

Intramuscular stimulation therapy for healthcare: a systematic review of randomised controlled trials

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Abstract

Objective A systematic review of randomised controlled trials was conducted to evaluate the efficacy and effectiveness of intramuscular stimulation (IMS).

Methods Electronic databases including Medline, EMBASE, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, the Cochrane Library, China National Knowledge Infrastructure, KoreaMED, Korean Studies Information Service System, RISS and DBPIA were searched through June, 2012. The Cochrane criteria were used to assess the risk of bias for the individual studies.

Results A total of 416 publications were initially collected and four studies were included in this review. One study evaluated the efficacy of IMS for chronic tension-type headaches; IMS showed a better effect than the sham (headache index: mean difference (MD) -4.90 , 95% CI -9.53 to -0.27). Three studies tested the effectiveness of IMS for various conditions. In the first study no significant difference was observed in a comparison of IMS and meloxicam therapy for chronic shoulder pain (pain-visual analogue scale (VAS): MD -0.05 , 95% CI -0.25 to 0.16). The second study in patients with myofascial pain syndrome of the upper trapezius muscle found that IMS had a greater effect than simple dry needling measured by the pain-VAS (MD -2.70 , 95% CI -3.77 to -1.63). In the third study, patients with lower back pain who received IMS plus the standard treatment had a better status at discharge than those receiving the standard treatment alone (relative risk 1.63 , 95% CI 1.18 to 2.24).

Conclusions Despite the positive results of these individual studies, the level of evidence supporting the efficacy and effectiveness of IMS for several conditions remains insufficient because of concerns about a lack of precision and a high risk of bias of the included studies. Rigorous large-scale clinical trials of IMS are needed to evaluate the clinical utility of this technique.

INTRODUCTION

Intramuscular stimulation (IMS) is a dry needling technique which targets myofascial trigger points (TrPs) and is based on Gunn's relatively novel model of the treatment of

chronic pain.¹⁻³ The underlying concept behind IMS is that chronic musculoskeletal pain is caused by a shortening of the paravertebral muscles which leads to radiculopathy of the spine and eventually induces neuropathic pain because of the peripheral nerve damage associated with compression of the nerve root.¹ Based on this theoretical model, the target points for needling are the painful muscle bands adjacent to the locus of subjective pain and the paravertebral muscles related to the affected segments.^{1,2}

Considering the current increased use of dry needling techniques including IMS,⁴ clinical evidence on the safety and effectiveness of these methods needs to be critically appraised. In addition, guidelines for the practice of IMS need to be established. A recent systematic review failed to demonstrate clinical evidence for the effectiveness of IMS techniques because the review was not conducted appropriately. First, the review did not use an extensive search strategy by not including EMBASE, Allied and Complementary Medicine Database (AMED) and Chinese databases that are the most important sources of literature on the clinical practice of needling techniques, which might contribute to publication bias. Second, they limited the selection criteria and the language to English and Korean even though the authors reported no limitations of the publication language. Furthermore, the review failed critically to appraise the quality of the evidence, which may introduce an interpretation bias when evaluating the results of the review.⁵

We therefore conducted a systematic review of the randomised controlled trials (RCTs) on IMS using an explicit searching strategy and appraising the methods of each study regardless of the language to include all the available clinical evidence on IMS.

METHODS

For the purpose of evaluating the efficacy and effectiveness of IMS, only RCTs were included in this review. All studies which used the IMS technique or IMS through dry needling for treating pain conditions on the basis of Gunn's theory were included regardless of the disease

or patient conditions.¹ We only included studies that compared IMS with a sham control or with the standard treatment. Studies comparing the standard treatment with an IMS combination therapy were also included if the same intervention was used in both groups. Studies comparing IMS with an injection therapy were excluded because the purpose of this study was not to compare the effect of the various stimulating interventions that are used for IMS. Studies using a dry needling technique but not following the IMS theory were also excluded.

Databases including Medline, Embase, PsycINFO, the Cumulative Index to Nursing and Allied Health Literature, the Allied and Complementary Medicine Database (AMED), the Cochrane Library, China National Knowledge Infrastructure, KoreaMED, Korean Studies Information Service System, RISS and DBPIA were searched by THK and TYC through June 2012. Although the details of the search strategy were altered to meet the characteristics of the various databases, the following terms were basically used for the search: IMS OR intramuscular nerve stimulation OR dry needling OR IMS OR intramuscular electrical stimulation (IMES) OR intramuscular electrical stimulation) AND (pain).

Data extraction and evaluation of the risk of bias were performed by two independent authors (THK and TYC). Any conflicts were resolved by discussion. The risk of bias was assessed in the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other risk of bias according to the Cochrane Collaboration criteria.⁶

The effect size for each individual outcome variable was estimated, and we planned to combine the data from the individual studies for a meta-analysis if the studies had little clinical heterogeneity. Continuous data were presented as the mean difference (MD) and dichotomous data were presented as the relative risk (RR) with 95% CI. The Review Manager 5.1 software (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011) was used for statistical analysis.

RESULTS

A total of four RCTs were selected from the 416 publications that were collected by the electronic database search (figure 1).⁷⁻¹⁰ Two RCTs were conducted in Korea,^{7, 10} one in Turkey⁹ and one in Canada.⁸ The participants in all study groups were classified as outpatients. The various conditions represented included chronic shoulder pain,⁷ myofascial pain syndrome (MPS) of the upper trapezius muscle,¹⁰ tension-type headaches⁹ and chronic lower back pain.⁸ All studies were small trials consisting of 20–56 participants and some studies included only female or only male patients.⁷⁻¹⁰

All of the included studies had a high or uncertain risk of bias in each domain. Only one study showed a low risk of bias in sequence generation.⁷ Allocation concealment was inappropriate in all of the included studies.⁷⁻¹⁰

Although an appropriate placebo control is difficult to implement in an acupuncture trial,¹¹ the personnel overseeing the treatment and the outcome assessors should be blinded to avoid performance and detection biases. However, most of the studies did not implement an accurate blinding procedure.⁷⁻¹⁰ Two studies excluded the dropout participants for statistical analyses on the per protocol basis which might cause an attrition bias.^{7, 8}

The included studies used different IMS treatment modalities.⁷⁻¹⁰ In three of the studies various TrPs were selected as the needling points for the individual IMS treatment,^{7, 9, 10} and motor points were used in the remaining study.⁸ Local and paravertebral muscles were chosen for needling in all of the studies.⁷⁻¹⁰ Two studies used electrical stimulation in addition to TrP needling.^{7, 10} Depending on the study, sham acupuncture,⁹ analgesics,⁷ simple dry needling,¹⁰ IMES¹⁰ or the standard treatment⁸ was used as a control intervention. Owing to this clinical heterogeneity, the effect estimates for individual studies could not be combined with the meta-analysis (table 1).

Efficacy of IMS: chronic, tension-type headaches⁹

One study evaluated the efficacy of the IMS technique for chronic tension-type headaches compared with sham acupuncture.⁹ A total of 4 weeks of either IMS or sham acupuncture was offered to patients with headaches and the pain and function were assessed. The headache index, which was calculated by multiplying the number of days with a headache by a 4-grade pain intensity scale, showed a significantly greater improvement in the IMS group (MD -4.90, 95% CI -9.53 to -0.27). In addition, the right-and-left neck movement limitation score, which reflects cervical movement, showed a significantly greater improvement in the IMS group compared with the sham (right neck movement: MD 0.60, 95% CI 0.05 to 1.15; left neck movement: MD 0.47, 95% CI 0.05 to 0.89). No reports of adverse events related to IMS or sham needling were described in this study.

Effectiveness of IMS: chronic shoulder pain, MPS of the upper trapezius muscle and chronic low back pain

The effectiveness of IMS for the treatment of chronic shoulder pain was evaluated in one study.⁷ Three weeks of IMS treatment were compared with meloxicam therapy. A 10-point visual analogue scale (VAS) of pain, sleep quality and active range of motion (ROM) of the shoulder joint were assessed. After treatment there was no significant difference in the severity of pain or the level of sleep disturbance between the two groups (pain-VAS: MD -0.05, 95% CI -0.25 to 0.16; sleep-VAS: MD -0.18, 95% CI -0.82 to 0.46). Active ROM was tested by the hand-to-shoulder blade test and no significant difference was found between the two groups (MD -0.22, 95% CI -1.66 to 1.21). One participant reported pain induced by needling and dropped out of the study.

One study evaluated the treatment of MPS of the upper trapezius muscle.¹⁰ Two weeks of IMS treatment were compared with simple dry needling of the upper

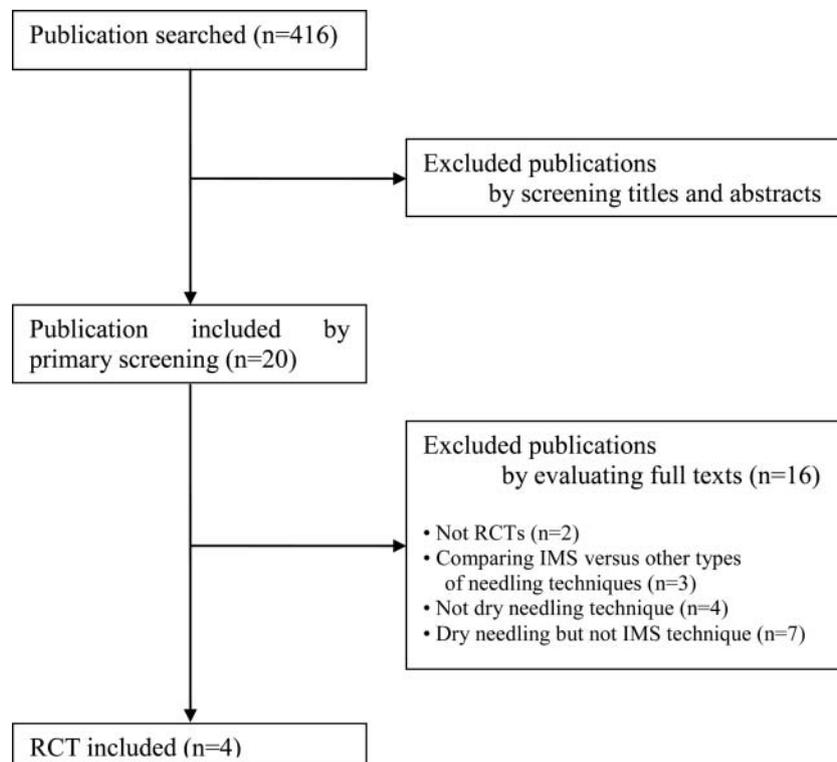


Figure 1 Study flow chart. IMS, intramuscular stimulation therapy; RCT, randomised controlled trial.

trapezius muscle and the IMES technique. Compared with dry needling, IMS had a more significant effect on the pain-VAS (MD -2.70 , 95% CI -3.77 to -1.63) and passive ROM (MD 3.70 , 95% CI 0.11 to 7.29). In addition, IMS significantly decreased the neck pain when compared with IMES (MD -1.30 , 95% CI -2.42 to -0.18). There was no report of adverse events related to either intervention.

In a study of chronic lower back pain, IMS plus the standard treatment was compared with the standard treatment alone.⁸ Two to 15 administrations of IMS plus the standard treatment had a greater effect on the pain and function (status) at discharge than the standard treatment alone (RR 1.63 , 95% CI 1.18 to 2.24). Furthermore, the patient status during the follow-up period improved more in the combination therapy group (RR 4.19 , 95% CI 2.05 to 8.54). Total hospitalisation time required for treatment and total time loss following enrolment of each patient were not significantly different between the two groups (hospitalisation time: MD 0.12 , 95% CI -2.08 to 2.32 ; total time loss: MD -4.64 , 95% CI -10.77 to 1.49). Only one patient reported pain induced by the needling, and no other adverse events were described.

DISCUSSION

Few rigorous RCTs have tested the effectiveness of IMS for use in various health conditions. One study tested the efficacy of IMS for tension-type headaches and found that IMS had a superior effect on the headache intensity and neck movement than a subcutaneous needle insertion (sham acupuncture).⁹ Three studies evaluated the

effectiveness of IMS in different clinical situations. There was no greater effect with the use of IMS than with the administration of an analgesic drug for the improvement of pain and function in chronic shoulder pain.⁷ However, the IMS treatments for MPS of the upper trapezius muscle¹⁰ were superior to simple dry needling (or IMES), and an IMS combination treatment was more effective than the standard treatment alone for chronic lower back pain.⁸ Nevertheless, these positive results do not provide conclusive evidence for IMS as the treatment of choice for various conditions because of the small sample sizes, only one trial for each condition and methodological flaws within the individual studies.

A recent systematic review of IMS concluded that IMS may be an effective intervention for a variety of pain conditions.⁵ However, this conclusion is unduly positive and does not take account of several limitations. First, the review included RCTs with a high or unclear risk of bias in a majority of the domains; thus, it includes a low level of evidence. Second, the results of this review were imprecise because of the small number of RCTs and the small sample sizes of the individual studies. To overcome these shortcomings, our study included only RCTs and assessed the risk of bias for each individual study.

Acupuncture, which is a needling method employed by traditional Asian medicine with several thousand years of history, is now widely used in European countries. Clinical guidelines for the safe practice and effective use of acupuncture have been established according to the needs of the patient.^{12 13} Although the IMS technique relies on the insertion of needles into the body, as with

Table 1 Summary of included studies

Study	Country/setting	Condition/disease or symptom duration	Age (mean, SD) M/F	Intervention group (n=sample size)	Control group (n=sample size)	Duration of treatment	Main outcomes	Comparison between groups at primary end point	AE	Risk of bias*
Ahn <i>et al</i> (2002) ⁷	Korea/outpatients in a university hospital	Chronic shoulder pain/mean 7.3 months	59.9, 5.68 0/50	(A) IMS: needling of TrP among levator scapulae, trapezius, subscapularis and infraspinatus with electrical stimulation (n=30)	(B) Drug: Meloxicam 7.5 mg orally twice daily for 3 weeks (n=20)	Once a week, total 3 weeks	1. Pain-VAS 2. Sleep-VAS 3. Active-ROM	(A) vs (B) 1. MD -0.05, 95% CI -0.25 to 0.16 2. MD -0.18, 95% CI -0.82 to 0.46 3. MD -0.22, 95% CI -1.66 to 1.21	Pain for needling (1 case)	L, U, H, U, H, U, H†
Gunn <i>et al</i> (1980) ⁸	Canada/outpatients in a rehabilitation clinic	Chronic lower back pain/mean 28.6 weeks	40.63, 10.84 56/0	(A) IMS: needling at motor points in the leg and erector spinae muscles of affected lumbar myotome (n=29)	(B) Standard treatment: attending physiotherapy, remedial exercises and occupational therapy (n=27)	Once or twice a week, average 7.9 times (2–15 times)	1. Status at discharge 2. Hospitalisation time needed for treatment	(A)+(B) vs (B) 1. RR 1.63, 95% CI 1.18 to 2.24 2. MD 0.12, 95% CI -2.08 to 2.32	Pain for needling (1 case)	H, H, H, L, H, U, H‡
Karakurum <i>et al</i> (2001) ⁹	Turkey/outpatients in a state hospital	Tension-type headache/25.2 months in control group, 29.6 months in IMS group	27.9, 10 in control group, 28.4, 11.6 in IMS group 0/30	(A) IMS: needling of 6 TrPs in mastoid and C5 level of splenius capitis and mid-trapezius muscle bilaterally (n=15)	(B) Sham acupuncture: subcutaneous needling in the same points as IMS group (n=15)	Total 4 weeks	1. HI 2. MTS 3. NMLS, Rt. 4. NMLS, Lt.	1. MD -4.90, 95% CI -9.53 to -0.27 2. MD -0.87, 95% CI -1.32 to -0.42 3. MD 0.60, 95% CI 0.05 to 1.15 4. MD 0.47, 95% CI 0.05 to 0.89	NR	U, U, L, L, L, U, H†
Byeon <i>et al</i> (2003) ¹⁰	Korea/outpatients in university hospital	MPS of upper trapezius muscle/at least 3 months	50.7, 10.1 18/12	(A) IMS: needling of TrP of upper trapezius muscle and paravertebral muscle of cervix with electrical stimulation (n=10)	(B) Dry needling: needling of TrP of upper trapezius muscle (n=10) (C) IMES: needling of TrP of upper trapezius muscle with electrical stimulation (n=10)	3 times a week, total 2 weeks	1. Pain-VAS 2. MPQ 3. Passive-ROM	(A) vs (B) 1. MD -2.70, 95% CI -3.77 to -1.63 2. MD -2.10, 95% CI -8.08 to 3.88 3. MD 3.70, 95% CI 0.11 to 7.29 (A) vs (C) 1. MD -1.30, 95% CI -2.42 to -0.18 2. MD -4.20, 95% CI -14.57 to 6.17 3. MD 2.90, 95% CI -0.63 to 6.43	NR	U, U, U, L, L, U, L

*Risk of bias (seven domains), random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other risk of bias; L, low risk of bias; H, high risk of bias; U, unclear risk of bias.

†Only female participants were included.

‡Only male participants were included and the treatment duration for each participant was inconsistent.

AE, adverse event; HI, headache index; IMES, intramuscular electrical stimulation; IMS, intramuscular stimulation therapy; MD, mean difference; MPQ, McGill Pain Questionnaire; MPS, myofascial pain syndrome; MTS, muscle tenderness score; NMLS, neck movement limitation score; NR, not reported; ROM, range of motion; TrP, trigger points; VAS, visual analogue scale.

acupuncture, IMS differs from acupuncture in its theoretical basis and techniques used.¹ Evidence on the effectiveness and safety of IMS therefore needs to be evaluated independently with rigorous clinical trials.

There are several more issues to be considered regarding the implementation of IMS. Before considering the efficacy of IMS, safety needs to be established based on reliable clinical evidence. Because IMS is a relatively new technique, the risks related to IMS and practices by insufficiently trained personnel have not been well established. Adverse events related to acupuncture have been actively discussed, and education programmes for the safe practice of acupuncture have been developed.¹⁴ As for acupuncture, the safe clinical practice of IMS techniques can be achieved through well-guided training programmes for practitioners. Second, the methods of IMS intervention employed by clinical trials have not been described in detail. The four studies included in this review provided an inadequate report of their needling methods, which limits the reproducibility of their interventions.^{7–10} In contrast, a standardised manual for acupuncture has been developed worldwide that reports detailed instructions for the treatment at individual acupuncture points, thereby providing well-established information on the location, depth and stimulating method.¹² Research on acupuncture has been required to provide rigorous methodological aspects and to be reported in a structured form for ensuring transparency and replication of the study results as well.¹⁵ Detailed guidelines for the practice and reporting of clinical trials are encouraged to ensure safe and effective use of IMS.

Our review has a number of important limitations. Although a considerable effort was made to retrieve all RCTs on the subject, we cannot be certain that our search was exhaustive. Moreover, selective publishing and reporting are other major causes of bias that should be considered. It is conceivable that several negative RCTs remain unpublished and may thus distort the overall understanding of IMS. Further limitations include the paucity and often suboptimal methodological quality of the primary data. These factors influence both the quality and quantity of research. In total, these factors limit the conclusiveness of this systematic review.

Further RCTs of IMS for healthcare should adhere to the accepted standards of trial methodology. In particular, trials should have sufficiently large sample sizes, based on formal power calculations, and include appropriately long treatment periods and treatment frequencies. They should also describe all aspects of their methodology according to STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA),¹⁵ even though IMS claims to be different from acupuncture, and CONSORT procedures in full detail to ensure reproducibility.¹⁶ The employment of validated primary outcome measures is another important issue for assessing the effectiveness or efficacy of these types of therapeutic modalities. Furthermore, the development of appropriate sham or placebo controls and protocols for

blinding should be considered when assessing and reporting on the success of the blinding procedures. Therefore, large-scale rigorous studies are needed to establish whether IMS has a definite therapeutic value for specific conditions.

In conclusion, the results of this systematic review do not provide conclusive evidence in support of IMS for several conditions. Although the trial data are positive for chronic tension-type headaches, for MPS of the upper trapezius muscle and lower back pain, too many important caveats—including small sample size and only one RCT for each condition—exist to draw firm conclusions.

Summary points

- ▶ Intramuscular stimulation (IMSO is a needling technique for treating chronic pain.
- ▶ Four RCTs provide some support for its effectiveness, but not conclusive.

Contributors THK conducted systematic review, wrote a draft and participated in revision. CRL participated in data extraction. TYC participated in Chinese database searching, data extraction and evaluation of the risk of bias. MSL conducted this review and participated in writing and revising this manuscript.

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Competing interests None.

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REFERENCES

1. **Gunn CC.** *The Gunn approach to the treatment of chronic pain, intramuscular stimulation for myofascial pain of radiculopathic origin.* 2nd edn. New York: Churchill Livingstone, 1996.
2. **Del Moral OM.** Dry needling treatments for myofascial trigger points. *J Musculoskel Pain* 2010;18:411.
3. **Williams T.** Colorado Physical Therapy Licensure Policies of the Director. *Policy 3: Director's policy on intramuscular stimulation.* Denver, CO: State of Colorado: Department of Regulatory Agencies, 2005.
4. **Dommerholt J,** Del Moral OM, Christian Gröbli P. Trigger point dry needling. *J Manual Manipulative Ther* 2006;14:E70–87.
5. **Lim SM,** Seo KH, Cho B, *et al.* A systematic review of the effectiveness and safety of intramuscular stimulation therapy. *J Korean Med Assoc* 2011;54:1070–80.
6. **Higgins J,** Green SE. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.0 (updated February 2008). The Cochrane Collaboration, 2008.
7. **Ahn SL,** Woo JW, Kim JA, *et al.* A comparison of NSAID and intramuscular stimulation therapy effectiveness in the female patient with chronic shoulder pain. *J Korean Geriatr Soc* 2002;6:55–66.
8. **Gunn CC,** Milbrandt WE, Little AS, *et al.* Dry needling of muscle motor points for chronic low-back pain: a randomized clinical trial with long-term follow-up. *Spine* 1980;5:279–91.
9. **Karakurum B,** Karaalın O, Coskun Ö, *et al.* The 'dry-needle technique': intramuscular stimulation in tension-type headache. *Cephalalgia* 2001;21:813–17.
10. **Byeon HT,** Park SH, Ko MH, *et al.* Effects of intramuscular stimulation in myofascial pain syndrome of upper trapezius muscle. *J Korean Acad Rehabil Med* 2003;27:753–6.
11. **White A,** Cummings TM, Filshie J. *An introduction to Western medical acupuncture.* Edinburgh: Churchill Livingstone/Elsevier, 2008.
12. **WHO Regional Office for the Western Pacific.** *WHO standard acupuncture point locations in the Western Pacific region.* Manila: World Health Organization, 2008.
13. **Anon.** NIH consensus conference. Acupuncture. *JAMA* 1998;280:1518–24.
14. **White A.** Towards greater safety in acupuncture practice—a systems approach. *Acupunct Med* 2004;22:34–9.
15. **MacPherson H,** Altman DG, Hammerschlag R, *et al.* Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement. *PLoS Med* 2010;7:e1000261.
16. **Schulz KF,** Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Obstet Gynecol* 2010;115:1063–70.



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