): 14 (14) Pain condition: Rheumatoid arthritis wrist
Interventions	Treatment groups: 1. HFTENS (n=14) 2. Sham TENS (n=14) TENS frequency (HF=>10 Hz LF= <10 Hz): HFTENS 70-100 Hz TENS intensity (threshold): Sub Electrodes: 2 rubber electrodes, 3 x 4 cm taped into position

Vinterberg 1978 (*Continued*)

	Stimulation site: Site of pain Treatment frequency and duration: One single 60 minute stimulation Total no of TENS sessions/treatments: 1 Total active stimulation time (TENS dose): 60 mins Device/Manufacturer: Perator, Sask electromedicin ApS
Outcomes	Authors' judgement on effectiveness: Positive: immediately post treatment Reviewers' judgement on effectiveness: Positive Dichotomous outcomes available for pain? No
Notes	Statistically significant difference reported in favour of active treatment for pain. NSD for grip pain & other outcomes. Blinding was claimed to have been maintained Adverse effects: Reported as none Dichotomous data available for adverse effects: 0/14 QS = 2 (2,0,0)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Warke 2006

Methods	Study design: Randomised Controlled Trial Subjective pain outcome measures: VAS for average Low Back Pain Blinding: Double TENS administered by: Patient
Participants	No. of patients randomised (analysed): 90 Pain condition: Chronic Low Back Pain with probable or definite MS.
Interventions	Treatment groups: LFTENS, HFTENS, Placebo TENS. TENS frequency (HF=>10 Hz; LF= <10 Hz): Both TENS intensity (threshold): Not stated Electrodes: 4 integrated self-adhering 5 x 5 cm electrodes Stimulation site: 3 cm on either side of the lumbar spine, centered over painful area Treatment frequency and duration: 45 minutes, minimum of twice daily for six weeks Total no of TENS sessions/treatments: Minimum of 84 Total active stimulation time (TENS dose): 10.5 hours/week Device/Manufacturer: EZ-Stim TENS unit/Nidd Valley Medical Ltd, North Yorkshire, UK

Warke 2006 (*Continued*)

Outcomes	Authors' judgement on effectiveness: No statistically significant differences in mean reductions in average Low Back Pain Reviewers' judgement on effectiveness: Same as author's Dichotomous outcomes available for pain? Yes - percentage of patients showing more than 20 mm reduction in VAS in each group at weeks 6 and 32
Notes	Results presented as: Mean differences in VAS scores between weeks 1 and 32 in each group Adverse effects: None reported Dichotomous data available for adverse effects: N/A QS = 2 (2, 0, 0)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

* - frequency not described
TMJ - temporomandibular joint
QS - quality score (randomisation, blinding, withdrawals/dropouts)
SD - standard deviation
VAS - visual analogue scale
VASPI - visual analogue scale pain intensity
NSD - no significant difference
MS QoL - Multiple Sclerosis Quality of Life
HF AL TENS - High Frequency Acupuncture-Like TENS
ENS - Electric Nerve Stimulation
EMS - Electric Muscle Stimulation
NMES - Neuromuscular Electrical Stimulation
NRS - Numerical Rating Scale SF-36 - Short Form 36

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

Abram 1992	Naloxone reversal of TENS
Airaksinen 1992	Headache excluded from review
Allais 2003	Transformed migraine excluded from review
Anderson 2004	Intermittent claudication not considered chronic pain; outcomes studied were functional capacity and systemic inflammation
Annal 1992	Headache excluded from review

(*Continued*)

Bloodworth 2004	Not genuine randomised controlled trial of TENS
Breit 2004	Post-operative pain not chronic pain
Bruce 1988	Combined therapies, sample size too small to evaluate, no adequate placebo control
Carlsson 2001	Mock TENS used as placebo for acupuncture study
Chao 2007	TENS for pain control in first stage of labour
Chee 1986	Non standard TENS, trigger points, non standard pain outcomes
Cheng 1986	No adequate sham TENS treatment comparison, problems with randomisation method
Chiu 1999	Post-op pain not chronic pain
Chiu 2005	No adequate TENS treatment comparison
Coletta 1988	No adequate sham TENS treatment comparison
Crockett 1986	No adequate sham TENS treatment comparison
Dawood 1990	Dysmenorrhoea trials not eligible
De-Angelis 2003	Not chronic pain. TENS evaluated for suppression of pelvic pain during hysteroscopy
Deyo 1990a	No subjective pain outcomes, methodological paper
Deyo 1990b	Results for TENS + exercise combined, cannot use data
Di Benedetto 1993	No adequate sham TENS treatment comparison
Dobie 1986	No subjective pain outcomes
Erdogan 2005	Post-thoracotomy pain not chronic pain
Fagade 2003	Post-IMF Trismus pain not chronic pain
Fargas 2001	Not RCT
Fargas-Babjak 1989	Codetron device, not standard TENS
Farina 2004	No adequate TENS treatment comparison
Freeman 1983	Naloxone reversal of TENS and spinal cord electrical stimulation

(*Continued*)

Furgala 2001	Effect of TENS stimulation on gastric myoelectric activity
Geirsson 1993	No adequate sham TENS treatment comparison
Ghoname 1999	No adequate TENS treatment comparison
Godfrey 1984	No adequate sham TENS treatment comparison
Graff-Radford 1989	TENS versus non standard TENS (pain suppressor unit), no sham TENS control. VASPI, 5 single treatments
Han 1991	No subjective pain outcomes
Hedner 1996	No adequate sham TENS treatment comparison
Herman 1994	Not chronic pain, no adequate sham TENS treatment comparison
Herrera-Lasso 1993	Combined therapy. No adequate sham TENS treatment comparison
Heydenreich 1988	Migraine studies excluded from review
Heydenreich 1989a	Migraine studies excluded from review
Heydenreich 1989b	Migraine studies excluded from review
Heydenreich 1991	Migraine studies excluded from review
Hsieh 1992	Not standard TENS, no adequate sham TENS treatment comparison
Hsieh 2002	No adequate TENS treatment comparison
Jeans 1979	Not RCT
Johannsen 1993	Rebox device, unconventional TENS device
Kerr 2003	No adequate TENS treatment comparison
Kibisa 2004	Not RCT
Lang 2007	Post-traumatic hip pain not chronic pain
Langley 1984	Not standard TENS device
Leandri 1990	No subjective pain outcomes
Lehmann 1983	Combined TENS and exercise programme
Leo 1986	Subjects randomised to therapist not treatment

(*Continued*)

Lewers 1989	No adequate sham TENS treatment comparison
Likar 2001	Post-operative pain not chronic pain
Linde 1995	No adequate sham TENS treatment comparison
Longobardi 1989	No adequate sham TENS treatment comparison
Lorenzana 1999	Episiotomy pain not chronic pain
Lucisano 1989	No adequate sham TENS treatment comparison
Lundeberg 1984	No adequate sham TENS treatment comparison
Lundeberg 1985	Dysmenorrhoea trials not eligible, treatment orders probably not randomised
Lux 1994	No pain outcomes
Macdonald 1995	No adequate sham TENS treatment comparison
Machin 1988	Methodological paper, insufficient data
Mannheimer 1978	Methodological problems, difficult to extract data because of inadequate reporting of information
Mannheimer 1982	Angina studies excluded from review
Mannheimer 1984a	Angina studies excluded from review
Mannheimer 1985a	Dysmenorrhoea trials not eligible
Mannheimer 1985b	Angina studies excluded from review
Marchand 1993	Inadequate method of randomisation ('pseudo' randomisation)
Melzack 1980	Not RCT
Melzack 1983	No adequate sham TENS treatment comparison
Milsom 1994	No adequate sham TENS treatment comparison
Morgan 1996	Not chronic pain
Naeser 2002	TENS used in combination with Low Level Laser Therapy
Neighbors 1987	No adequate sham TENS treatment comparison

(*Continued*)

Oncel 2002	Pain of uncomplicated minor rib fracture not chronic pain
Paker 2006	No adequate TENS treatment comparison
Pope 1994	No standard TENS. No adequate sham TENS treatment comparison
Rakel 2003	Post-operative pain not chronic pain
Razavi 2004	No adequate TENS treatment comparison
Reich 1989	Headache excluded from review
Reichstein 2005	No adequate TENS treatment comparison
Robinson 2001	Intra-operative pain not chronic pain
Roche 1985	Acute pain not chronic pain
Rutgers 1988	No adequate sham TENS treatment comparison
Scott 1994	No pain outcomes, no adequate sham TENS treatment comparison
Solak 2007	Post-thoracotomy pain not chronic pain
Sonde 1998	Not all patients had pain. Pain was not main outcome measure
Sunshine 1996	Electro-auroscope, unconventional TENS device
Tekeoglu 1998	No pain outcomes
Thomas 1995	Dysmenorrhoea trials not eligible for inclusion
Timm 1994	TENS in combination, no single treatment of TENS
Tsang 1994	No pain outcomes, no adequate sham TENS treatment comparison
Tsukayama 2002	No adequate TENS treatment comparison
Tugay 2007	Primary dysmenorrhoea not considered chronic pain
Van der Spank 2000	Labour pain not chronic pain
Wang 1988	Acute pain not chronic
Xue 2004	Electroacupuncture not TENS

(*Continued*)

Yokoyama 2004	No adequate TENS treatment comparison

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Example search strategy

ELECTRIC-STIMULATION-THERAPY or ELECTRIC-COUNTERSHOCK or ELECTROACUPUNCTURE or TRANSCUTANEOUS-ELECTRIC-NERVE-STIMULATION
(electric$ adj (nerve or therap$4))
electrostimulation.
electroanalgesia.
(tens or altens).
electroacupuncture.
(electric$4 adj current or electrotherap$4).

Appendix 2. Evidence for analgesic efficacy after TENS (Active compared to Sham TENS)

Author	Frequency activeTENS	Immediately after	Efficacy 24hrs-1week	Efficacy 1-4 weeks	Efficacy 1-6 months	Efficacy >6 months	Overall judgement
Abelson 1983	HF (MD)	+VE	NA	NA	NA	NA	+VE
Al-Smadi 2003	HF (MD)	NA	-VE	-VE	-VE	NA	-VE
Al-Smadi 2003	LF (MD)	NA	-VE	-VE	-VE	NA	-VE
Cheing 2003	HF (MD)	+VE	+VE	+VE	NA	NA	+VE
Grimmer 1992	HF (SD)	-VE	-VE	NA	NA	NA	-VE
Grimmer 1992	LF BURST (SD)	-VE	+VE	NA	NA	NA	+VE
Hsueh 1997	HF (SD)	+VE	NA	NA	NA	NA	+VE
Hsueh 1997	LF (SD)	+VE	NA	NA	NA	NA	+VE
Kumar 1997	LF (MD)	NA	+VE	-VE	NA	NA	+VE

(*Continued*)

Lewis 1984	HF (MD)	NA	NA	+VE	NA	NA	+VE
Lewis 1994	LF (MD)	NA	NA	-VE	NA	NA	-VE
Moore 1997	HF (MD)	-VE	NA	NA	NA	NA	-VE
Møystad 1990a	HF (SD)	+VE	NA	NA	NA	NA	+VE
Møystad 1990b	LF (SD)	-VE	NA	NA	NA	NA	-VE
Ng 2003	LF (MD)	NA	NA	+VE	NA	NA	+VE
Oosterhof 2006	HF (MD)	NA	+VE	-VE	NA	NA	+VE
Smith 1983	HF (MD)	+VE	NA	+VE	+VE	NA	+VE
Taylor 1981	TENS** (MD)	NA	NA	-VE	NA	NA	-VE
Thorsteinsson 1978	TENS** (MD)	-VE	+VE	NA	NA	-VE	+VE
Vinterberg 1978	HF (SD)	+VE	NA	NA	NA	NA	+VE
Warke 2006	HF (MD)	NA	-VE	-VE	-VE	-VE	-VE
Warke 2006	LF (MD)	NA	-VE	-VE	-VE	-VE	-VE
TOTAL +VE	-	7	5	4	1	0	13+VE
TOTAL -VE	-	5	5	8	4	3	9-VE
NOTES:	**Frequency not known	SD - single dose					
	HF - High frequency	MD - multiple dose					
	LF - Low frequency	NA - data not available					

Appendix 3. Evidence for analgesic efficacy after HFTENS (Active compared to Sham TENS)

Author	Frequency ActiveTENS	Immediately after	Efficacy 24hrs-1week	Efficacy 1-4 weeks	Efficacy 1-6 months	Efficacy >6 months	Overall Judgement
Abelson 1983	HF (MD)	+VE	NA	NA	NA	NA	+VE
Al-Smadi 2003	HF (MD)	NA	-VE	-VE	-VE	NA	-VE
Cheing 2003	HF (MD)	+VE	+VE	+VE	NA	NA	+VE
Grimmer 1992	HF (SD)	-VE	-VE	NA	NA	NA	-VE
Hsueh 1997	HF (SD)	+VE	NA	NA	NA	NA	+VE
Lewis 1984	HF (MD)	NA	NA	+VE	NA	NA	+VE
Moore 1997	HF (MD)	-VE	NA	NA	NA	NA	-VE
Møystad 1990a	HF (SD)	+VE	NA	NA	NA	NA	+VE
Oosterhof 2006	HF (MD)	NA	+VE	-VE	NA	NA	+VE
Smith 1983	HF (MD)	+VE	NA	+VE	+VE	NA	+VE
Vinterberg 1978	HF (SD)	+VE	NA	NA	NA	NA	+VE
Warke 2006	HF (MD)	NA	-VE	-VE	-VE	-VE	-VE
12 HFTENS studies in total		6 +VE	2 +VE	3 +VE	1 +VE	0 +VE	8+VE
		2 -VE	3 -VE	3 -VE	2 -VE	1 - VE	4-VE
		4 NA	7 NA	6 NA	9 NA	11 NA	
Notes:	HF - High Frequency TENS	SD - single dose					
	LF - Low Frequency TENS	MD - multiple dose					

Appendix 4. Evidence for analgesic efficacy after LFTENS (Active compared to sham TENS)

Author	Frequence ActiveTENS	Immediately after	Efficacy 24hrs-1week	Efficacy 1-4 weeks	Efficacy 1-6 months	Efficacy >6 months	Overall judgement
Al-Smadi 2003	LF (MD)	NA	-VE	-VE	-VE	NA	-VE
Grimmer 1992	LF BURST (SD)	-VE	+VE	NA	NA	NA	+VE
Hsueh 1997	LF (SD)	+VE	NA	NA	NA	NA	+VE
Kumar 1997	LF (MD)	NA	+VE	-VE	NA	NA	+VE
Lewis 1994	LF (MD)	NA	NA	-VE	NA	NA	-VE
Møystad 1990b	LF (SD)	-VE	NA	NA	NA	NA	-VE
Ng 2003	LF (MD)	NA	NA	+VE	NA	NA	+VE
Warke 2006	LF (MD)	NA	-VE	-VE	-VE	-VE	-VE
Total of 8 LFTENS studies		1+VE	2 +VE	1 +VE	0 +VE	0 +VE	4 +VE
		2 -VE	2 -VE	4 -VE	2 -VE	1 -VE	4 -VE
		5 NA	4 NA	3 NA	6 NA	7 NA	
Notes:	HF - High frequency TENS	SD - single dose					
	LF - Low frequency TENS	MD - multiple dose					
		NA - no data available					

Appendix 5. Evidence for analgesic efficacy (HFTENS compared to LFTENS)

Author	Dosing (MD or SD)	+result HFTENS	+result LFTENS	Overall difference
Al-Smadi 2003	MD	No	No	No
Grimmer 1992	SD	No	No	No
Hsueh 1997	SD	No	No	No
Jensen 1991	MD	No	No	No
Mannheimer 1979	SD	Yes	No	Yes
Nash 1990	MD	No	No	No
Tulgar 1991a	SD	No	Yes	Yes
Tulgar 1991b	SD	No	No	No
Warke 2006	MD	No	No	No
Total 9 studies		1/9	1/9	2/9
Notes:	HF - high frequency	SD - single dose		
	LF - low frequency	MD - multiple dose		

FEEDBACK

Lewis references corrected and Davies 1997 evidence information queried, 17 September 2009

Summary

Dear Miss Thomas
I have a query regarding the following publication: Nnoaham KE & Kumbang J. (2008). Transcutaneous electrical nerve stimulation (TENS) for chronic pain. *Cochrane Database of Systematic Reviews 2008.*

On page 2 it says: "One survey of 1912 participants treated at a single pain clinic (Davies 1997) suggested that 58% of participants benefited from TENS when it was tried as the first line treatment".
I'd like to cite this evidence, but when I read the original paper (Davies HT, Crombie IK, Brown JH & Martin C. (1997). Diminishing returns or appropriate treatment strategy? An analysis of short-term outcomes after pain clinic treatment. *Pain, 70*, (2-3): 203-8), I couldn't find any reference to 58% of 1912 patients benefiting from TENS. Table 4 of that paper indicates that 40.2% of 379 patients benefited from TENS when it was used as a first line treatment.
Perhaps I've misunderstood or misread the Davies paper, but I really can't understand where the '58% of 1912' figures came from. I'd much appreciate clarification on this please.
Regards
Patricia Rentowl

Reply

We actually considered benefit to include the 2nd level on the scale constructed by Davies et al (1997). In other words, while they considered good relief or good benefit to be score 2 or 3, we did consider scores 1, 2 or 3 to represent "benefit". So while only 40.2% of those who used TENS as first line treatment received "good benefit" (score 2 or 3), another ~18% actually had "little benefit" (score 1, which the authors did not explicitly report, but which we simply derived as 100% - sum of 40.2% and 42%). Furthermore, the 1912 did not refer to the number of people who received TENS but to the number of participants whose treatment modalities with outcomes were assessed. We could have worded this better to avoid confusion. This should thus be worded like this, change underlined: "One survey of 1912 participants treated at a single pain clinic (Davies 1997) suggested that 58% of 379 participants benefited from TENS when it was tried as the first line treatment".
The observation on the references is correct. The beginnings of the references should actually read Lewis 1994 and Lewis 1984.
We thank Patricia Rentowl for the feedback.

Contributors

Jessica Thomas acted as Feedback Editor for this issue. Kelechi Nnoaham, as author, responded to the feedback. Patricia Rentowl of Leicester General Hospital provided the feedback.

WHAT'S NEW

Last assessed as up-to-date: 27 April 2008.

30 September 2009	Feedback has been incorporated	Feedback incorporated regarding Davies 1997 and Lewis 1994 and Lewis 1984 references which were incorrectly cited. Please see feedback section for specific details of the changes made to this review.

HISTORY

Protocol first published: Issue 3, 2001

Review first published: Issue 3, 2001

28 April 2008	New search has been performed	This systematic review represents a substantial update and revision of the previous Cochrane Review published in 2001. The previous review was inconclusive of any beneficial effect of TENS in chronic pain. The studies identified (Al-Smadi 2003; Cheing 2003; Köke 2004; Ng 2003; Oosterhof 2006; Warke 2006) and included in this update offer little improvement upon earlier ones with respect to numbers (only six new studies included) , methodological rigour or adequate sample size to conclusively define an effect of TENS in chronic pain. The updated search strategy was executed from 1999 to April 2008. Forty-two new studies were identified for potential inclusion but thirty-six of these were excluded and six (representing 510 new participants) were included.1281 As the new studies were few and offered only marginal improvements in quality from previously included studies, meta-analysis and quantitative analysis were deemed inappropriate as in the previous review. Consequently, the new studies were only analysed qualitatively. Furthermore, this update considered issues such as the placebo effect in TENS and the potential synergy between TENS and other pain treatments. It was judged that the included studies did not present enough information upon which to make conclusions about these issues and readers may want to read this update bearing in mind these limitations. This updated review is a substantial update including six new studies which, however, do not alter previous conclusions.
28 April 2008	New citation required but conclusions have not changed	New authorship for this review.
4 April 2008	Amended	Converted to new review format.
11 January 2008	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Kelechi Nnoaham (KN) and Jharna Kumbang (JK) took responsibility for the update of this review.

KN and JK selected the studies for inclusion in the review, extracted the data, and assessed study quality independently.

KN assessed included studies for their characteristics and conducted the descriptive analysis.

JK updated the 'Characteristics of excluded studies' table.

KN wrote the first draft of the review with JK contributing to the final text and analysis.

Both review authors provided comments on the protocol or text of the review.

The original protocol and review were written by Carroll D, Moore RA, McQuay HJ, Fairman F, Tramèr M, Leijon G.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- None, Not specified.

External sources

- None, Not specified.

INDEX TERMS

Medical Subject Headings (MeSH)

*Transcutaneous Electric Nerve Stimulation [adverse effects]; Chronic Disease; Pain [*therapy]; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Humans