NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review consultation document

Review of Clinical Guideline (CG88) – Low back pain: early management of persistent non-specific low back pain

1. Background information

Guideline issue date: 2009
3 year review: 2012 (first review)
National Collaborating Centre: National Clinical Guidelines Centre (formally National Collaborating Centre for Primary Care)

2. Consideration of the evidence

Literature search

Through an assessment of abstracts from a high-level randomised control trial (RCT) search, new evidence was identified relating to the following clinical areas within the guideline:

- Assessment and imaging using X-ray and MRI
- Information, education and patient preferences
- Physical activity and exercise (including exercise programmes; yoga; physiotherapy; combined exercise and physiotherapy; combined exercise, manual therapy and education; group vs. individual exercise)
- Manual therapy for low back pain
- Other non-pharmacological therapies (including low-level laser therapy; home-based rehabilitation programmes; McKenzie method; manual material handling; chiropractic interventions; and traditional bone setting; massage therapy and low-frequency vibrating board therapy)

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balneotherapy; neuroflexotherapy; wet-cupping care; electrotherapy; traction; lumbar support and thermal mineral water

- Invasive procedures (including injections; acupuncture alone or combined with transcutaneous electrical nerve stimulation)
- Psychological interventions and combined physical and psychological therapy
- Pharmacological therapy (including NSAIDs and new drugs such as methylprednisolone acetate)
- New areas not currently covered by the guideline including:
  - Management of low back pain in primary care using a stratified approach incorporating use of prognostic screening with matched pathways
  - Implementation of an integrated care programme for patients sick listed with chronic low back pain

Through this stage of the process, a sufficient number of studies relevant to the clinical areas above were identified from the high level RCT search to allow an assessment for a proposed review decision and are summarised in Table 1 below.

From initial intelligence gathering, qualitative feedback from other NICE departments, the views expressed by the Guideline Development Group, as well as the high-level RCT search, additional focused literature searches were also conducted for the following clinical areas:

- The optimal frequency and duration of exercise for people with persistent non-specific low back pain
- The optimal frequency and duration of combined physical and psychological interventions for people with persistent non-specific low back pain
- The effectiveness and cost effectiveness of psychological treatments for non-specific low back pain greater than six weeks

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• The effectiveness/cost effectiveness of injections including facet joint injections, radiofrequency lesioning or nerve blocks for people with persistent non-specific low back pain compared with usual care or sham on functional disability, pain or psychological distress

• The clinical and cost effectiveness of using screening protocols to target treatments for patients with non-specific low back pain

The results of the focused searches are also summarised in Table 2 below. All references identified through the high-level RCT search, initial intelligence gathering and the focused searches can be viewed in Appendix 1.
Table 1: Summary of articles from the high level RCT search

<table>
<thead>
<tr>
<th>Clinical area 1: Assessment and imaging of non-specific low-back pain</th>
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</thead>
<tbody>
<tr>
<td>Clinical question</td>
</tr>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of</td>
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<tr>
<td>performing X-ray or MRI compared with no investigation to</td>
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<tr>
<td>improve functional disability, pain or psychological distress?</td>
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<tr>
<td>Relevant section of guideline</td>
</tr>
<tr>
<td>4.3 X-ray and MRI</td>
</tr>
</tbody>
</table>

Summary

In summary, the identified new evidence supports the current guideline recommendation which states:

- Do not offer X-ray of the lumbar spine for the management of non-
### 4.2.1 to 4.2.4 Specific Low Back Pain

<table>
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<tr>
<th>Clinical area 2: Information, education and patient preferences</th>
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</thead>
<tbody>
<tr>
<td><strong>Clinical question</strong></td>
</tr>
<tr>
<td>Q: What is the effectiveness of advice to maintain normal physical activity/general exercise levels compared with no advice or advice to rest on pain, functional disability or psychological distress?</td>
</tr>
<tr>
<td>Q: What is the effectiveness/cost effectiveness of advice to increase self directed</td>
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</table>
### Relevant section of guideline
6.2 Exercise Advice

### Recommendations
6.1.1 to 6.1.4

| physical activity/general exercise compared with no advice or advice to rest on pain, functional disability or psychological distress? |
| more studies investigating PNE by different research groups to support early promising findings. |
| - The effect of advice on bed rest and staying active for patients with acute low back pain or sciatica was assessed in a systematic review. For patients with acute low back pain, two studies suggested that advice to stay active lead to a small improvement in pain relief whilst, for patients with sciatica, there was little or no difference between those who received advice to rest in bed or stay active. |

### Summary
In summary, the identified new evidence evaluated different interventions in different populations and, as such, there is currently insufficient evidence to support the choice of one patient education intervention over another. In general, however, the studies indicated some improvement in patients with low back pain who received educational advice whilst a systematic review reported that advice to stay active lead to a small improvement in pain relief. As such, the identified new evidence is unlikely to change the direction of the current guideline recommendations which...
state:
- Provide people with advice and information to promote self-management of their low back pain
- Offer educational advice that:
  - Includes information on the nature of non-specific low back pain
  - Encourages the person to be physically active and continue with normal activities as far as possible

### Clinical area 3: Physical activity and exercise

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the effectiveness/cost effectiveness of general supervised exercise programmes or specific exercise training programmes (individual)</td>
<td>Through an assessment of the abstracts from the high-level RCT search, 28 studies relevant to the clinical questions covered in this clinical area of the guideline were identified. Exercise programmes (13 studies) - A systematic review examined the effectiveness of exercise in decreasing low back pain incidence and intensity and the impact of low back pain and disability. The results of the review indicated that</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
</tbody>
</table>
or group) compared with usual care on functional disability, pain or psychological distress?

Q: What is the effectiveness/cost effectiveness of general or specific group exercise training programmes compared with general or specific individual exercise programmes on functional disability, pain or psychological distress?

Relevant section of exercise is effective in reducing the severity of lower back pain however, further research is needed to clarify which exercises are effective.

- One RCT assessed the relative efficacy of supervised exercise, spinal manipulation, and home exercise for the treatment of chronic low back pain. The results showed that for chronic low back pain, supervised exercise was better than chiropractic spinal manipulation and home exercise in terms of satisfaction with treatment, trunk muscle endurance and strength. However, the differences for these individual outcomes were relatively small and not statistically significant.

- One RCT investigated the efficacy of motor control exercise vs. placebo for people with chronic low back pain. The authors concluded that motor control exercise produced short-term improvements in global impression of recovery and activity, but not pain.

- The effectiveness of aquatic exercise interventions with land-based exercises in the treatment of chronic low back pain was evaluated in an RCT. It was concluded that water-based exercises produced...
<table>
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<tr>
<td>6.3 Exercise Programmes</td>
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<tr>
<td><strong>Recommendations</strong> 6.1.1 to 6.1.4</td>
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- Better improvement in disability and quality of life in the patients with chronic low back pain than land-based exercise.
  - One small-scale RCT compared resistance training (RT) with aerobic training (AT) in patients with chronic nonspecific low-back pain.\(^9\) The results of the study indicated that participants in the RT group experienced improvements in pain, disability and quality of life outcomes compared with the AT group.
  - One RCT investigated whether strain-counterstrain treatment combined with exercise therapy was more effective than exercise alone in reducing levels of pain and disability in people with acute low back pain.\(^10\) The results showed that there was no advantage in providing strain-counterstrain treatment to patients with acute low back pain, although it is suggested that further studies could examine whether a subset of these patients can benefit from the treatment.
  - A small-scale RCT investigated the effect of pelvic floor muscle (PFM) exercise vs. routine treatment in the treatment of chronic low back pain in women.\(^11\) The results showed that PFM exercise combined with routine treatment was not superior to routine...
treatment alone in patients with chronic low back pain.

- One systematic review investigated whether exercise is more effective than usual care in reducing work disability in patients with non-acute non-specific low back pain, and if so, to explore which type of exercise is most effective.\(^\text{12}\) The authors concluded that exercise interventions had a significant beneficial effect on work disability in patients with non-acute non-specific low back pain in the long term although no conclusions could be made regarding exercise types.

- One RCT evaluated the effect of a graded exercise intervention vs. daily walks in patients with nonspecific, recurrent low back pain.\(^\text{13}\) The results showed that a graded exercise intervention for patients with recurrent low back pain still at work seems more effective in improving disability and health parameters than daily walks.

- A pilot RCT compared disability, physical functional capacity, and pain outcomes at 2, 6, and 12 months for two conventional and one novel physical therapy (functional movement training) for recurrent low back pain.\(^\text{14}\) The authors concluded that further large scale trials are warranted to determine whether an intervention based on
functional movement training is superior to a conventional, impairment-based intervention for individuals with recurrent low back pain.

- One RCT compared the effectiveness of an isokinetic exercise programme and a standard exercise programme in patients with chronic low back pain.\(^ {15}\) The results of the study indicated that isokinetic and standard exercise programmes were equally effective in the treatment of low back pain.

- One RCT investigated the effectiveness of home-based exercise vs. control group (given nonsteroidal anti-inflammatory drugs (NSAIDs)) in Japanese individuals with chronic low back pain.\(^ {16}\) The study showed that the home-based exercise prescribed and monitored by board-certified orthopaedic surgeons was more effective than NSAIDs in this population.

- The effect of an individualised functional training programme vs. standard care for patients with low back pain was evaluated in an RCT.\(^ {17}\) The study concluded that an individualised functional training programme benefited patients with low back pain.
In summary, the identified new evidence on exercise programmes generally indicated that exercise has a beneficial effect in people with low back pain. However, as the studies evaluated different types of exercise and reported different outcomes it is not possible to confirm the choice of one exercise intervention over another.

Yoga (Six studies)

- A small-scale RCT assessed the efficacy of yoga vs. usual care for the treatment of chronic low back pain.\(^{18}\) The yoga group experienced a reduction in back pain at the four week follow-up but no significant differences between groups were observed for any other clinical outcomes.
- One pilot RCT assessed the feasibility and effectiveness of studying yoga in a predominantly ethnic minority (English speaking adults in Boston) population with chronic low back pain.\(^{19}\) The results showed that a yoga study intervention in a predominantly ethnic minority population with chronic low back pain may be more effective than usual care for reducing pain and pain medication use.
- The efficacy of yoga in improving function and reducing symptoms
compared with conventional stretching exercises or a self-care book for primary care patients with chronic low back pain was evaluated in an RCT.\textsuperscript{20} The study showed that yoga classes were more effective than a self-care book, but not more effective than stretching classes.

- One RCT compared the effectiveness of yoga and usual care for chronic or recurrent low back pain.\textsuperscript{21} The results showed that offering a 12-week yoga programme to adults with chronic or recurrent low back pain led to greater improvements in back function than did usual care. However, there were missing data for the primary outcome (yoga group, n = 21; usual care group, n = 18) and differential missing data (more in the yoga group) for secondary outcomes.

- One RCT evaluated Iyengar yoga therapy vs. usual care on chronic low back pain.\textsuperscript{22} The authors concluded that yoga improves functional disability, pain intensity, and depression in adults with chronic low back pain when compared to standard medical care at six months post-intervention.

- One systematic review assessed the effectiveness of yoga as a
treatment option for low back pain. The authors concluded that yoga had the potential to alleviate low back pain although further research is required to confirm the findings.

In terms of yoga, the evidence identified showed clinical effectiveness in improving outcomes in patients with low back pain but some studies concluded that results should be treated with caution and report missing data. Additional evidence is required which compares the effectiveness of yoga therapy with other exercise programmes in order to support the choice of one intervention over another. As such, the identified new evidence is unlikely to change the current guideline recommendation which indicates that postural control and stretching may be included in exercise programmes:

- Exercise programmes may include the following elements:
  - Aerobic activity
  - Movement instruction
  - Muscle strengthening
  - Postural control
  - Stretching
Physiotherapy (Five studies)

- One study compared the outcomes of two different physiotherapeutic approaches to treatment of low back pain: a customised holistic physiotherapy programme of treatment (based on postisometric relaxation of muscles and ligaments, active mobilisation of the spine, Kibler Fold mobilisation, Kinesiology Taping and Maigne's relaxing exercises) vs. the control group treatment (electrotherapy procedures and performance of a set of exercises usually recommended for low back pain). The results confirmed that a customised holistic physiotherapy was more effective in reducing low back pain compared with the control group.
- A systematic review investigated whether physiotherapist-provided operant conditioning (POC) was more effective than comparison interventions in reducing low back pain disability. The authors concluded that POC may be considered efficacious in the treatment of low back pain, but further trials would be advised to validate the findings.
- One RCT compared long-term functional and work status after 3-
week functional multidisciplinary rehabilitation or 18 supervised outpatient physiotherapy sessions. The results showed that functional multidisciplinary rehabilitation was better than outpatient physiotherapy in improving functional and work status.

- A controlled study assessed the effectiveness of physiotherapy treatment based on the muscular and articular chains Godelive Denys-Struyf (GDS) method for nonspecific low back pain in primary care. The results showed that treatment of nonspecific low back pain using the GDS method provides greater improvements in the midterm.

- One study investigated the effectiveness of a functional restoration programme (FRP), including intensive physical training and a multidisciplinary approach, with an outpatient active physiotherapy program. The authors concluded that both programmes are efficient in reducing disability and sick-leave days and that the FRP was significantly more effective in reducing sick-leave days.

In terms of physiotherapy, the identified new evidence evaluated a variety of physiotherapy programmes, all involving different components and
reporting different outcomes. As such, it would be pertinent to wait for additional evidence focusing on the benefits and harms of physiotherapy for people with low back pain before updating the guideline.

**Group versus individual exercise (Two studies)**

- One study compared the efficacies of two active therapies (group-based multidisciplinary biopsychosocial rehabilitation vs. intensive individual therapist-assisted back muscle strengthening exercises) for chronic low back pain (CLBP). The results showed that both groups showed long-term improvements in pain and disability scores, with only minor statistically significant differences between the 2 groups.

- One study examined the efficacies of a group-based multidisciplinary rehabilitation program and oral drug treatment versus oral drug treatment alone in Iran. The findings revealed that the group-based multidisciplinary program could improve most domains of quality of life in chronic low back pain patients in the 6-month period.
The evidence on group vs. individual exercise was conflicting with one study showed effectiveness whilst the other did not. Further trial evidence would be required to confirm either finding. This is in keeping with the current recommendations in the guideline, as both group and individual sessions are already recommended.

Combined Exercise and Physiotherapy (One study)

- One study examined the effect of adding aerobic exercise to conventional physiotherapy treatment for patients with chronic low back pain in reducing pain and disability. The study showed that the addition of aerobic training to conventional physiotherapy treatment did not enhance either short- or long-term improvement of pain and disability in patients with chronic low back pain.

Combined Exercise, Manual Therapy and Education (One study)

- One study evaluated the effect of a multimodal physical therapy program with or without the addition of deep-water running on pain, physical disability, and general health. The authors concluded that pain, disability, health status, muscle strength and endurance, and lumbar range of motion significantly improved in both groups.
Only single trials were identified for combined exercise, manual therapy and education and combined exercise and physiotherapy therefore, further evidence is needed to validate the findings.

**Summary**

In summary, the identified new evidence on exercise programmes generally indicated that exercise has a beneficial effect in people with low back pain. However, as the studies evaluated different types of exercise and reported different outcomes it is not possible to confirm the choice of one exercise intervention over another. As such, the identified new evidence is unlikely to change the current guideline recommendations relating to physical activity and exercise:

- Advise people with low back pain to exercise
- Consider offering a structured exercise programme tailored to the person
- Exercise programmes may include the following elements:
  - Aerobic activity
  - Movement instruction
  - Muscle strengthening
Postural control
- Stretching

This area will be examined again in the next review of the guideline.

Clinical area 3: Manual therapy

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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</table>
| Q: What is the effectiveness/cost effectiveness of manual therapies compared with usual care on functional disability, pain or psychological distress? | Through an assessment of the abstracts from the high-level RCT search, nine studies relevant to the clinical questions covered in this clinical area of the guideline were identified. **Spinal manipulation (Nine studies)**  
- One RCT compared spinal manipulation, back school and individual physiotherapy in the treatment of chronic low back pain. The study showed that spinal manipulation provided better short and long-term functional improvement, and more pain relief in the follow-up than either back school or individual physiotherapy.  
- One systematic review assessed the current scientific literature related to spinal manipulation therapy for acute low back pain. | No new evidence was identified which would invalidate current guideline recommendation(s). |
<table>
<thead>
<tr>
<th>Relevant section of guideline</th>
<th>Recommendations</th>
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<tbody>
<tr>
<td>7.3 Manual Therapy – Effectiveness</td>
<td>Results suggested that five to ten sessions of spinal manipulative therapy administered over two to four weeks achieve equivalent or superior improvement in pain and function when compared with other commonly used interventions.</td>
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<td>• One RCT investigated whether manipulative therapy as part of a multidimensional approach may be more effective than standard physical therapy in treating acute nonspecific low back pain. The results showed a statistical significant effect for disability, but no statistically significant benefit of additional manipulative therapy over physical therapy found for pain and mobility.</td>
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<td>• An RCT examined the generalisability of three different manual therapy techniques in a patient population with low back pain that satisfy a clinical prediction rule (CPR). The results of the study supported the generalisability of the CPR to another thrust manipulation technique used in this study, but not to the nonthrust manipulation technique. However, additional research is needed to examine this issue.</td>
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<td>• One RCT compared the effects of two biomechanically distinct forms of spinal manipulation and minimal conservative medical care</td>
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</table>
(MCMC) for participants with sub acute or chronic nonradicular low back pain. The results showed that biomechanically distinct forms of spinal manipulation did not lead to different outcomes in older low back pain patients.

- One RCT investigated whether treatment with spinal manipulative therapy administered in addition to standard care is associated with clinically relevant early reductions in pain and analgesic consumption. The authors concluded that spinal manipulative therapy was unlikely to result in relevant early pain reduction in patients with acute low back pain.

- A Cochrane systematic review assessed the effects of spinal manipulative therapy for chronic low-back pain. The results suggested that spinal manipulative therapy has a small, significant, but not clinically relevant, short term effect on pain relief.

- One RCT assessed the effectiveness of spinal manipulation therapy vs. sham therapy for the management of chronic nonspecific low back pain. The authors concluded that spinal manipulative therapy was effective for the treatment of chronic nonspecific low back pain.

- An RCT assessed whether military health care beneficiaries with
low back pain who are likely to respond successfully to spinal manipulation experience a difference in short-term clinical outcomes. The results showed that the two manipulation techniques (lumbopelvic or lumbar neutral gap manipulation) used in this study were equally effective at reducing pain and disability when compared at 48 hours post treatment.

**Summary**

In terms of effectiveness of manual therapy, the identified evidence generally indicated that spinal manipulation therapy was beneficial in managing patients with low back pain, although some studies suggested that it was not effective. As such, further consistent evidence is required to change the direction of the current guideline recommendation which states:

- Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks

This area will be examined again in the future review of the guideline.
Clinical area 4: Other non-pharmacological therapies (Electrotherapy modalities)

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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</thead>
</table>
| Q: What is the effectiveness and cost effectiveness of electrotherapy modalities compared with usual care or sham on functional disability, pain or psychological distress? | Through an assessment of the abstracts from the high-level RCT search, two studies relevant to the clinical question covered in this clinical area of the guideline were identified.  
   - An RCT compared the effectiveness of dynamic transcutaneous electrostimulation vs. placebo in patients with low back pain. The results showed some effectiveness but further trials are required to validate these findings.  
   - One study evaluated the efficacy of microcurrent therapy (MCT) vs. a placebo patch in treating a specific, chronic low-back pain. The authors reported a positive trend in MCT use for specific chronic low-back pain. Further investigations are required to evaluate the significance and relevance of this. | No new evidence was identified which would invalidate current guideline recommendation(s). |

Relevant section of guideline
8.3 Electrotherapy modalities

Recommendations
The studies on electrotherapy modalities revealed that dynamic
### Clinical area 5: Other non-pharmacological therapies (Transcutaneous nerve stimulation)

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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<tbody>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of transcutaneous electrical nerve stimulation (TENS) compared with usual care or sham on functional disability, pain or psychological</td>
<td>Through an assessment of the abstracts from the high-level RCT search, one study relevant to the clinical question covered in this clinical area of the guideline was identified.</td>
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<tr>
<td></td>
<td>- This study compared the effects of transcutaneous electrical nerve stimulation (TENS) and interferential current among patients with nonspecific chronic low back pain. The study results revealed that there was no difference between TENS and interferential current for chronic low back pain treatment.</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
</tbody>
</table>
### Relevant section of guideline
8.4 Transcutaneous Electrical Nerve Stimulation (TENS)

### Recommendations
8.2.4

### Clinical question
Q: What is the effectiveness and cost effectiveness of lumbar supports compared with usual care or sham on functional disability, pain distress?

### Summary
The evidence on transcutaneous electrical nerve stimulation (TENS) showed there was no clinical effectiveness for chronic low back pain treatment. This evidence is in keeping with the current guideline recommendation which states:

- Do not offer transcutaneous electrical nerve stimulation (TENS)

### Clinical area 6: Other non-pharmacological therapies (Lumbar supports)

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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</thead>
</table>
| Q: What is the effectiveness and cost effectiveness of lumbar supports compared with usual care or sham on functional disability, pain distress? | Through an assessment of the abstracts from the high-level RCT search, three studies relevant to the clinical question covered in this clinical area of the guideline were identified.  
- One RCT evaluated the effects of an elastic lumbar belt vs. a control group on functional capacity and pain intensity in low back pain. | No new evidence was identified which would invalidate current guideline recommendation(s). |
<table>
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<tr>
<th>or psychological distress?</th>
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**Relevant section of guideline**

8.5 Lumbar Supports

**Recommendations**

8.2.4 pain treatment. The results of the study indicated that physical restoration improved more in the lumbar belt group compared with the control group.

- One small-scale study investigated the effects of Kinesio Taping (KT) vs. KT plus exercise or exercise alone on pain, disability and lumbar muscle function in sufferers of chronic low back pain. The results of the study demonstrated a significant reduction in pain after treatment in all three groups.

- An economic evaluation assessed the cost-effectiveness of wearing a lumbar support for home care workers with recurrent low back pain. The results showed that lumbar support seems to be a cost-effective addition to usual care for home care workers with recurrent low back pain. There is a need for more evidence to confirm these findings.

**Summary**

In terms of lumbar supports, the evidence suggested that elastic lumbar belt and Kinesio Taping revealed some clinical and cost effectiveness. However, further large scale trials are required to confirm these findings.
As such, it would be premature to consider updating the current guideline recommendation relating to lumbar supports. This area will be examined again in the next review of the guideline.

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<tr>
<th>Clinical area 7: Other non-pharmacological therapies (Traction)</th>
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<tbody>
<tr>
<td><strong>Clinical question</strong></td>
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</table>
| Q: What is the effectiveness and cost effectiveness of traction compared with usual care or sham on functional disability, pain or psychological distress? | Through an assessment of the abstracts from the high-level RCT search, one study relevant to the clinical question covered in this clinical area of the guideline was identified.  
- An RCT investigated the effect of intervertebral differential dynamics therapy (consisting of intermittent traction sessions) when added to a standard graded activity program for chronic low back pain patients. An improvement in low back pain, leg pain and quality of life was observed in both the intervention and the control group. | No new evidence was identified which would invalidate current guideline recommendation(s). |

**Summary**  
In terms of evidence on traction, intervertebral differential dynamics therapy was found to be as equally effective as a SHAM protocol.
**Recommendations**

8.2.6

Therefore, this new evidence would not change the direction of the current guideline recommendation which states:

- Do not offer traction

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**Clinical area 8: Invasive procedures (Acupuncture)**

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<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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<tbody>
<tr>
<td>Q: What is the effectiveness/cost effectiveness of acupuncture (including PENS and neuroreflexotherapy) compared with usual care or sham on functional disability, pain or psychological distress?</td>
<td>Through an assessment of the abstracts from the high-level RCT search, seven studies relevant to the clinical question covered in this clinical area of the guideline were identified.</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
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</table>

**Acupuncture (Six studies)**

- One study investigated the importance of needle placement and skin penetration in eliciting acupuncture effects for patients with chronic low back pain.\(^{49}\) The authors concluded that acupuncture was effective for chronic low back pain.

- One study investigated if laser acupuncture is more effective than sham laser in reducing pain and disability in adults with chronic non-specific low back pain.\(^{50}\) This study did not reveal a specific effect for laser acupuncture using infrared laser at 0.2 Joules per point for

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<th>chronic low back pain.</th>
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<tr>
<td>9.2 Acupuncture and related treatments</td>
<td>- One study compared the effectiveness of repeated acupuncture stimulation and local anaesthetic injection at the most painful points in patients with low back pain. The study showed that both injection and acupuncture relieved pain, but acupuncture was superior for the immediate and sustained effects.</td>
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<tr>
<td>Recommendations 9.1.1</td>
<td>- One study assessed the difference in effectiveness of pain relief between pulsed radiofrequency and electro-acupuncture. The study reported evidence of effectiveness for the pulsed radiofrequency therapy for low back pain relief compared with both electro-acupuncture therapy and the control group.</td>
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<td>- One study evaluated the efficacy, harms, and costs of the most common CAM treatments (acupuncture, massage, spinal manipulation, and mobilization) for low-back pain. The study showed that CAM treatments were significantly more efficacious than no treatment, placebo, physical therapy, or usual care in reducing pain immediately or at short-term after treatment.</td>
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<td>- One study examined the effectiveness and costs of acupuncture in addition to routine care in the treatment of chronic low back pain</td>
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</table>
The findings in the study suggest that acupuncture collaborative therapy for patients with chronic low back pain was cost-effective.

**Acupuncture and TENS combined (One study)**

- One study investigated whether a combined treatment of acupuncture and transcutaneous electrical nerve stimulation (TENS) is more effective than acupuncture or TENS alone for treating chronic low back pain. The authors concluded that combined acupuncture and TENS treatment was effective in respect of pain relief and quality of life for the sample of patients suffering from chronic low back pain. Further large trials are required to confirm this finding.

**Summary**

In terms of acupuncture, the identified new evidence evaluated different interventions and included different control groups. Although, several studies indicated that the use of acupuncture to treat patients with low back pain is clinically and cost effective. Therefore, currently there is insufficient consistent new evidence to update the following guideline.
recommendation:
- Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks

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<th>Clinical area 9: Invasive procedures (Injections)</th>
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<tr>
<td><strong>Clinical question</strong></td>
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<tr>
<td>Q: What is the effectiveness/cost effectiveness of injections including facet joint injections, radiofrequency lesioning or nerve blocks for people with persistent non-specific low back pain compared with usual care or sham on functional disability, pain</td>
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</table>
or psychological distress?

**Relevant section of guideline**
9.3 Injections

**Recommendations**
9.1.2

**Clinical area 10: Psychological interventions and mixed packages of care (combined physical and psychological interventions)**

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<thead>
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<th>Summary of evidence</th>
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<tbody>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of psychological treatments for non-specific low back pain</td>
<td>Please refer to focus search Question 3 in Table 2 below.</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
</tbody>
</table>

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greater than six weeks?

**Relevant section of guideline**
10.4 Psychological Interventions

**Recommendations**
10.2.1 to 10.2.2

<table>
<thead>
<tr>
<th>Clinical area 11: Combined physical and psychological therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical question</strong></td>
</tr>
<tr>
<td>Q: What is the effectiveness/cost effectiveness of combined physical and psychological interventions compared with usual care/other</td>
</tr>
<tr>
<td><strong>Summary of evidence</strong></td>
</tr>
<tr>
<td>Through an assessment of the abstracts from the high-level RCT search, one study relevant to the clinical question covered in this clinical area of the guideline was identified.</td>
</tr>
<tr>
<td>- This study examined whether the addition of motivational enhancement treatment to conventional physical therapy produces better outcomes than physical therapy alone in people with chronic pain.</td>
</tr>
<tr>
<td><strong>Relevance to guideline recommendations</strong></td>
</tr>
<tr>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
<tr>
<td>interventions on functional disability, pain or psychological distress?</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Relevant section of guideline</strong></td>
</tr>
<tr>
<td>10.5 Combined Physical and Psychological Therapy</td>
</tr>
<tr>
<td><strong>Recommendations</strong></td>
</tr>
<tr>
<td>10.2.1 to 10.2.2</td>
</tr>
<tr>
<td>Clinical area 12: Pharmacological therapies (NSAIDS)</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td><strong>Clinical question</strong></td>
</tr>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of oral NSAIDS compared with placebo, paracetamol, anti-depressants or opioids on functional disability, pain or psychological distress?</td>
</tr>
<tr>
<td><em>Relevant section of guideline</em></td>
</tr>
<tr>
<td>11.3 NSAIDs</td>
</tr>
<tr>
<td><strong>Recommendations</strong></td>
</tr>
<tr>
<td>11.2.1 to 11.2.10</td>
</tr>
</tbody>
</table>
### Clinical area 13: Pharmacological therapies (COX-2 inhibitors)

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
</table>
| Q: What is the effectiveness and cost effectiveness of COX-2 inhibitors compared with placebo, paracetamol, anti-depressants or opioids on functional disability, pain or psychological distress? | Through an assessment of the abstracts from the high-level RCT search, one study relevant to the clinical question covered in this clinical area of the guideline was identified.  
  
  - One study compared the analgesic efficacy, tolerability and safety of a non-steroidal anti-inflammatory drug (celecoxib) and an opioid (tramadol HCl) in subjects with chronic low back pain. The results showed that celecoxib was more effective than tramadol HCl in the treatment of chronic low back pain, with fewer adverse effects reported. | No new evidence was identified which would invalidate current guideline recommendation(s). |

**Relevant section of guideline**

11.3.3 COX-2 inhibitors

**Recommendations**

11.2.1 to 11.2.10

**Summary**

For COX-2 inhibitors, the evidence showed that celecoxib was effective. The current guideline recommends use of any COX-2 inhibitors therefore, these findings do not contradict the current guideline recommendations.
<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
</table>
| Q: What is the effectiveness and cost effectiveness of antidepressants compared with placebo, paracetamol, opioids or oral NSAIDS on functional disability, pain or psychological distress? | Through an assessment of the abstracts from the high-level RCT search, three studies relevant to the clinical question in this clinical area of the guideline were identified.  
- One RCT examined the efficacy of escitalopram compared with duloxetine for the treatment of chronic low back pain. The results of the study indicated that escitalopram and duloxetine demonstrated efficacy and safety in the management of chronic low back pain, with no significant differences. The authors concluded that this study should be replicated in a larger sample of patients to confirm the results.  
- One study assessed the efficacy and safety of duloxetine vs. placebo in the treatment of chronic low back pain. The study results indicated that duloxetine significantly reduced pain and improved functioning in patients with chronic low back pain.  
- A Cochrane systematic review assessed whether antidepressants | No new evidence was identified which would invalidate current guideline recommendation(s). |
are more effective than placebo for the treatment of non-specific low-back pain. The authors concluded that there was no clear evidence that antidepressants are more effective than placebo in the management of patients with chronic low back pain.

**Summary**

In terms of evidence on antidepressants, the studies revealed conflicting evidence with some studies suggesting escitalopram and duloxetine (a serotonin-norepinephrine reuptake inhibitor (SNRI)) to be effective. However, these are single trials, with few numbers of patients and results require further validation. A review concluded that there was no clear evidence that antidepressants were more effective. In summary, these findings do not contradict the current guideline recommendations.

**Clinical area 15: Pharmacological therapies (Opioids)**

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the effectiveness and cost</td>
<td>Through an assessment of the abstracts from the high-level RCT search, three studies relevant to the clinical question covered in this clinical area of</td>
<td>No new evidence was identified which would</td>
</tr>
<tr>
<td>effectiveness of opioids compared with placebo, paracetamol, antidepressants or oral NSAIDS on functional disability, pain or psychological distress?</td>
<td>Relevant section of guideline 11.4 Opioids</td>
<td>Recommendations 11.2.1 to 11.2.10</td>
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<tr>
<td>the guideline were identified.</td>
<td>One RCT assessed the efficacy and safety profile of a 7-day buprenorphine transdermal system (BTDS) in patients with moderate to severe chronic low back pain previously treated with &gt; or =1 tablet daily of an opioid analgesic.(^{62}) The results showed that BTDS was effective compared with placebo in the management of chronic, moderate to severe low back pain in patients who had previously received opioids.</td>
<td>One RCT evaluated the efficacy and safety of tapentadol vs. oxycodone or placebo extended release (ER) for the management of moderate to severe chronic low back pain.(^{63}) The results showed that tapentadol ER (extended release) effectively relieved moderate to severe chronic low back pain over 15 weeks and had better gastrointestinal tolerability than oxycodone hydrochloride.</td>
</tr>
</tbody>
</table>
that was similar to oxycodone HCl CR for the management low back pain.

Summary
For opioids, the evidence showed that tapentadol and the buprenorphine transdermal system were clinically effective. The current guideline recommends the use of weak and strong opioids taking into account patient’s preference and requirements. As such, the identified new evidence does not contradict the current guideline recommendations.

Clinical area 16: Pharmacological therapies

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of pharmacological therapies compared with placebo, paracetamol,</td>
<td>Through an assessment of the abstracts from the high-level RCT search, three studies relevant to the clinical question covered in this clinical area of the guideline were identified. Systematic reviews (Two studies) • One systematic review assessed the effectiveness of</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
</tbody>
</table>
antidepressants or oral NSAIDS on functional disability, pain or psychological distress?

Relevant section of guideline
11 Pharmacological therapies

Recommendations
11.2.1 to 11.2.10

| Pharmacological interventions (including non-steroid anti-inflammatory drugs (NSAIDs), muscle relaxants, antidepressants, and opioids) for non-specific chronic low back pain. The authors concluded that the overall quality of the evidence was poor and NSAIDs and opioids seem to lead to a somewhat higher relief in pain in the short term compared to placebo, in patients with non-specific chronic low back pain. There seemed to be no difference in effect between antidepressants and placebo.
| A meta-analysis was identified which aimed to estimate the analgesic effects of treatments for non-specific low back pain reported in placebo-controlled randomised trials. The results showed that the analgesic effects of many treatments for non-specific low back pain are small and that they do not differ in populations with acute or chronic symptoms.

New drug (One study)
| A pilot study investigated the effectiveness of caudal 40 vs. 80 mg methylprednisolone acetate (in 20 ml levobupivacaine 0.125%) in outpatients with chronic low back pain. The results showed that... |
there was no statistically significant difference between the dose groups in change in the Oswestry Disability Index.

**Summary**
Both the systematic reviews showed that there is weak evidence on clinical effectiveness of NSAIDs and opioids. However, further evidence is required to confirm the choice of one pharmacological therapy over another for low back pain.

<table>
<thead>
<tr>
<th>Clinical area 17: New areas not currently covered by the guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical question</strong></td>
</tr>
<tr>
<td>Relevant section of guideline</td>
</tr>
<tr>
<td>New areas not currently covered by the guideline</td>
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<tr>
<td></td>
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</tbody>
</table>

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that a stratified approach, by use of prognostic screening with matched pathways, will have important implications for the future management of back pain in primary care.

- One study evaluated the cost effectiveness, cost utility, and cost-benefit of an integrated care programme compared with usual care for sick listed patients with chronic low back pain.\(^6^9\) The authors concluded that implementation of an integrated care programme for patients sick listed with chronic low back pain has a large potential to significantly reduce societal costs, increase effectiveness of care, improve quality of life, and improve function on a broad scale.

**Physical therapy (Two studies)**

- One study evaluated the short-term effect of adding the McKenzie method to the first-line care of patients with acute low back pain.\(^7^0\) The authors concluded that when added to the currently recommended first-line care of acute low back pain, a treatment programme based on the McKenzie method does not produce appreciable additional short-term improvements.

- One study investigated the effectiveness of traditional bone setting
compared with conventional physical and exercise therapy in treating chronic low back pain.\textsuperscript{71} The result showed that the long-term dynamics of pain and disability did not differ between the groups.

**Water therapy (Two studies)**
- One study evaluated the effects of balneotherapy vs. physiotherapy only in patients with chronic low back pain.\textsuperscript{72} The results of the study showed that besides conventional physiotherapy, balneotherapy may be effective in the treatment of patients with chronic low back pain.
- One study evaluated the effectiveness of thermal mineral water, compared with tap water in the treatment of low back pain.\textsuperscript{73} The authors concluded that in the group treated with thermal water, improvement occurred earlier, lasted longer and was statistically significant.

**Combination therapies (Two studies)**
- One study undertook a review to determine the effects of combined
chiropractic interventions (that is, a combination of therapies, other than spinal manipulation alone) in adults with low back pain. The results showed that there was currently no evidence that supports or refutes that these interventions provide a clinically meaningful difference for pain or disability in people with low back pain when compared to other interventions.

- One study assessed overall responses to treatments among non-specific low back pain patients in clinical trials to examine the pattern following a wide range of treatments. The results indicated that non-specific low back pain symptoms seemed to improve in a similar pattern in clinical trials following a wide variety of active as well as inactive treatments.

**Pharmacological therapies (One study)**

- One study investigated the efficacy and safety of the association of celecoxib and pregabalin (an anticonvulsant) compared with monotherapy of each as treatment for chronic low-back pain. The result showed that combination of celecoxib and pregabalin is more effective than monotherapy for chronic low-back pain, with similar
Laser therapy (One study)
- One study compared the effectiveness of low-level laser therapy on pain and functional capacity in patients with acute and chronic low back pain caused by lumbar disk herniation. The study showed that no significant differences were detected between four treatment groups with respect to all outcome parameters.

Rehabilitation programmes (One study)
- One study assessed the efficacy and treatment compliance of a home-based rehabilitation programme vs. standard physical therapy for chronic low back pain. The study concluded that a home-based rehabilitation programme is as effective as standard physical therapy.

Massage (One study)
- One study compared the effectiveness of two types of massage and usual care for chronic back pain. The results showed that...
massage therapy may be effective however, further studies are required to validate these findings.

**Vibrating board therapy (One study)**
- One study investigated whether a 12-week course of low-frequency vibrating board therapy is a feasible therapy for non-specific chronic low back pain. The authors concluded that a 12-week course of low-frequency vibrating board therapy is feasible and may represent a novel physical therapy for patients with non-specific low back pain but advise further research.

**Wet-cupping therapy (One study)**
- One pilot study determined the effectiveness and safety of wet-cupping treatment vs. control group for persistent non-specific low back pain. The results showed preliminary data in this pilot study on the effectiveness and safety of wet-cupping treatments for persistent non-specific low back pain.

**Patient advice (One study)**
One study undertook a review to investigate the effectiveness of manual material handling advice and training and the provision of assistive devices in preventing and treating back pain.\textsuperscript{82} The authors concluded that there was evidence that manual material handling advice and training with or without assistive devices does not prevent back pain or back pain-related disability.

**Neuroreflexotherapy (One study)**

- A Cochrane systematic review assessed the effectiveness of neuroreflexotherapy for the treatment of non-specific low back pain in adults.\textsuperscript{83} The authors concluded that neuroreflexotherapy appears to be a safe and effective intervention for the treatment of chronic non-specific low back pain. However, the review was limited to three trials conducted by a small number of specifically trained and experienced clinicians, in a limited geographical location.

**Summary**

In terms of new evidence on management of low back pain, a study suggested that a stratified approach, by using prognostic screening with
matched pathways, will have important implications for the future management of low back pain in primary care. Another study concluded that implementation of an integrated care programme for patients with chronic low back pain has a large potential to significantly reduce societal costs, increase effectiveness of care, improve quality of life, and improve function on a broad scale. However, these are single trials and further large scale trials would be needed to validate the findings.

In terms of other forms of treatments for low back pain, studies indicated that low-level laser therapy, a home-based rehabilitation programme, the McKenzie method, manual material handling, chiropractic interventions, and traditional bone setting did not show any clinical effectiveness. Conversely, massage therapy and low-frequency vibrating board therapy, balneotherapy, neuroreflexotherapy (NRT), wet-cupping care, and thermal mineral water showed some effectiveness but these studies are single trials with small number of participants. Further larger trials are required to validate these findings. Therefore, it may be pertinent to await further evidence, particularly on the benefits, harms and cost-effectiveness of these interventions for low back pain, before an update is commissioned.
These interventions will be examined again in the next review of this guideline.
Table 2: Summary of articles from the focused search

| Clinical area 1: The optimal frequency and duration of exercise for people with persistent non-specific low back pain. |
|---|---|---|
| Clinical question | Summary of evidence | Relevance to guideline recommendations |
| Q: What is the optimal frequency and duration of exercise for people with persistent non-specific low back pain? | Through an assessment of the abstracts from the focused searches, three studies relevant to the clinical question covered in this clinical area of the guideline were identified. | No new evidence was identified which would invalidate current guideline recommendation(s). |
| Relevant section of guideline | 6.0 Physical activity and exercise |
| Recommendations | 6.1.1 to 6.1.4 |  |
| - One RCT assessed the efficacy of a short education program and short physiotherapy program for treating low back pain in primary care. The authors concluded that the addition of a short (four sessions each lasting one hour) physiotherapy program composed of education on postural hygiene and exercise intended to be continued at home, increases improvements in those areas, although the magnitude of that increase is clinically irrelevant. |  |
| - One study assessed the cost-utility of a three month exercise programme vs. usual care after functional multidisciplinary rehabilitation in patients with chronic low back pain. The results showed that adding an exercise programme after functional |  |
multidisciplinary rehabilitation compared with usual care does not offer significant long-term benefits in quality of life and direct and indirect costs.

- One study investigated if the volume of periodised musculoskeletal rehabilitation influences strength, pain, disability, and quality of life in untrained persons. The results showed that the four day training per week for 13 weeks compared with three day, two day and no training was most effective at treating chronic low back pain. Further validations of the findings were advised by the authors.

Summary
Two studies did not reveal clinical and cost effectiveness of using shorter duration for the exercise programme whereas one study showed effectiveness of an exercise programme lasting 13 weeks. The latter is greater than what is currently recommended in the guideline (12 week programme). Due to the variability in the exercise interventions assessed in the new literature, further evidence is required to confirm the optimal length and components of a structured exercise programme for people with low back pain. As such, there is currently insufficient new evidence to
invalidate the following guideline recommendation:

- Consider offering a structured exercise programme tailored to the person:
  - This should comprise up to a maximum of eight sessions over a period of up to 12 weeks

**Clinical area 2: The optimal frequency and duration of combined physical and psychological interventions for people with persistent non-specific low back pain.**

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the optimal frequency and duration of combined physical and psychological interventions for people with persistent non-specific low back pain?</td>
<td>Through an assessment of the abstracts from the focused searches, no studies relevant to the clinical question covered in this clinical area of the guideline were identified.</td>
<td>No new evidence was identified which would invalidate current guideline recommendation(s).</td>
</tr>
</tbody>
</table>
### Clinical area 3: The effectiveness and cost effectiveness of psychological treatments for non-specific low back pain greater than six weeks.

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the effectiveness and cost effectiveness of</td>
<td>Through an assessment of the abstracts from the focused searches, four studies relevant to the clinical question covered in this clinical area of the guideline were identified.</td>
<td>No new evidence was identified which would invalidate current</td>
</tr>
<tr>
<td>Relevant section of guideline</td>
<td>Recommendations</td>
<td>Behavioural therapies (Two studies)</td>
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<tr>
<td>-------------------------------</td>
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<td>--------------------------------------</td>
</tr>
<tr>
<td>10.4 Psychological Interventions</td>
<td>10.2.1 to 10.2.2</td>
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<tr>
<td></td>
<td></td>
<td>- One study reviewed evidence to determine the effects of behavioural therapy for chronic low back pain and the most effective behavioural approach. The results showed that for patients with chronic low back pain, there is moderate quality evidence that in the short-term operant therapy appears more effective than waiting list and behavioural therapy. The report suggests that further research is required to validate these findings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- One study reviewed evidence to estimate the clinical effectiveness of active management in general practice versus active management plus a group-based, professionally led cognitive behavioural approach for subacute and chronic low back pain. The study results suggested that the cognitive behavioural approach was effective and cost-effective in treating subacute and chronic low back pain in the long-term.</td>
</tr>
<tr>
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<td></td>
<td>Self-management skills (One study)</td>
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<td>- One study evaluated the efficacy of a pilot interactive online intervention to teach self-management skills vs. wait list control for</td>
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</table>

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chronic lower back pain.\textsuperscript{88} The authors concluded that use of this pilot intervention had positive effects on a number of pain-related outcomes, including disability. In addition, the authors suggested that future research is required to evaluate the effectiveness of the completed intervention, with particular attention to quality of life and disability.

\textbf{Meditation (One study)}

- One study investigated the impact and feasibility of an eight-week mindfulness meditation programme for older adults with chronic low back pain versus an education control program.\textsuperscript{89} The results showed that both the intervention group and the education control group improved on outcome measures suggesting both programs had a beneficial effect.

\textbf{Summary}

New literature was identified relating to psychological treatments for non-specific low back pain. However, due to the variability in the types of psychological interventions assessed in the studies, further evidence is
required to confirm the optimal psychological treatment programme for people with low back pain. As such, there is currently insufficient new evidence to invalidate the current guideline recommendations.

Clinical area 4: The effectiveness/cost effectiveness of injections including facet joint injections, radiofrequency lesioning or nerve blocks for people with persistent non-specific low back pain compared with usual care or sham on functional disability, pain or psychological distress.

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
</table>
| Q: What is the effectiveness/cost effectiveness of injections including facet joint injections, radiofrequency lesioning or nerve blocks for people with persistent non-specific low back pain compared with usual care or sham on functional disability, pain or psychological distress. | Through an assessment of the abstracts from the focused searches, five studies relevant to the clinical question covered in this clinical area of the guideline were identified.  
- One study investigated the efficacy and safety of intramuscular methylcobalamin vs. placebo in the treatment of chronic nonspecific low back pain. The authors concluded that intramuscular methylcobalamin is both an effective and safe method of treatment for patients with nonspecific low back pain.  
- One study systematically reviewed evidence to determine the | No new evidence was identified which would invalidate current guideline recommendation(s). |
usual care or sham on functional disability, pain or psychological distress?

**Relevant section of guideline**
9.3 Injections

**Recommendations**
9.1.2

efficacy of prolotherapy in adults with chronic low back pain. The authors concluded that there was conflicting evidence regarding the efficacy of prolotherapy injections for patients with chronic low back pain.

- One study provided an evaluation of the current evidence associated with the use of injection therapy and denervation procedures. The authors concluded that there was only low to very low quality evidence to support the use of injection therapy and denervation procedures over placebo or other treatments for patients with chronic low back pain.
- One study determined the clinical effectiveness of therapeutic lumbar facet joint nerve blocks with or without steroids in managing chronic low back pain. The authors concluded that therapeutic lumbar facet joint nerve blocks, with or without steroids, may provide a management option for chronic function-limiting low back pain of facet joint origin but that further validation is warranted.
- One study systematically reviewed evidence to determine if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low back pain. The authors

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concluded that there was insufficient evidence to support the use of injection therapy in subacute and chronic low back pain.

Summary
The evidence relating to injection therapy was conflicting with two studies indicating a potential benefit and three studies concluding that there is insufficient evidence to support the use of injection therapy for people with low back pain. Therefore, currently the evidence is inconsistent and is unlikely to change the direction of the following guideline recommendation:

- Do not offer injections of therapeutic substances into the back for non-specific low back pain

This area will be examined again in the next review of the guideline.

Clinical area 5: The clinical and cost effectiveness of using screening protocols to target treatments for patients with non-specific low back pain.

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q: What is the clinical</td>
<td>Through an assessment of the abstracts from the focused searches, three</td>
<td>Insufficient evidence to</td>
</tr>
</tbody>
</table>
and cost effectiveness of using screening protocols to target treatments for patients with non-specific low back pain?

(New area identified by GDG)

<table>
<thead>
<tr>
<th>studies relevant to the clinical question covered in this clinical area of the guideline were identified.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One study examined the generalisability of three different manual therapy techniques in a patient population with low back pain that satisfy a clinical prediction rule. The authors concluded that the results of the study supported the generalisability of the clinical prediction rule to another thrust manipulation technique, but not to the nonthrust manipulation technique used in this study.</td>
</tr>
<tr>
<td>• One study compared the clinical effectiveness and cost-effectiveness of stratified primary care (intervention) with non-stratified current best practice (control). The authors concluded that a stratified approach, by use of prognostic screening with matched pathways, will have important implications for the future management of back pain in primary care.</td>
</tr>
<tr>
<td>• One study tested the STarT Back Tool’s concurrent validity against an existing, popular low back pain sub grouping tool, the Orebro Musculoskeletal Pain Screening Questionnaire. The authors concluded that the STarT Back Tool baseline psychometrics consider for inclusion in the guideline.</td>
</tr>
</tbody>
</table>
performed similarly to the Orebro Musculoskeletal Pain Screening Questionnaire.

**Summary**

In summary, the clinical and cost effectiveness of using screening protocols to target treatments for patients with non-specific low back pain is a new area identified by the GDG. However, due to heterogeneity among the studies, further evidence is required to confirm the best screening protocol to target treatments for people with low back pain. Therefore, it would be pertinent to await further evidence before an update is commissioned.
Ongoing clinical trials (publication dates unknown) were identified focusing on:

- Effectiveness of tapentadol (immediate release) vs. oxycodone
- Effectiveness of an exercise program vs. Non-steroidal anti-inflammatory analgesics (NSAIDs)
- Efficacy and safety of oxycodone/ naloxone controlled-release tablets
- Efficacy and tolerability of etoricoxib monotherapy
- Effectiveness of a fixed dose combination of diclofenac and eperisone hydrochloride
- Effectiveness of facet joint infiltration
- Efficacy and safety of hydrocodone bitartrate
- Effectiveness of theramine
- Efficacy and safety of IV paracetamol, dexketoprofen or morphine
- Effectiveness of Pilates to treat patients with low back pain

No evidence was identified that was relevant to research recommendations in the original guideline.

**Guideline Development Group and National Collaborating Centre perspective**

A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Four responses were received with respondents highlighting 16 studies relating to the following areas:

- Cost effectiveness evidence supporting screening for chronicity
- Pharmacological treatment with opioids and tricyclics
- Evidence supporting low intensity combined physical and psychological interventions which may support inclusion in the guideline as one of the core therapies
- New evidence supporting yoga as a therapy for low back pain that may support inclusion in the guideline
- Testing the StartBack tool for sub-grouping of patients with low back pain to prioritise treatments (new area identified by GDG)
- Acupuncture
- Injections for low back pain
- Spinal manipulation

The studies highlighted by the GDG have been summarised in Tables 1 and 2.

In terms of ongoing research relevant to the guideline, the following areas were suggested:
- Acupuncture and Alexander techniques
- Behavioural therapy for chronic low back pain

One respondent commented that there was insufficient evidence or variation in practice to warrant an update of current guideline at this time. Two other respondents disagreed but did not mention any specific areas to update. One respondent did not comment on whether the guideline should be updated.

**Implementation and post publication feedback**

In total 267 enquiries were received from post-publication feedback, most of which were routine. Key themes emerging from post-publication feedback were as follows:
- Query as to why the guideline does not recommend the use of painkilling injections
- Whether acupressure was considered as a treatment option
- The rationale for not recommending transcutaneous electrical nerve stimulation
- Adoption of acupuncture at significant cost to the NHS - including criticism(s)
- Queries as to why the Alexander technique was not recommended
- Challenge to costing assumptions for facet joint injections
- What the term 'optimal package' means within the guideline
A query from an MP on whether Isopropyl Alcohol and transcutaneous electrical nerve stimulation machines for the relief of pain will be considered.

This feedback did not contribute towards the development of the clinical questions described above.

A field team implementation feedback report identified the following:

- Several comments were received which indicated that the guideline has been useful and that it had been incorporated into HR/Occupational Health sickness absence policies.
- Several comments on the recommendation on acupuncture which included encouragement that NICE gave a cautious endorsement to acupuncture for the treatment of low back pain; however there was disappointment that locally a PCT have issued a "blanket ban" on commissioning any acupuncture therapy even where it might be indicated by NICE guidance. Another comment was similar in that one PCT was not willing to provide acupuncture and felt that the guideline was written in a way that gave patients the impression they could almost demand acupuncture as they suggest that there is a sentence that alludes to treatment via discussion between doctor and patient.
- Concerns about the scope, since it covered a window of six weeks after onset to 12 months following onset and not before or after.
- There were also concerns about recommendations relating to therapeutic injections which they suggested meant that some clinicians were being unreasonably constrained with diagnostic injections.

In summary, no new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

**Relationship to other NICE guidance**

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The following NICE guidance is related to CG88:

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Review date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH2: Four commonly used methods to increase physical activity: brief interventions in primary care, exercise referral schemes, pedometers and community-based exercise programmes for walking and cycling, 2006.</td>
<td>Next review date: March 2013.</td>
</tr>
<tr>
<td>PH19: Management of long term sickness and incapacity for work. NICE public health guidance, 2009.</td>
<td>PH19: Management of long-term sickness absence and incapacity for work will be updated as part of the new referral, Workplace health – the role of line managers.</td>
</tr>
<tr>
<td>Audit programme for acute back pain guidelines. Developed by the Institute for Musculoskeletal Research and Clinical Implementation, 2001.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>Referral advice: a guide to appropriate referral from general to specialist service (acute low back pain section; pilot version, 2001).</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG83: Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain, 2004.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG141: Automated percutaneous mechanical lumbar discectomy, 2005.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG173: Percutaneous disc decompression using coblation for lower back pain, 2006.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG300: Percutaneous endoscopic laser lumbar discectomy, 2009.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG303: Percutaneous endoscopic laser cervical discectomy, 2009.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG306: Prosthetic intervertebral disc replacement in the lumbar spine, 2009.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG319: Percutaneous intradiscal electrothermal therapy for lower back pain, 2009.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>IPG321: Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine, 2009.</td>
<td>Next review date: TBC.</td>
</tr>
<tr>
<td>Guideline</td>
<td>Next review date</td>
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<tr>
<td>IPG357: Percutaneous intradiscal laser ablation in the lumbar spine, 2010.</td>
<td>TBC.</td>
</tr>
<tr>
<td>IPG365: Interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine, 2010.</td>
<td>TBC.</td>
</tr>
<tr>
<td>IPG366: Non-rigid stabilisation techniques for the treatment of low back pain, 2010.</td>
<td>TBC.</td>
</tr>
<tr>
<td>IPG387: Transaxial interbody lumbosacral fusion, 2011.</td>
<td>TBC.</td>
</tr>
<tr>
<td>TA159: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin, 2008.</td>
<td>Since the publication of TA159 there has been no new evidence that would affect the recommendations made within the guidance. Consequently it has been decided to defer the consideration of the review until the end of 2013 when more evidence on the use of spinal cord stimulation for the treatment of chronic pain of ischaemia origin becomes available (RASCAL study).</td>
</tr>
</tbody>
</table>

**Related NICE guidance in progress**


**Anti-discrimination and equalities considerations**

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is CG88: Low back pain, review proposal consultation document.
inclusive of people aged 18 or older presenting with symptoms of ‘non-specific’ (simple) low back pain; specifically low back pain that has not resolved within six weeks of initial onset, consultation, or exacerbation, up to a period of 12 months.

**Conclusion**
Through the process, the clinical and cost effectiveness of screening protocols to target treatments for patients with non-specific low back pain was identified by the GDG as a new area not currently covered by the guideline. This area was evaluated through a focus search. However, due to heterogeneity among the studies, it was concluded that further evidence is required to confirm the best screening protocol to target treatments for people with low back pain. Therefore, it would be pertinent to await further evidence before an update is commissioned.

No additional areas were identified through the process which were not covered in the original guideline scope or would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations. The low back pain guideline should not be updated at this time.

**3. Review recommendation**
The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

Centre for Clinical Practice
14 May 2012
Appendix I


44. Facci LM, Nowotny JP, Tormem F et al. (2011) Effects of transcutaneous electrical nerve stimulation (TENS) and interferential currents (IFC) in


CG88: Low back pain, review proposal consultation document


