# Low back pain and sciatica
## Consultation on draft guideline - Stakeholder comments table
## 24 march 2016 – 10 may 2016

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| Stakeholder | Document | Page No | Line No | Comments<br>Please insert each new comment in a new row | Developer's response<br>Please respond to each comment |
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| Acupuncture Association of Chartered Physiotherapists | GENERAL | 16 | 9 | With reference to orthotics NICE are now in the ridiculous position of being able to offer insoles for knee OA (even with age related changes) but not Spinal OA despite the presence of forces throughout the kinetic chain. | Thank you for your comment. The GDG found no evidence that foot orthotics or rocker soles were of benefit to people with low back pain with or without sciatica, and therefore recommended against their use for this population. |
| Acupuncture Association of Chartered Physiotherapists | GENERAL | 449 | GENERAL | Why has massage/ soft tissue techniques been recommended where it is stated that there was only low quality evidence available and there was a statement of no benefit? This potentially has a greater cost impact on the NHS than AP. | Thank you for your comment. Soft tissue techniques as well as other forms of manual therapy have been recommended only as part of a treatment package including exercise with or without psychological therapy. This is based on evidence in Chapters 9, 12 and 17 of studies using a two or three element treatment package. |
| Acupuncture Association of Chartered Physiotherapists | GENERAL | 453 | GENERAL | The GDG noted a lack of consistency across important outcomes for Manual Therapy yet how is this was still included in the recommendations as part of a multimodal package when AP is not? Particularly when the amount and quality of evidence appears to be substantially better than for most other non-pharmacological interventions (Vickers 2012). | Thank you for your comment. This recommendation is based on evidence from studies which used a treatment package comprising of a combination of exercise, manual therapy, and psychological therapy (see chapters 9, 12 and 17). As there was no evidence for acupuncture as part of a treatment package, acupuncture was not considered as part of this recommendation. |

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| Arthritis Researc h UK | Full 1 | 17 | 21 | Multidisciplinary biopsychosocial rehabilitation (MBR) programmes:<br>(see also short 5, 24 and invasive recommendations).The GDG recommend considering a combined physical and psychological programme (preferably in a group context, that takes into account a person's specific needs and capabilities) for people with persistent non-specific LBP or sciatica: when they have significant psychosocial obstacles to recovery, or when previous treatments have not been effective. The GDG do not provide a sufficiently clear rationale for why this should preferably be provided in a group. This is a similar point to the one made previously on group exercise/ individual exercise. In the absence of clear evidence that group treatment is superior or an economic model that demonstrates cost-effectiveness, then it would be more appropriate to recommend considering a combined physical and psychological programme, that can be delivered in either group format or individual sessions.<br><br>The STarTBack trial (Hill et al, 2011) was powered to compare psychologically informed physiotherapy (PIP) with best practice for the high risk (distressed/disabled) subgroup of LBP patients. The trial was conducted in the UK, involved 5 days of training in PIP for clinicians and a mean of less than 5 treatment sessions for patients. There was a significant difference in the primary outcome of disability (between group RMDQ differences of more than 2.5) in favour of psychologically informed physiotherapy at 4 months, but not at 12 months. PIP was cost effective at 4 and 12 months. We suggest the GDG include the results from this study when making their recommendations. *PIP is "a systematic approach to the integration of physical and psychological approaches to treatment for the management of people with low back pain by physiotherapists*" (Main et al, 2012)<br>Reference: Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, Konstantinou K, Main CJ, Mason E, | Thank you for your comment. A preference for group programmes was expressed in the recommendations in the light of clinical and economic evidence. Although there was evidence of effectiveness of both individually delivered programmes and those delivered in groups, group programmes were considered likely to be more cost effective and therefore it was agreed that this would be the preferable way to deliver this intervention.<br><br>The STarTBack trial was not included in the Multidisciplinary biopsychosocial rehabilitation (MBR) review because of stratification affecting original randomisation (participants were first randomised and then stratified, and received different interventions according to their strata). Discussing MBR programmes, the GDG nonetheless noted that evidence from the risk stratification review informed recommendations for identifying people who might benefit from a combined physical and psychological approach (see section 17.6 recommendations and link to evidence). |

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| | | | | Somerville S, Sowden G, Vohora K, Hay EM Comparison of stratified primary care management for low back pain with current best practice: (STarT Back) [ISRCTN37113406]: a randomised controlled trial. 2011 Lancet, 378(9802): pp. 1560-71 [33.63] C.J. Main, G. Sowden, J.C. Hill, P.J. Watson, E.M. Hay (2012) Integrating physical and psychological approaches to treatment in low back pain: the development and content of the STarT Back trial's 'high-risk' intervention. Physiotherapy June 98, 2 110-116, DOI: 10.1016/j.physio.2011.03.003 | |
| Arthritis Research UK | Full 1 | 17 | 21 | The GDG recommend considering a combined physical and psychological programme for people with persistent non-specific LBP or sciatica: when they have significant psychosocial obstacles to recovery, or when previous treatments have not been effective. It would be helpful if the GDG could suggest how clinicians should determine effectiveness. Could it be, when previous treatments have failed to improve pain, physical and psychological functioning or quality of life, in the longer term? | Thank you for your comment. We have now clarified in the 'Recommendations and link to evidence section' of the Multidisciplinary Biopsychosocial Rehabilitation (MBR) chapter (section 17.6 ) that lack of effectiveness of previous treatments can be determined as when previous treatments failed to improve pain adequately, or have not helped enough to enable people to return to normal activity of daily life, including work. |
| Arthritis Research UK | Full 1 | 18 | 38 | Surgery:<br>(see Also Short, 8, 7 and full, invasive, 10, 38) Consider spinal decompression for sciatica when non-surgical treatment has not improved pain and function. This is rather vague as there is no timeline attached to it – when should clinicians consider spinal decompression in the timeline of sciatica if there is no improvement? Trials of surgery versus conservative care suggest that timing is important. | Thank you for your comment. The issue regarding optimal timing to offer spinal decompression was not specifically considered by the review question. However, the GDG discussed attaching a timeline to the recommendation. It was GDG opinion that a reasonable period of conservative management could be around 6 weeks, however it was felt that the evidence was not strong enough to specify a time point. Furthermore, the GDG agreed that as non-surgical management should be pursued prior to surgery, this would negate the need to specify a specific time point. |
| Arthritis Research UK | Full 1 | 20 | 6-7 | Related to our last point above, we would query the language of 'improve spontaneously without intervention' and suggest a phrase along the lines of 'improve rapidly with primary care | Thank you for your comment. The introduction has been edited and this sentence has been edited as suggested. |

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| | | | | management alone, without the need for investigations or referral to specialised services'. | |
| Arthritis Research UK | Full 1 | 61 | 23-25 | Currently the guidelines say "There are many different proposed methods of stratification but in general they divide patients into one of 3 groups. However, it is important to appreciate that there is likely to be overlap between these groups". We believe this is an error, as although there may be overlap between the 3 approaches, there is not overlap between the 3 risk groups of patients (low, medium and high risk). We suggest the GDG change the wording to: 'However, it is important to appreciate that there is likely to be overlap between stratified care approaches". | Thank you for your comment. Section 6.1, lines 24-25 have now been edited as follows: 'it is important to appreciate that there is likely to be overlap between these methods'. |
| Arthritis Research UK | Full 1 | 331 | general | Alexander technique:<br>There is 1 large trial showing evidence for this approach but this does not lead to a positive recommendation by the GDG. However, the GDG did recommend other treatments with only 1 study to suggest benefit. This is another example where it would be helpful to have an explicit statement about why these decisions are different. | Thank you for your comment. Although there was one large trial showing some evidence of benefit in terms of quality of life, there was a smaller trial which did not demonstrate such positive results. The GDG therefore agreed that based on the body of evidence, across outcomes, there was no sufficient, consistent evidence of benefit to recommend a treatment that would mean a significant change in current practice. This is consistent with decisions made throughout the guideline. |
| Arthritis Research UK | Full 1 | 601 | 2 and 10 | Personnel costs: Delivery of psychological approaches requires training and expertise. These interventions have historically been provided by psychologists, however, increasingly, physiotherapists and other professionals are receiving training to deliver psychologically informed approaches. We can understand NICE desire to create 'low cost solutions' because of the challenges of implementation. However, we can see no evidence from the guidelines that a band 5 practice nurse can effectively deliver psychological interventions to people with low back pain, with or without sciatica.<br>We suggest the GDG highlight the importance of adjusting the intensity / quality / expertise required to deliver the treatment according to the complexity of the patient, i.e. | Thank you for your comment. We agree and we have amended the costing for nursing staff to reflect a band 7 is required to deliver this intervention.<br><br>Footnote c in the table is not about how many patients are seen by physiotherapists and psychologists in the same amount of time; it is simply the ratio between the total number of hours spent with actual patients and the total number of hours worked. |

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| | | | | psychological approaches for straightforward people with relatively acute back pain may be deliverable by less specialist staff with appropriate training but patients with chronic LBP and significant distress / disability require clinicians with a higher level of expertise, working together with other professional disciplines, as part of an interdisciplinary team.<br>The assumption that physiotherapists and psychologists see the same number of LBP patients in the same amount of time is incorrect. Our experience is that physiotherapists see more. However in the absence of data regarding this, we suggest that the GDG remove the statement pertaining to this. | |
| Arthritis Research UK | Full 1 | 604 | general | The GDG state that 'a further study was included in this review comparing cognitive behavioural approaches and behavioural therapy which demonstrated no difference between treatments in terms of pain and function when measured with the Quebec pain disability scale at longer term follow-up'. However studies did show (Page 601) clinical benefit in favour of cognitive behavioural approaches at greater than 4 months when measured by RMDQ. Why has this finding not been included in the summary on page 604? | Thank you for your comment. Section 15.7 has been edited to include reference to the missing function outcome (RMDQ scale, > 4 months) showing clinical benefit in favour of cognitive behavioural approaches over behavioural therapy. |
| Arthritis Research UK | Full 1 | 673 | 11 | The GDG mention the difficult transition from curative approaches to 'living well' and 'managing' with a long term health condition and also that long term or chronic pain requires management, rather than further investigation or long-term 'passive' treatments (long, 673, 17). It is difficult to understand why the GDG then go on to consider the evidence for and specifically mention, passive treatments (mobilisation, massage). We would recommend that the GDG do not include consideration of mobilisation and massage under the heading of MBR. | Thank you for your comment. The interventions that would be covered within the guideline were agreed during the scoping phase, and further refined by the GDG when setting the review protocols and it was agreed such passive treatments were important areas to investigate effectiveness of. There was evidence to support the addition of mixed modality manual therapies to exercise and psychological therapies, but this evidence did not allow us to determine the relative contributions of massage and mobilisation to these mixed manual therapy interventions. |

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| Arthritis Research UK | Full 1 | 673 | 14 | Definition and use of the term 'multidisciplinary': The GDG state that the rehabilitation process requires professionals working in a specialist pain service to work together (a multidisciplinary or unidisciplinary team), but elsewhere (Long 673, 39 and page 809) the GDG state that multidisciplinary programmes can include various components delivered by one individual. The GDG then consider studies conducted by non-specialists where the intervention is delivered by one individual, under the heading of MBR. For clarity, can we suggest that the GDG clearly differentiate the terms 'multidisciplinary approach' and 'multidisciplinary team'. The NHS England: Multi-disciplinary Team Handbook January 2014CCG (https://www.england.nhs.uk/wp-content/uploads/2015/01/mdt-dev-guid-flat-fin.pdf) provides the following definitions:<br>A multidisciplinary approach involves drawing appropriately from multiple disciplines to explore problems outside of normal boundaries and reach solutions based on a new understanding of complex situations.<br>Multi-disciplinary team working - how health and care professionals work together to support people with complex care needs that have been identified through risk stratification and case finding.<br>Transdisciplinary working means that one discipline may take on the traditional role of another by agreement.<br>Unidisciplinary is where the professional with continuing responsibility co-ordinates the care for the patient working with other professionals from their own organisation, as necessary. | Thank you for your comment. The definition of 'multidisciplinary' is stated in the MBR chapter, in section 17.1 (Introduction) and table 384 in section 17.2 (Review question). A programme is defined as multidisciplinary if it targets factors from different domains (physical, psychological and social), irrespective of the number of people who deliver the programme. Information about the interventions featured in the included studies, including the composition of teams delivering the programme (unidisciplinary/multidisciplinary), is summarized in table 349, section 17.3 (Clinical evidence). |
| Arthritis Research UK | Full 1 | 673 | 23 | The GDG state that the MBR approach combines education and physiotherapy, with different forms of cognitive-behavioural psychology to address participants' unhelpful beliefs about their pain, reduce 'fear-avoidance' behaviours and catastrophic thinking, and improve mood, *thus decreasing disability and improving function.* Many however would argue that the *primary* aim of a MBR approach for people with chronic pain is to increase quality of life with pain, | Thank you for your comment. The GDG acknowledges there is no consensus on the definition of MBR programmes. The definition used in the guideline is adapted from the Cochrane review by Kamper et al. cited in the introduction, Section 17.1. |

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| | | | | we therefore suggest the GDG reword this statement to reflect this. | |
| Arthritis Research UK | Full 1 | 673 | 39 and 809 | Definition of biopsychosocial. The experience of pain is the result of a dynamic interaction between physical, psychological and social factors and these shape the individual's response to the pain *(Turk & Flor, 1999).* In a biopsychosocial approach, psychological and social factors must therefore also be included along with the biological factors. At odds with this and with other definitions of a biopsychosocial approach, the GDG describe it as an intervention that involves a physical component (such as specific exercise modalities, mobilisation, massage) and at least one other element from a biopsychosocial approach, that is psychological or social and occupational or educational. Could the GDG perhaps consider amending their definition to include all three (bio, psycho and social) rather than exercise and one other. It is not clear why education (information provision) has been included here nor why 'bio' has been replaced with 'physical' and will therefore exclude pharmacological interventions.<br>Reference:<br>Turk, D. C., & Flor, H. (1999). Chronic pain: A biobehavioral perspective. In R. J. Gatchel & D. C. Turk (Eds.), Psychosocial factors in pain: Critical *perspectives* (pp. 18–34). New York: Guilford Press. | Thank you for your comment. The definition of MBR has been adapted from a recent Cochrane review by Kamper et al. Please find this referenced in the introduction to the MBR chapter, section 17.1. |
| Arthritis Research UK | Full 1 | 740 | general | We are concerned about the generalisability of the Vibe Fersum et al (2013) study from Norway to the UK NHS. It involved106 hours of CB-CFT training for clinicians. This roughly equates to 16 days of training before clinicians could deliver the intervention. We have concerns about how 106 hours of training would be implemented in the NHS and whilst a weekend training course on the approach is available, we suggest the GDG remove the sentence about the weekend course, as this was not what was delivered or tested in the Vibe Fersum et al (2013) study and consider the cost of 106 hours of clinician training. This study also had other key | Thank you for your comment. Although 106 hours of training were delivered as part of the trial, it is not clear whether this amount of training would be necessary for delivering this programme in clinical practice. However, to aid consideration of the potential costs for the NHS in practice, the example of the weekend training course available for an approach used in Vibe Fersum et al. 2013 was given, but no costs were calculated for this. |

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| | | | | weaknesses including a high drop-out rate and an already highly selected study population (for example, the exclusion criteria in the study included pain without a clear mechanical behaviour and continuous sick-leave duration for 4 or more months).<br>Reference: Vibe Fersum K[1], O'Sullivan P, Skouen JS, Smith A, Kvåle A. (2013) Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: a randomized controlled trial. Eur J Pain. Jul;17(6):916-28. doi: 10.1002/j.1532-2149.2012.00252.x. Epub 2012 Dec 4. | It is important to note that this recommendation was based on multiple studies, and the limitations of Vibe Fersum et al. 2013 were discussed by the GDG and are described in the LETR. |
| Arthritis Research UK | Full 1 | 765 | general | Work:<br>Whilst we agree with the recommendations that specific return to work programmes should not currently be recommended for the NHS, we would argue that this is due to there being no evidence either supporting or refuting the use of return to work programmes and would suggest therefore that a research recommendation is made specifically on this point. | Thank you for your comment. The GDG did not feel there was enough evidence to recommend specific return to work programmes separate from other clinical interventions for the NHS. Other areas have been prioritised for research recommendations. |
| Arthritis Research UK | Full 2 | 9 | 35 | Injections:<br>(see also Short, 7, Line 13- 21 and long invasive Pg 52, pg 59)<br>Cost-effectiveness model for nerve root ablation in those with suspected facet joint pain and using a pain clinic population. The stated ICER is £13,000 per QALY but the base case assumes no improvement in the control group without injection. This would seem to be the wrong base case since by the time patients are identified, then assessed for suitability, some patients will improve without the injection – so fewer will be eligible for the injection / nerve root ablation. The sensitivity analysis assumes improvement as per the studies included (£16,000 per QALY), so the probability of cost-effectiveness will reduce. Also, there are no harms incorporated in the economic model e.g., radiation exposure, allergic reactions, bleeding etc. Estimates for these risks | Thank you for your comment.<br>The population represented in the model is made of people who already had usual care and have exhausted all the possibilities in the non-invasive care; the GDG advised that longitudinal studies show that these patients do not improve with time; they could be different from the population in the RCTs where a regression to the mean could be observed. Therefore we do not think we need to change our base case. However we have also accounted for this possibility in a sensitivity analysis which shows that even when the placebo arm effect is used the intervention is cost effective.<br>No evidence was available on the harm of the procedure so this could not be incorporated into the model. However the GDG have considered potential |

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| | | | | could have been sought from GDG opinion, in line with most of the clinical parameters in the model | harm from the procedure, including radiation, and thought this was negligible. We have added some considerations in the model write up to explain this. |
| Arthritis Research UK | Full 2 | 9 | 38 | (see also Short, 7 23):<br>Epidural injections of local anaesthetic and steroid in people with acute sciatica. We are concerned that the evidence for epidural injection of local anaesthetic is of low quality and shows very small effects, yet the GDG recommend they should be considered. There are some effects for those with >70% disc prolapse in sciatica of less than 4 months, but the evidence (1 to 2 studies of low quality and small effect sizes) is, in our view, not sufficient to warrant consideration of epidural injections outside of a randomised controlled trial. | Thank you for your comment. The GDG acknowledged that evidence for epidurals of local anaesthetic alone did not show much benefit. However they noted that clinical benefit was observed against placebo/sham when the local anaesthetic was combined with steroid. The GDG agreed this should only be considered in people with acute severe sciatica, and there was sufficient evidence to warrant a 'consider' recommendation for epidurals with steroid and local anaesthetic for this subset of people. Please see section 24.6 for more details on the decision-making process. |
| Arthritis Research UK | Full 2 | 9 | 38 | (see also Short 7, 23 and pg116 and pg120) Cost-effectiveness for epidural injections for sciatica: This was based on Prof Nigel Arden's study which demonstrated that epidural steroid injection (ESI) led to a transient benefit in ODQ and pain relief, compared with placebo at 3 weeks (p = 0.017, number needed to treat = 11.4). There was no benefit over placebo between weeks 6 and 52. There were no significant differences in any other indices, including objective tests of function, return to work or need for surgery at any time-points. Prof Nigel Arden's study used a range of assumptions and concluded between £26,000 to >£300,000 cost per QALY. ESIs thus failed the QALY threshold recommended by the National Institute for Health and Clinical Excellence (NICE). We note the GDG has selected the lowest of these estimates to use for the modelling – this was from a sensitivity analysis which included assumptions that could not be confirmed from their own data. This ICER is above the NICE lower threshold (£20,000/QALY) and no probabilistic sensitivity analysis was undertaken, so we do not know the probability of cost-effectiveness at the £20,000 and £30,000/QALY thresholds. Interventions are generally only | Thank you for your comment. In the linking evidence to recommendation section we have explained why we gave more weight to the lower ICER estimate from the study (as the GDG advised only one injection is usually administered for the acute sciatica population) and the rationale for concluding that epidural injections could be cost effective. We would also like to note that this is not a strong recommendation as we recommend considering offering this intervention as opposed to routinely offering it.<br>Regarding the cost of the MRI scan, the study also included radiology costs so these costs should be covered by the analysis. |

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| | | | | recommended above £20,000/QALY (and below £30,000) if there is a reasonable level of certainty about the result and the results are robust. We really cannot say this is the case here. Although ESIs appear relatively safe, it was found that they confer only transient benefit in symptoms and self-reported function in a small group of patients with sciatica at substantial costs. We agree it should be a research recommendation and suggest NICE change the clinical recommendation from "Consider epidural injections of local anaesthetic and steroid in people with acute sciatica" to "Do not offer epidural injections of local anaesthetic and steroid in people with acute sciatica unless as part of a randomised controlled trial", in a similar way to some of the other interventions that are also research recommendations. Our group perceive that the NHS is under considerable pressure currently relating to the use of pharmacology, injections and surgery so it is essential that there is clarity and consistency in the GDG's recommendations.<br>Reference:<br>Price C, Arden N, Coglan L, Rogers P (2005) Cost-effectiveness and safety of epidural steroids in the management of sciatica. Health Technol Assess. 2005 Aug;9(33):1-58, iii.<br><br>Patients also need an MRI scan before the epidural so the cost of these MRI scans should be included in the economic model. | |
| Arthritis Research UK | Full 2 | 19 | 9 | Recommendations for research:<br>(see also full non-invasive 18, 8-23 , short line 6 pg 12 to pg 15)<br>The research recommendations are very specific, and we would encourage the GDG to take the opportunity to use their impressively wide-ranging survey of the literature to provide some big picture guidance as to where they would like to see LBP research going in the future to better inform clinical practice, policy and future NICE guidance. | Thank you for your comment. As detailed in section 4.5.1 of the Methods chapter, when areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research.<br>As stated in section 9.5 of the NICE manual (Developing NICE guidelines: the manual, November 2012), it would not be feasible for the GDG to draft research recommendations for every area of |

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| | | | | The research recommendations are focused on pharmacology and invasive treatments, the latter of which will apply to only a small proportion of patients. It seems that non-pharmacological interventions have been less likely to make it into future research recommendations yet these treatments would benefit from further high quality research. There are many gaps in the evidence highlighted very clearly in the documentation for several non-pharmacological interventions and we recommend these are also developed into clear research recommendations by the GDG.<br><br>Within the guideline there are clear statements about the limitations and difficulties surrounding the label of NSLBP but this is not a research recommendation.<br><br>There are 5 research recommendations listed on the short guidance document but 7 listed in the full. The 5 in the short guidance are selectively either pharmacological or surgical/invasive treatment research questions. We suggest including non-pharmacological research recommendations in the short guide too, since many people may rely on that document alone.<br><br>The Alexander technique (pg 331 of full guidance) is specifically mentioned as needing more research, yet this is not a clearly stated research recommendation in the guideline.<br><br>The orthotics section of the full guidance (pg 348) highlights the lack of high quality research yet no research recommendation is made.<br><br>The acceptability, take-up and cost-effectiveness of group exercise for LBP in the NHS could be a research recommendation. | uncertainty. Therefore the GDG selected key research recommendations that are likely to inform future decision-making for inclusion in the guideline. Decisions about the inclusion of a research recommendation were based on factors such as the importance to patients or the population, national priorities, potential impact on the NHS and future NICE guidance, ethical and technical feasibility. Further information about how research recommendations are derived can be found in the NICE research recommendation process and methods guide: https://www.nice.org.uk/Media/Default/About/what-we-do/Science-policy-and-research/research-recommendation-process-methods-guide-2015.pdf<br><br>The GDG took all of these factors into account when determining which areas warranted recommendations for future research and agreed the 7 topics in the full guideline were the most appropriate. From these, as per the NICE guidelines manual, only 5 are prioritised in the short version of the guideline, which are those considered to be most important to informing future updates of the guideline. |

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| | | | | We have listed below some other comments from the full guidelines about the lack of RCTs and in some cases cohort study evidence, which do not have corresponding research recommendations. We appreciate that some selectivity is needed in creating a list of specific research recommendations, but it would be helpful for the GDG to state their criteria for that selection – e.g. the ones likely to make the biggest difference for the largest volume of patients; the new studies that are most likely to resolve important controversies etc. On balance we think it might also be very helpful to have somewhere a list of all the clear evidence gaps the GDG have identified in the course of their review to act as a master-list for potential research topics.<br>- Full, non-invasive 571 9 Due to there being limited RCT evidence, the search was also extended to cohort studies for mindfulness and acceptance and commitment therapy, but no relevant cohort studies were identified.<br>- Full, non-invasive 601 31 and 602 7 No evidence was available to assess the clinical benefit of cognitive behavioural approaches or behavioural therapy or in terms of quality of life, or psychological distress for low back pain with or without sciatica or in the individual sciatica or low back pain populations.<br>- Full, non-invasive 602 16- 19 Mindfulness No evidence was available to assess the clinical benefit of mindfulness in terms of psychological distress in this population. No data were available for the individual sciatica or low back pain populations, nor for the comparison of mindfulness with placebo or sham.<br>- Full, non-invasive 602 41 No RCT or cohort evidence was found for acceptance and commitment therapy. | |

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| | | | | • If it is accepted that work may be beneficial to patients and is an important outcome for patients (pg 743 lines 20-21), a view that is supported by reports such as "Is work good for your health and wellbeing?" Waddell and Burton (2006), "Working for a healthier tomorrow" Black (2008), Health at work - an independent review of sickness absence" Black and Frost (2011), then we would argue that it is in the interests of patients and clinicians to conduct research that tests optimum methods for supporting patients with back pain to remain in or return to work.<br>References:<br>Waddell, G. & Burton, A.K. 2006. Is work good for your health and wellbeing? London: *The Stationary Office*<br>Black C. 2008. Working for a healthier tomorrow. London: *The Stationary Office*<br>Black C & Frost D. 2011. Health at work - an independent review of sickness absence. London: *Department for Work and Pensions* | |
| Arthritis Research UK | GENERAL | GENERAL | GENERAL | We share the concerns of the GDG that patients at 'low risk' on the STarT Back tool are being interpreted by commissioners as requiring 'no treatment', this is not supported by the evidence (Hill et al, 2011). Importantly 'low risk' means that investigations, repeat visits and referral for specialised treatments can be avoided, but there still needs to be a clear recommendation for positive initial primary care management (advice, education, written information, reassurance, simple analgesia).<br>Reference: Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, Konstantinou K, Main CJ, Mason E, Somerville S, Sowden G, Vohora K, Hay EM Comparison of stratified primary care management for low back pain with current best practice: (STarT Back) [ISRCTN37113406]: a randomised controlled trial. 2011 Lancet, 378(9802): pp. 1560-71 [33.63] | Thank you for your comment. The guideline includes recommendations on self-management and pharmacological treatment of people with non-specific low back pain and sciatica that apply to primary care management. We have reworded the recommendation to provide more guidance on what interventions should be considered. |

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| Arthritis Research UK | general | general | general | Top box of Figure 1 algorithm, page 15<br>As we are suggesting that supervised exercise programmes should be recommended for all, it should be included in the top box of Figure 1 (if the research evidence is the key basis for the recommendations). | Thank you for your comment. The algorithm has been extensively remodelled for clarity. Exercise programmes sit within the same box as other conservative treatments. |
| Arthritis Research UK | Short | 3 | 5 | Stratified care:<br>The language in the short guidance should preferably match the language of the full guidance i.e. 'using the risk stratification tool (e.g., STarT Back) plus matched treatments'. The evidence for improved patient outcomes is based on the use of the STarT Back tool and matched treatments, and not the use of the tool alone (Hill et al 2011, Foster et al 2014). This point is clearly made in the full guidance and we would like the GDG to consider linking one or two of the later recommendations - especially on psychological therapies - to the idea of using a risk stratification tool such as STarT Back; otherwise the link between using the tool and choosing the treatment may be obscure to some readers.<br>References:<br>Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, Konstantinou K, Main CJ, Mason E, Somerville S, Sowden G, Vohora K, Hay EM (2011) Comparison of stratified primary care management for low back pain with current best practice: (STarT Back) [ISRCTN37113406]: a randomised controlled trial. 2011 Lancet, 378(9802): pp. 1560-71 [33.63<br>Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DG, Doyle C, Konstantinou K, Main C, Somerville S, Sowden G, Wathall S, Young J, Hay EM on behalf of the IMPaCT Back Study team (2014). Effect of stratified care for low back pain in family practice (IMPaCT Back): a prospective population-based sequential comparison. Annals of Family Medicine, 12(2): doi: 10.1370/afm.1625 [5.355] | Thank you for your comment. The GDG recommended STarTBack tool as an example of a stratification tool that may be used to inform shared-decision making about stratified management. The GDG felt there was not enough evidence to recommend a specific tool, nor specific sets of interventions for stratified management. However, the recommendation has now been edited for clarity and the following has been added: "Based on risk stratification, consider:<br>• simpler and less intensive support for people likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management)<br>• more complex and intensive support for people at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach)." |

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| Association of NHS Occupational Physicians | Short | 1.1 Non invasive recommendations | | Occupational Risk – should be assessed by Occupational Health – as appropriate work adjustments (short and long term) may enhance ability to cope, reduce employment risk and increase personal and employer productivity. Some jobs are inherently risky – e.g ambulance front line, tractor driving, nurses etc.<br>Work is an important part and has been completely missed. | Thank you for your comment. The importance of work in the context of back problems has been acknowledged in chapter 18 (return to work programmes). |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 472 | general | The data reported for the pain severity (VAS 0-10) for both ≤ 4 months and ≥ 4 months in the table at p.472 are incorrectly reported. On inspection of the original articles, we found there are errors in the original data entered for meta-analysis by NICE (Guideline-Appendices K-Q, Page 153, Figures 667 and 668). In the meta-analysis, the absolute readings of VAS were cited for 5 studies but not for 2, namely Brinkhouse (2006a) and Leibing (2002). For these studies, baseline corrected results were used in the meta-analysis. This represents a clear inconsistency in source data in that a mix of baseline-corrected and raw primary end outcomes are used. This data entry error caused inaccuracy in the meta-analysis, leading to a result that is less favourable to acupuncture.<br><br>These errors have also been highlighted by Dr Mike Cummings, who is a member of the NICE Guideline Development Group, who has reanalyzed the corrected source data. In his revised analysis a more significant difference in favour of acupuncture over sham can be seen. (http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/). | Thank you for your comment. We apologise for any inaccuracies. The data included in the meta-analysis for both these figures has been checked. Data from Brinkhaus 2006 has been amended as suggested. The data from Leibing 2002 however has been checked, and the change scores have been accurately extracted and meta-analysed. The GDG revisited the evidence following the amendments and concluded that there was still no consistent evidence of benefit compared to sham to recommend acupuncture.<br>Please note that combining final values and change scores in meta-analyses is standard methodology employed by the centre when developing NICE guidelines. |
| Association of Traditional Chinese Medicin | Full 1 | 482 | general | Comparing acupuncture with usual care, the data of Pain Severity (VAS 0–10) ≤4 months for acupuncture are similar to or better than those from exercise compared with usual care (data for acupuncture can be seen in the Guideline-Appendices K-Q, Pages 158-159, Figures 694; Page 162-163, Figures 712; and data for exercise can be seen in the | Thank you for your comment. In order to determine whether the treatment effects of an intervention are over and beyond contextual or placebo effects, evidence of an intervention versus sham/placebo is given priority when developing recommendations. On re-visiting the exercise review, the GDG have agreed |

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| e and Acupuncture | | | | Guideline-Appendices K-Q, Page 62, Figures 223; Page 65, Figures 232). However, exercise is recommended but acupuncture is not. Based on the results presented, it is not clear on what basis this recommendation has been made. We must ask the question why acupuncture is not recommended. | that neither of the sham arms included in the exercise review are true exercise sham forms, therefore there is no longer any evidence in the exercise review against sham. Thus, the GDG have given usual care evidence priority when developing the exercise recommendation. However, the GDG recognise that there is a large body of sham evidence for acupuncture which is conflicting and does not consistently show benefit of acupuncture. As a result, the GDG decided against recommending acupuncture in NHS practice. |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 484 | general | All the data for Pain Severity (VAS 0-10) indicate that acupuncture is similar to or better than NSAIDs treatment either for short term or long term effects, suggesting acupuncture treatment has similar clinical effects in pain relief to that of NSAIDs.<br><br>In addition, there is another error where the data are presented with a reversed polarity of the measured effects. The data shown in the table are reversed from that shown in the Guideline-Appendices K-Q (Page 164, Figure 720), where acupuncture shows a better effect than oral NSAIDs but is less effective than intramuscular NSAIDs. | Thank you for your comment. We apologise for the inaccuracies, they have now been corrected.<br>When looking at evidence comparing acupuncture to NSAIDs, the GDG noted that there is no evidence of clinical difference at longer-term time points, or in terms of function. Therefore although these studies suggest similar effects, there are only 2 small studies reporting evidence of low or very low quality in people with acute pain only. The GDG agreed that considered alongside the more positive results from the review of NSAIDs demonstrating benefit over placebo, this limited evidence was insufficient to consider equivalence of acupuncture with NSAID. |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 491 | 26-28 | As mentioned above, there are errors in the data entry for the meta-analysis on pain severity (VAS 0-10) for both of short and long term of pain relief. It has been found that 2 sets of data from 2 clinical trials for short term pain relief and 1 set of data from a trial for long term pain relief were entered incorrectly for the meta-analysis. Consistent data (either the absolute reading values or the differences between baseline and outcome measures) should clearly be used in meta-analysis. Data in the Guideline-Appendices K-Q are evidently mixed. By using the absolute VAS value, the mean difference between real and sham acupuncture treatment is -1.03 with 95% CI of -1.53 to -0.54 (Cummings 2016). This is not only statistically significant but also achieves clinical significance. | Thank you for your comment. The data included in the pain severity outcomes have been checked. Data from Brinkhaus 2006 have been amended, however the change scores reported by Leibing 2002 were correctly extracted and meta-analysed. Please note that combining final values and change scores in meta-analyses is standard methodology employed by the centre when developing NICE guidelines. |

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| | | | | It has been recognised that the minimum VAS (0-10) change for clinical significance is between 1.0-1.4 (Kelly 2001).<br><br>Based on the correct data analysis and also with our clear clinical experiences, we believe there is no reason why NICE should not continue to recommend acupuncture for the treatment of lower back pain.<br><br>Reference:<br><br>Cummings M (2016) Musings on heterogeneity in quantitative outcomes of acupuncture trials in LBP. http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/<br><br>Kelly AM (2001) The minimum clinically significant difference in visual analogue scale pain score does not differ with severity of pain. *Emerg Med J* 18:205–207 | |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 491 | 14-15 | Clear evidence is presented in the draft guideline showing that acupuncture is significantly and clinically effective in the treatment of lower back pain with sciatica. With the recommendation of acupuncture use by the current NICE guideline, the NHS or NICE should have monitored/audited data on the use of acupuncture in the treatment of lower back pain with/without sciatica in NHS settings or sub-contracted clinics. ATCM as a professional body with about 800 qualified practitioners in traditional Chinese medicine and acupuncture would be very happy to provide feedback from lower back pain patients to supplement other collected data. | Thank you for your comment. The GDG has revisited the acupuncture review. Across all reviews in this guideline, sham/placebo evidence was given priority to demonstrate a treatment effect separate from the non-specific treatment effects. Based on the conflicting sham evidence base for acupuncture, the GDG agreed against recommending acupuncture in NHS practice.<br>NICE do not carry out audits of implementation of guideline recommendations. |
| Association of Traditional Chinese Medicin | Full 1 | 491 | 35 | According to data shown in the Guideline-Appendices K-Q, the participant number should be 256, not 187. | Thank you for your comment. This has been amended. |

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| e and Acupuncture | | | | | |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 492 | 3-7 | Comparing Pain VAS (0-10) of exercise with usual care with that of acupuncture with usual care, it is clear that acupuncture performs better than, or as well as exercise, at least for the short term (Acupuncture/usual care -1.61 [-2.23, -0.99] vs Group aerobic exercise/usual care -1.13 [-1.60, -0.66]). | Thank you for your comment. In order to determine whether the treatment effects of an intervention are over and beyond contextual or placebo effects, evidence of an intervention versus sham/placebo is given priority when developing recommendations. On re-visiting the exercise review, the GDG have agreed that neither of the sham arms included in the exercise review are true exercise sham forms, therefore there is no longer any evidence in the exercise review against sham. Thus, the GDG have given usual care evidence priority when developing the exercise recommendation. However, the GDG recognise that there is a large body of sham evidence for acupuncture which is conflicted and does not consistently show benefit of acupuncture. Therefore, although the GDG has the considered usual care evidence for acupuncture, priority was given to sham evidence when developing the recommendation. |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 492 | 27-29 | This section provides evidence to show that acupuncture is as effective as all listed active treatments including pharmacological interventions such as NSAIDs. | Thank you for your comment. When looking at evidence comparing acupuncture to NSAIDs, the GDG noted that there is no evidence of clinical difference at longer-term time points, or in terms of in function outcomes. Therefore although these studies suggest similar effects, there are only 2 small studies of low or very low quality evidence in people with acute pain only. The GDG agreed that considered alongside the more positive results from the review of NSAIDs demonstrating benefit over placebo, they did not agree that this limited evidence was sufficient to consider equivalence of acupuncture with NSAID. |
| Association of Traditional | Full 1 | 493 | 7 | We are very disappointed with the new draft guideline proposes not to offer acupuncture for managing non-specific low back pain with or without sciatica. As the leading professional body in traditional Chinese medicine and | Thank you for your comment.<br>The updated recommendation is based on a detailed systematic review of the best available evidence for acupuncture and this has been discussed at length |

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| Chinese Medicine and Acupuncture | | | | acupuncture, we feel there are several points that need to be noted:<br><br>1. We found that the proposed new draft guideline did not reflect the clinical development and outcomes of acupuncture treatment for lower back pain in recent years following the recommendation of acupuncture by the current NICE guideline from 2009. Consistent with, and in recognition of the recommendation, hundreds of thousands of lower back pain sufferers have used acupuncture for pain relief. NICE should take the progression and the therapeutic outcomes of acupuncture treatment for lower back pain into account when updating/reviewing the guideline. There is insufficient evidence that the new draft guideline has considered any such important information sufficient to warrant a reversal of the 2009 recommendation.<br><br>2. In the section of "Trade-off between clinical benefits and harms", it states "for the placebo/sham - controlled evidence in the low back pain population, the GDG agreed that no clinical benefit was seen for pain or function". We must point out that this statement is based on an analysis with clear error in data entry. These errors have been mentioned in the comments above and also been pointed out by Dr. Mike Cummings (http://blogs.bmj.com/aim/2016/04/04/nice-musings-on-heterogeneity/ ). It has been noted that the corrected analysis result indicates that acupuncture treatment of lower back pain over sham is not only statistically better but also achieves clinical significance.<br><br>As noted in the above comments, there are a number of errors in the data analysis. We believe that these | by the GDG when developing the recommendation. In considering this evidence the GDG do not believe there is sufficient evidence to recommend acupuncture on the NHS due to their being a lack of a consistent effect demonstrated when compared to sham / placebo.<br>We apologise for the inaccuracies found within this review, these have been amended and the GDG has reviewed the updated evidence. However the GDG observed that the evidence was still conflicting for acupuncture versus sham, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up. |

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| | | | | | kinds of mistakes should not happen in documents prepared by reputable organisations such as NICE. Such errors cast doubt on recommendations made on the basis of non-robust analysis. | |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 495 | general | 3. | In acupuncture trials, sometimes no significant difference can be seen between real and sham acupuncture treatments. This issue has been a long-term point of debate. The key question is whether sham acupuncture is really a sham control. According to traditional Chinese acupuncture theory, the meridian and collateral system is a network in the body. Both meridian and acupoints are not just a thin line or a pin point but are an area/region of the body. Inserting needles in the area will likely produce some effects. Although the mechanisms underlying acupuncture treatment are not fully understood, it is believed that sham acupuncture may also produce clinical effects to a certain extent. This is probably why some trials showed significant difference between real and sham acupuncture but some did not. It may depend on how the sham acupuncture was performed.<br><br>In comparison with nil treatment or normal physiotherapy, significantly better clinical effects can be seen with acupuncture treatment for lower back pain (Brinkhaus 2006; Leibing 2002; Molsberger 2002). With such significantly better clinical outcomes and considering the low cost of acupuncture practice, it is still valuable to recommend acupuncture as a treatment for lower back pain, in spite of difficulties to explain why sham acupuncture is also effective. More research needs to be done to find a proper placebo control for clinical trials of acupuncture.<br><br>References: | Thank you for your comment. Evidence from Brinkhaus 2006, Leibing 2002 and Molsberger 2002 have been included in this review and considered by the GDG when decision-making.<br>The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. Therefore, sham evidence was given priority by the GDG when developing the recommendation. |

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| | | | | Brinkhaus B, Witt CM, Jena S, Linde K, Streng A, Wagenpfeil S et al. Acupuncture in patients 26 with chronic low back pain: a randomized controlled trial. Archives of Internal Medicine. 2006; 166(4):450-457<br><br>Leibing E, Leonhardt U, Koster G, Goerlitz A, Rosenfeldt JA, Hilgers R et al. Acupuncture treatment of chronic low-back pain -- a randomized, blinded, placebo-controlled trial with 9 month follow-up. Pain. 2002; 96(1-2):189-196<br><br>Molsberger AF, Mau J, Pawelec DB, Winkler J. Does acupuncture improve the orthopedic management of chronic low back pain--a randomized, blinded, controlled trial with 3 months follow up. Pain. 2002; 99(3):579-587 | |
| Association of Traditional Chinese Medicine and Acupuncture | Full 1 | 496 | general | 4. We feel there is clear bias in use of evidence for recommendations of the new NICE guideline. This is exemplified by the contrasting recommendation of exercise vs acupuncture. To illustrate this, The Guideline Development Group of NICE (GDG) "agreed that there was insufficient evidence that one form of exercise was superior to another and a recommendation for a specific exercise modality was not supported from the current evidence base." (Draft-guideline-1, p304). In addition, for exercise over placebo/sham, only two trials are listed as supporting evidence and these were clearly misinterpreted in the new draft of guideline since no real sham exercises were reported in the papers. Therefore, no any evidence of an effect of exercise over sham is presented. Despite this lack of evidence the new draft report still recommends exercise for lower back pain.<br><br>In contrast, acupuncture is removed from the NICE recommendation list even though there is evidence | Thank you for your comment. On revisiting the 'sham exercise' evidence that was included in the draft guidance, the GDG agreed that none of the included sham interventions could be considered as true forms of 'sham exercise' (one was a psychological therapy and the other was an alternate form of exercise), therefore these have now moved to another comparison or excluded as appropriate according to the review protocol. Therefore the revised guideline will no longer have any evidence for exercise versus sham. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology). Although there was insufficient evidence to identify which specific modality to recommend, the GDG felt there was evidence of clinical and cost-effectiveness to support a recommendation for exercise in general for the management of low back pain with or without sciatica. |

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| | | | | that it clearly shows better clinical improvement vs sham treatment. As mentioned previously, there is clear evidence showing that acupuncture provides similar or better clinical outcomes over usual care in comparison with exercise. Taking in consideration the different recommendations of NICE on exercise and acupuncture, it is clear that the NICE GDG applied different criteria in use of evidence to support their recommendations. Based on our considered view of the presented evidence and its interpretation, we strongly call for the NICE GDG to reconsider their recommendations. | |
| British Council for Yoga Therapy | Short | 4 | 14 | We are concerned that this recommendation is not specific in its guidance. The term mind-body exercise could be construed to mean a number of different techniques and specific mention of the relevant mind-body group exercise programmes that NICE are recommending, such as Yoga, would be helpful. | Thank you for your comment. The protocol for the exercise review (section 9.2, table 68) outlines examples of relevant mind-body programmes. |
| British Council for Yoga Therapy | Short | 8 | 23 | Putting this Guideline into practice.<br><br>British Council for Yoga Therapy recommend that where Yoga group exercise is used for people with non-specific low back pain and sciatica, the group Yoga programme is taught by a well-qualified and experienced person, in order to obtain the best outcome for patients. A suitable programme should be directed specifically to back care or back pain as this will provide appropriate guidance, a high level of individual attention and increase the likelihood of a positive outcome for the patient.<br>Yoga therapy, where the Yoga taught is directed to specific health conditions or health needs, is provided by Yoga therapists who are experienced Yoga teachers with further training in Yoga for health needs. Yoga therapists are suitably qualified and experienced to run and teach such group Yoga programmes in order to provide the best patient care and | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |

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| | | | | outcomes. Voluntary regulation of Yoga therapists is provided by the Complementary and Natural Healthcare Council and this provides a high degree of protection and confidence for those using Yoga for health conditions or employing Yoga therapists. Suitable group Yoga exercise programmes can be designed and implemented by trained Yoga therapists who commonly have experience of working with people with non-specific low back pain.<br><br>One of the stronger pieces of Yoga research that NICE considered for this guideline was Tilbrook 2011, (NICE Draft Guideline, Appendix H, Clinical Evidence Tables Page 1227 line 1494). Subsequent to publication of this research, the group Yoga programme used in the trial has been taught to over 400 qualified and experienced Yoga therapists and Yoga teachers in the UK. The training of those 400+ Yoga therapists / Yoga teachers and methodology of the programme has been the same as used in the research study and was carried out by the Yoga for Healthy Lower Backs Institute, a member organisation of British Council for Yoga Therapy. Yoga for Healthy Lower Backs Institute was set up to disseminate the information from this study and train Yoga therapists and teachers in implementing the high quality programme devised for the Arthritis Research funded research study. Using the same programme as used in the research trial provides a level of confidence that this tested Yoga group exercise programme will provide the same positive results as the research study when used more widely.<br>British Council for Yoga Therapy would like to highlight that significant numbers of trained and experienced Yoga therapists and teachers are already offering these programmes to people with non-specific low back pain nationwide and would welcome the extension of this effective intervention into NHS provision as a way of providing low cost treatment to this patient group and where possible to avoid low back pain and sciatica becoming a chronic and disabling condition for significant numbers of people. | |

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| | | | | Through our member organisations, the British Council for Yoga Therapy can access a wide pool of suitably qualified teachers able to offer group Yoga exercise programmes for low back pain and sciatica and would be happy to be contacted to look at ways in which this Guideline can be implemented and GP's can easily direct patients to suitable programmes. Contact British Council for Yoga Therapy Chair: Barbara Dancer at barbaradancer@gmail.com tel:01494 726141 | |
| British Institute of Musculoskeletal Medicine | Full 1 | 20 | 9 | "This is because 'sciatica' is a term that patients and clinicians understand, and it is widely used in the literature to describe neuropathic leg pain secondary to compressive spinal pathology."<br><br>Patients and clinicians frequently do not "understand" this term and will often [more correctly] use sciatica simply to describe pain extending down the leg about which they would then need to decide whether it is originating from a nerve root or referred from other structures. Even should the pain show clinical features suggesting a root origin, most pain is likely to be due to inflammation of the dural root sleeve, a connective tissue pain that is nociceptive rather than neuropathic. Further, only the minority of dural/root pain will be due to actual "compressive" situations when neural deficits may occur and in some cases pain show clinical neuropathic features. Linking sciatica and neuropathic in the same sentence is more reminiscent of an effective marketing device than a description based on evidence. [Olmarker, Bogduk]. | Thank you for your comment, the definition of sciatica used for the purposes of the guideline has now been clarified in the introduction. |
| British Institute of Musculoskeletal | Full 1 | 39 | 29 | For "specified as" we suggest "to include". To 'specify' something already stated to be 'non-specific' is a logical incongruity and, more importantly, appears to exclude any as yet unrecognized entities.<br><br>Many authorities internationally recognize abnormal function | Thank you for your comment.<br>Sacroiliac joint pain was not included within the guideline on the basis that it is a 'pelvic ring' pain problem rather than a low back pain problem. Facet joint pain was included however and the guideline |

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| Medicine | | | | of spinal structures as a primary entity, concordant with accumulating laboratory observations including proprioceptive and muscle activation abnormalities, and with some independence from any of the five ill-defined categories in the list for NSLBP offered. Spinal segmental and somatic dysfunction Code 99.0 of the WHO International Classification of Diseases 2016 is recognised like many other medical syndromes and yet gets no mention at all!<br><br>Most surprisingly your definition covers pain from the upper lumbar region down to the lower buttock yet you exclude sacroiliac dysfunction entirely. A region that has been suggested to be around 15% of all causes of NSLBP (Schwarzer1994). Posterior pelvic pain of pregnancy is also excluded for no good reason.<br><br>There is no mention of Facet joint pain or syndrome | introduction does refer to pain from joints. This has been added to the list of examples. |
| British Institute of Musculoskeletal Medicine | Full 1 | 108 | 29 | Recommendation: “Consider using risk stratification (for example, theSTarTBack risk assessment tool) at first point of contact with a healthcare professional for each new episode of non-specific low back pain with or without sciatica to inform shared decision-making about stratified management.”<br><br>We were pleased that the advice concerning the STarTBack tool was not as prescriptive as in some published guidelines and the analysis of its supporting data puts its effectiveness into perspective.<br><br>A member contributes a view shared widely in our organisation. “If you had an acute back for one week and were asked whether you agreed or disagreed with the following statement (which contains the questionable conflation of two questions) : “My back pain is terrible and it’s never going to get any better”<br><br>What would you think of your interviewer? – I find myself apologising to the patient and promising never to use | Thank you for your comment. The GDG considered that the evidence for STarT Back was amongst the more accurate of the tools. The GDG acknowledged that people could be misclassified by the tool, and recommended that a stratification tool should be considered as an assessment tool at point of first contact, thus allowing for people to be re-assessed for eventual further treatment. Furthermore, the GDG recommended that the tool should inform, but not be a substitute of, clinical decision-making, The GDG acknowledged the predictive value of the STarTBack risk assessment tool. These issues are discussed in section 6.6 (Recommendations and link to evidence) in the Risk assessment and stratification chapter. |

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| | | | | the tool again..<br><br>Interestingly it is used to identify patients with high levels of distress and unhelpful perceptions to allow a more psychologically directed management – but distress may derive from high levels of symptoms and impairment that the tool would not identify - I have had 2 patients who had serious spinal pathology. It does not differentiate."<br><br>We are also concerned that there is reputed to be a 20% error in group allotment. The presence of the tool on the internet with its scoring system and intent could result in some of those it is applied to "gaming" the system, supplying the answers that would get them more attention and validation.<br><br>We would hope that those in the role of clinicians of first contact would have the training to elicit the various aspects of a bio-psychosocial assessment with more accuracy and sensitivity [in all aspects of the word] than this tool.<br><br>There is the question of equity: if some patients are going to have more resources devoted to their management than others they will need to have confidence that this is decided by individual clinical judgement and not a hasty short questionnaire with what many may find uncomfortable forced-choice questions that do not have a very reliable outcome. | |
| British Institute of Musculoskeletal Medicine | Full 1 | 199 | 13 | Recommendation 6. "Provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, including: □□information on the nature of non-specific low back pain and sciatica; □□encouragement to continue with normal activities as far as possible. "<br><br>As faulty perceptions of their situation and unhelpful behaviours, such as fear avoidance, have been widely held to be the origins of chronicity in NSLBP, should there not be a | Thank you for your comment. On consideration of the evidence, the GDG prioritised other areas for research. The self-management recommendation has now been edited as follows: 'All healthcare professionals should provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, at all steps of the treatment pathway. This should include: information on the nature of non-specific low back pain and |

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| | | | | recommendation for more research on specific inputs of information and advice. The evidence for self-management is accepted to be of poor quality. Many patients seen with prolonged episodes of NSLBP are uncertain what their response should be to pain during activity: what does “as far as possible “ mean in the preceding recommendation? | sciatica; encouragement to continue with normal activities’. |
| British Institute of Musculoskeletal Medicine | Full 1 | 607 | 42 | 16.1 “Skeletal muscle relaxants are used for treating chronic muscle spasm, which may also be painful. These drugs bind to different receptors and exert their effect on muscles by central nervous system mechanisms, and are distinct from the peripherally acting muscle relaxants “<br><br>Although the draft report finds no evidence for their effectiveness and does not recommend using “muscle relaxants”, it does refer to drugs by that title, suggests research into the effectiveness of benzodiazepines, and acknowledges that they are used, and so reinforces the idea that they are part of clinical practice. This ‘product placement’ should have no place in the report; better a more rational statement that people may be anxious as a result of a sudden onset of disabling back pain and have difficulty relaxing with the result that muscles involved in the problem may go into spasm. In the short term a sedative may be useful provided that, to reduce anxiety, clear prior information is given that muscle spasm pain does not signify increasing harm to any structure any more than does an attack of cramp in the calf. The mention of “chronic muscle spasm” is surprising as few clinicians seem aware of this as a clinical entity and advice is against prolonged use of these agents.<br><br>What is the basic science proof of concept for describing benzodiazepines as “muscle relaxants”? Animal model work originally justifying these drugs crudely assessed motor control during ‘voluntary’ activity on rotating drums at drug levels where contemporaneous tests of spontaneous activity would suggest marked central sedation rather than any direct | Thank you for your comment. The GDG considered that this is common terminology. The BNF defines benzodiazepines as a skeletal muscle relaxant, as does a Cochrane review on muscle relaxants for nonspecific low back pain (Van Tulder, M. W., Touray, T., Furlan, A. D., Solway, S., & Bouter, L. M. (2003). Muscle relaxants for nonspecific low back pain: a systematic review within the framework of the Cochrane collaboration. Spine, 28(17), 1978-1992.). We therefore believe this wording is appropriate and should remain unchanged. |

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| | | | | muscle effect [Indian J Pharmacol. 2015; 47(4): 409-13]. Is this experimental model testing a homologous phenomenon, a meaningful surrogate, for muscle spasm in acute back pain? Some patients may be anxious and find it difficult to relax in which case sedation may be useful – is this muscle relaxation? | |
| British Institute of Musculoskeletal Medicine | Full 1 | 666<br><br>669 | 34 | Recommendation 19: "Offer oral NSAIDs for managing non-specific low back pain taking into account potential differences in gastro-intestinal, liver and cardio-renal toxicity and; the person's risk factors, including age."<br><br>Outcomes of RCTs are all short-term effects on pain and function while taking the drug. In chronic NSLBP that may be useful but in acute first attacks or relapses the use of any drug should surely test the expectation of patient and clinician that it may hasten recovery.<br><br>Research recommendations: We suggest:<br><br>NSAIDs vs placebo; effects on rate of recovery of acute episodes of back pain, rather than short-term symptom levels during drug-use.<br><br>This would be to test the often-stated rationale for analgesia that it facilitates mobilisation into otherwise painful activities thereby accelerating recovery. There are strong rational arguments and some experimental evidence against confronting pain barriers during activity as a means of hastening recovery. | Thank you for your comment. The recommendation for NSAIDs has been revised to 'consider' rather than 'offer' to reflect the evidence base. However, the GDG did not consider that this area is a priority for further research given that there is existing evidence available. |
| British Institute of Musculoskeletal | Full 2 | 37 | 16 | Recommendation 30 : "Do not offer spinal injections for managing non-specific low back pain."<br><br>Prolotherapy: We found it very difficult from your tables with breakdown of the studies to work out which study was which without knowing them myself in some detail. | Thank you for your comment.<br><br>References are not provided in the GRADE summary tables to focus on the body of the evidence rather than the individual studies. . |

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| Medicine | | | | However you mention only 3 studies – the small one with only 11 patients (? Matthews) and then the Ongley and Klein studies which you rightly criticise as 'weak'. However you fail to mention the importance of the subgroup analysis in the Klein study which subtracted the hyperalgesic patients from both groups and then reanalysed the data to find a significant result in favour of the prolotherapy group.<br><br>Most importantly you excluded the Yelland study of 2004 altogether due to 'SR – used as a source of references' which needs explaining. [ Yelland MJ, Glasziou PP, BogdukN, Schluter PJ,McKernon M. Prolotherapy injections, saline injections and exercises for chronic low back pain: a randomised trial. Spine 2004; 29(1):9–16.]<br><br>Considering the growing popularity of this treatment around the world and the relative simplicity I am most surprised that you do not consider it worthy of a recommendation for further research using defined subgroups of NSLBP which are now clearly accepted as existing. | The Klein subgroup analysis has not been included in our review as it did not match the subgroup analysis pre-specified at protocol stage (please see Appendix C.15 for details.<br>The exclusion reason for Yelland 2004A has been corrected in the excluded papers list; it was excluded from this on account of incorrect intervention (Appendix L.15). Participants were randomised to both spinal injections or saline and exercise or normal activity. Some of the participants in the prolotherapy group would also have received exercise, and therefore this did not meet our protocol for inclusion.<br>Regarding research recommendations, the GDG considered that there was a sufficient evidence base for this topic to inform recommendations and prioritised research recommendations in other areas. |
| British Institute of Musculoskeletal Medicine | Full 2 | 59 | 29 | Rec. 31."Consider referral for assessment for radiofrequency denervation for people with chronic non-specific low back pain with suspected facet joint pain when:  non-surgical treatment has not worked for them, and they have moderate or severe levels of back pain (rated as greater than 5 on a visual analogue scale, or equivalent)."<br><br>'if you suspect facet joint pain' when all else has failed then proceed to a diagnostic medial branch block – with no clinical features supposedly helpful every candidate should get this. We know that the prevalence of facet pain in the population of chronic low back pain patients is 15% in the younger adult rising to 40% in the older adult.(Schwarzer1994, Schwarzer 1995). | Thank you for your comment. The false positive rate following single blocks is one of the reasons that radiofrequency denervation is only successful for a proportion of patients – this is reflected in the meta-analysis. The majority of the reviewed trials incorporated a 50% relief from a single block paradigm and the results reflect the inclusion of patients who have a false positive response to the test injection. Where studies introduced two blocks or higher expectations of relief following the blocks, no heterogeneity was observed. |

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| | | | | Limiting factors applying to the recommendation:<br>High false positive rate "placebo" of 32-38%<br>Given that facet pain accounts for approx.. 25% all chronic low back pain (15-40%)<br>1000 patient injections would yield > 600 positive results<br>- of which only 250 would be true positive and 320-380 false positive.<br>You could improve the specificity by doing double diagnostic blocks<br>eg. 1600+ patient injections would yield 250 true positive<br>However your cost /resource calculations seem to have been generously assuming that upwards of 40% of patients (Nath's study suggests 69%) will give a true positive response. | |
| British Medical Acupuncture Society | full 1 | 303 | 7 | "The GDG noted that there was some evidence of benefit for all exercise types compared to sham,…"<br>This is incorrect – see point 1 above. There is no data presented that shows a significant effect of an exercise intervention over over sham – this must be reconsidered, and the superior efficacy data on acupuncture must be reconsidered. | Thank you for your comment. On revisiting the sham exercise evidence, the GDG agreed that none of the included sham interventions were true forms of sham exercise. Therefore the revised guideline no longer has any evidence for exercise versus sham. This statement has been updated in the LETR to reflect the lack of evidence for exercise compared to sham. The GDG considered the changes to the evidence and decided that this did not change the recommendation. Due to the absence of sham evidence, the GDG considered the usual care evidence as a comparator primarily instead, which still supports the original recommendation. The GDG also reconsidered the evidence for acupuncture, however agreed that the evidence compared to sham was conflicting and therefore should not be recommended within the NHS setting. |
| British Medical | full 1 | 452 | 15 | Table 12.6 "12. Consider manipulation, mobilisation or soft tissue techniques (for example, massage) for managing non- | Thank you for your comment. This recommendation is only for the use of manual therapies in combination |

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| Acupuncture Society | | | | specific low back pain with or without sciatica, but only as part of multi-modal treatment packages."<br><br>Which forest plots from Appendix K are used to support this recommendation?<br>I cannot find data for these interventions that exceeds the data supporting acupuncture – this must be reconsidered, and the superior data on acupuncture must be reconsidered.<br><br>Acupuncture is often used alongside rehabilitation and exercise in order to facilitate increased physical activity in patients with low back pain. There is no reason to avoid recommendation of acupuncture alongside exercise, particularly if similar manual interventions with a less convincing body of evidence are recommended. Acupuncture should be recommended in the management of low back pain. | with other treatments, based on evidence from chapters 9, 12 and 17 looking at multidisciplinary biopsychosocial rehabilitation, exercise, and manual therapy. The corresponding forest plots are in sections K.5.25.8, K.8.5.3.7, K.8.5.3.8, K.8.5.3.9, K.13.1.4<br>Acupuncture could not be considered as part of a treatment package as none of the trials looking at such packages included acupuncture as part of the intervention. |
| British Medical Acupuncture Society | full 1 | 493 | 7 | Table 13.6 "Acupuncture versus placebo/sham in low back pain without sciatica<br>For the placebo/sham -controlled evidence in the low back pain population, the GDG agreed that no clinical benefit was seen for pain or function. Heterogeneity was observed in the meta-analysis that was unexplained by pre-specified subgroup analysis of type of acupuncture or duration of pain. "<br><br>See forest plots in point 2&3 above – with correct data there is an effect on pain in both short and long terms. Heterogeneity is explained by Haake – a trial with an uncharacteristically large number of participating clinicians.<br><br>Based on the corrected data there is a stronger statistical argument for recommending acupuncture as compared with either exercise or manual therapies. This is particularly the case considering the more favorable health economic data. Acupuncture should be recommended in the management of low back pain. | Thank you for your comment. The data in forest plots 667 and 668 has been checked. Data from Brinkhaus 2006 has been amended however no amendments were necessary for data from Leibing 2002 as the change scores reported were correctly included in the meta-analysis.<br>The GDG agreed a priori at protocol development stage that heterogeneity would be assessed based on subgroup analysis for chronicity of pain or the type of acupuncture administered where applicable. However, this was not possible for these studies, therefore the heterogeneity present is unresolved. The GDG reconsidered the evidence after amendments to the review were made but agreed that there was still not sufficient consistent evidence of benefit to recommend acupuncture. |

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| Centre for Rehabilitation Research, University of Oxford | Full 1 | 41 | Table 6 | The guideline is open to substantial criticism relating to interpretation of important differences. An MCID is not the same as a between group difference. The expected between group difference depends on the size of the difference, the number of people you anticipate responding in each group, and the variability in the sample. The review has many examples where modest but important differences detected in large multi-centred trials have been ruled as not important, and the variability of the underlying data not considered. To consider an standardised effect of 0.5 as indicative of clinical significance and 2 point change on the RMQ seems open to substantial question. | Thank you for your comment. We are aware that the term MCID or minimal important difference (MID) is frequently used to imply the difference that is meaningful to an individual. However, it can also be used to define the minimum between group differences. Where possible the GDG used values defined in the literature (established between-group MIDs e.g. for the SF-36). However where these were lacking, GDG consensus was used to agree what would be considered as a meaningful difference between groups to demonstrate that something was more effective than the comparator. The MID was not used in isolation for decision making, but it was taken into account, alongside the quality of the evidence and clinical expertise, to interpret the body of evidence (across all outcomes) and to assess if each intervention was good enough to be recommended. |
| Centre for Rehabilitation Research, University of Oxford | Full 1 | 578 | Table 285 | Why is the type of intervention reported for some but not all the studies. Banth 2015 is described as MBSR but the others are not classified (MBSR, MBCT, Abbreviated version). If we do not know this then we do not know which programme we should use and whether the full programme is necessary or just abbreviated version. | Thank you for your comment. Details about the intervention have been added to the Summary of evidence table (see table 285). For full details as reported by the original papers, please see Appendix H section 11. |
| Centre for Rehabilitation Research, University of Oxford | Full 1 | 595 | Table 299 | This data is reported in Lamb et al HTA 2010 vol 14 no 41 page 41. If you are unable to find data, it is all in the HTA monograph, we are happy to point you in the right direction. | Thank you for your comment. The quality of life outcomes in Table 299 (section 15.4.2) and relative forest plots (Appendix K, section K.11) and GRADE table (Appendix J, Table 258) have now been updated. |
| Centre for | Full 1 | 736 | | The following recommendation is made: | Thank you for your comment. We have now clarified that ‘significant psychosocial obstacles to recovery’ |

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| Rehabilitation Research, University of Oxford | | | | *Consider psychological therapies for managing non-specific low back pain with or without sciatica but only as part of multi-modal treatment packages. Consider a combined physical and psychological programme (preferably in a group context, that takes into account a person's specific needs and capabilities) for people with persistent non-specific low back pain or sciatica:*<br>□ *when they have significant psychosocial obstacles to recovery,*<br>*or*<br>□ *when previous treatments have not been effective.*<br><br>There is no description or definition of psychosocial obstacles to recovery. This should be much more transparent.<br><br>What evidence is there to suggest that this treatment does not help unless previous treatment has failed? Many trials have demonstrated that using MDR or psychological interventions as a first off is helpful.<br><br>The evidence that STARTback provides on a variety of treatments as well as stratification seem to be missing. | include avoidance of normal activities based on inappropriate beliefs about their condition. This has now been added to the wording of the recommendation and to the Recommendations and link to evidence sections of the MBR chapter (section 17.6).<br><br>The GDG acknowledged the difficulty of defining who should be offered a CPP programme, as discussed in the 'other considerations section of the 'evidence and link to recommendations' section of this chapter. They agreed that a CPP programme might be helpful and appropriate in the early stages in some group of people, i.e. those with significant psychosocial obstacles to recovery. Otherwise, the GDG felt that such intervention would be most effective when previous treatments have failed as part of a stepped care approach. This is reflected in the wording of the recommendation.<br><br>The STarTBack trial was not included in the multidisciplinary biopsychosocial review because of stratification affecting original randomisation (participants were first randomised and then stratified, and received different interventions according to their strata). Discussing CPP programmes, the GDG nonetheless noted that evidence from the risk stratification review informed recommendations for identifying people who might benefit from a combined physical and psychological approach this was discussed in the recommendations and link to evidence section (see section 17.6). |
| Centre for Rehabilitation | general | General | General | The guideline is very long and complex. | Thank you for your comment, which has been noted.<br><br>NICE are continually looking at how to improve presentation and clarity across all NICE guidelines. |

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| Research, University of Oxford | | | | The short summary could be strengthened by providing a brief description of how decisions were made.<br><br>Short summaries of each section would improve digestion and might outline how clinicians use the guidance in their practice. | |
| Centre for Rehabilitation Research, University of Oxford | general | General | General | We could not find definitions easily. Self-management appears to cover many different elements (stay active, bed rest, unsupervised exercise, patient education, reassurance). This should be made clearer.<br>There is no definition of multimodal.<br>Definitions are essential and would help implementation of the guideline. | Thank you for your comment, the interventions included within the self-management review are specified in the protocol in table 33 and appendix C. The term multimodal has now been removed and replaced with 'a package of treatment including..' as relevant to the recommendation. |
| Centre for Rehabilitation Research, University of Oxford | general | 37 | 11 | The document states: *All searches were updated on 15 December 2010.*<br>If this is correct then this guideline is out of date by a substantial amount.<br>The guideline is missing important definitive new evidence (for example Cherkin 2016, JAMA; Richardson et al PLOS One ; Comer, C., Redmond, A. C., Bird, H. A., Hensor, E. M. and Conaghan, P. G., A home exercise programme is no more beneficial than advice and education for people with neurogenic claudication: results from a randomised controlled trial, PLoS One, 2013,) | Thank you for your comment. This was a typing error. The searches were actually updated on the 15 December 2015. This has now been amended in the guideline. |
| Centre for Rehabilitation Research, Universi | general | 39 | Lines 33 and 40 | Spinal stenosis is included under non-specific low back pain and neurogenic claudication is included under sciatica. Neither of these classifications fits with current understanding of LBP. Spinal stenosis is a specific cause of LBP, and neurogenic claudication is not sciatica. Perhaps a stronger rationale should be given to convince clinicians of the credibility of the decision. | Thank you for your comment. We apologise for this error, spinal stenosis is now included as sciatica rather than low back pain. It was agreed with the GDG that as neurogenic claudication refers to neurological symptoms, usually in the legs and often includes sciatica. Therefore this population was considered as a sciatica population, and not a low back pain population. |

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| ty of Oxford | | | | | |
| Centre for Rehabilitation Research, University of Oxford | Short | 8 | 23 | *NICE has produced tools and resources [link to tools and resources tab] to help you put this guideline into practice.* Please consider linking to the Back Skills Training Package which is an internet based resource, free to NHS clinicians. The development of this online training programme was funded by the NIHR and is available at https://backskillstraining.co.uk/prelogin/. Or www.backskillstraining.co.uk<br><br>The training is for a group based cognitive behavioural intervention which targets physical activity and exercise as the key behaviours (hence is a combined physical and psychological intervention). The training has been accredited by the British Psychological Society. The intervention has been tested for effectiveness in a large multi-centre UK study with extended follow up (quoted in the guideline). The trial was commissioned by the NIHR for the NHS. The trial also provides evidence of cost-effectiveness which is already cited in the guideline. The on-line training is currently being rolled out to 18 trusts across the UK.<br><br>Please contact us if you would like more detail, or have problems accessing the site.<br><br>[eg Ref 269 Lamb SE, Hansen Z, Lall R, Castelnuovo E, Withers EJ, Nichols V et al. Group cognitive 31 behavioural treatment for low-back pain in primary care: a randomised controlled trial and 32 cost-effectiveness analysis. Lancet. United Kingdom 2010; 375(9718):916-923]. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Chartered Society of | Full 1 | 20 | 4-7 | Introduction<br>The use of the phrase “improve spontaneously without intervention” is not in line with the later recommendation about stratification of NSLBP. We would suggest altering the wording to “improve with initial primary care management, | Thank you for your comment. The introduction has been edited and this sentence has been edited as suggested. |

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| Physiotherapy | | | | without the need for investigations or referral to specialist services". This is more aligned with the recommendation later in the document, giving consistency in language throughout. This comment also applies to the short version of the guideline, page 11, line 10. | |
| Chartered Society of Physiotherapy | Full 1 | 22 | 3-5 | Development of the guideline<br>We welcome the focus on assessment and management from first presentation onwards, as opposed to having restrictions on the duration of low back pain as in the previous guideline. However, further information is needed on the rationale behind this move, as many clinicians are used to categorising patients as acute or chronic. This change may act as a barrier to implementation if guideline users do not understand the rationale and evidence base behind it, and why the use of "chronic" and "acute" are less prevalent. | Thank you for your comment. We agree that defining low back pain in terms of duration can be unhelpful. The GDG agreed that low back pain almost certainly represents a continuum where defining populations at risk of poor outcome, regardless of duration, is more important than defining the population in terms of duration alone. The introduction has been amended to reflect this view. |
| Chartered Society of Physiotherapy | Full 1 | 108 | 29 | Risk stratification<br>We welcome this recommendation, and how the wording emphasises that stratification tools should be used to support shared-decision making for further management. We note that the GDG highlighted the importance of the tool both in stratifying subgroups and informing appropriate management. The capability of the tool to inform management should be made more explicit throughout the guideline by linking/referring to the stratification tool in later recommendations e.g. psychological interventions, multidisciplinary biopsychosocial rehabilitation (MBR). | Thank you for your comment. The GDG recommended to consider the use of a stratification tool that may be used to inform shared decision-making about stratified management. The GDG felt there was not enough evidence to recommend a specific tool, nor specific sets of interventions for stratified management. However, the recommendation has now been edited for clarity as follows: Based on risk stratification, consider simpler and less intensive support for those likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach). For more details please see section 6.6 (Recommendations and link to evidence). |
| Chartered Society | Full 1 | 147 | 23 | Clinical imaging<br>We welcome this recommendation which encourages sensible use of imaging rather than overuse. | Thank you for your comment |

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| of Physiotherapy | | | | | |
| Chartered Society of Physiotherapy | Full 1 | 147 | 23 | Question 2 response<br>Whilst we welcome this recommendation, we anticipate this could be a challenge to implement due to patient expectations. However, we also recognise that it is the clinician responsibility to educate patients about the purpose of imaging, fully explaining why they do not feel a referral for imaging is necessary. Whilst this guideline will be helpful in supporting clinicians when explaining imaging choices to patients, we anticipate that further resources may be required to gain patient buy-in when imaging isn't indicated. | Thank you for your comment. Section 7.6 (recommendations and link to evidence, 'trade-off between clinical benefits and harms') reports the rationale for recommendation n.3. The GDG were concerned that if imaging should only be performed in specialist settings, people being referred to a specialist would expect imaging to be performed. The GDG therefore advised that the primary aim of a referral to a specialist service would be a clinical opinion and not necessarily imaging.<br>Your comment will be considered by NICE where relevant support activity is being planned. |
| Chartered Society of Physiotherapy | Full 1 | 199 | 13 | Self-management<br>We welcome this recommendation. Promoting self-management is well-established as part of physiotherapy management of low back pain. We agree with the GDG conclusion that although the evidence for self-management in isolation is far from conclusive, it is important to provide advice to people about their condition. This also helps aid shared-decision making and gives the individual more control over their condition.<br>Could further information be provided on what self-management should look like? For example, it requires a skilled assessment and intervention, as opposed to just the provision of information. | Thank you for your comment. Several types of self-management interventions were reviewed: self-management programmes (including patient education and reassurance for example, the Back Book), advice to stay active, advice to bed rest and unsupervised exercise (including exercise prescription, advice to exercise at home). The evidence reviewed did not enable a more specific definition of what self-management would look like beyond what was stated in the recommendation, although it was noted as important to state that it should be tailored to the individual. |
| Chartered Society of Physiotherapy | Full 1 | 303 | 7 | Exercise<br>Whilst we welcome a recommendation focused on exercise, this recommendation highlights some inconsistencies in how the GDG has approached the evidence. We are unsure as to why the recommendation is only a "consider" recommendation rather than an "offer" when the evidence suggests that supervised exercise is more effective than self-management and unsupervised exercise in reducing pain, improving function, and decreasing healthcare utilisation. This | Thank you for your comment. A consider recommendation was made for exercise as although there was evidence of an effect, there was not strong consistent high quality evidence providing certainty of the effect. This is as per guidance in the NICE manual for strength of recommendations.<br>This is consistent with the approach taken in other reviews. |

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| | | | | is inconsistent with the strength of recommendation given for self-management, and we would recommend that recommendations about exercise are “offer” instead of “consider”. | Regarding self-management, the GDG have clarified that the recommendation is intended to apply as a principal alongside all treatment for people with low back pain and sciatica as part of routine practise. They noted that the evidence from the review was weak, however it was also acknowledged that this review should be considered alongside evidence from the review of multidisciplinary biopsychosocial rehabilitation programmes and combinations of interventions which also included self-management principles. Considering this as a body of evidence, the GDG agreed that a good practice statement to support self-management was justified.. The LETR and recommendation have been updated to clarify this. |
| Chartered Society of Physiotherapy | Full 1 | 303 | 7 | We are also unclear as to why there is a focus on group-based exercise interventions, when there is no evidence in the review to suggest that this is superior to individual exercise interventions. The impact of higher cost associated with individual exercise is used as a reason for this decision, yet this is not based on economic evidence or economic modelling. Physiotherapists also report concerns over group exercise with regards to DNA rates.<br>In light of this, we would suggest altering the recommendation to “*offer* supervised exercise that incorporates individualisation and progression of exercises”. This can be delivered in a group or individual basis, depending on the needs of the individual. | Thank you for your comment. The GDG found no difference between group and individual exercise in terms of clinical evidence. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care. Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the cost effectiveness evidence, they concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. |
| Chartered Society of Physiotherapy | Full 1 | 329 | 25 | Postural therapies<br>We understand and agree with the rationale behind making no recommendation with regards to postural therapies, namely the Alexander technique. However, we are less clear on why this is not included as a research recommendation. Throughout the text explaining the recommendation and link | Thank you for your comment. The GDG considered making a research recommendation; however felt that due to the likelihood of a follow up to the ASPEN trial, one should not be prioritised for this topic. The GDG recognise that as of yet this has not been funded, however, are aware that NICE research |

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| | | | | to evidence, it is clear that the Alexander technique could be clinically and cost effective. However, this conclusion is based on just one trial, and therefore further research is needed. The decision is then made not to include this as a research recommendation, because the existing trial is a feasibility trial. Whilst it is likely that this will be followed by a larger trial, unless this is registered, we are not sure how the research recommendation can be rejected on this assumption. If there are no larger trials registered, we would recommend that further research into postural therapies (namely Alexander technique) are included as a research recommendation. | recommendations are primarily picked up by the same funding body in charge of determining the funding for the ASPEN trial, and therefore would be subject to the same funding stream and would be considered by this funder. |
| Chartered Society of Physiotherapy | Full 1 | 452 | 15 | Manual therapies<br>We welcome the focus on multi-modal treatment here. Physiotherapists report that the use of manual techniques can often open a “window of opportunity” to then enable the patient to participate in more active treatment such as exercise. This recommendation reflects the practice of a number of physiotherapists who use manual techniques as just one aspect of their treatment. | Thank you for your comment. |
| Chartered Society of Physiotherapy | Full 1 | 493 | 7 | Acupuncture<br>This “do not use” recommendation is being contested by a number of physiotherapists who use acupuncture to help facilitate an active rehabilitation approach in treating low back pain. There are a number of different concerns about how this recommendation was reached.<br>The first concern is the approach taken in reviewing the evidence. We recognise that the approach taken is the same as the approach to the evidence for acupuncture use in osteoarthritis (CG 177), i.e. the evidence needs to show superiority of acupuncture over sham. However, we believe this rationale is flawed and at odds with the review question. “Developing NICE guidelines: the manual” clearly states that “NICE prefers data from head-to-head RCTs to compare the *effectiveness* of interventions” (page 109). Sham controlled trials demonstrate the efficacy of an intervention, rather than the effectiveness. Therefore, to answer the review question | Thank you for your comment. Effectiveness is used here as a broad term to include efficacy and we will clarify this in the glossary. All of the reviews do look to determine both (using ‘effectiveness’ as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. |

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| | | | | "What is the clinical and cost-effectiveness of acupuncture in the management of non-specific low back pain and sciatica?" it seems appropriate for trials comparing acupuncture to usual care to be the basis of the recommendation. | |
| Chartered Society of Physiotherapy | Full 1 | 493 | 7 | The approach taken to favour the sham-controlled evidence is not only at odds with the review question, it is also inconsistent with the approach taken for other modalities. Other modalities have been recommended despite not having evidence to show they are superior to sham interventions (e.g. psychology therapies, exercise).<br>The approach either needs to be consistent or the inconsistencies fully explained. | The GDG were careful to ensure consistency in their decision making across the evidence reviews, giving placebo/sham evidence priority across reviews. However, for some interventions, sham/placebo comparisons were either not possible to conduct or not available Where evidence reviews lack sham comparisons because they were not feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to first demonstrate a treatment effect separate from the non-specific treatment effects. |
| Chartered Society of Physiotherapy | Full 1 | 493 | 7 | The recommendation for "do not use" is particularly strong, considering evidence from 2 large trials showed a clinically important benefit of using acupuncture vs sham in the physical component of SF-36 in the short term and long term (on page 491). To state that any benefit in the acupuncture vs usual care trials was "probably the result of non-specific contextual effects" is quite vague without explicit explanation to justify a "do not use" recommendation. | Thank you for your comment. Although the usual care evidence was considered by the GDG, it was agreed a priori to give priority to sham evidence in order to demonstrate a treatment effect separate from the non-specific treatment effects. The GDG felt that the sham evidence was conflicting, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up. It was agreed that as there was a large body of evidence, that did not demonstrate a consistent effect a definitive statement was required to advise what should be offered or considered on the NHS that would make best use of available resources and best benefit to patients. Therefore 'do not use' was agreed as the most appropriate recommendation in this context. |

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| Chartered Society of Physiotherapy | Full 1 | 494 | general | The GDG state that the benefits of acupuncture vs usual care for pain were not sustained longer than 4 months. However, the forest plot in Appendix K (page 159) shows superiority of acupuncture versus usual care. This is a further example of inconsistency in the GDG analysis of the evidence.<br><br>In light of this, and the preceding comments, we would recommend the GDG revisit how they have used the evidence to reach a recommendation on acupuncture. | Thank you for your comment. The GDG has revisited the acupuncture review and have considered the evidence for acupuncture against usual care. However, across all reviews in this guideline, sham/placebo evidence was given priority to demonstrate a treatment effect separate from the non-specific treatment effects. Based on the conflicting sham evidence base for acupuncture, the GDG agreed against recommending acupuncture in NHS practice. |
| Chartered Society of Physiotherapy | Full 1 | 500 | general | Electrotherapies<br>We recognise that much of the literature around the use of TENS is conflicting. However, this is not uncommon for other modalities covered in this guideline. The evidence review suggests that TENS is effective at improving quality of life and decreasing pain in the short term in patients with low back pain only, when compared to sham (page 560, lines 25-27). Whilst the evidence is conflicting around the effect of TENS on function when compared to sham, this is unsurprising given research cross-matching patient-reported functional benefits of TENS against the RMDQ, which found RMDG has limited capacity to capture patient-reported benefits (Gladwell, 2013).<br><br>*Gladwell PW. Focusing outcome measurement for transcutaneous electrical nerve stimulation evaluation: incorporating the experiences of TENS users with chronic musculoskeletal pain [PhD Thesis]. Bristol, UK: University of the West of England; 2013*. | Thank you for your comment. Although a clinical benefit was seen for quality of life and pain in the low back pain population when compared with sham, this was from very limited evidence in a small sample, and overall the body of evidence did not demonstrate benefit.<br>The GDG agreed that outcomes should be measured consistently throughout reviews and across interventions and agreed that RMDQ should be included as an appropriate measure of function.<br>On the basis of the evidence reviewed, the GDG concluded that there was insufficient evidence of clinical benefit to support a recommendation for the use of TENS for low back pain or sciatica. |
| Chartered Society of Physiotherapy | Full 1 | 601 | 6 | The reference to the cost of a band 5 nurse seems irrelevant in the unit cost table. Why have band 5 costings been used for nursing staff, whereas band 7/8a costings are used for psychologists and physiotherapists? This may reflect the range of expertise in delivering psychological approaches, but this is not made clear. Perhaps further clarity could be provided on the need for different levels of expertise/input depending on the complexity of the patient. | Thank you for your comment. We agree and we have amended the costing for nursing staff to reflect a band 7 is required to deliver this intervention. |

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| Chartered Society of Physiotherapy | Full 1 | 666 | 34 | Pharmacological interventions<br>Physiotherapists have raised concerns about the lack of options with regards to pain relief that these recommendations offer. Given the lack of good quality evidence available, would a more nuanced approach to this be more helpful in aiding decision making by prescribers? This could include clearer guidance about trialling analgesics in individual patients, including guidance on how/when to stop them in the absence of effectiveness, and suggest specialist assessment for those with complex pain needs. | Thank you for your comment. The GDG can only make recommendations based on evidence included and reviewed within this guideline. When or how to stop analgesics was not prioritised as an area for the scope of this guideline and the evidence reviewed did not inform different management for people with complex pain needs. Therefore it will not be possible to make the suggested recommendations within this guideline. |
| Chartered Society of Physiotherapy | Full 1 | 671 | general | The GDG highlights the need to also use NICE clinical guideline 173 for the pharmacological treatment of sciatica – could this be made clearer in the recommendations, as there is potential for confusion with regards to recommendations 26 and 27. | Thank you for your comment. We have now added a recommendation to cross refer to CG173 for the pharmacological treatment of sciatica. |
| Chartered Society of Physiotherapy | Full 1 | 673 | 25 | Multidisciplinary biopsychosocial rehabilitation (MBR)<br>Would it be more accurate to focus on the improvement in quality of life as the primary aim of MBR, rather than decreasing disability and improving function? | Thank you for your comment. The GDG agreed that the outcomes should be consistent across reviews, and that quality of life was a critical outcome to decision making, as well as function, pain and psychological distress. This is defined in the protocols and the 'relative value of different outcomes' section of each 'evidence and link to evidence' table in the chapters. |
| Chartered Society of Physiotherapy | Full 1 | 736 | 1 | Whilst we welcome this recommendation, we are unclear as to why there is a preference for a group programme. The evidence does not suggest that group treatment is superior to individual, and there is no economic model demonstrating cost-effectiveness. We would suggest re-wording to "either group or individual sessions, depending on individual's needs". | Thank you for your comment. A preference for group programmes was expressed in the recommendations in the light of clinical evidence and cost effectiveness analysis which indicated that group programmes were likely to be more cost effective. |
| Chartered Society of Physiotherapy | Full 1 | 764 | 5 | Return to work<br>We welcome this recommendation. Return to work is a key area where physiotherapy can impact, and we are supporting our members to consider how they can facilitate people to return to work, including people with low back pain. | Thank you for your comment. |

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| Chartered Society of Physiotherapy | Short | 1 | 6 | It could be beneficial to also include what the guideline does *not* cover here, rather than towards the end of the document where this information currently sits (page 11, lines 21-29) i.e. that it does not include progressive neurological deficit or cauda equine syndrome. | Thank you for your comment. This information is found in the Context section of the short version of the guideline. A clearer explanation has been added to explain who is covered by this guideline. |
| Chartered Society of Physiotherapy | Short | 6 | 8 | In the full version of the guideline, reference is made to NICE guidelines on neuropathic pain (CG173) for guidance on the pharmacological management for sciatica. Could this guideline be referenced here too? Or further clarity that the recommendations are for NSLBP alone? | Thank you for your comment. We have now added a recommendation to cross refer to CG173 for the pharmacological management of sciatica. |
| Complementary and Natural Healthcare Council | Full 1 | 308 | 3, 7−8, 11−14, 21 | We note that NICE has categorised the Alexander Technique as a 'postural therapy'. However, in our work with the Alexander Technique teaching profession we have come to understand that it is in fact a taught approach to improving functioning (including of postural support mechanisms), movement, response to stimuli and breathing. There may be a positive impact of Alexander lessons on posture but it is not a postural therapy as such. We therefore support the comments submitted by the Society of the Teachers of the Alexander Technique about this issue. | Thank you for your comment. While the GDG recognises the complex nature of the Alexander Technique, and the description provided by STAT, it was felt that due to the focus of the technique being on postural movements and support, the categorisation of the technique as 'postural therapy' was appropriate. We acknowledge that falling under the broad heading of 'postural therapy' may be an over-simplification, but each comparison was labelled to state the technique used and the GDG were made aware of the components of each trial, and these were stated in detail in the evidence tables as described by the included studies. |
| Complementary and Natural Healthcare Council | Full 1 | 331 | 25 | In relation to the Alexander Technique, we were pleased to see that the GDG recognised promising results for use of Alexander Technique lessons to support people with low back pain. However, we were disappointed to see that the GDG made no recommendation for further research. The rationale provided was that further research was already being planned as a possible follow-up to the ASPEN feasibility study. However, no such trial has been funded, and so, given the promising initial findings, it would seem to be in the interest of those with low back pain to recommend further research. | Thank you for your comment. The GDG considered making a research recommendation, however due to the likelihood of a follow up to the ASPEN trial, one would not be prioritised for this topic. The GDG recognise that as of yet this has not been funded, however are aware that NICE research recommendations are primarily picked up by the same funding body in charge of determining the funding for the ASPEN trial, and therefore would be subject to the same funding stream and would already be under consideration without prioritisation. |

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| Complementary and Natural Healthcare Council | Short | 5 | 24 - 27 | Question 1: We are pleased to see that yoga is included in the recommendations for combined physical and psychological programmes. We agree that the group approach would suggest a cost-effective way to address low back pain. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Complementary and Natural Healthcare Council | Short | 5 | 24-27 | Question 3: As in our comments 2 above we recommend that practitioners selected are yoga therapists registered with CNHC's Accredited Register. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Complementary and Natural Healthcare Council | Short | 5 | 2-3 | We are pleased to see that massage remains in the guidelines, albeit only as part of a multi-treatment package. | Thank you for your comment. |
| Complementary and Natural Healthcare Council | Short | 5 | 2-3 | Question 3: We recommend that to ensure good practice, only massage therapists registered with an Accredited Register such as the Complementary and Natural Healthcare Council (CNHC) are used. The Accredited Register Programme is a government-backed programme to accredit voluntary registers and is a guarantee of standards. All practitioners on CNHC's Accredited Register have met UK wide standards, hold professional indemnity insurance, abide by a strict Code of Conduct, Ethics and Performance and must take part in CPD each year. For more details see www.professionalstandards.org.uk . For more details of CNHC see www.cnhc.org.uk | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |

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| Complementary and Natural Healthcare Council | Short | 5 | 6-7 | Although not directly within our remit, we are disappointed to see that recommendation 1.2.8 proposes not offering acupuncture. It appears that NICE has focused on studies which compare acupuncture to sham acupuncture, rather than to other treatments, and so has made a decision based on an assessment of efficacy rather than effectiveness. We suggest NICE reviews this approach and includes a continued recommendation for acupuncture, prior to publishing the final guideline. | Thank you for comment. Effectiveness is used here as a broad term to include efficacy and we will clarify this in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. |
| Department of Health | General | general | general | No comments | Thank you |
| East Kent Hospital University NHS Foundation Trust | general | General | general | NICE posed the question: 1. Do any recommendations represent a substantial increase in costs, and do you consider that the reasons given in the guideline are sufficient to justify this?<br><br>Response: Yes. The guideline recommends to refer early after trial of simple analgesics for early possible interventions. It will be putting increase pressure as increase in the referral rates to secondary care. The recommendations of considering advanced technologies like SCS for sciatica will need extra resources to support increased clinical demands. The evidence used are sufficient to justify that. | Thank you, your comment has been passed to the NICE resource impact team. |
| East Kent Hospital University NHS Foundation Trust | general | General | general | NICE posed the question: 2. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.<br><br>Response: Establishment of multidisciplinary team approach as we don't have a multidisciplinary team in our pain management department. There are funding issues to get dedicated psychology and physiotherapy input which is | Thank you, your comment has been passed to the NICE resource impact team. |

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| | | | | recommended in the guideline. There are no integrated pathways developed for the transfer of these patients back to the community where their management is continued after interventions from the secondary care. | |
| East Kent Hospital University NHS Foundation Trust | General | General | general | NICE posed the question: 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)<br><br>Response: The shared care pathways and risk assessment tools need to be established between primary and secondary care so that the patient transition from one to the other will be smooth and help to ease the pressure for just one system. Promotion of self-management and patient education from an early stage with the help of medical professional will only be possible by pooling resources. Redefining the pathways and service developments will be needed to overcome this. | Thank you, your comment has been passed to the NICE resource impact team. |
| Esoteric Practitioners Association | short | 3 | 4 | Risk Assessment and Risk Stratification - We support the move towards a more holistic approach of dealing with musculo-skeletal conditions within a framework of treating the whole person including their lifestyle and their beliefs and behaviours. Only treating a specific physical anatomical dysfunction (which can sometimes be the main medical approach) from our clinical experience is incomplete and unsuccessful in the longer term.<br><br>There is a case for the combination of a broader medical approach (which includes psycho-social factors) and complementary practices for treating musculo-skeletal conditions based on observances in our own clinical practices, but the absence of a dedicated commitment to researching the use of complementary (not alternative) medicine modalities working alongside conventional medical practices has prevented this from becoming a key NICE guideline consideration. | Thank you for your comment. |

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| Esoteric Practitioners Association | short | 4 | 4 | Self-Management - We support the approach that all patients and health care workers in health care systems are encouraged to take more responsibility for their health and wellbeing. Self care through examining working conditions as well as personal lifestyle choices is a vital part in decreasing the burden that illness and disease currently has on our health systems. | Thank you for your comment. |
| Esoteric Practitioners Association | short | 4 | 26 | Manual therapies - We support the inclusion of personalised one-on-one hands-on gentle manual therapy as one of the most natural and traditionally established approaches to low back pain and sciatica in combination with a holistic approach which includes the person's lifestyle choices and behaviour patterns which are influenced by psycho-social factors. This is a notable move away from the recent observed trends in therapy, which have included 'treatments by telephone' that have been advocated by some health insurance companies and NHS commissioning groups, and that we do not support. It has been our clinical experience that patients with lower back pain benefit greatly from gentle and supportive touch, as a 'role-modeling' reflection from the practitioner to the client in how they may take responsibility for the quality in which they could care for themselves. We observe that this has regularly resulted in clients taking more care of their bodies and supported overall and ongoing body awareness. This in turn supports any personal lifestyle changes that the patient needs to make in order to aid recovery and prevention of their condition. It is important that group work such as 'Back Schools' do not replace personalised care, as each patient's symptoms and circumstances are unique and need to be addressed individually as well. | Thank you for your comment. We agree with you and have not included any evidence from studies of manual therapy interventions delivered over the phone within the review. We have also excluded back schools as an intervention. |
| Esoteric Practitioners Association | short | 5 | 5 | Acupuncture - Whilst we do not promote the specific use of Chinese or Japanese based acupuncture in low back pain, it is an example of how narrow NICE's criteria appears to be when selecting treatment modalities based on selection of research studies that are deemed 'suitable evidence base.' It | Thank you for your comment. When setting the protocol for the evidence reviews, in order to make a well informed decision on the effectiveness of treatments, the GDG agreed the best available evidence should be included. Therefore the inclusion |

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| | | | | is true that we need evidence to guide our medicine and we should constantly review how we do things and what works and what does not for the protection of the public's health and wellbeing. However it is alarming to see an ever-increasing reliance on only selected randomised control studies that due to their nature can only consider fragments of life and never be all inclusive of all factors that contribute to the cause of illness and disease.<br><br>We observe that the 2009 NICE Guidelines on Low Back Pain were far more open to complementary modalities than they are heading toward today. We note that funding commitments since that time, dedicated to the researching of the efficacy of complementary medicine in the UK has actually diminished. We ask then what is the evidence base upon which NICE is making a case for reducing the inclusion of complementary medical practices from its guidelines?<br><br>When studying the efficacy of many interventions or treatment modalities it is almost impossible to remove all bias given the subtle human interactions between client and practitioner and the expectations and beliefs of both the practitioner and the client. It is widely known in medicine through clinical experience and anecdotal evidence that there are many clinically highly effective treatments that are known to work and yet have very little so called unbiased high powered research behind them simply because to test them against a true placebo is impossible.<br><br>Ironically we noted that many studies were eliminated due to apparent excessive bias, however many known and potential useful interventions are more challenging and expensive to research without bias than pharmaceutical studies, so this selection criteria process is in itself flawed and strongly biased towards pharmaceuticals and funded research.<br>In our combined extensive clinical experience, we find the combination of self-management, manual therapy and gentle | of RCTs was agreed for intervention reviews, with non-randomised studies included if there was insufficient RCT evidence available. For the acupuncture review the GDG agreed that there was a large body of RCT evidence available with the inclusion of 29 trials. As stated in the review protocol (appendix C.9), trials were not excluded based on the type of acupuncture the included.<br>The GDG are aware that despite the original guideline for low back pain (CG88 published in 2009) recommending that a course of acupuncture should be considered, this was poorly implemented within the NHS. In updating and re-reviewing the evidence, the GDG do not believe there is sufficient evidence to maintain this recommendation and therefore no longer recommend acupuncture in an NHS setting. |

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| | | | | exercises a simple and effective way of treating low back pain but sadly qualitative studies combining these modalities have been dismissed as having high bias, imprecision or poor quality. Lack of sufficient research evidence does not prove lack of efficacy, in many cases it simply means that more high quality research is required, something we strongly encourage. An important part of the role of NICE, acting on behalf of public interest and safety, is to keep an open agenda for modalities with currently insufficient evidence that could become the recognised treatments of the future. Good quality qualitative research needs to be treated of equal value as quantitative research.<br><br>Medicine and healing are a science but also an art, the art aspect involving the very personal and individual factors that can only be considered in the practitioner - client relationship that by nature is biased but nevertheless valuable and vital in every healing process. It seems that unless an intervention or modality has been proven beyond a doubt to be effective using very narrow research criteria which today is defined as 'evidence-based', it is not included in the NICE guidelines.<br><br>Many years of clinical experience has shown that there is no 'one size fits all' treatment where unique individual patients are concerned, and far from it. It is only the quality of our interaction with them that should remain constant, whilst adapting to suit each individual. The same goes for the treatments. It is only by persisting at times and trying different and sometimes less proven yet clinically effective tools in the tool box that satisfactory results can be obtained. Those tools need to remain in the box, for practitioners and recognised as needed by the finance administrators aided by NICE guidelines.<br><br>In some cases there are modalities which do not have enough research evidence to prove they work beyond a doubt, however they have not been shown to not work either. | |

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| | | | | There is also a wealth of other forms of evidence, which are just as valid as RCTs (e.g. case studies, clinical experience, patient testimonials) and if an intervention is safe and cost effective and appears to work for some people then why rule it completely out of the guidelines? Why not have a section in the NICE guidelines stating that there are some modalities which have some evidence to show that they may be effective but have not been fully researched yet? This would broaden the possibilities of medicine and encourage further research into these modalities.<br><br>It seems to only base our medical interventions and treatments on such a narrow approach to evidence and research is increasingly stifling innovation and creativity and is filtering down the line by influencing the NHS and private insurance companies who are increasingly narrowing what treatment options are allowed to be used at the point of delivery and restricting clinician autonomy. Many of these organisations base their increasingly restrictive policies on the authority of NICE guidelines.<br><br>NICE have a responsibility here - how will new innovations be introduced in the future? Even the treatments suggested in these NICE guidelines started out as anecdotal evidence in clinical practice for centuries long before we arrived at the evidence used here today. This is the very nature of physiotherapy and allied health professions and their long and ever evolving history and the guidelines need to support that process going forward. | |
| Esoteric Practitioners Association | short | 5 | 19 | Psychological Therapy - We support the premise that low back pain is a condition that is more than just physical dysfunction of human tissue but involves much more than this in terms of psychological and emotional factors that play a significant role in the condition and can influence recovery. | Thank you for your comment. |
| Extended Scope Practitio | Full 1 | 19 | general | The diagnosis of "non-specific low back pain" suggests there is no specific cause for the pain (perhaps a combination of pathologies at a number of levels) and hence interventional | Thank you for your comment. |

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| ners Professional Network | | | | management that targets a specific structure such as injection or discectomy would not be indicated.<br>The guidelines suggest that if there is no serious pathology that all back pain is NSLBP. This would not be true or helpful and fair for the patient. Given this diagnosis by a non-specialist at initial assessment without imaging and by following the algorithm could delay treatment for certain patients.<br>The whole guideline seems to chop and change between NSLBP and "specific" back pain/sciatica. | The intended meaning of the term 'non-specific' has been defined in the guideline introduction and, now, modified for further clarity. |
| Extended Scope Practitioners Professional Network | Full 1 | 146 | 23 | The ESPPN would support the more judicial use of imaging and education of patients as to its relative usefulness. Would it be helpful to define "non-specialist" settings for clarity? | Thank you for your comment. The definition of 'specialist setting of care' has been detailed in the recommendation for clarity as 'for example, a musculoskeletal interface clinic or hospital' |
| Extended Scope Practitioners Professional Network | Full 1 | 303 | 7 | Although we welcome the use of group exercise as a helpful and cost-effective way to manage back pain, many patients for various reasons including personal preference, capabilities and needs are unable to participate in a group setting. We feel it would be appropriate to add individual exercise into this recommendation. | Thank you for your comment. Whilst we recognise that there are some individuals who would prefer individual exercise, we were unable to recommend it as an option as group exercise was demonstrated to be cost effective and likely to be more cost effective than individually delivered programmes. However, the recommendation emphasises that people's specific needs, preferences and capabilities are to be taken into account when choosing the type of exercise. |
| Extended Scope Practitioners Professional Network | Full 1 | 452 | 15 | We feel the term "massage" should be removed from the document. This term has different meaning to therapists and the lay person. General massage is rarely used, although some therapists may use more directed soft-tissue techniques such as on trigger points or fascial release. | Thank you for your comment. The recommendation has been reworded to: consider manual therapy for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy, Therefore the term 'massage' has been removed from the recommendation. The term massage has been used in the review under the category of soft tissue techniques as agreed the by |

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| | | | | | the GDG. The term also reflects language used in papers from which the data was extracted. |
| Extended Scope Practitioners Professional Network | Full 1 | 493 | 7 | Acupuncture is a useful part of the multi-modal package provided by physiotherapists. It often gives short-term pain relief which allows patients to then more actively participate in exercise or manual therapy. Staff should be encouraged to use treatment modalities with the most supporting evidence initially but treatments such as acupuncture and TENS have a role to play. Making such dogmatic statements that they should not be used may result in CCGs refusing to fund such treatments. Patients who had previously found acupuncture to be helpful may find they can no longer get the treatment that they find helpful.<br>Perhaps the wording should be “do not offer acupuncture/TENS alone but as part of a multimodal treatment.” | Thank you for your comment. The GDG did not find any evidence in favour of acupuncture or TENS as part of treatment packages, and therefore the GDG could not consider these in a combined treatment context. |
| Extended Scope Practitioners Professional Network | Full 1 | 736 | 1 | Psychological support is often used in secondary care and Pain Services programmes. It would seem appropriate to be able to provide more psychological support in Primary care to prevent unnecessary referrals into secondary and tertiary services. This would involve up-skilling current staff and/or moving secondary care services into the community. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Faculty of Pain Medicine | GENERAL | GENERAL | GENERAL | Spinal Stenosis: A concern is for people with spinal stenosis who seem left with very few options. This is of major concern as this is an elderly group of patients, who tolerate analgesia poorly, who are often not fit for surgery and for whom an intervention may be the only option.<br><br>What are the alternatives in a population unable to tolerate NSAIDs, opioids and anti-neuropathics and not fit for surgery? | Thank you for your comment, however the evidence reviewed demonstrated that epidurals are unlikely to be of significant benefit in spinal stenosis with neurogenic claudication and this would apply equally to those suitable or unsuitable for surgery. Other non-pharmacological treatments recommended in the guideline may be considered. |

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| | | | | The group discussed the evidence that had been conducted in sciatica patients with central spinal canal stenosis. The populations studied comprised people with neurogenic claudication primarily. There was insufficient evidence that epidural injections of local anaesthetic and steroid were effective in this group of people and it was noted that current opinion also reflects this. The group therefore agreed to make a recommendation against using epidurals in people with claudicant leg symptoms caused by central spinal canal stenosis."<br><br>The other paragraph says:<br>"The GDG had more confidence in the evidence for epidurals in sciatica patients with spinal stenosis (steroid was given as an adjunct) because the main study contributing to the meta-analysis was conducted in 400 participants. The group were less confident in the results of the other contributing study, since it was smaller and although it was also conducted in spinal stenosis patients, it differed considerably to the other studies in the review. The population consisted of chronic sciatica patients with over 100 months of pain, and patients could be given as many epidural injections as they needed (the average given was 4). The GDG felt that this did not reflect clinical practice"<br><br>So their conclusions are contradictory. | |
| Faculty of Sport and Exercise Medicine | Full 1 | 17 | 40 | Why are epidural injections not recommended in those with central canal stenosis and neurogenic claudication? What about those not suitable for surgery? | Thank you for your comment. The evidence review demonstrated that epidural injections were not effective in terms of function, responder criteria, quality of life or pain in those with central canal stenosis and neurogenic claudication.<br>The GDG agreed therefore that there should be a recommendation to advise against their use in this population.<br>The recommendation also applies to those patients who are unsuitable for surgical intervention as the |

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| | | | | | evidence demonstrates that epidural injections are unlikely to be of benefit. |
| Faculty of Sport and Exercise Medicine | Full 1 | 19 | 25-30 | This is an important explanation to include and will provide a useful educational model for patient explanation | Thank you for your comment |
| Faculty of Sport and Exercise Medicine | Full 1 | 20 | 9-11 | What about 'sciatica' due to chemical nerve root irritation from an annular disc tear without significant compression? Would that be included here? | Thank you for your comment, the definition of sciatica used for the purposes of the guideline has now been clarified in the introduction. |
| Faculty of Sport and Exercise Medicine | Full 1 | 303 | 7 | Other considerations section: potential for future consideration / research to further investigate sub classification systems for patients with non specific low back pain with or without sciatica and trialling specific exercise therapy according to the sub classification. | Thank you for your comment. Unfortunately, the GDG are unable to make research recommendations on topics that have not been reviewed in the guideline. As sub classification systems were not addressed in this review, the GDG are unable to make a research recommendation on this topic. |
| Faculty of Sport and Exercise Medicine | Full 1 | 667 | Table | Research recommendations: could further study of anti-convulsants be justified on the basis of the evidence presented? | Thank you for your comment. Since there were 3 studies included for anticonvulsants within the review with multiple outcomes, the GDG agreed that there were other areas in the guideline where research recommendations should be given priority. |
| Faculty of Sport and Exercise Medicine | Short | 3 | 9 | 'Stratified' management: will this terminology make sense to the lay reader? Or consider providing a definition in 'Terms used in this document' section page 8, line 17 | Thank you for your comment. The 'Information for the public' document published alongside this guideline explains this in lay terms. |
| Federation of Holistic | Full 1 | 458 | 30 | Table 222 summarises the studies included in the review.<br><br>The FHT would like to highlight that a large, multi-centre study by Haake (2007)[1], which compared verum | Thank you for your comment. Haake 2007 was fully included in this evidence review, and can be found in table 222 labelled 'GERAC trial: Haake 2007'. |

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| Therapists | | | | acupuncture, sham acupuncture and conventional therapy for chronic low back pain, was not included in the review.<br><br>A large, multi-centre study by Haake (2007), which had three arms (verum acupuncture, sham acupuncture and conventional therapy – comprising 387, 387 and 388 patients, respectively) found that at six months, 47.6% of the verum acupuncture group had a 33% or above improvement in three pain-related items on the Von Korff Chronic Pain Grade Scale Questionnaire or 12% improvement or better on the back-specific Hanover Functional Ability Questionnaire. In comparison, 44.2% of the sham group experienced the same response/improvement, and 27.4% of the conventional therapy group experienced the same response/improvement. These results indicate that not only was pain improvement significantly higher in the verum acupuncture control group compared to sham acupuncture, both verum acupuncture and sham acupuncture were more effective than conventional therapy. The FHT is concerned that this significant study was not included in the review.<br><br>1. Haake M, Müller HH, Schade-Brittinger C, et al (2007). German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups, *Archives of Internal Medicine* 167(17): 1892-8. http://www.ncbi.nlm.nih.gov/pubmed/17893311 | |
| Federation of Holistic Therapists | Full 1 | 495 | 7 | In the section, 'Trade-off between clinical effects and costs' in 'Recommendations and link to evidence', it is stated that: '...the GDG decided to ascertain if the intervention [acupuncture] has treatment-specific effects over and above the contextual or placebo effects, and the best comparator to prove this would be a placebo or sham'.<br><br>The FHT disagrees with sham being a 'best comparator' to prove whether acupuncture has treatment-specific effects, over and above contextual or placebo effects. | Thank you for your comment. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG |

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| | | | | It is widely acknowledged that sham acupuncture is not biologically inert and can produce some of the same physiological effects and therapeutic outcomes as acupuncture, including pain relief.[1-4] As such, sham acupuncture is not a 'best comparator' (control) when trying to ascertain if acupuncture 'has treatment-specific effects over and above contextual or placebo effects'. Comparing the outcomes of two interventions that produce similar physical and therapeutic outcomes may impact (reduce) the level of statistical significance between the two interventions in some studies.<br><br>1. Takano T, Chen X, Luo F, et al (2012). Traditional acupuncture triggers a local increase in adenosine in human subjects, *Journal of Pain* 13(12):1215-23. http://www.ncbi.nlm.nih.gov/pubmed/23182227<br>2. Kagitania F, Uchidaa S and Hotta H (2010). Afferent nerve fibers and acupuncture, *Autonomic Neuroscience* 157(1–2): 2–8. http://www.sciencedirect.com/science/article/pii/S1566070210000512<br>3. Harris RE1, Zubieta JK, Scott DJ, et al (2009). Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on mu-opioid receptors (MORs), *NeuroImage* 47(3): 1077-1085. http://www.ncbi.nlm.nih.gov/pubmed/19501658<br>4. Lin D, Lin L, Sutherland K, et al (2016). Manual acupuncture at the SJ5 (Waiguan) acupoint shows neuroprotective effects by regulating expression of the anti-apoptotic gene Bcl-2, *Neural Regeneration Research* 11(2): 305–311. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810996/ | were of the view that the sham comparisons were essentially credible on that basis. |
| Federation of Holistic | Full 1 | 495 | 7 | In the section, 'Trade-off between clinical effects and costs' in 'Recommendations and link to evidence', it is stated that: | Thank you for your comment. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for |

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| Therapists | | | | 'The GDG concluded that there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture and so consideration of cost-effectiveness was not considered relevant.'<br><br>The FHT is disappointed that cost-effectiveness was not considered, as the GDG's conclusion that there was 'insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture' was partly based on evidence/research that used an active control. In addition, errors were present in the data analysis.<br><br>The GDG concluded that there is 'insufficient evidence of an overall treatment-specific effect to support the recommendation of acupuncture'. This conclusion was based, in part, on evidence/research that compares acupuncture to sham acupuncture, and it is widely acknowledged that sham acupuncture can produce similar physiological and therapeutic outcomes to acupuncture, including pain relief.[1-4] Comparing the outcomes of two interventions that produce similar physical and therapeutic outcomes may impact (reduce) the level of statistical significance between the two interventions in some studies. The GDG's conclusion to not consider cost-effectiveness was therefore based, in part, on evidence/ a research model that does not successfully ascertain whether acupuncture has 'treatment-specific effects over and above contextual and placebo'. In addition, errors were made when analysing the data for included studies that compared acupuncture with sham acupuncture (see comments 1 and 2 above).<br><br>1. Takano T, Chen X, Luo F, et al (2012). Traditional acupuncture triggers a local increase in adenosine in human subjects, *Journal of Pain* 13(12):1215-23. http://www.ncbi.nlm.nih.gov/pubmed/23182227<br>2. Kagitania F, Uchidaa S and Hotta H (2010). Afferent nerve fibers and acupuncture, *Autonomic Neuroscience* 157(1–2): | acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.<br>Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. However the GDG observed that the evidence was still conflicting for acupuncture versus sham, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up. Therefore, the GDG felt this evidence did not support a positive recommendation for acupuncture in NHS practice. As explained in the recommendations and link to evidence section, if there is no evidence supporting the clinical effectiveness of an intervention, this would not be considered cost effective as it would increase costs without improving effectiveness. |

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| | | | | 2–8. http://www.sciencedirect.com/science/article/pii/S1566070210000512<br>3. Harris RE1, Zubieta JK, Scott DJ, et al (2009). Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on mu-opioid receptors (MORs), *NeuroImage* 47(3): 1077-1085. http://www.ncbi.nlm.nih.gov/pubmed/19501658<br>4. Lin D, Lin L, Sutherland K, et al (2016). Manual acupuncture at the SJ5 (Waiguan) acupoint shows neuroprotective effects by regulating expression of the anti-apoptotic gene Bcl-2, *Neural Regeneration Research* 11(2): 305–311. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810996/ | |
| General Council of Massage Therapists | Short | 5 | 1,2,3,4, | There is tremendous variation in the quality of education of Massage and Soft Tissue Therapists in the UK. You will also be aware that the profession is not regulated by statute and relies on the efforts of the various Professional Associations to ensure the protection of the public. We would therefore strongly suggest that the guidelines recommend that only therapists belonging to Professional Associations that are council members of the General Council of Massage Therapists (GCMT) be considered. These suggestions would ensure that therapists are educated to an appropriate standard, properly insured and are subject to the disciplinary procedures of both their professional associations and a regulatory body.<br><br>Belonging to a Professional Association provides the primary level of public protection, but as a further layer of security it may also be desirable that, ideally, Massage and Soft Tissue Therapists are additionally registered with a Professional Standards Authority (PSA) accredited register. If this suggestion is adopted we would suggest that the appropriate accredited registers would be the voluntary regulator the Complementary and Natural Healthcare Council (CNHC) and | Thank you for your comment. It is beyond the scope of this review to specify who should deliver an intervention, the review focussed on whether or not manual therapy was clinically and cost-effective and was based on the best available evidence identified according to the review protocol. |

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| | | | | the British Association of Sports Rehabilitators and Trainers (BASRaT). | |
| Grunenthal | general | General | general | It is not clear from the layout that the recommendations for the pharmacological management only refer to low back pain without sciatica. Given that all the other recommendations refer to low back pain and sciatica there is a danger patients with a neuropathic component to their pain will be sub-optimally treated. | Thank you for your comment. The populations considered when reviewing pharmacological interventions within this guideline are people with low back pain and people with low back pain with/ without sciatica. Therefore people with sciatica were excluded. This has been made clear within the review protocol (Appendix C) and sciatica has not been mentioned within the recommendations regarding pharmacological interventions. Although recommendations for other interventions refer to people with both low back pain and sciatica, there are also recommendations which focus on sciatica alone. |
| GSK | general | General | General | GSK would like to thank NICE for its work on the development of the Low Back Pain and Sciatica guidelines and for the opportunity to comment on the draft clinical guideline. | Thank you for your comment. |
| Guy's and St. Thomas NHS Foundation Trust | Short | | 12-13 | Spinal fusion We agree that fusion for purely non specific LBP should not be recommended within any standard management pathway. Within our organization, at a specialist level, coexisting pathologies like degenerative listhesis and or incidental stenosis are often present in fusion cases and are therefore outside the scope of this guidance. We agree that fusion or TDR should only be carried out once a full conservative program including CBT has been undertaken and that all patients are entered into a registry prospectively and that should be the British Spine registry. Insisting that all fusion or TDR patients are included in an RCT in impractical and will be unable to be implemented. | Thank you for your comment. We have included a statement in the 'evidence and link to recommendations' sections of the relevant chapters to highlight that when surgical procedures are undertaken, information should be submitted to a registry. |
| Guy's and St. Thomas NHS Foundation Trust | short | 3 | 5-9 | Startback and Stratification<br>Q2 We acknowledge the potential benefit of stratification in targeting treatment provision. We anticipate barriers to the use of StartBack in primary care at the point of first contact. We conducted an audit which showed that GPs in our local area found it difficult to use. There was a general reluctance from GPs to use the tool in clinical practice due to time | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |

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| | | | | pressures and the diversity of the patient population in our area.<br>Each identified StartBack group requires adequate well resourced pathways to succeed. Physiotherapy services are well placed to administer StartBack and provide management pathways<br>Q2 Challenges in the low risk group:<br>- Addressing the patient expectation of 'Treatment'. Most will not consider advice and reassurance as sufficient. particularly if they have already been seen by a GP<br>- Ensuring information is accessible to all in a multi-ethnic population<br>- Promoting equality of opportunity is a challenge in organisations supporting a multi-ethic population.<br><br>Challenge in the High Risk group:<br>Obtaining psychological support for this group is a challenge locally. Using physiotherapists who have trained in psychologically informed treatments, can help to alleviate this shortfall in-part but does not remove the need for accessible psychological therapies.<br><br>Q3<br>Support needed to overcome these barriers::<br>1) Adequate resourcing/ national education initiatives targeting LBP ( As for Stroke and OA), to manage patient expectation and change locus of control to self management first.<br>2) Building on any current language provision at a local and national level<br>3) Nationally scoping the use of digital support: EG 'patient support appt ,' to provide motivational support in self management<br>4) Review resourcing to ensure pyschological support is adequate nationally | |

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| | | | | 5) Review a national drive for self referral to physiotherapy<br>6) Drive the direct referral to physiotherapists as first contact for LBP to avoid the GP as an 'extra step ' if StrartBack can not be administered at the GP level. | |
| Guy's and St. Thomas NHS Foundation Trust | short | 4 | 13-18 | Exercise The broader guideline on exercise is welcomed . Exercise can be tailored locally because of the more inclusive nature of this broader recommendation | Thank you for your comment. |
| Guy's and St. Thomas NHS Foundation Trust | short | 4 | 5-7 | Q2 ( our locality) The challenge in providing information is ensuring all culturally diverse groups are included. The need to provide information in multiple languages / translation services has a cost implication<br>Q3 Standardisation of quality information at a national level should be strengthened | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | short | 4 | 11-12 | Imaging: Q2 We support the recommendation of not referring patients for imaging in a non specialist setting. A barrier to reducing imaging for patients with non specific LBP is their need to seek a tissue based diagnosis. A cultural shift is needed<br>Q3The right education and access to the right management in a timely manner will help achieve this. Q3 Direct Access physiotherapy would enable this and can administer stratified care pathways. A national initiative to educate on LBP will support the cultural shift needed | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 5 | 24-27 | Q2 As stated above psychological support is difficult to access. Group classes do discriminate against non English speaking patients. The implementation challenge in a multicultural locality is to ensure access and equity of provision of these services for all | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |

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| Guy's and St. Thomas NHS Foundation Trust | Short | 5 | 20-22 | Psychological therapies Q2 There is lack of availability of Psychological Therapies needed to provide CBT for the high risk group identified by StartBack<br>Q3 Review of funding for psychological therapies would enable more complete multidisciplinary pain management pathways to be developed | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 5 | 6-7 | Acupuncture Q2 The Acupuncture Association of Chartered Physiotherapists ( AACP) view on the benefit of Acupuncture in a multimodal management package for LBP deviates from this guidance. Implementation will be challenging.<br>Staff trained in its use with anecdotal experience of its benefits and patient demand for treatment that has helped in previous management will drive demand to continue to offer services The AACP have submitted concerns refuting the strength of the research support used. Implementation of the guidance against this bodies recommendations when many staff are members of this organisation and want to continue to use their skills, presents a challenge | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 6 | 8-28 | Pharmacology Q2/3 If LBP management was redirected from GP care to therapist led assessment , using of specialist and Consultant physiotherapists as necessary, ( direct referral) non medical prescribing ( NMP ) could be used to implement these pharmacology recommendations. Challenges to analgesic management occurs when management is divided between GP (medication) and physiotherapist ( management package) Joined up care would be optimised by LBP management including prescribing being led by a single service. | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 6 | 5-7 | Physiotherapists are already present in occupational health Continued support nationally for return to work programmes and mandating within work support services is needed to combat the variability of work place support | Thank you for this information. |

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| Guy's and St. Thomas NHS Foundation Trust | Short | 7 | 10-11 | Facet injections Locally facet injection are used in a secondary care setting to provide an analgesic window in patients thought to have facet type pain patterns and concordant imaging, to enable multimodal management to take place Our challenge will be to join up management pathways to prioritise denervation | Thank you. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 7 | 23-24<br><br>25-26 | Spinal injections: ( Epidurals )<br>Q2 We support the timely use of injections in patients with sciatica. Locally we have found that pathways that capitilise on extended therapist roles in this management pathway, can provide efficient access.<br>In practice caudal epidurals are easier to administer than tranforaminal epidurals and patients report a good response and so may be more cost effective than more targeted transforaminals. Currently both are offered at a secondary care level They can be organised by therapists based on clinical assessment including imaging review. We recommend this pathway.<br>Caudal epidurals are offered in our organisation to stenotic patients with claudicant leg pain after the risk/ benefit analysis of all management options including surgery has taken place. Changing this management option may be difficult. | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundation Trust | Short | 8 | General | Putting guidance into practice. There will be a gap analysis of our organisation and associated services' compliance with the final NICE guidance to assess the need for any practice change and raise awareness | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |
| Guy's and St. Thomas NHS Foundat | Short | 8 | General | LBP should be treated as a long term condition. Increased media support and GP education will be required, and enhanced long term support strategies need scoping. Increasing the use of physiotherapists as first contact practitioners and self referral into physiotherapy will help with the uptake and implementation of these guidelines. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |

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| ion Trust | | | | | |
| Guy's and St. Thomas NHS Foundation Trust | Short | 8 | 3-5 | BMI, Smoking and Psychological distress do influence surgical decision making. There is a cost implication in not considering this when assessing the best management pathway for patients. Outcome data supports the need to consider these factors in any decision equation to ensure best outcome for the patient.<br>Q3 National funding for strategies to manage these factors are welcomed. . Using expert therapists in potential surgical cases can offer a specialist review and add to the multidisciplinary approach needed in these patients | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. |
| Homerton University Hospital NHS Foundation Trust | full 1 | 18 | 4 | Although it is not possible to separate low back pain costs, the redesigned Homerton Locomotor service (integrated MSK Physiotherapy and specialist pain service) has saved the City & Hackney health economy at least £172,000 in its first year. | Thank you for your comment. |
| Homerton University Hospital NHS Foundation Trust | full 1 | 40 | 21 | We disagree that there is a difference between the validity of a 'sham comparison' in acupuncture and massage. | Thank you for your comment. The GDG agreed that when an intervention is being compared to sham/placebo, the sham/placebo must be for the intervention delivered within the same trial. The example given here being that of an inappropriate sham comparison; acupuncture compared to sham massage, as it is not possible to determine whether the treatment effect is a result of placebo effect or the intervention. Therefore, for acupuncture, only sham acupuncture would be considered a suitable sham, the same principle applies for all other interventions included within this guideline. All interventions labelled as sham were discussed and agreed with the GDG to determine whether they were appropriate shams for the intervention of interest. |

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| Homerton University Hospital NHS Foundation Trust | full 1 | 41 | 19 | The GDG agreed for the following comparators to be excluded*: "A combination intervention given both groups if considered over and above 'standard non-invasive care in NHS' (therefore cannot be classed as usual care)".*<br>The guideline development group due to the absence of a Physiotherapist, lack the expertise to fully assess whether interventions may be not currently or potentially be provided as standard in the NHS | Thank you for your comment. The composition of the GDG was agreed during the scoping phase of the guideline and at stakeholder consultation as the correct mix of expertise to appropriately cover all aspects of the guideline. A physiotherapist was appointed as a full member of the group. |
| Homerton University Hospital NHS Foundation Trust | full 1 | 496 | GENERAL | It was suggested that availability of acupuncture in the NHS is 'patchy'. Considering that there are currently over 6500 Physiotherapists in the UK who are members of the AACP alone, this statements misunderstanding reflects the absence of a practicing NHS physiotherapist on the panel.<br>There is variation in Physiotherapy resources due to funding which will have a knock on effect on availability of integrated acupuncture.<br>The cost of training a Physiotherapist in acupuncture is low (£495). | Thank you for your comment and this information. However, NICE guidance is based on the best available evidence for each intervention, and on the basis of the systematic review for acupuncture, the GDG do not agree that there is sufficient evidence to recommend acupuncture as a treatment for low back pain or sciatica on the NHS. The discussion on setting the protocol for this review and interpreting the evidence was informed by a co-opted acupuncturist as well as the GDG therefore we believe it had appropriate expertise. |
| Homerton University Hospital NHS Foundation Trust | Full 2 | General | GENERAL | Part 2 general invasive. Treatments - **Patients should be assessed within a multidisciplinary pain team**, patients should be provided with information on non-invasive pain management options as part of informed decision making. | Thank you for your comment. Although the guideline investigated various forms of assessment such as STarT back and Örebro, it not consider evidence regarding who should carry out such assessments, therefore the GDG are not able to make recommendations on this. We agree that patients should have access to information to allow for informed decision making. All patient treatment decisions would be discussed with the patient. Please see the introduction on page 4 of the short version about patient decisions, and the linked 'Your Care' web page. |
| Homerton Universi | Full 2 | 11-123 | GENERAL | Part 2- Invasive treatments - Spinal Injection and Denervation- | Thank you for your comment. Spinal injections for low back pain have not been recommended in this guideline. |

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| ty Hospital NHS Foundation Trust | | | | **It should be stressed that repeat injections should not be offered without demonstrating efficacy,** Homerton's Locomotor pain service has stopped offering repeat injections unless patients attend for a post injection specialist pain Physiotherapy review and demonstrate benefit (increased function and reduction in pain) over a three month period | |
| Homerton University Hospital NHS Foundation Trust | Full 2 | 11 | 25 | Trigger point injections are discussed for example using local anesthetic. However the benefit of an injectable drug over dry needling performed using either a standard or acupuncture needle is not examined.<br><br>Dry needling via an acupuncture needle is a common skill currently used by NHS physiotherapists. | Thank you for your comment. Dry needling and acupuncture were included as comparators within the review protocol, listed as: Other treatment (non-invasive and invasive treatments being considered by the guideline). However, no studies were identified directly comparing dry needling or acupuncture. |
| Homerton University Hospital NHS Foundation Trust | Full 2 | 42 | 23.1.15 | The guidelines consider injections in isolation from the rest of the MDT**. We feel it is poor practice to deliver any spinal injection without ongoing MDT support (physiotherapy, psychology, consultant anaesthetist).** Current clinical practice in Homerton's Locomotor pain service is to offer all patients physiotherapy during the window of opportunity of a facet joint injection, before further injections or progression to denervation, are considered by the MDT. | Thank you for your comment. The review protocol includes combinations of treatment with any other intervention within the scope of the guideline, therefore this is considered if evidence were identified, but no such trials were identified relevant to the review. |
| Homerton University Hospital NHS Foundation Trust | Full part 1 | 496 | GENERAL | Trigger point techniques are a common part of NHS Physiotherapy acupuncture practice as part of a multimodal package of care. The other name for acupuncture trigger point therapy is 'dry needling'.<br><br>The use of acupuncture/dry needling to treat muscular trigger points is not considered in either non-invasive sections as within acupuncture nor as an alternative to manual trigger point release. | Thank you for your comment. The evidence included in the acupuncture review was based on trials meeting the criteria of the review protocol, with all forms of acupuncture considered for inclusion. The GDG could not consider acupuncture as part of a treatment package due to the lack of this evidence for this. |

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| | | | | It is unclear whether these guidelines cover dry needling delivered as part of a multimodal package of care. | |
| Homerton University Hospital NHS Foundation Trust | full part 1 | Page 560 | GENERAL | **The cost of a TENS unit is inaccurate and misleading.** Only a simple dual channel variable unit in most cases is required, this costs no more than £30 e.g Body clock http://bodyclock.co.uk/1st-choice-plus-tens/.<br><br>Each machine can be used on a trial basis by multiple patients (thereby reducing this cost considerably), with those who find the machine helpful purchasing their own. | Thank you for your comment.<br>When calculating unit costs we report the cost incurred to the NHS and therefore sourced this cost from the NHS Supply Chain Catalogue, 2014. As there are multiple types of machine, a cost range has been reported.<br>It is also noted in the report that "TENS devices may either be provided on loan to people with low back pain and sciatica or purchased by the individuals themselves" and was therefore taken into consideration by the GDG. This discussion is noted in the 'Trade-off between net clinical effects and costs' section of the LETR. |
| Homerton University Hospital NHS Foundation Trust | full part 1 | 568 | GENERAL | "*TENS The GDG highlighted that in trials of TENS, a problem affecting all studies is that the intervention only works while in progress providing temporary relief rather than intending to have long term benefits,"*<br><br>This statement irrelevant as TENS works via the pain gate mechanism so is only intended to provide temporary relief during the time it is operated by the patient. The value of TENS lies particularly in helping particularly to manage pain flare ups, which may help patients avoid attending A&E or GP appointments with flare ups they feel unable to manage. | Thank you for your comment. From the evidence reviewed, we were unable to demonstrate that TENS was helpful for a subgroup of patients who might otherwise attend A&E or GP appointments. We believe this statement is important to retain as it highlights the limitations of the evidence. |
| Homerton University Hospital NHS | full part 1 | 604 | GENERAL | The guidelines place great emphasis on sham treatments, yet do not adequately explain how these definitions are arrived at e.g Sham CBT. | Thank you for your comment. The summary of included studies table at the start of each review provides a detailed description of each intervention arm in the included studies. These were discussed with the GDG to determine if they were appropriate. |

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| Homerton University Hospital NHS Foundation Trust | full part 1 | 604 | GENERAL | **The guidelines suggest the aim of CBT is to reduce fear avoidance to enable physical rehabilitation, this is an overly narrow definition, CBT is a means of reducing distress and enabling strategies that will increase quality of life.** This may come from defining CBT by the measures used in research sampled, rather than clinical utility. | Thank you for your comment. The guideline-specific working definition of CBT was agreed by the GDG to be appropriate in the context of management of people with low back pain and sciatica. |
| Homerton University Hospital NHS Foundation Trust | full part 1 | 604 | GENERAL | Mindfulness is not intended as an analgesic medium and is usually used as an adjunct strategy to be utilized within a therapeutic approach. Mindfulness for example is one of the techniques used within ACT. | Thank you for your comment. Mindfulness was reviewed as one of the intervention eligible for inclusion in the Psychological therapies review and all reported outcomes consistent with the review protocol were considered. |
| Homerton University Hospital NHS Foundation Trust | Full part 2 | 59 | 23.6.29 | Anecdotally there seems to be a population of patients who derive good benefit from standard FJI but gain no extra duration of pain relief from the radiofrequency treatment. In these cases time and money will be expended to no extra advantage. | Thank you for your comment. We did not review any evidence that would support this. As described in sections 22.6 and 23.6, the GDG decided against recommending facet joint injections due to the inconsistency of the evidence across the review. Furthermore, for the comparison against placebo/sham, benefits in long-term outcomes were seen which did not appear in short-term measures. This created uncertainty among the GDG regarding the true nature of the benefits seen in the longer-term outcomes. The GDG therefore did not feel they could justify recommending facet joint injections in a NHS setting.<br>Evidence for radiofrequency denervation compared to placebo/sham showed consistent short and long-term benefit for pain and responder criteria |

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| | | | | | outcomes, as well as benefits for some quality of life measures. Along with the low incidence of adverse events and the evidence from the economic model, the GDG felt they could form positive recommendations for radiofrequency denervation. |
| Homerton University Hospital NHS Foundation Trust | full1 | 736 | 17.6.1 | **The document in general for example this section is poorly written and feels as it if is written by numerous authors who are writing purely for an academic audience rather than NHS clinicians**. | Thank you for your comment. We have attempted to make the guideline as readable as possible to NHS clinicians. NICE also produces a short version of the guideline which contains just the recommendations for clinicians who do not wish to read the more detailed description of the methods and evidence reviewed that are contained in the full guideline. |
| Homerton University Hospital NHS Foundation Trust | general | general | | Our trusts integrated Musculoskeletal Physiotherapy and specialist community pain service has had experience of implementing this approach and would be willing to submit its experiences to the NICE shared learning database.<br>Contact: Elizabeth Slee<br><br>Elizabeth.Slee@homerton.nhs.uk | Thank you for your comment. We would encourage you to submit your example to the shared learning database. You can do so on the NICE website here: https://www.nice.org.uk/about/what-we-do/submit-local-practice-example |
| Homerton University Hospital NHS Foundation Trust | General | general | general | **Non-specific low back pain is generally managed with a functional and bio-psychosocial approach and indeed first line of contact after the GP is generally physiotherapy.**<br><br>We feel the guidelines have an overly medical perspective and that physiotherapy need a greater voice within this guideline development group. | Thank you for your comment.<br><br>Exercise programmes, manual therapy and psychological therapy with exercise, and combined physical and psychological programmes are recommended in this guideline.<br><br>The GDG had representatives from manual therapy and physiotherapy. |

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| Homerton University Hospital NHS Foundation Trust | General | GENERAL | GENERAL | The poor clarity of writing of these draft guidelines, means that they are not accessible to frontline clinicians | Thank you for your comment.<br><br>This guideline is available in a number of formats to appeal to a wide range of readers and, as with all NICE guidance, has been subject to strict editorial processes. |
| Homerton University Hospital NHS Foundation Trust | Short | general | general | We are concerned that this guideline covers pain from acute onset, without acknowledging that different approach may be required when treating patients with longstanding pain.<br><br>Costly Invasive procedures are presented in the algorithm as the ultimate destination for patients, rather than a niche treatment suitable for specific patient populations. | Thank you for your comment. The guideline covers both acute and chronic pain as agreed during scoping. These were included as subgroups within the review protocols to investigate if heterogeneity was observed. Where evidence suggested different approaches were required, this was specified in the recommendation.<br>Surgery interventions are recommended for people with non-specific low back pain or sciatica for whom conservative treatments have failed. |
| Homerton University Hospital NHS Foundation Trust | short | GENERAL | 1.1.1 | The STarT Back risk assessment tool, is currently embedded within our electronic choose and book GP referral form and questionnaires given to new patients. Homerton's Locomotor referral pathway advises that only moderate and high risk patients are referred to physiotherapy/pain service, internal audit has found this to be the case.<br><br>However in practice, GPs report feeling able to guess the risk factors so that this as well as time constraints mean the STarT form is rarely completed by GPs.<br><br>It is however used by Homertons physiotherapists in the service. The STarT back tool contributes to Physiotherapists consideration as to whether to refer | Thank you for your comment. |

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| | | | | to the interdisciplinary pain service that is embedded within our Physiotherapy department. | |
| Homerton University Hospital NHS Foundation Trust | Short | GENERAL | 1.1.2 | When patients do receive copies of their imaging reports the medical language used can elicit distress, fear and confusion.<br><br>Imaging reports detailing clinically unimportant changes using potentially frightening terms such as 'degenerative' or 'tear' can be detrimental to patients recovery if not accompanied by considerable education and explanation by clinicians who have received training in explaining imaging reports, as would be the case in of pain clinics or physiotherapy departments.<br><br>It would be helpful for NICE to recommend that patient information should be embedded within imaging reports, such as the % of symptom free patients in *their* age bracket that would be expected to present with *this* age related change.<br><br>The guidelines should place greater emphasis on the potential harm to patients of imaging results that might be interpreted by the patients as suggesting the spine is lacks the structural robustness to permit return to normal function. Imaging reports can in this way become a risk factor for chronic pain.<br><br>Patient information leaflet providing elements covered in the 'vomit poster' would be useful in helping patients accept that imaging is unnecessary and potentially counterproductive. (VOMIT (victims of modern imaging | Thank you. Your comment will be considered by NICE where relevant support activity is being planned. The issue of imaging reporting was not prioritised as an area to review within the scope of the guideline, we are therefore unable to comment on patient information in reports or the harms of interpretation of results. |

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| | | | | technology)—an acronym for our times *BMJ* 2003;326:1273) | |
| Homerton University Hospital NHS Foundation Trust | short | GENERAL | 1.3 general | The design of a specialist pain service to be more therapy lead has been shown to reduce demand for spinal injections.<br><br>Homerton's redesigned Locomotor specialist community pain service has reduced all spinal injections by 20% a year, by redesigning its patient pathway and giving patient's access to the MDT at point of entry.<br><br>This pain service redesign has earned Homerton's Pain service has reached the finals of the 2016 **HSJ Value in Healthcare Award (specialist services and community health service redesign)** and is currently being shared with a number of specialist pain services such as Royal free hospital London, Barts Health. | Thank you for your comment. |
| Homerton University Hospital NHS Foundation Trust | Short | GENERAL | 1.2.13 | This statement could be elaborated upon in that multimodal care can be done individually and as long as there is an umbrella of close collaboration within the MDT along a shared care pathway. | Thank you for your comment. Recommendation 12 has been reworded as follows: consider manual therapy for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy, where manual therapy is defined as manipulation, mobilisation or soft tissue techniques, for example massage. |
| Homerton University Hospital NHS Foundation Trust | Short | GENERAL | 1.2.14 | **MDT working does not mean that concurrent work only occurs in a group setting, joint working can be conducted by individual clinicians within a coordinated care pathway, with close liaison.** | Thank you for your comment. The different components of an MBR intervention are offered as an integrated programme involving communication between the providers responsible for the different components. These programmes may include various components (we have recommended combined physical and psychological programmes) delivered by one individual, or by a number of people, such as the multi-disciplinary aspect applies to the |

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| | | | | | interventions included in the package (across disciplines), not to the number of people / disciplines delivering this. For full details regarding the definition of MBR programmes, please see chapter 17, or the Glossary (section 21.1). |
| Homerton University Hospital NHS Foundation Trust | Short | GENERAL | 1.2.15 | **Return to work programs.**<br>A pilot program of a specialist occupational therapist helping patients return to work was successful at Homerton. This enabled face to face discussion with MSK outpatient physiotherapists and chronic pain therapists who were able to focus their rehabilitation so that patients could achieve the function required to return to work or remain in work. Unfortunately substantive funding was not available for this post. | Thank you for your comment. |
| Homerton University Hospital NHS Foundation Trust | Short | GENERAL | 1.2.16 | Pharmacological interventions<br><br>Often patient's ability to be an active participant in their medicines management relies on having a larger repertoire of self-management skills. This needs supporting through an MDT and not solely prescribers. Teaching the MDT (Physio, OT, psychology) basic medicines management skills and the prescriber self-management techniques such as CBT/ACT this enables them to work together to optimise the patients overall management of their long term condition. | Thank you for your comment. Since this was not an area reviewed by this guideline, the GDG are unable to make any recommendations for this. |
| Homerton University Hospital NHS Foundation Trust | short | GENERAL | 1.2.22 | GP's will need to be supported not to prescribe opioids, they will need early support from NHS pain services. | Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. |

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| Homerton University Hospital NHS Foundation Trust | short | GENERAL | 1.3.2 | Radiofrequency denervation carries greater cost and a stronger placebo effect than facet joint injections. | Thank you for your comment. As described in sections 22.6 and 23.6, the GDG decided against recommending facet joint injections due to the inconsistency of the evidence across the review. Furthermore, for the comparison against placebo/sham, benefits in long-term outcomes were seen which didn't appear in short-term measures. This created uncertainty among the GDG regarding the true nature of the benefits seen in the longer-term outcomes. The GDG therefore did not feel they could justify recommending facet joint injections in a NHS setting.<br>Evidence for radiofrequency denervation compared to placebo/sham showed consistent short and long-term benefit for pain and responder criteria outcomes, as well as benefits for some quality of life measures. Along with the low incidence of adverse events, the GDG felt they could form positive recommendations for radiofrequency denervation. |
| Homerton University Hospital NHS Foundation Trust | short | GENERAL | 1.1.2 – 1.1.5 | Due to a focus on clinical examination and a biopsychosocial model of care, the use of MRI scans by Homerton's Locomotor service is low. | Thank you for your comment. |
| Homerton University Hospital NHS Foundat | Short | GENERAL | 1.2.9 & 1.2.12 | Ultrasound and interferential therapy are already considered inappropriate modalities in modern NHS physiotherapy due to lack of evidence. | Thank you for your comment. |

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| ion Trust | | | | | |
| Homerton University Hospital NHS Foundation Trust | short | 5 | 1.2.7 | This section should read:<br><br>Consider manual therapy for patients who have the potential to respond, for managing non-specific low back pain with or without sciatica, but only as part of multi-modal treatment packages. Treatment should be informed by risk stratification and best practice in chronic pain management.<br><br>The phrase massage is unhelpful.<br><br>Various authors have considered targeting manual therapy:<br><br>Childs, John D., et al. "A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study." Annals of internal medicine 141.12 (2004): 920-928.<br><br>Bialosky, Joel E., et al. "The mechanisms of manual therapy in the treatment of musculoskeletal pain: a comprehensive model." Manual therapy 14.5 (2009): 531-538. | Thank you for your comment. The GDG have re-reviewed the recommendation for manual therapies and have agreed that it should read as follows: consider manual therapy for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy. This also has removed the phrase 'massage' from the recommendation. |
| Homerton University Hospital NHS Foundat | Short | 6 | 1.2.21 | NSAIDS are quite effective for the acute flare up or acute non-specific low back pain as long as not contraindicated (which is stated).<br><br>The guidelines do not appear to be differentiating between acute and chronic non-specific low back pain so the recommendations are correct. Although they do | Thank you for your comment. It was agreed a priori that evidence would be pooled unless there was heterogeneity, in which case chronicity of pain would be considered for subgroup analysis (please see appendix c).<br><br>We have considered the recommendation order, but believe they should remain in the order stated. |

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| ion Trust | | | | mention not to offer paracetamol alone it is not clear that recommendation is to add it to NSAIDs.<br><br>1.2.21 should be swapped with 1.2.20 to follow some sort of order. | |
| Homerton University Hospital NHS Foundation Trust | Short | 7 | 1.3.6 .& 1.3.7 | These simplistic statements imply that surgery should be considered for anyone with chronic low back pain (such as those whose persistent pain has not been cured by pain management). It suggests a lack of understanding of both chronic pain physiology and pain management research. Surgery has a place however it has not been justified in a coherent way. | Thank you for your comment. Both the surgery and prognostic factors review and the spinal decompression review deal with people who have failed to respond to appropriate conservative treatment.<br><br>For the surgery and prognostic factors review, this is detailed in the introduction and specified in the protocol (section 25.1 and 25.2).<br><br>For the spinal decompression review, specifically dealing with people with sciatica, this is detailed in section 28.6 (Recommendations and link to evidence). The GDG agreed that management of people with sciatica should be guided by the recommendations set in CG173 before discectomy is considered as an option. Discectomy should be considered for a subgroup of people with sciatica who had failed to respond to conservative management of their symptoms. |
| HQT Diagnostics | Full version 1 | General | General | Back pain is strongly associated with low vitamin D<br>Back pain has been relieved in 95% of patients after supplementing with vitamin D - *to the right blood level*<br><br>At first presentation GP should measure Vitamin D 25(OH)D and supplement to achieve 100-150 nmol/L<br>This level should be maintained for at least 30 days<br>Then review and consider re-test before referral to specialist or chiropractor<br><br>Evidence: | Thank you for this information. However, vitamin D was not prioritised as an area to be covered within the scope of this guideline. |

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| | | | | http://www.vitamindwiki.com/Back+Pain<br>http://grassrootshealth.net/epidemic | |
| Institute of Osteopathy | general | General | General | Terminology of service providers.<br>There is inconsistent and interchangeable use in the term physiotherapist and manual therapist in the report.<br>The term manual therapist includes physiotherapists, osteopaths and chiropractors, all of whom are qualified to provide manual therapy and are working within an NHS setting. We would suggest the authors consistently use the term manual therapist throughout the report. | Thank you for your comment. We understand your concerns regarding the terminology, however the use of 'physiotherapist' has only been used when directly reporting what the included studies have specified. Therefore it wouldn't be correct to replace the term physiotherapist with manual therapist. |
| Institute of Osteopathy | general | General | general | Consistent use of evidence criteria<br>We have been advised by our researchers that there are inconsistencies in the level of evidence criteria applied to non-invasive therapies, including manual therapy, compared to that of invasive therapies. If the level of evidence criteria used to inform recommendations has not been applied consistently, the decision criteria used for non-invasive and invasive therapies are not equal.<br><br>We would recommend review of the National Council of Osteopathic Research (NCOR) response which details the specific examples where these inconsistencies have been applied. | Thank you for your comment. Please see our responses to the comments mentioned where all of these have been addressed. |
| Institute of Osteopathy | General | general | general | Access to services outside NHS settings<br>While we fully appreciate this consultation relates to clinical guidelines for services delivered within NHS settings, the recommendations for a multi-modal package of care (manual & exercise therapy/exercise with advice and self-management strategies) can equally be delivered by regulated primary health care professionals in manual therapies, operating in the private sector.<br><br>When considering a patient-centred approach, for those patients where the choice of private services is a viable | Thank you for your comment. Settings delivering care not funded by the NHS are outside the remit of the guideline. |

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| | | | | option, it can expedite access to recommend care, particularly as these guidelines now cover acute as well as chronic presentations of non-specific low back pain with or without sciatica.<br><br>Private sector services delivered by primary health care practitioners qualified to deliver multi-modal package of care (as previously defined), can provide an alternative option for patients and potentially lessen the burden of provision of these services, and the associated costs, within NHS settings.<br><br>We would suggest inclusion of information on those providers qualified in the delivery of these services in the private sector as an optional pathway to access recommended care services. | |
| Institute of Osteopathy | general | 4 | 15-18 | Implementation of exercise<br>The recommendation is for group exercise programmes, while stating a need to take into account specific preference and capabilities (page 4, short version).<br><br>Most clinicians provide specific bespoken exercises programmes, to take into account of specific presentations and capabilities, as recommended by the guidance (page 4). The experience of clinicians is that there is greater compliance by patients with bespoke programmes, compared the high drop-out rates that are commonly seen in group classes as reported in the studies.<br><br>According to our researchers the review of the evidence does not support the use of group exercise over individual bespoke programmes. Therefore, the implementation of a group exercise programmes could have significant cost implications if organised and implemented in an NHS setting, while seeing high drop-out rates and not meeting the specific needs of the patients as required. | Thank you for your comment. The evidence showed no difference between individual and group exercise in terms of clinical outcomes, however, as group exercise is more cost effective, this was recommended rather than individual exercise.<br>The GDG are aware some patients may not fully engage with group exercise, however state in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise. |

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| | | | | We also suggest the clarification of the implementation of exercise as part of the multi-modal package to acknowledge the role manual therapist as qualified in delivering bespoke exercise programmes. (See comment 7 on the implementation of multi-modal care.) | |
| Institute of Osteopathy | general | 8 | general | Definition of multi-modal treatment package<br>We have been advised by our researchers that the emphasis of exercise as the only compulsory element of multi-modal care (page 8, short version) is not substantiated by the evidence. An example of this is on page 456 – where a large trial included in the combinations evidence was helpful in informing the manual therapy recommendation, because this large study showed clinical benefit of mixed modality manual therapy. If the study was mixed modal/manual therapy, we would question why is exercise is the only mandatory component of the multi-modal package.<br><br>There is no evidence to show which combinations of therapies, if any, are more effective and or active than others and this is not reflected in the draft recommendation.<br><br>If recommending exercise plus self-management or manual therapy and exercise, it is suggested that they need to recommend them as treatments in their own right as there is no evidence presented to show that combining them makes them more effective. | Thank you for your comment. This recommendation is based on evidence from studies which used a treatment package comprising of a combination of exercise, manual therapy, and psychological therapy (see chapters 9, 12 and 17). Exercise was a component in all comparisons whereas the other interventions where not. Therefore, exercise was the only compulsory element, based on the evidence reviewed. |
| Institute of Osteopathy | general | 8<br>349 | 15<br><br>11 | Implementation of multi-modal package of care<br>We would suggest that the section on multi-modal package of care needs clarification and consistency in the recommendations. Most manual therapists would argue that the treatment package they give is multi-modal consisting of psychological and self-management support, exercise, general and public health advice plus hands on manual therapy. This is reflected in the full guidelines (page 349, line 11) which clearly states that: | Thank you for your comment. The recommendation has been reworded following stakeholder feedback. It now reads: consider manipulation for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy.<br><br>Regarding the professional delivering interventions, for many of the interventions included in the guideline levels of training may differ according to the expertise |

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| | | | | *"Manual therapists often combine a range of techniques in their approach and may also include exercise interventions and advice about self-management".*<br><br>However, in the short version it currently states (page 8, line 15) that:<br><br>"*Multi-modal treatment include exercise and at least one of the following:*<br>• *Self-management*<br>• *Manual therapy*<br>• *Psychological therapy (for example, cognitive behavioural therapy)"*<br><br>To redefine multi-modal care as separate packages as implied in the implementation would be resource intensive and costly if delivered by multiple people rather than multi-skilled practitioners such as manual therapists. We would suggest that the authors reflect the ability of manual therapists to deliver multi-modal care. | of the practitioner, however this cannot be assessed within the systematic review and it has been assumed that unless otherwise stated, that the people delivering the interventions are trained to do so. Professionals delivering interventions should be appropriately trained to do so. |
| International Neuromodulation Society | Full 2 | General | General | Spinal cord stimulation TA Guideline 159. I understand that no requirement for SCS to be evaluated in this LBP guideline. However there must be clear signposting from this guideline to TA159 for SCS. The aim is to prevent suitable SCS patients being caught within a cycle of revision surgery; injections and non-invasive pain management that does nothing to increase health related quality of life. This has been proven within the evidence submitted for SCS in refractory neuropathic pain (Back and Lef pain/Failed Back Surgery Syndrome)<br>We must improve patient access to effective treatments such as SCS. This LBP guideline is an opportunity to put that right. | Thank you for your comment. We have included the TA in the list of related NICE technology appraisals in section 4.3 of the guideline, and it is noted within the footnote of the algorithm for the guideline. |
| International Neuromodulatio | Full 2 | General | General | NHS England is evaluating a policy on intrathecal drug delivery (ITDD) in non-cancer pain. There is a small cohort of patients with Chronic refractory neuropathic back and leg pain who were suitable for SCS but fail to get relief during | Thank you for your comment. Spinal cord stimulation is outside of the scope for this guideline. We are unable to make recommendations for populations who fail to get relief from SCS. |

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| n Society | | | | SCS trial or have other co-morbidity that excludes them from SCS. These patients benefit from ITDD. Their should be clear signposting towards ITDD after SCS is considered. | |
| James Cook University Hospital | Full 2 | 54 | general | Algorhythm for denervation.<br>It has been suggested (da Rocha 2014, (5) that prolonged relief from a medial branch block is evidence that facet joint pain is not the cause of the symptoms and actually prolonged relief would be a contra indication to subsequent denervation. It would be greatly appreciated if the GDG would consider providing guidance on the evidence for an apparent prolonged response to medial branch block being an indication of active facet joint pain, given the duration of the local anaesthetic agents most commonly employed. This is a significant factor as the GDG have recommended a denervation procedure in patients with prolonged response to a local anaesthetic injection but have at present not based this in evidence. The GDG might wish to provide this evidence in the light of different opinions in the literature. | Thank you for your comment. Denervation would only be offered to those who experienced relief from medial branch blocks and in whom the pain has subsequently returned. The assumption that prolonged relief from medial branch blocks equates to another mechanism for pain other than pain arising from the facet joints (as proposed by Rocha), whilst an interesting premise, remains theoretical. Studies of repeated medial branch blocks (by Manchikanti for example) show that prolonged relief can be observed and that repeating the same intervention if pain returns, results in a similar degree and duration of pain relief. Relief by targeting the same structure on more than one occasion implies that the mechanism for the pain remains the same throughout. |
| James Cook University Hospital | Full 2 | 56 | 15 | Economic evaluation. It is not clear why GDG chose to use the expert opinion of the group for an estimate of the duration of the therapy. In a systematic review published in 2010 (1), five RCT's were included in the analysis for radio frequency denervation of facet joints in a placebo model following positive response to medial branch block. They reported evidence favouring denervation in short term outcomes (4 weeks). They report evidence of no improvement in the intermediate term (one to six months) or in the long term (six months). In a single cohort study of repeated denervation treatments, a publication in 2004 (2) indicated average duration of relief of 10.5 months for a first injection, 11.6 months for a second injection, 11.2 months for a third injection and nine months for a fourth injection. Gofeld 2007 (3) in a ten year perspective audit noted 68 percent "success" at 12 months and 30 percent at 24 months. Cohen 2010 (4) reported in their single nerve block paradigm a 42 percent successful outcome at three months (8 of 19). | Thank you for your comment.<br>A systematic review was also conducted for this guideline and this included the studies identified in the systematic review that you have cited. Both reviews show the average pain score obtained at different time points after radiofrequency denervation. These studies were used in the model; however they did not report on the duration of pain relief.<br>We have edited the model write up to explain that other studies on duration of effectiveness were considered and that more weight was given to the study by MacVicar.<br>The study by Schofferman et al (2004) is a retrospective chart review including only patients for whom the initial procedure was successful but then benefits were subsequently dissipated and at least one additional radiofrequency denervation was performed. This study is selecting people in whom |

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| | | | | The GDG may wish to review the availability of evidence of duration of treatment effect before relying on consensus opinion. If published evidence is preferred then the treatment would not be cost effective on the new model. | the procedure is less likely to be successful in the long run as all of them had a repeat procedure. The study by Gofeld et al (2007) does not report the mean pain score at baseline and at follow up; also they report the median pain relief duration, while we are interested in the mean. The median would not take into account the outliers (possibly on the higher end) and therefore could reduce the overall duration. The study by Cohen at al (2010) was considered unreliable due to the small sample size (n=19). |
| James Cook University Hospital | Full 2 | 59 | General | 23. Radiofrequency denervation for facet joint pain.<br><br>Potential Conflict of Interest<br><br>Five members of the GDG are professionally associated with pain services, but remained present during the discussion and decision making. This permits the perception of potential conflict of interest. | Thank you for your comment. We were mindful of the comments that were received following consultation and publication of CG88. At the beginning of development discussions were held with the GDG regarding conflicts of interest and the appropriateness of declaring work in private practice. It was agreed in accordance with the conflicts of interest policy relevant at the time of development, that this was not viewed as a conflict that would require members to withdraw from decision making. Members of committees are recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (appendix B). |
| James Cook University Hospital | Full 2 | 60 | General | Recommendations and link to evidence.<br><br>Consistency of Approach to Evidence There is inconsistency in the evaluation of the evidence for this therapy as compared to all other therapies.<br><br>In the second paragraph in the section trade-off between clinical benefits and harms, a trend is reported and has the appearance of being given weight. No trend is reported in any other treatment. | Thank you for your comment. Although the GDG were aware of non-clinically significant trends, this did not bare weight when making decisions about recommendations, and therefore this sentence has been removed to avoid confusion. |

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| James Cook University Hospital | Full 2 | 60 | general | paragraph 3 it is recorded “the GDG noted that one would not expect any treatment related pain to occur beyond four months”. This appears an opinion of the expert group rather than based on evidence. It may be appropriate for the GDG to consider that in other circumstances injury related neuropathic pain may be persistent and indeed require management in its own right. | Thank you for your comment. As stated in section 4.5 of the full guideline, when clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The GDG were aware of Kornick 2004, which reported a complication rate of 1%. As adverse events are often poorly reported, the GDG used this knowledge to inform their decision making. This has been added into the LETR to avoid confusion |
| James Cook University Hospital | Full 2 | 60 | general | paragraph 4, there are two remarks that in the expert opinion of the GDG the adverse event rate of 5 percent was “higher than expected”. This mitigation of the reported complications by expert opinion is not repeated elsewhere in the guidance and is an inconsistency in the use of evidence in the guidance overall. | Thank you for your comment. As stated in section 4.5 of the full guideline, when clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The GDG were aware of Kornick 2004, which reported a complication rate of 1%. As adverse events are often poorly reported, the GDG used this knowledge to inform their decision making. This has been added into the LETR to avoid confusion. |
| James Cook University Hospital | Full 2 | 64 | general | The GDG have proposed clinical features which may be helpful in identifying patient suitable for denervation. This proposal represents the only place in the overall guidance document where clinical advice on identification is proffered, and may be held to represent an area where the treatment of evidence and analysis is distinctly different for one treatment than others in the guidance. The consensus document referred to was constructed on the Delphi principal and no evidence of the sensitivity or specificity of these clinical findings were available in the original publication. Published investigations of specificity and sensitivity have demonstrated little utility of the features investigated (6,7,8). The GDG may wish to consider providing evidence for the use of this paradigm. | Thank you for your comment. The LETR details clinical features which may be helpful in determining which patients may be suitable for this intervention although the GDG accept that reliably identifying patients with facet joint pain is challenging and the evidence to support this identification is conflicting. For this reason this full level of detail is not included in the recommendation, which states that it should be considered in people in whom the main source of pain is thought to come from structures supplied by the medial branch nerve. |
| James Cook Universi | Full 2 | 120 | general | Epidural Injections | Thank you for your comment. We were unable to demonstrate, given the available evidence, that image guided epidurals, or that one route of epidural |

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| ty Hospital | | | | 24.6. It has been recommended that epidural injections of local anaesthetic and steroid in people with acute sciatica be considered. In the preamble it is made clear that all routes of administration are included and specifically nerve root block. However, it is possible that commissioners and others reading the brief version of the guidance will not appreciate this and fail to commission appropriately. This is perhaps made more likely as nerve root block and epidural have separate OPCS codes and, therefore, appear separately in SUS and HES data. The CRG are requested to consider a form of words clarifying the scope of their recommendation. | administration was superior to another. A research recommendation was written to address this uncertainty, but we are unable to be more specific in the recommendation. Your comments will be considered by NICE where relevant support activity is being planned. |
| James Cook University Hospital | Full 2 | 153 | general | Total Lumbar Disc replacement<br><br>Potential conflict of interest. Two members of the GDG were spinal surgeons but were not excluded from discussion and recommendation process. This permits the perception of conflict of interest. | Thank you for your comment. All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee. Members of committees are recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (appendix B). |
| James Cook University Hospital | Full 2 | 153 | general | Trade Off between Clinical Benefits and Harms<br><br>First paragraph, the GDG note that anterior lumbar interbody fusion is not commonly performed "due to a perceived lack of effectiveness". This statement appears supported only by the collected expert opinion, which may have been coloured by a trial against fusion with BAK cages which were subsequently demonstrated to have unsatisfactory results. | Thank you for your comment.<br><br>The GDG was concerned about the use of BAK cages to achieve anterior lumbar interbody fusion in the control group of the Gornet 2011 trial. The GDG was aware that anterior procedures in the lumbar spine for back pain are not commonly performed in the UK setting, and that the BAK cages technique shows a low fusion rate and would not be considered appropriate for a stand-alone anterior fusion in |

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| | | | | An unmatched cohort series of 150 anterior fusions and 150 postero-lateral fusions indicated superiority of anterior fusion over instrumented postero-lateral fusion in function and return to work (9). The GRADE quality rating in surgical trials is usually low because of the inevitable risk of bias owing to the lack of blinding. The GDG may wish to consider the value of lower quality evidence in surgical studies to inform the expressed opinion. | clinical practice. For this reason, as most of the evidence in favour of disc replacement in the review came from the Gornet 2011 trial, the GDG wished to stress that such evidence should be regarded with caution. This has now been clarified in section 26.6 (Recommendations and link to evidence). The comparison of different spinal fusion routes was outside the scope of the guideline.<br><br>The protocol for this, and all intervention reviews in the guideline included both RCTs and observational studies where RCT evidence was lacking. In this review 2 cohort studies were included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent as stated in the methods, section 4.3.2. |
| James Cook University Hospital | Full 2 | 153 | general | Paragraph 2. The GDG expressed concern over the risk of patient harm from surgical intervention and quote figures from one study with 80 participants in the disc replacement arm, noting that it was not powered to detect harm. This imprecision must be in both directions however, the risk of an excess of serious complications by chance in a small group is higher. Many of the studies referred to by the GDG were included in the systemic review by Wei in 2013 (10). This systemic review examined the reported complications in five randomised controlled trials comprising of 1081 total disc replacement operations. The complication rate reported was 5.8 percent and in the 500 fusion patients of the same trials, the complication rate was 10.8 percent. In this review the re-operation rate was 5.2 percent for total disc replacement and six percent for spinal fusion. | Thank you for your comment. The GDG were aware of the Hellum 2011 study, which reported the serious adverse events related with disc replacement, in particular 1 lower leg amputation and 4 cases of considerable blood loss out of 80 participants. It was the GDG concern that this was a high rate of adverse events in a study not powered to detect harm, but believed that this high adverse event rate was reflective of the risks observed in practice. This is detailed in the LETR (section 26.6). The systematic review by Wei et al (2013) was not included, as some of the included studies were conducted in populations that were not relevant to our review protocol; however the relevant studies were included and did inform the recommendation. |

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| | | | | It is acknowledged that spinal surgery is a major intervention and will carry a significantly greater risk of patient harm than conservative management. These data were considered in the original NICE guidance IP 306. It is suggested that the GDG may wish to re-consider their presentation and evaluation of the risk of complications. | |
| James Cook University Hospital | Full 2 | 153 | general | Trade-off between net clinical effects and costs<br><br>The GDG notes that two studies were considered for the economic evaluation. One study (Johnsen 2014) demonstrated cost effectiveness against multi-disciplinary rehabilitation. The evidence extract describes this as a three element MBR programme. In paragraph two, the GDG then note that comparator interventions might not be cost effective themselves. However, in the evaluation of multi-disciplinary bio-psychosocial rehabilitation in another part of the guidance, the 3 element MBR is noted to be a cost effective intervention. There appears to be a contradiction here.<br><br>There does not appear to be a rationale for preferring the analysis using the FS6D over the EQ5D. | Thank you for your comment. The inconsistency of the terminology for the multidisciplinary rehabilitation in Johnsen 2014 has been amended and is now consistent across the review. We have amended the LETR in response to your comment.<br><br>When choosing outcomes EQ-5D scores are to be preferred over SF-6D according to the NICE Reference Case and therefore the analysis using EQ5D data was used in the base-case analysis. The SF-6D was reported as a one-way sensitivity analysis and was therefore presented to the GDG as an additional consideration of uncertainty. Changes have been made to the LETR to clarify this. |
| James Cook University Hospital | Full 2 | 154 | general | Quality of Evidence<br><br>The GDG note that the GRADE quality rating of the evidence was low to very low. This was driven by a high risk of bias. It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass.<br><br>Given the paucity of evidence and the inevitably low GRADE evaluation of randomised surgical trials there is a strong case for reviewing evidence from other sources. There has been an increase over time of the use of spinal surgical registries in a number of specialities including spinal surgery. The use of such data with a properly structured methodology (STROBE) | Thank you for your comment. The protocol for this, and all intervention reviews in the guideline included both RCTs and observational studies where RCT evidence was lacking. In this review 2 cohort studies were included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent as stated in the methods, section 4.3.2. |

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| | | | | has been investigated by a number of authors and its use has been supported (11-16).<br><br>The GDG may wish to consider evidence from the Swedish Spine Registry which covers 42 of 45 Spine Centres in Sweden. The 2012 report (ref 17) indicates that total disc replacement provides better outcomes in most modalities than spinal fusion. The data in the registry is sufficiently detailed to permit evaluation of the influence of pre-operative functional scores. They also note that the RCT as a technique for comparison with other fusion techniques might be possible. Not stated in this report is the consideration that to achieve a satisfactory GRADE quality rating, the comparator in such a trial would have to be stand alone anterior fusion otherwise blinding would be impossible with one operation done from the front and the other from the back.<br><br>The 2014 report of the Swedish Spinal Registry (18) evaluates the results of surgery for degenerative disc disease at one year, two years and five years. These surgeries are fusions of various types and disc replacement (16 percent). Considering the evidence review undertaken by the GDG, outcomes of total disc replacement may be considered not inferior to those of spinal fusion and so these results have validity. The change in EQ5D score from pre-operative to one year follow up was 0.32. The improvement at two years was 0.3 and at 5 years 0.29. Thus surgical procedures resulted in approximately a third of a Qualy in improvement per year for five years. Pain on the VAS scale reduced from 6.2 pre operatively to 2.7 at one year, 2.9 at two years and 3.3 at five years. ODI results are available for two years only, with a reduction from 44 pre operatively to 23 at one year and 24 at two years. Registries have the additional advantage of representing surgery in the real world, with normal health care provision and normal surgical teams. | The GDG were aware of the availability of spine registries, however when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Observational data was used within the review, but no published analysis of registry data was identified to inform the review, and evidence was available from the included studies. Furthermore, the GDG highlighted that many spine registries are filled on a voluntary basis, and therefore are at very high risk of reporting bias. |

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| | | | | The GDG are invited to consider whether in the absence of the possibility of high quality studies on the GRADE quality rating, data from spinal registries should be included in the evidence base. | |
| James Cook University Hospital | Full 2 | 154 | general | Other considerations - Patient Choice<br>The GDG note that total disc replacement in the lumbar region is effective. It notes the risk of complications associated with major surgery.<br>It is clear that any form of spinal surgery for axial lumbar spine pain is a much larger intervention with significant risk of complications. As such it is appropriate that total disc replacement should be considered only after an inadequate response to an appropriate NBR (CPPP). All health care delivery is patient centred and is undertaken in partnership with the patient themselves. It is perhaps inappropriate that the choice of an effective treatment should be denied to patients without their involvement. The uptake of a surgical option after full and open discussion of potential benefits and potential risks is a decision which should be made by patients. It is requested that the GDG consider whether patient choice should take a higher priority. | Thank you for your comment. Patient choice is integral to all NICE guidelines and should apply across all recommendations. This is stated in section 4.5.4 and inside the cover page, highlighting that: "The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources". However, having reviewed the evidence for disc replacement the GDG agreed that the risks of harms associated with the surgical procedure outweighed the potential benefits and the GDG decided it was appropriate to recommend against the use of disc replacement for non-specific low back pain. |
| James Cook University Hospital | Full 2 | 154 | general | The GDG note that total disc replacement in the lumbar region is effective. It notes the risk of complications associated with major surgery. It is plain that the risk of complications is potentially correlated with the experience of the surgeon and of the multi-disciplinary team. Lumbar total disc replacement is a specialised procedure, directly commissioned by NHS England. The potential for complications might be addressed by performing such surgery only under the auspices of a specialised surgical centre.<br><br>The audit and governance all surgical procedures are of great importance, especially with regard to patient satisfaction, patient outcomes and complications. All specialised spinal surgery is now mandated to be entered on the British Spine | Thank you for your comment. Patient choice is integral to all NICE guidelines and should apply across all recommendations. This is stated in section 4.5.4 and inside the cover page, highlighting that: "The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources". However, having reviewed the evidence for disc replacement the GDG agreed that the risks of harms associated with the surgical procedure outweighed the potential benefits and the GDG decided it was appropriate to recommend against the use of disc replacement for non-specific low back pain. |

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| | | | | Registry. In this regard, what has been termed "special arrangements for clinical governance, consent and audit for this procedure" might be expressed as entry into the British Spine Registry, which would also permit research.<br><br>The GDG may wish to consider whether improved safeguards, audit and governance might be sufficient reason to modify the recommendation in this manner and allow patient choice. | The GDG is unable to comment about how changes in audit and governance may affect the outcomes of surgery. |
| James Cook University Hospital | Full 2 | 178 | general | Conflict of Interest<br><br>There are two spinal surgeons on the GDG who took part in the discussion and the decision making. This permits the perception of a conflict of interest. | Thank you for your comment. All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee.<br>Members of committees are recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (appendix B). |
| James Cook University Hospital | Full 2 | 178 | general | Research Recommendation<br><br>The GDG recommend "a large multi-centre randomised trial with sufficient power to answer these important questions". It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass. This will inevitably result in a low GRADE evaluation for randomised surgical trials<br><br>The GDG also suggest within the trial investigating possible predictors of response. It is clear that the trial size would be | Thank you for your comment. The protocol for this, and all intervention reviews in the guideline included both RCTs and observational studies where RCT evidence was lacking. In this review 1 cohort study was included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and |

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| | | | | significantly larger than the Oxford Stabilisation Trial (Fairbank et al). The Fairbank study came under the auspices of the MRC, cost £1.8 million and took 9 years. The study included 349 subjects and achieved a GRADE quality rating of low due to risk of bias. As the risk of bias cannot be eliminated it seems extremely unlikely that funding could be obtained for any such further study and indeed it would appear difficult to justify such a use of research resources. | consideration is consistent as stated in the methods, section 4.3.2.<br><br>As detailed in section 4.5.1 of the Methods chapter, when areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research. The GDG is unable to comment regarding the funding of further trials. |
| James Cook University Hospital | Full 2 | 179 | general | Trade-off between Clinical Benefits and Harms<br><br>The GDG note evidence formed one large study indicating clinical benefit of spinal fusion over usual care. They also note a number of studies collectively indicating broad equivalence between spinal fusion and MBR programmes.<br><br>The GDG noted that the GRADE quality rating of the evidence was low to very low. This was driven by a high risk of bias. It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass.<br><br>Given the paucity of evidence and the inevitably low GRADE evaluation or randomised surgical trials there is a strong case for reviewing evidence from other sources. There has been an increase over time of the use of spinal surgical registries in a number of specialities including spinal surgery. The use of such data with a properly structured methodology (STROBE) has been investigated by a number of authors and its use has been supported (11-16).<br><br>The GDG may wish to reconsider evidence from the Swedish Spine Registry which covers 42 of 45 Spine Centres in Sweden. The 2014 report of the Swedish Spinal Registry (18) evaluates the results of surgery for degenerative disc | Thank you for your comment. Data from spinal registries was not used to inform this review as the GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Observational data was used within the review, but no published analysis of registry data was identified. Furthermore, on consideration of this suggestion, the GDG highlighted that many spine registries are filled on a voluntary basis, and therefore are at very high risk of reporting bias. |

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| | | | | disease at one year, two years and five years. These surgeries are fusions of various types and disc replacement (16 percent). The change in EQ5D score from pre-operative to one year follow up was 0.32. The improvement at two years was 0.3 and at 5 years 0.29. Thus surgical procedures resulted in approximately a third of a Qualy in improvement per year for five years. Pain on the VAS scale reduced from 6.2 pre operatively to 2.7 at one year, 2.9 at two years and 3.3 at five years. ODI results are available for two years only, with a reduction from 44 pre operatively to 23 at one year and 24 at two years. Registries have the additional advantage of representing surgery in the real world, with normal health care provision and normal surgical teams.<br><br>The GDG are invited to consider whether in the absence of the possibility of high quality studies on the GRADE quality rating, data from spinal registries should be included in the evidence base. | |
| James Cook University Hospital | Full 2 | 181 | general | Other Considerations<br><br>It the GDG note the existing guidance on non-rigid stabilisation recommending “normal arrangements for clinical governance, consent and audit for this procedure”. Non-rigid stabilisation as a technique has fallen out of favour in spinal surgery owing to a substantial re-operation rate and less satisfactory long term results. The GDG is requested to consider whether by effectively recommending against fusion surgery that a large patient population may then be subjected to a recrudescence of less satisfactory technique.<br><br>The GDG note the existing guidance on trans-axial interbody lumbosacral fusion (IPG387) and lateral (including extreme extra and direct lateral) interbody fusion IPG321. The GDG are requested to consider whether their advice is internally consistent with recommending against the majority of fusions | Thank you for your comment. The GDG were aware of the existing IP guidance and have been in communication with the IPG team during the development of the guideline. Both IPG321 and IPG387 recommend special arrangements for the procedures covered and therefore are not considered to conflict with the recommendation that fusion should only take place in the context of an RCT. |

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| | | | | but permitting these forms of fusion which have a significantly lower evidence base. | |
| James Cook University Hospital | Full 2 | 181 | general | Other Considerations - Patient Choice<br><br>It is clear that any form of spinal surgery for axial lumbar spine pain is a much larger intervention with significant risk of complications. As such it is appropriate that spinal fusion should be considered only after an inadequate response to an appropriate NBR (CPPP). All health care delivery is patient centred and is undertaken in partnership with the patient themselves. It is perhaps inappropriate that the choice of an effective treatment should be denied to patients without their involvement. The uptake of a surgical option after full and open discussion of potential benefits and potential risks is a decision which should be made by patients. It is requested that the GDG consider whether patient choice should take a higher priority. | Thank you for your comment. Patient choice is integral to all NICE guidelines and should apply across all recommendations. This is stated in section 4.5.4 and inside the cover page, highlighting that: "The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources". However, having reviewed the evidence for spinal fusion the GDG agreed that the risks of harms associated with the surgical procedure outweighed the potential benefits and the GDG decided it was appropriate to recommend against its use for non-specific low back pain (unless as part of a clinical trial). |
| James Cook University Hospital | Full 2 | 181 | general | It is plain that the risk of complications is potentially correlated with the experience of the surgeon and of the system. Lumbar fusion is a specialist procedure. The potential for complications might be addressed by performing such surgery only under the auspices of a specialist spinal surgeon.<br><br>All specialised spinal surgery is now mandated to be entered on the British Spine Registry. In addition the entry of lumbar spinal fusion into the British Spine Registry would provide a thorough evaluation of the outcomes, the important predictive factors, the complications and the cost effectiveness of the procedure. With the increasing evidence for the utility of registries, this might meet the requirement for further evaluation and research in an effective but achievable manner. | Thank you for your comment. showing no consistent benefit of spinal fusion over comparator treatments and potential harm, the GDG agreed it was appropriate to recommend against the use of spinal fusion for non-specific low back pain unless as part of a randomised controlled trial.<br>We are unable to specify that data should be entered onto a registry in a recommendation, however we have added a statement to the 'evidence and link to recommendations' section of the review to state that the GDG suggest where fusion is carried out in the context of a randomised controlled trial, data should be entered in spinal registries.<br>The GDG is unable to comment about how changes in audit and governance may affect the outcomes of surgery. |

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| | | | | The GDG may wish to consider whether improved safeguards and the improved audit, research and governance which is available through the registry might be sufficient reason to modify the recommendation in this manner and allow patient choice. | |
| James Cook University Hospital | general | General | General | Line numbering is not provided in the Recommendation and link to evidence sections. It would be helpful to responders if these elements were numbered | Thank you for your comment. This is a limitation of the template. We are constantly reviewing the best way for NICE guidance to be presented. |
| James Cook University Hospital | general | General | General | In the evidence extraction tables, it would be extremely helpful to responders if the studies contributing to each outcome were identified. This would save a lot of time as at present one has to back track by considering the number of participants in each study. | Thank you for your comment. References are not provided in the GRADE summary tables so that the focus is on the body of evidence rather than the individual studies..<br>GRADE tables and Forest plots are reported in the same order however to enable identification of studies contributing to each result should it be required. |
| James Cook University Hospital | general | general | general | 1. Henschke et al. Injection therapy and denervation procedures for chronic low back pain: a systematic review. European Spine Journal (2010) 19:1425-14449.<br>2. Schofferman and Kine. Effectiveness of repeat radio frequency neurotomy for lumbar facet pain. Spine. 29 (21): 2471-2473.<br>3. Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints: 10-year prospective clinical audit. Pain Physician 2007;10: 291–99<br>4. Cohen SP, Williams KA, Kurihara C, et al. Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology 2010: 113: 395–405<br>5. da Rocha ID, a Cristante AF, Raphael Martus Marcon RM, Oliveira RP, Letaif OB, de Barros Filho TEP. Controlled medial branch anesthetic block in the diagnosis of chronic | Thank you for this information. |

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| | | | | lumbar facet joint pain: the value of a three-month follow-up. CLINICS 2014;69(8):529-534<br>6. Schwarzer AC, Aprill C, Derby R, Fortin JD, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine. 1994;15:1132–1137<br>7. Manchikanti L, Pampati V, Fellows B, Baha GA. The inability of the clinical picture to characterize pain from facet joints. Pain Physician. 2000;3:158–166.<br>8. M. J. Hancock, C. G. Maher, J. Latimer, M. F. Spindler, J. H. McAuley, M. Laslett, and N. Bogduk Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain. Eur Spine J. Oct 2007; 16(10): 1539–1550<br>9. Greenough et al, Instrumented Postero-Lateral Lumbar Fusion; results and comparison with anterior interbody fusion. Spine 1998; 23:479-486.<br>10. Wei et al (cut and paste reference)<br>11. Benson K1, Hartz AJ. A comparison of observational studies and randomized, controlled trials. N Engl J. Med. 2000 Jun 22;342(25):1878-86.<br>12. Concato J, Lawler EV, Lew RA, Gaziano JM, Aslan M, Huang GD. Observational methods in comparative effectiveness research. Am J Med. 2010 Dec;123(12 Suppl 1)<br>13. Concato J1, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000 Jun 22;342(25):1887-92.<br>14. Colditz GA. Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. Crit Rev Food Sci Nutr. 2010;50 Suppl 1:10-2.<br>15. Jacobs WC et al. Spine surgery research: on and beyond current strategies. Spine J 2012.<br>16. Phillips et al. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine 2013. | |

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| | | | | 17. http://www.4s.nu/pdf/Report_2012_swespine_english version.pdf<br>ISBN: 978-91-979924-5-9<br>18. http://www.4s.nu/pdf/Report_2014_Swespine_Engl_ver_141204.pdf<br>ISBN: 978-91-88017-00-0 | |
| Johnson and Johnson | Full 2 | general | general | The recommendations made by the GDG are contradictory to recommendations made by IPAC on spinal fusion and disc replacement surgery. For example, lateral interbody fusion in the lumbar spine (IPG321) and transaxial interbody lumbosacral fusion (IPG387) both have special arrangements for use recommendations, not research only. In addition, IP guidance on non-rigid stabilization techniques for the treatment of low back pain (IPG366) makes normal arrangements for use i.e. the procedure is safe and efficacious. With regards to intervertebral disc replacement in the lumbar spine (IPG306), this has normal arrangements for use. Yes, this difference is "noted" within the GDG considerations but with no indication of how this discrepancy will be resolved by NICE. Which recommendations should patients and commissioners use to inform their decision making? How will this discrepancy be resolved by NICE to avoid any misunderstanding or confusion amongst stakeholders? | Thank you for your comment. The GDG were aware of the existing IP guidance and have been in communication with the IPG team to highlight the differences within the evidence reviews.<br>Both IPG321 and IPG387 recommend special arrangements for the procedures covered and therefore are not considered to conflict with the recommendation that fusion should only take place in the context of an RCT.<br>Although as you state IPG366 and IPG306 do recommend normal arrangements, the evidence reviewed in this guideline does not demonstrate sufficient evidence of effectiveness for spinal fusion or disc replacement that would enable a recommendation in a clinical guideline for their use. Given the finding from this guideline that neither spinal fusion nor disc replacement are clinically effective for low back pain, these treatments should not be offered (unless in the case of an RCT for spinal fusion as stated in the recommendation). |
| Johnson and Johnson | General | general | general | There are inconsistencies in how this Guideline is being referred to by NICE and we are concerned that this is causing confusion amongst stakeholders, specifically with regards to the indication within scope. It needs to be consistently clear in all emails and written NICE documents that this Guideline is not for low back pain – it is only relevant to non-specific low back pain as defined in the scope (please look to the title of this comment table provided for example here). There is a significant difference here which is being overlooked in all | Thank you for your comment. This has been noted.<br><br>The guideline documents make it clear that this guideline is for the management of non-specific low back pain and sciatica. Definitions of these terms are explained within the guideline introduction. |

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| | | | | documentation. We believe the original scope has been compromised by these inconsistencies and therefore believe the guidance in its current form is not fit for purpose and poses the possibility of adding confusion rather than supporting stakeholder clarity. | |
| Johnson and Johnson | Short | 8 | 12/13 | We understand the importance of robust evidence generation strategies to demonstrate clinical safety and efficacy, and where there are significant evidence gaps which flag real safety concerns and/or uncertainties impacting clinical outcomes we are supportive of a restrictive research only recommendation. However, in the absence of significant safety concerns, we are not supportive of a research only recommendation that restricts solely to RCT design. In addition, the British Spine Society have established the British Spine Registry which could be utilised to generate valuable evidence and we consider this a huge oversight by NICE. The long term, longitudinal view of follow up which is supported by a national registry has been demonstrated by the National Joint Registry and in this instance we believe a recommendation which supports mandatory inclusion to the British Spine Registry has the ability to adequately feed the evidence generation requirements and is significantly less restrictive and costly than a recommendation solely aligned to the use of RCT evidence. | Thank you for your comment. The GDG did have serious concerns about the safety of the procedure. The GDG agreed there was a considerable evidence of harm coming from the body of evidence that was reviewed. We are unable to make a recommendation that data should be submitted to a registry, but have added a statement to the 'evidence and link to recommendations' section to state that the GDG suggest if done within an RCT data should be submitted to a registry. |
| Medtronic | Full 1 | 40 | 1-11 | *"Other than the excluded populations listed in the scope (4.3.1), the following exclusions were agreed 1 by the GDG:*<br>• *Mixed populations e.g. people with low back pain and neck pain (unless the results 3 presented in the studies are split so data for people with low back pain only is extractable).*<br>• *Pregnancy-related back pain*<br>• *Sacroiliac joint dysfunction*<br>• *Adjacent-segment disease*<br>• *Failed back surgery syndrome* | Thank you for your comment. We agree that imaging may be used to identify some of these conditions, however their diagnosis and management is not directly covered by this guideline, and they remain out of scope. The review on imaging within the guideline focussed only on whether imaging improved functional disability, pain or psychological distress in people with non-specific low back pain or sciatica, not its use as a diagnostic tool. |

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| | | | | • *Spondylolisthesis*<br>• *Spondylosis*<br>• *Osteoarthritis »*<br><br>We ask you to consider that imaging is required to diagnose conditions such as spondylolisthesis and spondylosis and thereby identify patients who are excluded from the scope of this guideline. | |
| Medtronic | Full 1 | 115 | 27-29 | *Whether or not imaging is of benefit in terms of improving patient related outcomes for people with non-specific back pain or sciatica, either at initial presentation or later in the pathway, remains an area of uncertainty. This review intends to address this uncertainty.*<br><br>We ask you consider that this is not specific to low back pain; this is one of the major issues encountered when assessing the clinical benefit and the cost-effectiveness of imaging (diagnostic) techniques since the imaging results do not have a direct impact on the patients but through the selection of treatment. Benefits to patients are therefore impacted by the appropriateness of the decision around the treatment as well as the expertise of the physician to administer the treatment (especially in surgery), | Thank you for your comment. We agree that this is not specific to low back pain alone, however considering the impact on other co-morbidities is beyond the scope of this guideline. The review intended to address whether imaging improved outcomes for people with low back pain or sciatica, which would also demonstrate whether changes to their management (if within the trial period) had occurred and subsequently led to improved outcomes. |
| Medtronic | Full 1 | 147 | 23 | Recommendation 7.6 (2) “Do not routinely offer imaging in a non-specialist setting for low back pain with or without sciatica”.<br><br>We are concerned that this recommendation may restrict appropriate access for Primary Care (MSK/ESP) triage services that require access to imaging to ascertain the specific mechanical spinal pathology and facilitate appropriate referral to respective specialist MDT. | Thank you for your comment. The definition of ‘specialist setting of care’ has been detailed in the recommendation for clarity as ‘for example, a musculoskeletal interface clinic or hospital’. |

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| Medtronic | Full 2 | 152 | 33 | *Recommendation 36: Do not offer disc replacement in people with non-specific low back pain.*<br><br>We ask you to consider that appropriate imaging is required to a diagnosis of specific versus non-specific low back pain | Thank you for your comment. The importance of assessing an individual's signs and symptoms when considering the appropriate form of imaging has been highlighted in section 7.1, lines 24-26 on page 116 (Full guideline- Assessment and non-invasive). Furthermore, section 7.6, 'Other consideration' box states that 'the presence of symptoms or signs suggestive of possible serious underlying pathology (red flags), including a past history of cancer or trauma may warrant early imaging'. However guidance on assessment of such underlying pathology is beyond the scope of this guideline. |
| Medtronic | Full 2 | 178 | 36 | *Recommendation 37: Do not offer spinal fusion for people with non-specific low back pain unless as part of a randomised controlled trial.*<br><br>We ask you to consider that appropriate imaging is required to a diagnosis of specific versus non-specific low back pain | Thank you for your comment. As detailed in the Introduction (chapter 2), this guideline only covers non-specific low back pain, and excludes the evaluation of serious spinal pathology. The clinical and cost effectiveness of imaging to improve functional disability, pain or psychological distress in people with low back pain and/or sciatica has been reviewed in chapter 7. |
| Medtronic | Full 2 | 181 | 52 | *(Spinal fusion research recommendation)*<br>*"Non-specific back pain affects a large number of individuals in UK. The condition has a huge cost to the individual, society and the country's economy. Over the past 2 decades, increasing numbers of procedures have been proposed for the surgical management of LBP. These include but are not limited to surgical fixation with internal metal-work applied from the back, front, side or any combination of the three routes. The costs of these operations have escalated and with the advent of minimally invasive approaches more of the operations are performed with uncertain benefit. As well as the monetary cost, there are complications associated with the surgical approaches with some studies reporting around 20% complication rate in the short to medium term".* | Thank you for your comment. The paragraph has now been edited as follows: 'The costs of these operations have escalated, and as well as the monetary cost, there are complications associated with the surgical approaches with some studies reporting around 20% complication rate in the short to medium term'. |

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| | | | | We agree that the overall number of operations have increased due to the ageing population and this will have a financial impact however we question whether minimally invasive procedures, which are performed in a limited number of centres, are having a significant impact on the escalating costs or overall increase in operations.<br>This sentence also seems to allude that the benefit is more uncertain with minimally invasive procedures. We ask you to consider that literature shows that mid-term benefits are the same when comparing open fusion surgery to minimally invasive fusion with fewer perioperative complications in favour of the minimally invasive technique. | |
| MPP | Short | 6 | 19-20 | I imagine this will be quite a controversial recommendation in practice. Would it be possible to give additional information on what to do with patients currently being managed on paracetamol alone? Given the wording of the rec – is it acceptable for people to receive paracetamol in combination with *any* other analgesic, or just weak opioids (as per rec 1.2.21). I think it's really important to make any recommendations regarding paracetamol crystal clear with no ambiguity.<br><br>As a side note- this recommendation seems very familiar to the controversial one made in the draft osteoarthritis guidance on 2013, a recommendation that did not makeit to the published guideline, the medicines related part of that guideline remains to be updated.<br><br>This change will be a challenge in practice and people will need to be informed on *why* the recommendation has changed, and *how* to manage existing patients. | Thank you for your comment. We believe it is important to include this recommendation as there was no evidence of benefit of paracetamol alone and it is widely used so this is important to highlight. People currently being managed on paracetamol should consider other treatment options in the guideline.<br>Recommendations 1.2.20 clearly states that weak opioids can be given with or without paracetamol, therefore there can be no confusion regarding which analgesic is being considered in combination with paracetamol.<br>Whereas the draft recommendation for osteoarthritis was based on potential harms of paracetamol, in this guideline recommendation 1.2.21 is based on a lack of effects seen as well potential harms and we believe it is important to include. Detail on why this recommendation has been made is included in the 'evidence and link to recommendations' table of the full guideline. |
| MPP | Short | 6 | 21-22 | I'm not sure if this rec is slightly redundant – there will be a lot of people can't take NSAIDs (due to AEs, contraindications, | Thank you for your comment, however we believe it's important to note that opioids should not be routinely used for acute low back pain as the evidence |

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| | | | | other meds etc). I'd suggest losing this rec and just state in whom they can be used (1.2.21) | reviewed did not support their use. The subsequent recommendation is only specific to those who can't tolerate or for whom NSAIDs are unsuitable, and is a clarification of when opioids can be considered, so the two recommendations should both be included for clarity. |
| MPP | Short | 6 | 27-28 | I notice that opioids is the only class of drug in which the distinction between acute and chronic back pain is made (with all other rec just referring to 'non-specific low back pain'. I assume this is because of concerns about long-term opioid use! How should patients who present with acute pain which is adequately managed with opioids be managed? Is a time limit for 'acute treatment' needed (ie no more than 4 weeks). | Thank you for your comment. Recommendation 25 states 'do not offer opioids for managing chronic non-specific low back pain'. In terms of acute low back pain, recommendation 23 states 'do not routinely offer opioids for managing acute non-specific low back pain'. When considering the evidence, the GDG found no evidence for the use of opioids in acute low back pain or for the management of acute episodes of low back pain and therefore the effectiveness of opioids alone for the management of acute low back pain could not be determined from this review. |
| MPP | Short | 7 | 1-3 | Should we be making a recommendation on the use of muscle relaxants here? I note from pg 664 limited evidence was found for this class. | Thank you for your comment. Due to a lack of evidence, the GDG made a research recommendation regarding benzodiazepines (see Chapter 16, research recommendation number 3). |
| Napp Pharmaceuticals | Full 1 | 17 | 13 | It may be useful to provide a classification of weak opioids to support the recommendation that weak opioids be considered for patients with acute low back pain that are unsuitable for NSAIDs | Thank you for your comment. Weak opioids are defined in the BNF. Therefore we do not think this need to be specified within the recommendation. |
| National Ankylosing Spondylitis Society | general | General | General | I am a member of the NICE Spondyloarthritis (SpA) Guideline Development Group as well as the Chief Executive of the National Ankylosing Spondylitis Society. I participated in the GDG discussion to formulate the Group's views on the guidance and therefore the views of NASS strongly echo the views of that Group.<br><br>NASS is extremely concerned that, although the draft LBP guideline appears to provide clear, evidence-based guidance | Thank you for your comment. Assessment of specific causes of low back pain are beyond the scope of this guideline. We have added a statement in the introduction to clarify this. |

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| | | | | for people with non-specific low back pain, the limits of its scope are not clear. I believe it is essential that the LBP guideline explicitly reminds healthcare professionals of specific causes of low back pain. In particular, I believe there should be clear guidance on excluding inflammatory causes of low back pain.<br><br>Delays to diagnosis in spondyloarthritis remain very long. In particular, people with ankylosing spondylitis report a mean delay from emergence of symptoms to diagnosis of 8.57 years [Hamilton et al. 2011]). One of the main reasons for this delay to diagnosis is that symptoms are misdiagnosed as being mechanical in origin. We feel that the proposed guidance will exacerbate this problem unless changes are made.<br><br>I note that the LBP guideline emphasises modes of management – NSAIDs and exercise – that may provide temporary relief from SpA symptoms and thereby mask the true diagnosis.<br><br>Together with the Spondyloarthritis Guideline Development Group I would additionally note that use of the STarT Back tool for risk stratification and care pathway decisions may further contribute to misdiagnosis of SpA because of the way the tool will weight people with persistent problems towards a chronic pain management route, assuming the problems are mechanical. This makes it makes it doubly important that inflammatory causes of back pain are excluded before the pathway is initiated. | |
| National Ankylosing Spondylitis Society | general | General | General | In my role as Chief Executive of NASS, I echo the views of the Spondyloarthritis Guideline Development Group in believing the following are essential to mitigate the risks detailed above:<br>• An initial recommendation should be introduced to (a) remind healthcare professionals of key specific | Thank you for your comment. Assessment of specific causes of low back pain are beyond the scope of this guideline. We have added a statement in the introduction to clarify this and a box with other causes to consider has been included in the algorithm. |

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| | | | | causes of low back pain, (b) guide them to exclude these before following the LBP guideline and (c) signpost them to relevant NICE guidance (including our forthcoming guideline)<br>• The algorithm should be much clearer about excluding specific causes of back pain:<br>o it should start with 'person presenting with low back pain'<br>o it should have a step that explicitly asks whether any criteria suggestive of specific causes are present<br>o it should direct readers to sources of guidance (including the forthcoming SpA guideline) if the answer is 'yes'<br>it should be clear that a diagnosis of non-specific back pain can only be assumed – and the rest of the pathway applied – only once specific causes of back pain have been excluded | |
| National Council for Osteopathic Research | general | general | general | This guideline was undoubtedly an enormous undertaking, reflected in the sheer volume and range of studies reviewed. We thank the team for this extensive review and appreciate the hard work involved and the difficulties surrounding decision making with such varied evidence. We also recognise that the consultation is an important element in guideline development and therefore we hope that the team will find our comments and indeed our suggestions helpful for the final recommendations. | Thank you for your comment. |
| National Council for Osteopathic Research | general | General | general | Comment re: use of terminology - manual therapist<br><br>Please can the editors ensure the term physiotherapist is replaced with manual therapist throughout the report and the term manual therapist used consistently throughout the report.<br>Manual therapists can be physiotherapists, osteopaths and or chiropractors all of whom are statutory registered health care | Thank you for your comment. We understand your concerns regarding the terminology, however the use of 'physiotherapist' has only been used when directly reporting what the included studies have specified. Therefore it wouldn't be correct to replace the term physiotherapist with manual therapist. |

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| | | | | professionals who provide manual therapy. Please can this also be clearly stated in the glossary.<br><br>In addition this terminology would more clearly reflect the intervention based approach to the review of evidence and align with the National Back Pain Pathway that considers competencies of the practitioners delivering care rather than professions.<br><br>Suggestion: consistently use the term manual therapist throughout the report in the text for the discussions, recommendations and press releases.<br><br>Suggestion: Define manual therapists, in the body of the report and the glossary, as osteopaths, chiropractors and physiotherapists. | |
| National Council for Osteopathic Research | General | general | general | Suggestions for additional research recommendations. We feel there are a number of research recommendations that are missing and would be valuable to explore:<br><br>1) Stratifying patients - these recommendations are based on one main study, further work to validate stratification and explore whether stratification can predict outcomes of subgroups responders and non-responders to various treatments. This would be of value to patients and commissioners of services.<br><br>2) Behaviour change interventions are not fully explored. If exercise is being promoted as a key component of effective treatment strategies then more work needs to be done to optimise and maximise exposure to exercise due to high drop-out rates.<br><br>3) If multi-modal therapy packages are recommended more research is needed on how best to deliver these packages | Thank you for your comment. As detailed in section 4.5.1 of the Methods chapter, when areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research.<br>As stated in section 9.5 of the NICE manual (Developing NICE guidelines: the manual, November 2012), it would not be feasible for the GDG to draft research recommendations for every area of uncertainty. Therefore the GDG selected key research recommendations that were likely to inform future decision-making for inclusion in the guideline. Decisions about the inclusion of a research recommendation were based on factors such as the importance to patients or the population, national priorities, potential impact on the NHS and future NICE guidance, ethical and technical feasibility. Further information about how research recommendations should be derived can be found in the NICE research recommendation process and |

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| | | | | and what combinations of treatment and care work best for whom.<br><br>4) Methodological research to advance scientific rigour specifically for pragmatic trials, such as exploration of the use of a single primary outcome in pragmatic trials, sample size calculation, quality appraisal. | methods guide. https://www.nice.org.uk/Media/Default/About/what-we-do/Science-policy-and-research/research-recommendation-process-methods-guide-2015.pdf |
| National Council for Osteopathic Research | General | general | general | Comment on rejection of acupuncture. There is evidence that acupuncture reduces pain, but acupuncture has been rejected as a treatment despite the GDG using pain as an important outcome for pharmaceuticals. We would like to highlight the inconsistent use of evidence in the decision making process for rejecting acupuncture whilst NSAIDs have been recommended. In addition the follow-up period assessed for pain relief is 4 months, but for those with significant acute pain this follow-up time period is probably not appropriate.<br><br>Suggestion: With respect, we recommend that the decision to reject acupuncture should be reconsidered in the light of: the poor evidence for pain relief of the drugs reviewed, their potential side-effects, some reduction of pain with acupuncture and the limited options for patients in acute pain. | Thank you for your comment. The outcome of pain severity has been given the same importance across all reviews in this guideline. When discussing the evidence of acupuncture versus NSAIDs, the GDG acknowledged that although there were similar effect levels observed for acupuncture and NSAIDs, the GDG noted that these were only from 2 small studies of low and very low quality. Given the more positive results seen in the pharmacological review for NSAIDs compared to placebo, the GDG agreed that the limited evidence for acupuncture versus NSAIDs was insufficient to consider equivalence between them. |
| National Council for Osteopathic Research | general | 27-37 | general | Comment on effectiveness vs efficacy. Of the 23 GDG review questions 20 are clinical and cost effectiveness questions (Table 1 page 27). Effectiveness studies rather than efficacy studies explore 'real world' settings i.e. pragmatic trials, in these cases why compare interventions with sham and placebo rather than usual care? (For example 5.2 Review questions). The results may be viewed in a completely different way if sham and placebo arms were not used (as | Thank you for your comment. Effectiveness is used here as a broad term to include efficacy and we will clarify this in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific |

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| | | | | these are designed to study efficacy and mechanism). For example the analysis of evidence and perhaps the recommendations for acupuncture would be different if sham comparisons were excluded. | effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. |
| National Council for Osteopathic Research | general | 8 | general | Comment on definition of multi-modal treatment package. Defining a multi-modal treatment package as exercise plus manual therapy, self-management and psychological therapy (NICE guideline short version page 8) seems to imply that the effectiveness of exercise was superior to the other modalities. This is not the case according to the evidence presented by the GDG. There is no evidence to show which combinations of therapies, if any, are more effective and or active than others. This recommendation does not reflect the findings as presented. If the GDG are recommending exercise plus self-management, manual therapy and exercise they need to recommend them as treatments in their own right as there is no evidence presented to show that combining them makes them more effective. In addition on page 456 'The GDG noted that a large trial included in the combinations evidence was helpful in informing the manual therapy recommendation, because this large study showed clinical benefit of mixed modality manual therapy. If the study was mixed modal manual therapy why is exercise recommended as the only mandatory component (page 8 NICE guideline short version).<br><br>Comment on implementation of multi-modal care package. Perhaps the definition of multi-modal care could be expanded upon. Most manual therapists would argue that the treatment package they give is multi-modal consisting of psychological and self-management support, exercise, general and public health advice plus hands on manual therapy. To redefine multi-modal care as separate packages as implied in the implementation would be resource intensive and costly if delivered by multiple people rather than multi-skilled practitioners such as manual therapists. | Thank you for your comment. The recommendation has been reworded following stakeholder feedback. It now reads 'consider manipulation for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy'. This recommendation was based on evidence from studies of treatment packages including the 2 or 3 of the aforementioned elements (see chapters 9, 12 and 17). Exercise was a component in all comparisons whereas the other interventions where not. Therefore, exercise was the only compulsory element, based on the evidence. |

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| | | | | The concept of multi-modal treatment intervention might be better phrased as integrated multi-modal care. This seems sensible but the implementation, description and rationale has got a bit lost in the body of the report. The guideline might incorporate a recommendation to multi-skill professionals to deliver an integrated multi-modal package of care that might include: manual therapy, exercise, self-management and psychology.<br><br>Suggestion: consider manual therapy as a stand-alone intervention and recommend that therapists deliver a multi-modal package of care that includes manual therapy, exercise, psychological support, advice and guidance | |
| National Council for Osteopathic Research | general | 456 | general | Comment on inconsistent use of evidence.<br><br>The level of evidence criteria used to inform recommendations is not applied consistently. It appears that the decision criteria used for non-invasive and invasive therapies are not equal. It would be helpful if the rationale for this was made explicit.<br><br>1) The rationale for NOT recommending manual therapy as a stand-alone treatment entity is based on different rationale, for example to the evidence presented for surgical intervention for discectomy. The evidence for recommending spinal disc decompression was of much lower quality than that for manual therapy. Spinal decompression showed no long term superiority in effectiveness and with more adverse events, yet spinal decompression was recommended as a treatment.<br><br>2) Part 2 Invasive treatment on page 221, in the Quality of Evidence it is stated: 'The evidence for all comparisons and all outcomes was rated as low or very low quality, mainly due | Thank you for your comment.<br>Regarding the rationale for recommending discectomy, the GDG felt that evidence for spinal decompression in people with sciatica showed benefits in terms of prognosis and long-term pain relief. The evidence reviewed supported a recommendation for discectomy to be considered only for a subgroup of people with sciatica who had failed to respond to conservative management of their symptoms and in whom radiological findings are concordant with sciatic symptoms.<br><br>There was insufficient evidence compared to sham to recommend manual therapies as an intervention in isolation. Furthermore there was no evidence to enable us to identify a subgroup who may respond (in contrast with discectomy),<br><br>Regarding the use of a historical and consensus-based time point, section 28.6 (Recommendations and link to evidence) further specifies that the GDG felt there was no need to give a specific time point in |

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| | | | | to risk of bias (and some imprecision)……later page 222 'The group agreed that surgical intervention following a period of conservative management for around 6 weeks would be reasonable. However it was noted that there was little evidence to support this time point and that the conservative treatment interval was largely historical and consensus based'.<br><br>3) The GDG down-graded evidence in the manual therapy analysis due to poor blinding (page 456), it is however impossible to fully blind a pragmatic trial.<br><br>We feel the use of consensus may have led to a predominance of bias towards more invasive treatment recommendations<br><br>This is also reflected in the research recommendations: there are none for primary care.<br><br>Suggestion: Manual therapy should be recommendation as a stand-alone treatment | the recommendation. In fact, as non-surgical management should be pursued prior to surgery, it is likely that it would be at least 3-6 months before surgery was offered.<br><br>Finally, the GDG are aware of the difficulties of fully blinding interventions such as manual therapy, and took this into account when considering the evidence. This is detailed in section 12.6 (Recommendations and link to evidence, paragraph Quality of evidence). GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. This is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent as stated in the methods, section 4.3.2. |
| NHS England | Full 2 | 152-4 | 33 | Lumbar Disc Replacement: Potential conflict of interest. Two members of the GDG were spinal surgeons but were not excluded from discussion and recommendation process. This permits the perception of conflict of interest.<br>• The CRG supports that lumbar total disc replacement should be considered only after an inadequate response to an appropriate NBR (CPPP).<br>• As stated above, high GRADE quality RCTs are difficult in surgery and perhaps the GDG should consider the value of lower quality evidence<br>• The GDG note that total disc replacement in the lumbar region is effective. However, recommendation is made against this procedure on the grounds of risk of | Thank you for your comment. All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee.<br><br>The GDG found the comparison between Disc replacement and an MBR or CPP programme inappropriate, as people with low back pain would often be offered the latter before undergoing surgery. |

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| | | | | complications. The studies quoted are not powered to detect harm. When recommending against a procedure on safety grounds, systematic reviews of large numbers of patients will give a better impression of complications. Wei et al (2013) reported complications in five randomised controlled trials of 1081 lumbar disc replacement surgeries. The reported complication rate was 5.8% v 10.8% for the 500 fusion patients of the same trials. In this review the re-operation rate was 5.2 percent for total disc replacement and six percent for spinal fusion. We suggest the GDG reconsider the decision to recommend against lumbar disc replacement for non-specific low back pain on grounds of risk of complications. (Wei J, Song Y, Sun L, Chaoliang L. Comparison of artificial total disc replacement versus fusion for lumbar degenerative disc disease: a meta-analysis of randomized controlled trials. International Orthopaedics 2013: 37(7), 1315-25).<br>• The 2014 report of the Swedish Spinal Registry (http://www.4s.nu/pdf/Report_2014_Swespine_Engl_ver_141204.pdf ) evaluates the results of surgery for degenerative disc disease at one year, two years and five years. These surgeries are fusions of various types and disc replacement (16 percent). Considering the evidence review undertaken by the GDG, outcomes of total disc replacement may be considered not inferior to those of spinal fusion and so these results have validity. The change in EQ5D score from pre-operative to one year follow up was 0.32. The improvement at two years was 0.3 and at 5 years 0.29. Thus surgical procedures resulted in approximately a third of a QALY in improvement per year for five years. Pain on the VAS | Regarding the consideration of lower quality evidence, the protocol for this, and all intervention reviews in the guideline included both RCTs and observational studies where RCT evidence was lacking.<br>In this review 2 cohort studies were included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent throughout the guideline as stated in the methods, section 4.3.2.<br><br>The GDG noted that the evidence of benefit of disc replacement was not convincing. Furthermore, the GDG were aware of the Hellum 2011 study, which reported the serious adverse events related with disc replacement, in particular 1 lower leg amputation and 4 cases of considerable blood loss out of 80 participants. It was the GDG concern that this was a high rate of adverse events in a study not powered to detect harm, and believed that this high adverse event rate was reflective of the risks observed in practice. This is detailed in the LETR (section 26.6) Wei et al (2013) was not included as some of the included studies were conducted in populations that were not relevant to our review protocol, however the relevant studies were included and did inform the recommendation.<br><br>The GDG were aware of the availability of spine registries, however when setting the protocol that |

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| | | | | scale reduced from 6.2 pre operatively to 2.7 at one year, 2.9 at two years and 3.3 at five years. ODI results are available for two years only, with a reduction from 44 pre operatively to 23 at one year and 24 at two years. Registries have the additional advantage of representing surgery in the real world, with normal health care provision and normal surgical teams.<br>• Lumbar Disc Replacement is considered a specialised procedure by NHS England and as such can only be performed in centres meeting the D14 service specification (https://www.england.nhs.uk/wp-content/uploads/2013/06/d14-comp-spinal-surg.pdf) . This restriction will limit where this procedure can be performed and is likely to improve safety. Multi-disciplinary Team review is accepted as good clinical practice and mandated in the Spinal Specialised Surgery Service Specification. We urge the GDG to consider adding this to their recommendation. The service specification also mandates that all these operations are entered into the British Spine Registry with recording of complications and prospective patient reported outcome and experience measures. We would suggest the GDG considers adopting the same suggested guidance for lumbar disc replacement as we have suggested for spinal fusion: 'Do not offer spinal fusion for people with non-specific low back pain unless the patient has been discussed at a Spinal MDT meeting and prospective diagnostic, operative, complications and patient reported outcome and experience measures entered into a suitable Registry such as the British Spine Registry.' | studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Observational data was used within the review, but no published analysis of registry data was identified to inform the review, and evidence was available from the included studies.<br>Furthermore, on consideration of this suggestion, the GDG highlighted that many spine registries are filled on a voluntary basis, and therefore are at very high risk of reporting bias, particularly regarding complications.<br><br>Based on the evidence reviewed the GDG agreed it was appropriate to recommend against the use of disc replacement for non-specific low back pain. This is detailed in section 26.6 (Recommendations and link to evidence). |

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| NHS England | Full 2 | 178 | 36 | The Complex Spinal Surgery CRG considers spinal issues related to specialised spinal surgery. As such, we would like to make 2 points:<br>1. Recommendation 37: 'Do not offer spinal fusion for people with non-specific low back pain unless as part of a randomised controlled trial.' Multi-disciplinary Team review is accepted as good clinical practice and we urge the GDG to consider adding this to their recommendation. Quality RCTs in this area are unlikely to gain ethical approval as a double blind situation requiring sham surgery will probably not be approved. There is good evidence that observational studies from prospectively collected Register data give comparable results to RCTs:<br><br>Benson K1, Hartz AJ. A comparison of observational studies and randomized, controlled trials. N Engl J. Med. 2000 Jun 22;342(25):1878-86.<br>Concato J, Lawler EV, Lew RA, Gaziano JM, Aslan M, Huang GD. Observational methods in comparative effectiveness research. Am J Med. 2010 Dec;123(12 Suppl 1)<br>Concato J1, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000 Jun 22;342(25):1887-92.<br>Colditz GA. Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. Crit Rev Food Sci Nutr. 2010;50 Suppl 1:10-2.<br><br>Jacobs WC et al. Spine surgery research: on and beyond current strategies. Spine J 2012.<br>Phillips et al. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine 2013.<br>We would therefore suggest that this recommendation is reworded to state: 'Do not offer spinal fusion for people with | Thank you for your comment. We are unable to specify this in a recommendation however we have added a statement to the 'evidence and link to recommendations' section of the review to state that the GDG suggest where fusion is carried out in the context of a randomised controlled trial, data should be entered in spinal registries.<br>It is noted in the 'evidence and link to recommendations' table that there are causes of low back pain for which spinal fusion might be an appropriate treatment, however these are beyond the scope of this guideline. |

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| | | | | non-specific low back pain unless the patient has been discussed at a Spinal MDT meeting and prospective diagnostic, operative, complications and patient reported outcome and experience measures entered into a suitable Registry such as the British Spine Registry .' | |
| NHS England | General | General | General | No comments | Thank you. |
| Pain Concern | General | general | general | The emphasis on self management and communication with patients is welcomed. | Thank you for your comment |
| Pain Concern | General | general | general | We would like to see more emphasis on regular assessment of pain and regular review. This is important as there is no upper time limit to this guideline. | Thank you for your comment. Assessment and review of pain was not prioritised as an area to review within the guideline. However, section 4.5.4 states that: "Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. […] The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources." |
| Pain Concern | Short | 4 | 14-15 | Why should exercise classes be "within" the NHS?. A small but growing number of leisure centre staff are trained in long term conditions. There are teachers trained by the Yoga for Healthy Lower Backs Institute who train teachers to follow an evidence based approach | Thank you for your comment. NICE guidelines are produced for the NHS and only cover settings in which NHS funded care is provided. |
| Pain Concern | Short | 8 | 10 | Surgical Interventions: Even though this guidance doesn't cover neuropathic pain, any reference made to Nice Guidance 173 on neuropathic pain should be placed in appropriate context. The pharmacological management of sciatica should be referenced in the section on page 6 on pharmacological interventions. It is not in context under surgical interventions. Changing this will reduce the potential for confusion, especially for lay persons. | Thank you for your comment. We have now added a recommendation to cross refer to CG173 for the pharmacological management of sciatica. |
| Primary Care Rheuma | General | General | General | References (for the points 1 to 11 above)<br><br>1. PCR Society: www.pcrsociety.org | Thank you for this information. |

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| tology Society | | | | 2. NICE in development guidelines: Low back pain and sciatica (Feb' 2016); GID-CGWAVE0681; https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0681/consultation/html-content<br><br>3. NICE OA Guideline CG177 (2014); https://www.nice.org.uk/guidance/cg177<br><br>4. NIH: National Institute of Drug Abuse (2014); America's addiction to opioids: Heroin and prescription drug abuse; Senate caucus on international narcotics control; https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse<br><br>5. Advisory Council on the Misuse of Drugs (14/1/2016); Pregabalin and Gabapentin Advice; https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf<br><br>6. The North of England regional back pain and radicular back pain pathway (2015); http://www.ahsn-nenc.org.uk/wp-content/uploads/2014/12/The-North-of-England-Regional-Back-Pain-and-Radicular-Pain-Pathway.pdf<br><br>7. Dickson, A. & Dickson, J. (2016); Personal correspondence with the North of England regional back pain and radicular back pain pathway pilot study group<br><br>8. Keele STarT Back Screening Tool (SBST); https://www.keele.ac.uk/sbst/startbacktool/ | |

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| | | | | 9. Sheffield Back Pain; http://www.sheffieldbackpain.com/neck-pain/dealing-with-neck-pain/is-my-pain-likely-to-persist/ | |
| Professional Alliance of Chinese Acupuncturists | FULL 1 | 457 | 7 and 8 | "In the UK, doctors, physiotherapists and manual therapists are increasingly using acupuncture on the basis of neuro-physiological mechanisms, known as western medical acupuncture". The scope of the research does not make clear the clinical differences between western medical and traditional Chinese acupuncture both in theory and in practice. Without clarity from the outset, we are concerned that it will have a negative impact on traditional Chinese acupuncture worldwide.<br><br>Our organisation, PACHA is made up of a group of Chinese doctors from all over the globe, whom collectively, have a passion to establish closer collaboration between western and Chinese medicine in order to raise awareness of the benefits of traditional Chinese acupuncture in western medicine and to create positive allegiances and synergistic views with organisations in the field of public health. We would be willing to bridge the knowledge gap between western and Chinese acupuncture through a series of defined training programs and share our knowledge and research base. Please contact our office at the details provided on the stakeholder registration application. | Thank you for your comment. The GDG are aware of the diversity of the theories and medical systems which are often lumped together under the label "acupuncture". However, in the process of evaluating published research trials we adopted a pragmatic approach and observed that needle positions in both paradigms did not differ much, mainly local needle positions were used. |
| Professional Alliance of Chinese Acupuncturists | FULL 1 | 491 | 7 | A qualified Chinese acupuncturist is required to study and train for 3 to 7 years (minimum) under a standardised and regulated system. Conversely, in the UK, acupuncture maybe administered by a hospital physiotherapist, a private acupuncture practitioner or in some pain clinics by a trained member of staff from nurse to consultant. As such, training and qualification requirements are non specific. Having a group of health professions from various clinical backgrounds administering acupuncture poses the issue and impact on the quality of acupuncture intervention at patient level. PACHA is | Thank you for your comment.<br>It was acknowledged by the GDG that a range of health professionals may deliver acupuncture and that this would have both cost and quality implications.<br>The GDG agreed that in an NHS setting, although other clinicians could deliver the intervention, it was most likely that acupuncture would be delivered by a physiotherapist who had undertaken a post-graduate course in acupuncture. This was also believed to |

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| | | | | keen to work with NICE and their associated members in creating a set of standardised guidelines that focuses on the quality of acupuncture intervention. | reflect the mode of delivery in the clinical trials reviewed. We are unable to comment on the training and qualification requirements. |
| Professional Alliance of Chinese Acupuncturists | general | General | General | PACHA will continue to provide constructive input throughout the consultation process with the aim of re-instating acupuncture for managing NLBP with or without sciatica. It also hopes to encourage NICE to re-review the scope and undertake greater collaboration with traditional Chinese acupuncturists groups to realise the economic and health benefits of traditional Chinese Acupuncture.<br><br>Traditional Chinese acupuncture has been practised and affirmed as effective for thousands of years. The art of acupuncture is synonymous with China. Its long history and its growing list of cures should place traditional Chinese acupuncture as a mainstream treatment to be offered alongside western medicines and practices.<br><br>It is common knowledge that China and the UK have strong business connections. What might not be common knowledge is that the visit by China's premiere, President Xi in October 2015 led to China and the UK signing £2 billion of healthcare trade and investments deals. This is commitment on China's behalf to invest in the UK to boost global health. Though, it is solely our opinion, we believe that the UK government has a political and economical interest to look favourably at collaborative work with Chinese acupuncturists to better understand the benefits of this 2000 year old practice and its potential applications in Western medicine. | Thank you for your comment and this information. However, NICE guidance is based on the best available evidence for each intervention, and on the basis of the systematic review for acupuncture, the GDG do not agree that there is sufficient evidence to recommend acupuncture as a treatment for low back pain or sciatica on the NHS as there is insufficient evidence of benefit compared to sham. |
| Professional Alliance of Chinese | SHORT | 5 | 6 and 7 | We are concerned that this recommendation would cause confusion amongst health professions who have prescribed acupuncture to their patients under the NICE 2009 guidelines (Guidelines state "to consider offering a course of acupuncture needling comprising of up to 10 sessions over a period of 12 weeks)". The confusion is likely to stem from the | Thank you for your comment. During the stakeholder workshop at the start of the guideline development process, we allow any registered stakeholders (details for registering are openly available to all on the NICE website) to attend and give comments on the scope for this guideline. At this stage acupuncture |

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| Acupuncturists | | | | health professionals who have successfully prescribed acupuncture and patients who have been treated for non specific lower back pain with or without sciatica (hereinafter referred to as NLBP) from a course of acupuncture. Furthermore, the scope of the research neglects feedback from front line practitioners involved in the administering of acupuncture treatment and NHS patients who have been successfully treated by acupuncture for NLBP. We are unable to glean from either the full or short versions of the guidelines the therapeutic outcomes of acupuncture for NLBP and would urge NICE, through the consultation process, to re-review the scope to include patient and front line practitioner feedback .<br>By removing acupuncture treatment for patients who have successfully been treated for NLBP will highlight:<br><br>A. Potential credibility concerns over the use of acupuncture and raises concerns over the efficacy of acupuncture, albeit western medical acupuncture, (not to be confused with traditional Chinese acupuncture) for those who administer the treatment.<br><br>B. Potential credibility concerns for frontline practitioners, in particular general practitioners who have advised and prescribed acupuncture. How do they explain to their patients that they can no longer be prescribed a course of acupuncture despite benefiting from the treatment previously?<br><br>NICE will also need to manage any potential fallout from patients (particularly the most vulnerable in society) who have received acupuncture through the NHS. A clear, succinct script issued to front line practitioners must make certain that all health concerns raised by former patients over the withdrawal of acupuncture are managed effectively without any recourse on the NHS for previously | practitioners would have been able to comment on the scope and all review questions. Furthermore, when discussing the evidence for acupuncture, we had a co-opted acupuncture practitioner attend the GDG meeting and contribute to the decision-making process. Throughout the development of this guideline, we have had 2 patient members who have contributed to all discussions and decision-making processes including those around acupuncture.<br>The GDG are aware that despite the original guideline for low back pain (CG88 published in 2009) recommending that a course of acupuncture should be considered, this was poorly implemented within the NHS. In updating and re-reviewing the evidence, the GDG do not believe there is sufficient evidence to maintain this recommendation and therefore no longer recommend acupuncture in an NHS setting. |

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| | | | | recommending a treatment that has now been withdrawn.<br><br>C. Potential credibility concerns for NICE as advisors to the NHS with the removal of a recommendation that it once fully backed previously. | |
| Professional Alliance of Chinese Acupuncturists | SHORT | 6 | 9 to 18 | It is clear that the unit cost of a single treatment of acupuncture outweighs prescribing a course of Non Steroidal Anti-Inflammatory Drugs (hereinafter referred to as NSAID's) alongside recommending an exercise plan. With this said, the scope does not take into account the loss in productivity to the UK through absenteeism. The Guardian reported in an article published on the 24th March 2016, that lower back pain is thought to affect one in ten people, whilst it cost to the UK economy is estimated to exceed £12 billion a year in lost productivity. Furthermore, the scope fails to provide evidence that a course of combined NSAID's and exercise reduces the number of absent days from work compared to a course of acupuncture.<br><br>PACHA would be willing to submit details of client experiences using traditional Chinese acupuncture to cure of NLBP. Our shared learning database concludes that patients suffering from NLBP are relieved from pain after receiving a single treatment. This would suggest a return to work of 1-2 days after treatment. Clinical research suggests that NSAID's could take up to two or more weeks to feel the full therapeutic effect of prescribed NSAID's. This would potentially suggest a return to work of up to 10+ working days.<br><br>When the cost of loss productivity is factored into the equation, it is our opinion that there is a substantial indirect increase in costs which excludes the unqualified and unquantifiable cost and risk associated with prescribing NSAID's. | Thank you for your comment.<br>As reported in the Manual for developing NICE Guidelines, "productivity costs and costs borne by people using services and carers that are not reimbursed by the NHS or social services should not usually be included in any analyses". This is for different reasons, for example time off work is implicitly incorporated in QALY. Also if we included productivity costs in our analyses we would favour those interventions aimed at the working population. We would discriminate against the elderly, children, unemployed people and people with disabilities. |

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| | | | | Our clinics collectively receive approximately 50% of new patients with NLBP conditions. The scope of the research does not include the cost savings and labour hour savings of an NHS patient turning to private traditional Chinese acupuncture clinics for treatment after exhausting all options available on the NHS. This is a fundamental cost saving that we believe should be factored in when looking at cost behaviour and impact in any guideline revision. | |
| Royal College of Chiropractors | Full 1 | 349 | 9-13 | We welcome the clear statement that, *'It is noted that mobilisation and soft tissue techniques are performed by a wide variety of practitioners; whereas manipulation is usually performed by chiropractors or osteopaths, and by doctors or physiotherapists who have undergone additional training in manipulation. Manual therapists often combine a range of techniques in their approach and may also include exercise interventions and advice about self-management.'* | Thank you for your comment. |
| Royal College of Chiropractors | Full 1 | 453 | 6-11 | We are concerned that anecdotal evidence from GDG members, which was not described or evaluated in the guidance documentation, was apparently used to inform the recommendation to consider manual therapy only in conjunction with exercise, despite the fact that the systematically reviewed evidence did not indicate any serious adverse events.<br><br>We question (a) whether this approach is in keeping with NICE guideline development policy, (b) whether the issue of adverse events associated with manual therapy of the lumbar spine was further investigated in the literature, and (c) whether anecdotal evidence in relation to other treatment modalities was considered when formulating the recommendations in this document. | Thank you for your comment. The GDG considered the adverse events reported in the studies included in the review, which were common, minor and transient. They mainly consisted of muscle soreness for a few days after treatment. Furthermore, none of the studies included in the review reported serious events attributable to manual therapy. The GDG were in fact aware that adverse events are rarely reported in clinical trials. Although it is not possible within the resources of the guideline to undertake a systematic review of adverse events for all treatments, GDG clinical expertise is used to inform this area, where data from the clinical trial data is lacking, consistent with NICE guideline development policy. The GDG were aware of possible serious but very rare adverse events that may be related to spinal manipulation and this was taken into account in writing the recommendation, however the decision to only offer manual therapies as part of a package of treatment was not based solely on this evidence, but also the |

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| | | | | | lack of consistent evidence for other outcomes as a sole intervention, but evidence of benefit when used in combination. |
| Royal College of Chiropractors | Full 1 | 809 | Table of terms | The definition of manual therapies incorrectly states that these are delivered by a GP and contradicts the accurate paragraph we have highlighted above (Full, part 1; p349, lines 9-13). It should be altered for correctness and consistency. | Thank you for your comment. The GDG do not agree that this statement is incorrect and are aware that manual therapies may be delivered by a range of healthcare professionals, including GPs as stated. |
| Royal College of Chiropractors | Full, part 1 | 306<br><br><br><br>4<br><br>16 | Summary in table, lines 19-21<br><br>13-16<br><br><br>22-24 | The GDG apparently based its decision to recommend *group* exercise rather than *individual* exercise on cost.<br><br>We question whether the basis of this decision is made sufficiently clear to health professionals and members of the public, particularly in the summary (short version) document. Individual exercise prescription, both supervised and self-supported, is commonly provided as part of the package of care given by chiropractors, and other practitioners who deliver manual therapy, and so it may be unnecessary for patients seeing these practitioners privately or within the NHS to be prescribed separate group exercise classes.<br><br>The full exercise recommendation highlights the importance of taking people's specific needs, capabilities and preferences into account when choosing the type of exercise. We suggest that it will be challenging to deliver this in a group exercise situation and that individual exercise prescription provides a better prospect of delivering the required patient support. | Thank you for your comment. Whilst we recognise that there are some individuals who would prefer individual exercise, we were unable to recommend it as an option as it was not demonstrated to be cost effective. However, the recommendation emphasises that people's specific needs, preferences and capabilities are to be taken into account when choosing the type of exercise.<br>The short version of the guideline is designed for clinicians to refer to the recommendations. The rationale behind the recommendations can be found in section 9.6 of the full guideline. |
| Royal College of Chiropractors | Short | general | general | While the GDG's definition of 'multi-modal' is outlined in the table of terms in part 1 of the full document, it should also be explained in the short version as this is the only document to which members of the public and some health professionals are likely to refer. | Thank you for your comment, this has now been addressed. |
| Royal College of General | Short | 3 | 4 | STarT tool does not identify Red Flags. These should be sought in both history and exam. (DA) | Thank you for your comment. Evaluation and management red flag signs was outside the remit of this guideline (please see chapter 2, Introduction). |

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| Practitioners | | | | | The STarT Back tool is not intended to identify red flag signs. |
| Royal College of General Practitioners | Short | 4 | 13 | Health care professional doing initial assessment can usefully teach simple mobilisation techniques such as McKenzie exercises or dynamic stretches. They can also apply simple manipulation if they are skilled in this. This will particularly be the case if the initial assessment is done by a physiotherapist (as should probably be the case most often). (DA) | Thank you for your comment. For many of the interventions included in the guideline, levels of training may differ according to the expertise of the practitioner, however this cannot be assessed within the systematic review and it has been assumed that unless otherwise stated, that the people delivering the interventions are trained to do so. Professionals delivering interventions should be appropriately trained to do so. |
| Royal College of General Practitioners | Short | 5 | 6 | Previously acupuncture was recommended and this change should be highlighted as a change. (MH) | Thank you for your comment. This guideline is a full update to the 2009 guideline. All existing recommendations are replaced and, as such, changes are not noted in the recommendations, |
| Royal College of General Practitioners | Short | 6 | 9 | Should be: “CONSIDER offering non-steroidal…” NSAIDS kill a lot of patients. They should not be used simply because a guideline says so. (DA) | Thank you for your comment. On reconsidering stakeholder comments and the evidence, this change has been made to the recommendation. |
| Royal College of General Practitioners | Short | 6 | 13 | Previous has advised that a proton pump inhibitor should be taken with non-steroidal anti-inflammatories for people over the age of 45 years but this is not present in this guidance. (MH) | Thank you for your comment. Since evidence for proton pump inhibitors were not reviewed in this guideline, the GDG cannot make such a recommendation. However the recommendation does include taking into account ‘gastrointestinal toxicity’ and ‘the person’s risk factors, including age’. |
| Royal College of General Practitioners | Short | 6 | 17 | Can a specific non-steroidal anti-inflammatory review recommended as being more effective than other non-steroidals? (MH) | Thank you for your comment. The evidence review for pharmacological interventions separated different classes of drugs, however within-class comparisons were not considered (see appendix C for review protocol). Therefore NSAIDs were not compared against each other to consider effectiveness of one over the other. |

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| Royal College of General Practitioners | Short | 6 | 28 | Diazepam and similar should be mentioned: whether to advise their use or advise against. Diazepam is frequently prescribed for spinal spasm in both primary care and in the ED. (DA) | Thank you for your comment. Due to a lack of evidence, the GDG made a research recommendation regarding benzodiazepines (see Chapter 16, research recommendation number 3). |
| Royal College of General Practitioners | Short | 7 | 1 | The lack of evidence of whether diazepam is effective or not is not mentioned except on page 12 Lines 21 to 23. It should be mentioned specifically that the evidence is not known as this drugs often used in practice. (MH) | Thank you for your comment. This has also been made clear in section 16.6 of the full guideline as well in the research recommendation. |
| Royal College of Nursing | General | General | General | No comments | Thank you. |
| Society for Back Pain Research | Full 1 | 19 | General | The definition of non-specific low back pain is clear and very helpful. Thank you. | Thank you for your comment. The definition has been updated in response to other stakeholder comments to add further clarification on how the term has been used in the guideline and now the document refers to 'low back pain' throughout with the definition remaining in the introduction. |
| Society for Back Pain Research | Full 1 | 108 | General | We support the recommendation for employing a risk stratification tool.<br>However, it would be helpful to make it clear that the evidence for the STarT back is for risk stratification and matched treatment.<br>There is no evidence that stratification alone improves outcome.<br>It would also be helpful to highlight that:<br>• Stratification improves consistency of care.<br>• A biopsychosocial approach is indicated at all stages.<br>• The low risk group had treatment: advice, education and information, reassurance, pain relief. There needs to be guidance for recommendations appropriate for initial primary care | Thank you for your comment. The GDG recommended STarTBack tool as an example of a stratification tool that may be used to inform stratified management. The GDG felt there was not enough evidence to recommend a specific tool, nor specific sets of interventions for stratified management. However, the recommendation has now been edited for clarity to state that based on risk stratification, simpler and less intensive support should be considered for people likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management), and more complex and intensive support for those at higher risk of a poor outcome (for example, exercise programmes with or without |

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| | | | | | manual therapy or using a psychological approach). For more details please see section 6.6 (Recommendations and link to evidence)<br><br>Regarding biopsychosocial approaches, the evidence showed that combined physical and psychological programmes should be considered for people with persistent non-specific low back pain or sciatica when they have significant psychosocial obstacles to recovery (for example, avoidance of normal activities based on inappropriate beliefs about their condition) or when previous treatments have not been effective. This is detailed in section 17.6 (Recommendations and link to evidence).<br>Regarding advice, education, information and reassurance, the GDG have clarified that the recommendation for self-management is intended to apply as a principle alongside all treatment for people with low back pain and sciatica as part of routine practice rather than a separate intervention that is offered. Recommendation 1.2.1 has been reworded as follows: All healthcare professionals should provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, at all steps of the treatment pathway. This should include: information on the nature of non-specific low back pain and sciatica; encouragement to continue with normal activities as far as possible. |
| Society for Back Pain Research | Full 2 | GENERAL | GENERAL | CURRENT PRACTICE:<br>• The national back pain pathway (aligned with CG88) recommend referral for consideration of spinal fusion after patients have completed a combined physical and psychological programme. There is no RCT data on this subgroup to inform effectiveness post CPPP.<br>• The trials reviewed predate the use of Transforaminal Lumbar Interbody Fusion (TLIF). It would be helpful | Thank you for your comment. The algorithm included in the guideline has been edited to include a statement to say that if an inadequate response to treatment has been observed, there should be a consideration as to whether every appropriate treatment above has been explored and the risks and benefits of ongoing treatment. |

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| | | | | if the GDG clarify whether the recommendation applies to this fusion technique.<br><br>EVIDENCE:<br>• The recommendation is based on low evidence – very low from a small number of trials.<br>  ○ The quality rating is significantly affected by the fact that blinding in fusion surgery is highly unlikely to ever be given ethical approval.<br>• The evidence demonstrate clinical benefit.in a difficult client group at the end of the pathway.<br>• The concern is the complication rate.<br>  ○ Given the limitations of the RCT literature it would be appropriate to seek clarification on the complication rate from the spine registries. (Swedish Spine registry (www.4s.nu), Spine Tango and the British Spine Registry).<br>  ○ It is highly likely that the complication rate will be lower in specialist spine centres.<br>  ○ Given the importance of this It is worthy of GDG to revisit and consider prospective cohorts, the registry data is closest to this.<br><br>Error:<br>• The algorithm advises that additional treatment is unlikely to be of benefit. This is not true. For a small subgroup spinal fusion is beneficial but has risks.<br>• Should patients be given a choice based on a very clear informed discussion of the trade-off between risk and benefit? Give patients the opportunity to make decisions autonomously about the risks they would be prepared to undertake<br>• Otherwise this highly affected sub-group have no other options. | This guideline recommends against the use of spinal fusion for people with non-specific low back pain, unless in the context of a randomised controlled trial. The GDG recognises that due to the nature of spinal fusion, the evidence is unlikely to achieve a high quality rating, and took this into account when considering the evidence and recommendations. Please note that the GDG prioritised a research recommendation on fusion as a surgical option in people with non-specific low back pain.<br><br>Data from spinal registries was not used to inform this review as the GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Observational data was considered and used within the review, but no published analysis of registry data was identified. We are aware that it is difficult to get an accurate estimate of adverse event occurrence from clinical trial data, however this applies to all of the interventions studied in the guideline, and where adverse event data was limited, GDG expert opinion and knowledge of adverse event occurrence in clinical practice has further informed the recommendations in this area. The GDG have noted in the LETR that where fusion is carried out in the context of a randomised controlled trial, they would advise that data should be entered in spinal registries.<br>Regarding the algorithm, the wording had now been updated. The GDG agreed that there was considerable concern regarding the risk of complications and harm, outweighing any potential benefits from the procedure. Therefore agree it is |

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| | | | | SUGGESTED AMENDMENT TO THE RECOMMENDATION:<br>Do not offer spinal fusion for people with non-specific low back pain, unless part of a national registry or randomised controlled trial.<br><br>POTENTIAL CONFLICT OF INTEREST<br>• Two members of the GDG were spinal surgeons who declared and participated. It is not clear whether they attract a private income form this procedure. | appropriate to restrict the scenarios under which spinal fusion for people with non-specific low back pain is offered to those that are part of a randomised controlled trial only.<br>All patient treatment decisions would be discussed with the patient. Please see the introduction on page 4 of the short version about patient decisions, and the linked 'Your Care' web page.<br><br>The GDG discussed the wording of the recommendation, however agreed that there was considerable concern regarding the risk of complications and harm from this procedure, and therefore agree it is appropriate to restrict the scenarios under which spinal fusion for people with non-specific low back pain is offered to those that are part of a randomised controlled trial only. It was noted that at present in the UK submission to registries is voluntary, although this is in the process of changing. However, the GDG considered that at the present time being part of a registry would not reduce the concerns regarding risk of complications. It is noted in the 'evidence and link to recommendations' table that there are causes of low back pain for which spinal fusion might be an appropriate treatment, however these are beyond the scope of this guideline.<br><br>All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee. |

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| Society for Back Pain Research | Full 2 | 42-64 | General | We welcome the recommendation for further research for radiofrequency denervation.<br><br>Based on the findings and discussion suggested Research is as follows:<br>• What is the validity and reliability of clinical features of suspected facet joint pain in a population presenting with non-specific low back pain.<br>• What is the clinical and cost effectiveness of radiofrequency denervation in people with suspected facet joint pain, who have completed an optimal pathway of care (NICE algorithm) and have a positive response to a medial branch block?<br>• What are the adverse effects of facet joint pain?<br>• What is the clinical and cost effectiveness of facet radiofrequency denervation versus fusion in people who have completed an optimal pathway of care (NICE algorithm) and have a positive response to a medial branch block?<br><br>CONCERN related to the identification of facet joint pain as a distinct subgroup,<br>• The clinical reliability of clinical features subjected of facet joint pain has not yet been validated. The GDG acknowledge this in the introduction to this section.<br>• We support that some pain may come from facet joints, but is it is highly likely that symptoms arise from other lumbar structures.<br>• There are 10 facet joints in the lumbar spine. Are the proposed clinical features able to reliably differentiate which level to perform RF denervation at?<br>• We note that in the literature review the population studied had low back pain with/without sciatica. This is in conflict with the proposed criteria of clinical features supporting the diagnosis of facet joint pain. | Thank you for your comment. Research recommendations can only be drafted on areas that were specifically reviewed within the guideline. Therefore, whilst we acknowledge that there are other elements relating to radiofrequency denervation that may benefit from further research, our research recommendation has focussed on the area of uncertainty identified from the review.<br><br>The LETR details clinical features which may be helpful in determining which patients may be suitable for this intervention although the GDG accept that reliably identifying patients with facet joint pain is challenging and the evidence to support this identification is conflicting.<br>We would recommend proceeding to radiofrequency denervation for those who experience 50% relief or greater from medial branch nerve blocks. This suggests that there are patients who might have facet joint pain but an additional contribution of pain from other spinal structures or sources.<br>The evaluation prior to radiofrequency denervation would include a clinical examination to determine the likely level (and side) of facet joint involvement. The recommendation has been amended to suggest that radiofrequency denervation should be restricted to those patients who have 'localised' pain.<br>Medial branch nerve blocks are then used to confirm the clinical suspicion and to determine whether or not radiofrequency denervation is then offered.<br>In the review protocol it was agreed that mixed populations in which it was unclear whether people also had sciatica (not stated) as well as low back pain would be included if identified, but low back pain and sciatica as inclusion criteria for trials would not. This is not in conflict with the proposed criteria. |

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| | | | | ECONOMIC MODEL:<br>• It is not clear why the GDG selected this topic over other interventions for economic modelling.<br>• Probability data: Nath 2008 was used to inform, but the population in the study had 2 diagnostic blocks. This is not reflected in the Table 27-base costs inputs.<br>• Table 25: the proportion of patient requiring repeat radiofrequency denervation is likely to be higher than the 10% quoted. The GDG acknowledge this under the other considerations section.<br>• Page 56;line 4. It is wrong to assume that there would be no improvement from baseline pain in the radiofrequency arm. Back pain is variable and improvement is observed without treatment in all populations, including chronic back pain.<br>• The duration of effectiveness was GDG opinion (potential bias), but this is not based on evidence and seems to conflict with evidence. We are disappointed that a literature search was not undertaken to inform this point.<br>• The mechanism for prolonged pain relief is also questionable: nerve regrowth of 1mm/month would see facet innervation return around 4/12 and certainly well before 16/12.<br>• Table 27: The cost of diagnostics (MRI or x-ray) is not included and highly likely to be done in this population prior to receiving an invasive procedure.<br>• The conclusion was that there was “not enough evidence to make a firm recommendation”.<br><br>CONCERN related to the strength of the recommendation<br>• The reported adverse effect (5%) is concerning as this is a treatment aiming to reduce pain, but may be increasing pain for 4/12 for a clinically important | ECONOMIC MODEL:<br>a) We have added some more details to why this was prioritised in Appendix N, section N.1.<br>b) Although people had more than one block in the study, we only used the data referring to the screening (first) block in our model.<br>c) The proportion of patients requiring repeat procedure was varied in a sensitivity analysis and this showed that RFD is always cost effective (ICER ranges from £13,658 per QALY when 0% of patients repeat RFD to £16,270 per QALY when 100% of patients repeat RFD).<br>d) We do assume there is an improvement in pain in the radiofrequency arm.<br>e) None of the studies included in our systematic review reported the duration of effectiveness. These values were subject to sensitivity analyses which influenced the GDG final recommendations.<br>f) There are no studies that we are aware of that suggest medial branch nerves, once coagulated, regenerate at this rate. The evidence reviewed by the GDG suggests that relief of pain relief exceeding at least 12 months duration is not an unreasonable expectation (Tekin 12 month outcomes). Observational studies (MacVicar et al 2013) support this view.<br>g) The GDG advised that a diagnostic test such as MRI or x-ray would not be done before this procedure.<br><br>The 4 month time-point at which adverse events are reported is not a reflection of the length at which adverse events occurred for. The GDG are aware that literature in the past few decades has not associated any serious adverse events with radiofrequency ablation. The GDG also agree that 31% repeat procedures does not equate to treatment |

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| | | | | number of people. We appreciate that this is only from one paper, but the adverse effects really are unknown,<br>• The GDG report that 31% (17 out of 55) have repeat procedures. We recognise that repeat denervation (outwith research) is not being recommended, but 31% requiring repeat injection raises concern about the effectiveness.<br>• The quality of evidence is low and from small trials. This is acknowledged by the GDG.<br><br>SUGGESTED AMENDED RECOMMENDATION:<br>Do not offer facet joint denervation for people with non-specific low back pain, unless part of a national registry or randomised controlled trial.<br><br>ALGORITHM<br>• We support that facet joint denervation should not be considered until after the person has had insufficient response to optimal non-invasive care, including combined physical and psychological programme.<br>• It would be helpful if this point is highlighted in both the short and long guideline documents.<br><br>INCONSISTENCY in the discussion compared to other interventions<br>• Page 60: A "trend towards benefit" was not considered to be important in the discussion of any other interventions.<br>• Page 62: The assumption "plausible that downstream healthcare utilisation (such as other interventions) might also be reduced". This statement is not evidence based and has not been included in other interventions. | failure. The adverse event profile of radiofrequency denervation cannot be adequately determined from the trials reviewed by the GDG. The topic experts were unaware of any major adverse events reported in the literature since the advent of this intervention almost 4 decades ago.<br>When discussing risk, the GDG were aware of a study by Cormick et al (Spine 2004) where a total of 616 radiofrequency lesions, over a period of 5 years yielded a 1.0% overall incidence of minor complications per radiofrequency site. Complications included: 3 cases of localized pain lasting more than 2 weeks (0.5%) and 3 cases of neuritic pain lasting less than 2 weeks (0.5%).<br>This level of risk was consistent with the clinical experience of the topic experts.<br><br>ALGORITHM<br>The recommendation does highlight that radiofrequency denervation should be considered when non-surgical treatment has not worked for them, therefore this will appear in both the short and long guideline documents as well as in the algorithm.<br><br>INCONSISTENCY<br>Regarding your comment about inconsistency in the discussion, we apologise for the apparent inconsistency and have removed the statement about trend to benefits and have removed the statement regarding dependence from the acupuncture review.<br><br>CONFLICT OF INTEREST:<br>All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on |

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| | | | | • Like acupuncture this intervention is passive and as such likely to create dependence. This point was not included in the discussion<br><br>CONFLICT OF INTEREST<br>• As stated previously there is over-representation from pain service clinicians on the GDG. It is of concern that these clinicians attract private income from this procedure.<br>• It is of significant concern that despite declaring that the interventional pain clinicians participated in the discussion and recommendations. This is in contrast to the pharmacological section where there was declaration and withdrawal.<br><br>Concern regarding cost to the NHS:<br>• It is well known that back pain persists through life. Many treatments have not been recommended. We predict that this will result in an increased number of patients who have completed the non-invasive pathway and have pain greater than 5/10 who will then be referred for consideration of a facet joint denervation. As demonstrated in the economic model this is a costly procedure with uncertain benefit which is certainly not long term. | topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee.<br><br>Concern regarding cost to the NHS:<br>this weak recommendation is not considered to have major cost impact issues on the NHS.<br>The effectiveness of radiofrequency denervation may diminish with time and this is reflected in the difference in outcomes at our defined short and long term time points.<br>That 31% of trial subjects required repeat denervation is not an estimate of effectiveness but duration. The economic review has suggested the intervention is likely to be cost effective provided this duration exceeds 15 months and further evaluation of long term outcomes forms part of our research recommendation.<br>Therefore we believe the recommendation is appropriate and do not agree it should be changed to the suggested amended recommendation. |
| Society for Back Pain Research | Full 2 | 37-40 | General | We note that aligned with other international guidelines the recommendation is “do not offer spinal injections for non-specific low back pain” | Thank you for your comment. |
| Society for Back Pain Research | Full 2 | 120-122 | General | RECOMMENDATION<br>• The evidence presented does not look strong enough for the recommendation “consider”<br>• Low quality, weak, meets MID in the short term.<br>• Cost of MRI not included. | Thank you for your comment. Following stakeholder feedback, the GDG discussed the recommendation and the evidence. The GDG are aware that the evidence is conflicting, however considered that epidural injection is a relatively safe and routinely |

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| | | | | CLARITY:<br>• Does this recommendation apply to therapeutic nerve root blocks?<br>• Guidance on the use of repeat injections would be helpful.<br><br>CONFLICT OF INTEREST:<br>• Several of the GDG receive a private income from epidural. It appears that these individuals did not withdraw from the discussion/recommendation. This is in contrast to the pharmacological process. | used procedure, and that some evidence demonstrated by placebo-controlled trials for effectiveness in pain relief. They agreed that this should only be considered for people with acute, severe sciatica, and that for this specific subset of people there was sufficient evidence to maintain the recommendation for epidurals.<br>This recommendation does apply to therapeutic nerve root block, which is synonymous with transforaminal epidural.<br>The GDG considered the effectiveness of giving multiple / subsequent epidural injections but noted that as the recommendation for epidurals was for the acute sciatica population (most likely to be defined as having symptoms for <3 months), then multiple injections would not usually be performed within this short period of time. This is stated in the 'other considerations' section of the evidence and link to recommendations table of this chapter.<br><br>All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee. |
| Society for Back Pain Research | Full 2 | 152-154 | General | INCONSISTENCY:<br>This recommendation is not consistent with other recommendations.<br>• Perceived lack of effectiveness. This is not supported by evidence.<br>• The GDG acknowledge that Disc replacement has been shown to be better than CPPP. | Thank you for your comment. There was limited evidence of clinical benefit of disc replacement over spinal fusion. This evidence came from two trials and was limited to quality of life and number of reoperations outcomes. Limited evidence of benefit of Disc replacement compared to multidisciplinary biosychocial rehabilitation (MBR) programmes came |

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| | | | | • Having done CPPP first does not mean that the intervention is not needed or effective.<br><br>EVIDENCE:<br>• Given the limited evidence it would be appropriate to refer to the spine registries.<br><br>DISCUSSION:<br>• The risk of complications are not clear.<br><br>POTENTIAL CONFLICT OF INTEREST<br>• Two members of the GDG were spinal surgeons who declared and participated. It is not clear whether they attract a private income form this procedure. | from a single RCT. The evidence included in the review ranged from low to very low. The GDG was also not convinced of the appropriateness of the comparison of disc replacement versus MBR, as the latter would commonly be offered earlier than surgery in clinical practice The GDG felt that the risk of harms associated with disc replacement outweighed the potential benefits noted in the evidence.<br><br>The GDG expressed concern on the serious adverse events recorded in the papers included in the review. Particularly, the GDG were aware of the Hellum 2011 study, which reported the serious adverse events related with disc replacement, in particular 1 lower leg amputation and 4 cases of considerable blood loss out of 80 participants. It was the GDG concern that this was a high rate of adverse events in a study not powered to detect harm, and believed that this high adverse event rate was reflective of the risks observed in practice. GDG concerns on adverse events are discussed in more details in section 26.6 Recommendations and link to evidence. It was agreed this was sufficient to warrant recommending against disc replacement.<br><br>All GDG members' private practice was discussed and declared in appendix B and agreed that this was not a conflict to their involvement in discussions on topics relevant to these areas. All members who have private practice provide the same treatments as in their NHS clinics. All GDG members who had not withdrawn from the discussions were involved in all recommendation making and no member unduly influenced the decision of the committee. |
| Society for Back | Full 2 | 59 | General | Only do RF denervation | Thank you for your comment. This recommendation is in line with current NICE editorial policy. |

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| Pain Research | | | | As far as we are aware NICE policy prevents a recommendation starting with “only” | |
| Society for Back Pain Research | general | General | General | It is important for the guidance in the short v full versions to be identical to optimise clarity of the recommendation. Most users will only refer to the short document. | Thank you for your comment. The recommendations within the short and full versions of the guideline are identical. |
| Society for Back Pain Research | GENERAL | GENERAL | GENERAL | Research recommendation:<br>• As it stands the research recommendations are limited to a small proportion of the back pain population.<br>• The current research recommendations are unlikely to significantly change the outcome of back pain long term.<br>• There are many interventions that have not yet been reviewed in a high quality trial e.g. Orthotics, mindfulness, acceptance and commitment therapy.<br>• The GDG have acknowledged the difficulties with the label of NSPLB, but this is not a research recommendation.<br><br>CONFLICT OF INTEREST:<br>• The research recommendations are biased to pharmacology and injection. We are concerned that this may be reflective of the make-up of the GDG.<br><br>SUGGESTED RESEARCH RECOMMENDATIONS:<br>• What is the effectiveness and cost effectiveness of the NICE back pain & sciatica algorithm, compared to usual care?<br>• For people with persisting back pain impacting on quality of life what is the cost effectiveness of no care versus supported care?<br>• Development of an imaging stratification tool for use in a specialist setting. | Thank you for your comment. As detailed in section 4.5.1 of the Methods chapter, when areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research.<br>As stated in section 9.5 of the NICE manual (Developing NICE guidelines: the manual, November 2012), it would not be feasible for the GDG to draft research recommendations for every area of uncertainty. Therefore the GDG selected key research recommendations that are likely to inform future decision-making for inclusion in the guideline. Decisions about the inclusion of a research recommendation were based on factors such as the importance to patients or the population, national priorities, potential impact on the NHS and future NICE guidance, ethical and technical feasibility. Further information about how research recommendations are derived can be found in the NICE research recommendation process and methods guide: https://www.nice.org.uk/Media/Default/About/what-we-do/Science-policy-and-research/research-recommendation-process-methods-guide-2015.pdf<br><br>The GDG took all of these factors into account when determining which areas warranted recommendations for future research and agreed the 7 topics in the full guideline were the most |

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| | | | | • Can back pain be managed by non-invasive treatment?<br>• Does stratification affect outcomes in people with low back pain with/without sciatica?<br>• What is the clinical and cost effectiveness of multi-modal care versus individual therapy in people with low back pain with/without sciatica?<br>• What is the effectiveness and cost effectiveness of combinations of pain relief in people with acute, severe back pain, with or without sciatica which limits activity participation?<br>• What is the clinical and cost effectiveness of return to work programmes for people with non-specific low back pain with or without sciatica?<br>• What are the different needs of unemployed vs employed people with non-specific low back pain with or without sciatica, in return to work.<br>• Is there a dose response to exercise in people with non-specific low back pain with/without sciatica? | appropriate. From these, as per the NICE guidelines manual, only 5 are prioritised in the short version of the guideline, which are those considered to be most important to informing future updates of the guideline.<br><br>Members of the GDG who had conflicts of interest relating to the pharmacological treatment of low back pain were not involved in writing or prioritising these research recommendations. |
| Society of British Neurological Surgeons | Full 1 | 115 | general | Imaging – The recommendation that imaging should be decided by a specialist will result in a huge increase in the number of referrals to spinal surgery units. This will potentially delay the 18 week pathway to the extent that NHS targets will be adversely affected.<br>• Suggest Protocols of referral to a specialist from Primary care and Physiotherapy/Allied therapists<br>• Suggest to include a minimum time period before referral is considered unless clinical features dictate urgency | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned.<br><br>The objective of the review was to determine the clinical and cost effectiveness of imaging techniques in the management of non-specific low back pain and sciatica. Therefore, reviewing the timing of imaging was beyond the scope of the review.<br>Regarding the need to exclude cancer and infection, the importance of assessing an individual's signs and symptoms when considering the appropriate form of imaging has been highlighted in section 7.1, lines 24-26 on page 116 (Full guideline- Assessment and non-invasive). Furthermore, section 7.6, 'Other |

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| | | | | • In the clinical pathway, there is a need to exclude cancer and infection. This will inevitably involve imaging. | consideration' box states that 'the presence of symptoms or signs suggestive of possible serious underlying pathology (red flags), including a past history of cancer or trauma may warrant early imaging'. |
| Society of British Neurological Surgeons | Full 1 | 493 | GENERAL | Acupuncture - Why acupuncture is receiving bad press is beyond me – even if its all placebo (and for the record I don't believe it is- western medicine has a habit of disregarding anything that doesn't conform to modern science) | Thank you for your comment. |
| Society of British Neurological Surgeons | Full 2 | 11 | general | Facet Injections - On the specific treatment issues- it is interesting that radio frequency denervation is recommended but facet joint injection is not, whilst facet injection is advised as diagnostic! No advise is given in whom this diagnostic injection should be tried! Clarity is needed in this area. | Thank you for your comment. As described in sections 22.6 and 23.6, the GDG decided against recommending facet joint injections due to the inconsistency of the evidence across the review. Furthermore, for the comparison against placebo/sham, benefits in long-term outcomes were seen which didn't appear in short-term measures. This created uncertainty among the GDG regarding the true nature of the benefits seen in the longer-term outcomes. The GDG therefore did not feel they could justify recommending facet joint injections in a NHS setting.<br>Evidence for radiofrequency denervation compared to placebo/sham showed consistent short and long-term benefit for pain and responder criteria outcomes, as well as benefits for some quality of life measures. Along with the low incidence of adverse events, the GDG felt they could form positive recommendations for radiofrequency denervation. The recommendation developed is for a diagnostic medial branch nerve block prior to radiofrequency denervation and not an intraarticular facet joint injection. The LETR details clinical features which may be helpful in determining which patients may be suitable for this intervention although the GDG accept |

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| | | | | | that reliably identifying patients with facet joint pain is challenging and the evidence to support this identification is conflicting. |
| Society of British Neurological Surgeons | Full 2 | 152 | GENERAL | Disc Replacement – The guideline has reversed the decision made in 2009 when this procedure was approved for clinical use with NORMAL arrangements for governance. The decision not to recommend this operation in the current guideline is based on further evidence (which is not of high quality) and the adverse events reported weighed against the benefits. We recommend the procedure to be recommended with SPECIAL governance arrangements.<br><br>Surgeons may decide to still offer this operation on the basis that a 'Black disc' is the likely source of the LBP (see further comments below).<br><br>The problem with the NICE guidelines are such that the disc replacement for black disc believers will disregard the guidelines on the basis that they believe (rightly or wrongly) that the pain generator is the disc itself. | Thank you for your comment and this information. |
| Society of British Neurological Surgeons | Full 2 | 152 | GENERAL | Disc replacement - people will interpret NSLBP is a way that fits with their practice and this term needs clarity. To make a point, I would like to ask- in a 42 year old patient with severe back pain for 2-3 years preventing him to function fully, what is the diagnosis? After failure of conservative treatment should an MRI be done? Should he be asked to "live with this" at this stage? If MRI shows disc degeneration at L4/5 with adjacent modic changes, no facet joint tenderness or failed facet injection, would it be appropriate to consider surgery? | Thank you for your comment. The evidence reviewed does not support a recommendation for disc replacement. Therefore for people in whom other treatments have failed to adequately remove their symptoms, this evidence suggests further treatment, including surgery, is unlikely to be of benefit. |

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| Society of British Neurological Surgeons | Full 2 | 152 | GENERAL | Disc replacement and Spinal Fusion - Surgery for back pain has always been an controversial subject. GDG has acknowledged that disc replacement is at least similar to fusion in results. In 27.5.1.32 GDG has acknowledged that fusion may be less effective than disc replacement! GDG should come up with some criteria in which fusion or disc replacement may be considered. A statement to say that this surgery is not totally recommended is possibly not correct. Consideration should be given (after failure of conservative treatment) to level of disc involved, facet joint pathology, modic changes, discogram, SPECT CT etc to guide the decision. | Thank you for your comment. We agree there is consistency across the disc replacement review and the spinal fusion review for benefits of the former type of surgery over the latter in terms of quality of life outcomes. However after consideration of the evidence reviewed in both chapters, the GDG agreed that disc replacement should not be offered to the population described in the guideline due to risk of harm and lack of cost-effectiveness. Similarly, while acknowledging that other causes of low back beyond the scope of this guideline might be appropriately treated with spinal fusion, people with non-specific low back pain should not be offered spinal fusion, unless as part of a randomised controlled trial. |
| Society of British Neurological Surgeons | Full 2 | 178 | GENERAL | Spinal Fusion – The recommendation to undertake a RCT is noted. This will involve a large multi-centre study and a number of variables will need to be taken into account. We suggest evidence from the large spinal databases to be considered by the GDG. | Thank you for your comment. We are unable to specify this in a recommendation however we have added a statement to the 'evidence and link to recommendations' section of the review to state that the GDG suggest where fusion is carried out in the context of a randomised controlled trial, data should be entered in spinal registries. |
| Society of British Neurological Surgeons | GENERAL | 147 | 9.6 | Some recommendation on when to use imaging would be useful (like pain severity, duration, effect on life etc). | Thank you for your comment. The aim of the review was to establish clinical and cost effectiveness of imaging in people with low back pain or sciatica. It is recommended that imaging is not routinely offered in a non-specialist setting, and it is considered in a specialist setting of care if the result is likely to change management. The identification of which subgroup of patients would benefit more from the use of imaging was beyond the scope of the review. |
| Society of Teachers of the Alexander | Full 1 | 151 202 | | Just to point out that many of the comments above regarding the reporting of the ATEAM trial will also apply to other sections of the Full draft guidelines document as the trial is also reviewed in Section 8, Self-management and Section 9, Exercise therapies. | Thank you. Please see our reply to the comments referred to in the relevant sections. |

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| Technique | | | | | |
| Society of Teachers of the Alexander Technique | Full 1 | 308 | 3, 7−8, 11−14 | We do not recognise the categorisation of Alexander Technique lessons as a *'postural therapy'* − neither do we recognise the aim of Alexander lessons to be *'focusing on the correction of postures'* which is the definition of postural therapy given in the draft guidelines. The Alexander Technique is a taught practical educational approach for improving coordination of postural support, movement, breathing and control of response; Alexander lessons can lead to therapeutic and self-development-related benefits. Descriptions like *'Postural therapy also focuses on exercises and practice at adopting postures and movements that are considered healthy'* (page 308; lines 7−8) seems rather a crude caricature of what we do and misses its essence − we give a comprehensive description of the Alexander Technique and how it is taught at the end of this comment.<br><br>We have raised this issue of inappropriate categorisation previously, in our submission to the scoping exercise for these guidelines, and are disappointed that our concern has not been addressed in the current draft guidelines. We had suggested an alternative to 'postural therapy' that we hoped would be meaningful to a general clinical audience, as well as being acceptable to the Alexander Technique teaching profession, namely, 'Postural and movement re-education'. We had further proposed that Alexander Technique lessons belong to 'Self-management strategies' as the Alexander Technique is inherently a taught self-management method.<br><br>The issue is exacerbated by the fact that the 'Postural therapies' category in the current draft guidelines encompasses two interventions, Alexander Technique lessons and forward head posture corrective exercises. The specific aims and methods of the latter are diametrically opposed to those of the Alexander Technique and its | Thank you for your comment. While the GDG recognises the complex nature of the Alexander Technique, and the description provided by STAT, it was felt that due to the focus of the technique being on postural movements and support, the categorisation of the technique as 'postural therapy' was appropriate. We acknowledge that falling under the broad heading of 'postural therapy' may be an over-simplification, but each comparison was labelled to state the technique used and the GDG were made aware of the components of each trial, and these were stated in detail in the evidence tables as described by the included studies. Since the Alexander technique requires attendance at lessons where people are provided with guidance and supervision from teachers, this does not fit into our definition of self-management, in the same way that that being asked to walk more would be considered self-management as it isn't monitored or taught and therefore wouldn't be classified as aerobic exercise in the exercise review.<br><br>The GDG are aware that the two interventions included in the review (alexander technique and head posture corrective exercises) are distinct, but feel that both fall under the overarching heading of postural therapy, in the same way that yoga and aerobic exercise are distinct but both fall under exercise. |

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| | | | | fundamental principles; yet, in several places the report discusses the two as if they are compatible and comparable.<br><br>As a general principle, we consider that any intervention should be defined by the profession in question, this being the only professional body with the required knowledge and experience. So, we request that Alexander Technique lessons and the Alexander Technique itself are not described as 'postural therapy' and not conflated with interventions with which it they have little or nothing in common. A potential solution to this problem would be to create a separate section for the Alexander Technique (as has been done for other interventions such as acupuncture).<br><br>Description of the Alexander Technique provided by STAT for reference<br><br>The Alexander Technique a taught practical method and an embodied, contemplative practice. Alexander lessons help people to free themselves from unhelpful postural and movement habits and develop a more intelligent and skilled control of the manner in which they respond to stimuli and engage in activity.[1] Alexander Technique teachers think in terms of movement, and encouraging a tendency to overall expansion rather than contraction when initiating any action. We focus on restoring the working of the postural supporting mechanisms through experiential learning aided by hands-on guidance and encouraging changes in an individual's own thinking and attitude. We teach intentional inhibition[2] of maladaptive habitual responses, enhancement of spatial perception and awareness, and clarity in framing purposeful intent. We help people attend to postural sensory feedback and make use of this information; show them how to allow the neuromuscular mechanisms to determine appropriate postural support and the pathways of skilled movement without habitual interference in the underlying non-conscious processes; and how to initiate movement through | |

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| | | | | clarity of intention in a way that is compatible with current theories of skilled motor control.[3]<br><br>Further description of the Alexander Technique and the aims and content of Alexander lessons are provided in the published appendix to the ATLAS trial.[4]<br><br>References<br>1. Skills for Health. Competencies / National Occupational Standards; CNH3 Deliver Alexander Technique teaching June 2010. Available at: https://tools.skillsforhealth.org.uk/competence/show/pdf/id/2800/<br>2. Filevich E, Kühn S, Haggard P. Intentional inhibition in human action: the power of “no”. Neurosci Biobehav Rev. 2012 Apr;36(4):1107–18.<br>3. Ballard K. Ideomotor principle – was Alexander correct? In: Connected Perspectives – The Alexander Technique in context. Editors: Rennie C, Shoop T, Thapen K. Hite Books and Publishing 2015.<br>4. MacPherson H, Tilbrook H, Richmond S, Woodman J, Ballard K, et al. Alexander Technique lessons or acupuncture sessions for persons with chronic neck pain: A randomized trial. *Annals of Internal Medicine 2015;163:653−62*. | |
| Society of Teachers of the Alexander Technique | Full 1 | 330 | Boxed text | This section incorrectly states *'Two studies were identified looking at postural therapies (in this case, the Alexander technique) in combination with other interventions.'* In fact, of the two studies, only one involved Alexander Technique lessons. | Thank you for your comment. This statement has now been amended. |

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| Society of Teachers of the Alexander Technique | Full 1 | 331 | Boxed text | Inappropriate categorisation of Alexander Technique lessons<br><br>In the analysis that forms the basis for the draft report, Alexander Technique lessons are grouped together with another intervention. The aims and methods of this intervention are in complete opposition to those of Alexander lessons − see comment 6 below. Because of this disparity, we do not believe that overall conclusions regarding 'postural therapies' can be drawn − for example: *'and the fact that all evidence came (from) group single studies of a small sample size, it was decided that no recommendation would be given for postural therapies'* | The GDG are aware that the two interventions included in the review (alexander technique and head posture corrective exercises) are distinct, but feel that both fall under the overarching heading of postural therapy, in the same way that yoga and aerobic exercise are distinct but both fall under exercise. |
| Society of Teachers of the Alexander Technique | Full 1 | 331 | Boxed text | With regard to the statement: *'as this is a usual care comparison it is not possible to tell if it is the technique itself or simply the contact with a therapist that is causing any effects seen'*, please note that Alexander practitioners are 'teachers' and not 'therapists' | Thank you for your comment. This has been corrected and all reference to alexander technique 'therapists' has been changed to 'teachers. |
| Society of Teachers of the Alexander Technique | Full 1 | 331 | Boxed text | It is incorrect to state that none of the outcomes in the ATEAM trial were assessed at less than 4 months. In addition to the main endpoint at 1 year, all outcomes were assessed at 3 months.[1] (see Table 3)<br><br>Reference<br>1. Little P, Lewith G, Webley F, Evans M, Beattie A, et al. Randomised controlled trial of Alexander Technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008; 337: a884. | Thank you for your comment. Although the ATEAM trial did assess outcomes at 3 months, this data could not be extracted. This is because the 3 month data (table 3) was not presented by individual group, as the 1 year data was (table 5). The 3 month analysis pooled individual groups, and therefore not all participants in each arm in the 3 month analysis received the same intervention. For example, the control group for the alexander technique factor consisted of 72 participants who received normal care, and 72 participants who received exercise only. Therefore this data could not be used in our analysis. |
| Society of Teachers of the | general | 12 | 6<br><br>Boxed text | Research recommendation<br><br>The draft report states: *'The GDG agreed that the evidence reviewed was promising....The GDG agreed that further* | Thank you for your comment. The GDG considered a research recommendation, however agreed that as research recommendations are primarily picked up by the NIHR and so are subject to the same funding |

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| Alexander Technique | | 330 & 331 | | *research was warranted to test this further.'* And, *'Given the potential benefit demonstrated for the Alexander technique in the evidence reviewed, the GDG considered making a research recommendation on this therapy to be conducted in order to re-evaluate its use in the future. It was however noted that following completion of the ASPEN feasibility trial (included in this review), it is likely that a larger trial will follow and therefore a research recommendation was not prioritised for this topic*'.<br><br>We are pleased that the GDG recognises the importance of further research on the effectiveness of Alexander Technique lessons for people with low back pain. However, we are very concerned about the decision not to make a research recommendation. The report implies that the main reason for not giving a research recommendation is that further research is already in planning, with a potential follow-up to the ASPEN feasibility study.<br><br>Given the difficulties in obtaining research funding, there is a significant risk that a follow-up trial to ASPEN will not take place. The Chief Investigator of ASPEN has informed us[1] that the funding body for the feasibility study, the MRC/NIHR Efficacy and Mechanism Evaluation Programme (EME) does not wish to fund the ASPEN follow-up trial. The EME Board commented that one of the reasons for not providing funding was that the efficacy of Alexander Technique lessons for chronic back pain had been sufficiently established by the ATEAM trial.[1,2]<br><br>We agree that more research is needed and, given the decision of EME not to fund the larger ASPEN follow-up, a research recommendation by NICE for more research on Alexander lessons for back pain is warranted, particularly given the encouraging preliminary findings of the ASPEN feasibility study. Key issues to assess are what the 'dose- | stream. Therefore, if the NIHR have decided not to fund a follow up to the ASPEN trial, it is unlikely that a research recommendation would change this decision. |

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| | | | | response' relationship is (between the number of lessons and effectiveness) since from the ATEAM trial it is clear that it is not a linear relationship and that as many as 24 lessons are unlikely to be needed to achieve clinically important benefit. Other important research areas are: a better understanding of mechanisms, particularly as the ASPEN feasibility study pointed towards a number of novel markers of recovery that require robust exploration; and also filling the current knowledge gap of older patients and patients with sciatica (age >65 years and sciatica below the knee were exclusion criteria for the ATEAM trial[2]).<br><br>We would, therefore, ask NICE to re-consider their decision and to make a research recommendation for Alexander Technique lessons in the low back pain guidelines.<br><br>References<br>1. Personal communication from Paul Little, ASPEN Chief Investigator.<br><br>2. Little P, Lewith G, Webley F, Evans M, Beattie A, et al. Randomised controlled trial of Alexander Technique lessons, exercise and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008; 337: a884.<br><br>3. Little P, Stuart B, Stokes M, Nicholls C, Roberts L, Preece S, et al. Alexander technique and Supervised Physiotherapy Exercises in back paiN (ASPEN): a four-group randomised feasibility trial. *Efficacy Mech Eval* 2014;1(2). | |

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| Society of Teachers of the Alexander Technique | Short | General | General | We would like to thank the GDG for including in the review an analysis of the evidence for the effectiveness of Alexander Technique lessons for people with low back pain. We are, however, disappointed that Alexander Technique lessons are not included in the general recommendations, nor in the research recommendations and we present an evidence-based rationale for why these decisions deserve to be re-considered. Our response below is in three parts addressing: i) the analysis that formed the basis of the overall recommendations ii) the description of the Alexander Technique and of the intervention (Alexander Technique lessons) iii) minor comments. | Thank you for your comments. Please see our responses to each of your comments below. |
| South West Yorkshire Partnership NHS Foundation Trust | short | 4 | 22 | If a patient has a biomechanical cause for their LBP foot orthotics can be helpful in addressing this. | Thank you for your comment. The GDG found no evidence that foot orthotics were of benefit to people with low back pain with or without sciatica, and therefore recommended against their use. |
| South West Yorkshire Partnership NHS Foundation Trust | short | 4 | 27 | In practice traction can often be helpful for reducing pain enabling to exercise and allowing a return to normal function, especially in chronic LBP | Thank you for your comment. The GDG discussed the evidence, and found that there was very limited evidence of benefit for traction. Two studies showed a benefit of traction, however due to methodological concerns, the GDG did not consider this sufficient. Therefore, based on the evidence the GDG agreed that traction should not be offered for low back pain or sciatica. |
| South West Yorkshir | short | 5 | 6 | In practice acupuncture can often be helpful for reducing pain enabling to exercise and allowing a return to normal function. It can also reduce the need for pharmacological intervention. | Thank you for your comment. |

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| e Partnership NHS Foundation Trust | | | | | |
| South West Yorkshire Partnership NHS Foundation Trust | short | 5 | 14 | In practice TENS can often be helpful for reducing pain enabling to exercise and allowing a return to normal function. It can also reduce the need for pharmacological intervention. | Thank you for your comment. The GDG considered evidence of TENS compared to sham TENS, usual care, and active comparisons. Although there were some benefits for TENS, this was overall inconsistent and conflicting, therefore the GDG concluded that there was insufficient evidence of clinical benefit to support a positive recommendation. |
| Spine Intervention Society | Full 2 | 11 | 30-31 | Authors are evaluating “what is the clinical and cost effectiveness of spinal injections in the management of non-specific low back pain”. As stated above, the entity “non-specific low back pain” presents a symptom, not a diagnosis. | Thank you for your comment. The definition of the population being considered in the guideline is defined in section 4.3.1 in the Methods chapter and the term non-specific low back pain is no longer used throughout the guideline. |
| Spine Intervention Society | Full 2 | 11 | 28-29 | In the introduction to the review section, the authors note that, “The GDG agreed that the main uncertainty …was the effectiveness of various agents, rather than the route or mode of administration.” As a result, no consideration is given to the proper diagnosis of the low back condition prior to assessing an intervention for that particular condition. In essence, as previously mentioned, the review lumps all forms of back pain (except lumbar facet pain) in one basket, and assesses their treatments together by considering manuscripts that have not identified a specific etiology of the LBP. Since many different etiologies may account for “non-specific low back pain” obviously there is substantial, unaccounted heterogeneity. There was also heterogeneity in the procedures performed for non- specific etiologies: intra-articular facet injections, peri-capsular injections, peri-facet injections, intra-discal injections, nerve blocks, caudal epidurals, interlaminar epidurals, EMG-guided trigger point | Thank you for your comment.<br>The review does consider the effectiveness of injections for facet joint pain, disc pain (intradiscal injection) and soft tissue/ligament pain. However, the GDG agreed that the key area of uncertainty was the injectate, so the review was stratified by agent and image guidance, however full details of the inclusion criteria of trials were available to the GDG in the evidence tables and they GDG did consider the evidence for injections for a particular structural pathology as part of this review. The review only considered therapeutic injection procedures and not diagnostic injection interventions. Injections of the sacroiliac joint were not included as the sacroiliac joints were considered a 'pelvic ring structure' and were excluded from the scope of the guidance. |

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| | | | | injections, spinal ligament injections, spinal ligament injections and non-image guided paraspinal injections. The SIS guidelines adequately describe evidence-based methodologies for stratifying low back pain patients based on etiology. Stratification based on cause then allows a meaningful analysis of various types of treatment. The authors would find that quality evidence based data already exists in this realm. The flaws in this analysis render the authors' conclusions equally flawed.<br><br>Reference:<br>Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013. | |
| Spine Intervention Society | Full 2 | 42 | 12 | Two Manchikanti references are given with respect to prevalence of facet joint pain. The first (98) is a study of adhesiolysis and seems to be included here in error.<br>Manchikanti L, Pampati V, Bakhit CE, Pakanati RR. Non-endoscopic and endoscopic adhesiolysis in post lumbar laminectomy syndrome: a one-year outcome study and cost effectiveness analysis. Pain Physician. 1999; 2(3):52-58 | Thank you for your comment. Reference 98 has been removed. |
| Spine Intervention Society | Full 2 | 42 | 12 | The prevalence of 25-40% quoted from Manchikanti is higher than that from other studies, particularly for younger people. We recommend reviewing and revising this per the findings of Schwarzer and DePalma. These studies suggest a prevalence of facet joint pain in younger people of 10-15%, and Schwarzer's data, in particular, are likely to be an overestimate, as a criterion of 50% relief from a single block was used.<br><br>References:<br>1. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine 1994;19:1132-1137. | Thank you for your comment. There is no widely accepted figure for the prevalence of facet joint pain. The range provided in the introduction was given as mid-range example. The trials reviewed suggest a 69% prevalence, therefore we do not believe this should be amended to a lower prevalence. |

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| | | | | 2. DePalma MJ, Ketchum JM, Saullo TR. Multivariable Analyses of the Relationships Between Age, Gender, and Body Mass Index and the Source of Chronic Low Back Pain. Pain Medicine 2012; 13: 498–506. | |
| Spine Intervention Society | Full 2 | 43 | Table | Regarding study inclusion criteria for radiofrequency denervation, the guideline stipulates, "RCTs and SRs will be included in the first instance. If insufficient RCT evidence to form a recommendation is found, non-randomised studies will be included." The critical analysis of all of the quoted studies (with the exception of a more recent one by Civilek) was provided by Bogduk et al. (2009). The Civilek study, which wasn't included in the Bogduk et al. appraisal, has a number of flaws but most importantly, the technique itself appears to be invalid. Civilek's supplied images seem to indicate that the needle was placed in an anteroposterior (AP) view onto the superior articular process along a portion of the course of the nerve. Because the lateral view was not obtained, the needle tip could therefore lie on the nerve but is as likely to still be on the SAP. At best, this would create a pinpoint lesion of 1-2 mm, resulting in a short-term response. The radiofrequency (RF) technique is too poor to justify further analysis of the study. The controlled trials are sufficient to demonstrate efficacy, but not to optimize the technique. It is imperative to review high quality prospective studies that implement appropriate technique (e.g. Dreyfuss 2000, MacVicar 2013). The best practices document from the British Pain Society in the reference list refers to the SIS Guidelines as the correct methodology for both medial branch blocks and radiofrequency neurotomy.<br><br>References:<br>1. Bogduk, Nikolai, Paul Dreyfuss, and Jayantilal Govind. "A Narrative Review of Lumbar Medial Branch Neurotomy for the Treatment of Back Pain: Narrative Review of Lumbar Medial Branch Neurotomy." Pain Medicine 2009; 10(6): 1035–45.. | Thank you for your comment. The GDG considered the study and did not see a reason to exclude it. We are not able to include Dreyfuss 2000 or MacVicar 2013 as they are case series studies, which were not included within the review protocol. |

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| | | | | 2. MacVicar, John, James M Borowczyk, Anne M MacVicar, Brigid M Loughnan, and Nikolai Bogduk. "Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand." Pain Medicine 2013; 14(5): 639–45.<br>3. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine (Phila Pa 1976). 2000 May 15;25(10):1270-7.<br>4. "mbb_2013_-_FINAL.pdf." Accessed April 25, 2016. https://www.britishpainsociety.org/static/uploads/resources/files/mbb_2013_-_FINAL.pdf. | |
| Spine Intervention Society | Full 2 | 55 | 20-36 | The patients in the sham arm had already had usual care. Therefore, adding the sham placebo effect to the baseline to simulate the effect of usual care does not make sense. The effectiveness of the RF neurotomy should be compared to the baseline scores as stated in lines 23-24. The GDG notes on page 63 that the patients studied had pain from between 3-5 years. It is unlikely that spontaneous remission would occur in this group, and no citation is provided to justify this supposition. In addition, the cost analysis control group was given the placebo effect but no cost associated with it. Comparing RF to baseline would provide an improved cost efficiency factor. | Thank you for your comment. Based on your comment, we believe you are in agreement with our preferred approach. In our base case we did compare the effectiveness of RFD to the baseline score as you suggested as well. We only used the sham effect in a sensitivity analysis to explore the impact on the results if people experienced some form of remission with no treatment. |
| Spine Intervention Society | Full 2 | 55 | 15-17 | "The probability of a positive response to the diagnostic block was based on a study included in the clinical review. Due to a lack of data, all other probability data in the model were based on GDG opinion". The algorithm used to diagnose facet pain failed to include several high quality studies addressing the validity of diagnostic blocks and made recommendations based on one study and biased opinions.<br><br>References:<br>1. Kaplan M, Dreyfuss P, Halbrook B, Bogduk N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. A physiologic challenge. | Thank you for your comment.<br>We have amended the model write up to explain that other studies were also considered. Regarding the studies you have cited, the study by Kaplan et al (1998) was conducted on 18 asymptomatic individuals, and therefore does not reflect the population in our model.<br>• In the study by Schwarzer et al (1994) only 40% of patients had medial branch blocks, while 45% had intra-articular blocks and the remaining 15% had both. The assumption in the model is that patients would only have a single medial branch block as this |

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| | | | | Spine 1998;23:1847–52.<br>2. Schwarzer AC, Aprill, CN, Derby R, et al. The falsepositive rate of uncontrolled diagnostic blocks of the lumbar zygapophysial joints. Pain 1994;58:195–200.<br>3. Manchikanti L, Pampati V, Fellows B, Bakhit CE. The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or without adjuvant agents. Curr Rev Pain 2000;4:337–44.<br>4. Bogduk N, Holmes S. Controlled zygapophysial joint blocks: The travesty of cost-effectiveness. Pain Med 2000;1:24–34. | is UK standard practice endorsed by the British Pain Society.<br>• The study by Manchikanti et al (2000) was excluded from our review as the allocation of intervention was by patient choice, therefore its data were considered unreliable.<br>• The study by Bogduk was an economic analysis on diagnostic blocks for spinal pain; in this study the response to diagnostic block was evaluated only for the second block which was compared to placebo; this is not the intervention we wanted to get data for as people in our model would only have one diagnostic block. |
| Spine Interven tion Society | Full 2 | 59 | Table | "Only do radiofrequency denervation after a positive response to a diagnostic medial branch block for people with chronic non-specific low back pain with suspected facet joint pain."<br>We are pleased to see support for radiofrequency denervation, but have concerns about a relying on results of a single positive response to a diagnostic lumbar medial branch block. Single medial branch blocks have a credibility of 50% when 100% relief is considered a positive response. (Engel 2016)<br>The combination of the low prevalence of the condition and the known risk of false positive responses to medial branch blocks means that a single block will identify far too many patients who do not have the condition as appropriate for treatment. Giving physicians permission to treat people who have had a response to a single block will result in a large number of failed treatments, and harm the reputation of the procedure. RF should only be recommended when there have been positive responses to two sets of medial branch blocks. The criterion for a positive response to medial branch blocks should be 80-100% relief of the index pain.<br><br>Reference: | Thank you for your comment. The false positive rate following single blocks is one of the reasons that radiofrequency denervation is only successful for a proportion of patients – this is reflected in the meta-analysis. The majority of the reviewed trials incorporated a 50% relief from a single block paradigm and the results reflect the inclusion of patients who have a false positive response to the test injection. Where studies introduced two blocks or higher expectations of relief following the blocks, no heterogeneity was observed.<br>50% relief from single medial branch blocks is consistent with current accepted UK practice. |

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| | | | | Engel AJ, Bogduk N. Mathematical Validation and Credibility of Diagnostic Blocks for Spinal Pain. Pain Med. 2016 Mar 19. pii: pnw020. [Epub ahead of print] | |
| Spine Intervention Society | Full 2 | 64<br><br>65 | Table | Regarding longer-term outcomes, MacVicar has clearly shown exceptional durability of response from this procedure. If the placebo rate from lumbar and cervical medial branch blocks is the same, the NNT for complete relief is 3. We recommend a controlled trial using the optimal technique and selection criteria as described in the SIS guidelines and implemented by MacVicar, 2013.<br><br>References:<br>1. Bogduk N (ed). Practice guidelines for spinal diagnostic and treatment procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.<br>2. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. Pain Med. 2013 May;14(5):639-45. | Thank you for your comment. The GDG agree that the patient selection and technique applied for the research recommendation should be based on the best available evidence for example from MacVicar. This has been added to the research recommendation. |
| Spine Intervention Society | Full 2 | 67 | 1-30 | Stratification of studies according to their technical approach and quality of evidence was not adequately addressed. Caudal, interlaminar, and transforaminal epidural steroid injections were all lumped in a same category despite the fact that their technical approach may influence outcomes as supported in literature. | Thank you for your comment. The GDG agreed that the route of administration was important to consider if heterogeneity was observed, therefore this was considered as a subgroup analysis in the presence of heterogeneity and has been carried out accordingly. For the comparison of steroid and anaesthetic versus anaesthetic (>70% prolapse), such subgroup analysis mostly explained the heterogeneity between meta-analysed studies for pain at longer term follow-up and responder criteria for pain at both long and short term and the results have therefore been presented as per the pre-defined subgroup analysis. There was no difference between interventions in subgroups for pain. However clinical benefit of steroid plus anaesthetic for responder criteria (pain) was observed when intrelaminar (parasagittal) approach was used, and not other route of delivery. Subgroup |

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| | | | | | analysis for route of administration did not explain heterogeneity for pain and responder criteria for function in the short term.<br>For the comparison of steroid and anaesthetic versus anaesthetic (mixed population / unclear spinal pathologies), the route of administration did not explain the heterogeneity for pain between the meta-analysed studies.<br>Where heterogeneity was not explained by the subgroup analysis, pooled results are presented with random effects, as described in the methods. |
| Spine Intervention Society | Full 2 | 120 | Table | "Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis." If patients have central canal stenosis with neurogenic claudication, and ESIs are being considered for treatment of neurogenic claudication for the established diagnosis, the recommendation does not pertain to non-specific LBP. | Thank you for your comment. The epidural review is for the sciatica population only. |
| Spine Intervention Society | Full 2 | 120 | Table | The authors recommend ESI and local anesthetic in patients with acute sciatica. They recommend against the use of ESI in neurogenic claudication and central stenosis. When one reviews the evidence, 2 papers are excluded for risk of bias. It is unclear if the analysis includes 2 or 3 papers. These papers are not cited, disallowing an independent review of the results. The authors thus deprive patients with stenosis, a condition known to be poorly responsive to conservative care, of any alternative but surgery (surgery for stenosis was not assessed in the guidelines). | Thank you for your comment. The inclusion and exclusion of all studies in this guideline are based on their meeting the criteria of the evidence reviews (appendix C). Studies are not excluded based on their risk of bias. All included studies for the epidural injections review are detailed in section 24.3 of the full guideline. The number of studies and study names (first author and year of publication) included for each outcome are specified in the clinical evidence summary tables (section 24.3.4 and 24.3.5) and in the forest plots (appendix K.17) respectively, and are fully cited within the reference list of the guideline.<br>The GDG agreed that neurogenic claudication is a clinical diagnosis; the symptoms may not always include leg pain. Patients often present with neurological symptoms rather than pain (e.g. my legs feel heavier and heavier when I walk). Pain can often be in the back and buttocks rather than the legs. |

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| | | | | | The cause is usually central spinal canal stenosis. If the search found studies describing 'neurogenic claudication' as the inclusion and we weren't able to discern whether this meant leg pain or weakness/back and buttock pain then they had to be excluded.<br>For this group with the broad term 'neurogenic claudication' , there is little evidence to suggest that epidural injections are helpful and our view, based more on consensus than anything, was that they were unlikely to be of benefit. |
| Spine Intervention Society | Full 2 | 123 | Table | Research Recommendations:<br>"There is a rationale that transforaminal epidurals might be most effective, by ensuring delivery of corticosteroids directly to the region in which the nerve root might be compromised. However, transforaminal epidural injection requires imaging, usually within a specialist setting, potentially limiting treatment access and increasing costs. Caudal epidural injection might be undertaken without imaging, or with ultrasound guidance in a non-specialist setting, but, it has been argued, the drug might not reach the affected nerve root and therefore this approach might not be as effective as would be transforaminal injection. Empirical evidence that 1 approach is clearly superior to the other is currently lacking. Access to the two procedures varies between healthcare providers, and people who do not respond to caudal corticosteroid injection might subsequently receive image guided epidural injection. People with sciatica might therefore currently experience unnecessary symptoms at unnecessary cost to the NHS than would be the case if the most cost effective modes of delivering epidural corticosteroid injections were used."<br><br>The techniques utilized in the administration of epidural steroids are also critical. No randomized studies examined the use of image guidance as a variable. This has, however, been well examined in non-randomized studies demonstrating that up to 74% of "epidural" steroid injections | Thank you for your comment. The GDG recognise that there is some existing guidance in the UK suggesting epidurals should be given under image-guidance based on safety grounds. However the epidurals review did not show much difference in the clinical effectiveness between image-guided and non-image guided epidurals. Bearing in mind the additional costs to the NHS for imaging when delivering image-guided epidurals, the GDG agreed that a recommendation for future research should be drafted. |

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| | | | | performed without image guidance either deposit medication external to the epidural space or do not reach the targeted pathology within the ventral epidural space. (1-4).<br><br>1. Fredman B, Nun MB, Zohar E, Iraqi G, Shapiro M, Gepstein R, Jedeikin R. Epidural steroids for treating "failed back surgery syndrome": is fluoroscopy really necessary? Anesth Analg 1999; 88 (2): 367-72.<br>2. Bartynski WS, Grahovac SZ, Rothfus WE. Incorrect needle position during lumbar epidural steroid administration: inaccuracy of loss of air pressure resistance and requirement of fluoroscopy and epidurography during needle insertion. AJNR Am J Neuroradiol 2005; 26 (3): 502-5.<br>3. Botwin KP, Natalicchio J, Hanna A. Fluoroscopic guided lumbar interlaminar epidural injections: a prospective evaluation of epidurography contrast patterns and anatomical review of the epidural space. Pain Physician 2004; 7 (1): 77-80.<br>4. Weil L, Frauwirth NH, Amirdelfan K, Grant D, Rosenberg JA. Fluoroscopic analysis of lumbar epidural contrast spread after lumbar interlaminar injection. Arch Phys Med Rehabil 2008; 89 (3): 413-6.<br><br>Data from explanatory trials of non-image guided injections yields a number needed to treat (NNT) greater than 90. (5-9) In contrast, a high quality explanatory trial of image-guided transforaminal injection of steroids yields a NNT of 3. (10)<br><br>5. Dilke TF, Burry HC, Grahame R. Extradural corticosteroid injection in management of lumbar nerve root compression. Br Med J. 1973 Jun 16;2(5867):635-7.<br>6. Carette S, Leclaire R, Marcoux S, et al. Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus. N Engl J Med. 1997 Jun 5;336(23):1634-40. | |

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| | | | | 7. Breivik H, Helsa PE, Mohar I, Lind B. Treatment of chronic low back pain and sciatica: comparison of caudal epidural injections of bupivacaine and methylprednisolone with bupivacaine followed by saline. In: Bonica JJ, Albe-Fessard D, editors Advances in pain research and therapy. New York: Raven press; 1976.pp. 927-932.<br>8. Bush K, Hillier S. A controlled study of caudal epidural injections of triamcinolone plus procaine for the management of intractable sciatica. Spine (Phila Pa 1976). 1991 May;16(5):572-5.<br>9. Valat JP, Giraudeau B, Rozenberg S, et al. Epidural corticosteroid injections for sciatica: a randomised, double blind, controlled clinical trial. Ann Rheum Dis. 2003 Jul;62(7):639-43.<br>10. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. Pain Med 2010; 11 (8): 1149-68.<br><br>It is the position of the Spine Intervention Society that image guidance is absolutely essential for the safe and efficacious performance of epidural procedures, based on a large body of non-RCT evidence. | |
| United Chiropractic Association | Short | general | general | Section 1.1.2-1.1.5 – Imaging – As chiropractors are specialists in primary contact with NMSK patients, the clinical skill and rationale for imaging referral/ procurement is well within the scope of practice. Imaging is an integral part of the precision of due diligence in the assessment and patients presenting with NSLBP and Sciatica. We are concerned that this recommendation may cause unnecessary delays to the timely, thorough and accurate assessment. | Thank you for your comment. Most of the evidence supporting the use of imaging in the review came from a single RCT performed in a secondary setting of care. The GDG considered that the level of diagnostic uncertainty in specialist settings is likely to be lower, therefore they agreed that imaging should not be carried out in primary care but in specialist settings of care only, for example, a musculoskeletal interface clinic or hospital. |
| United Chiropractic | Short | general | general | Section 1.2.1 – Self management – We are concerned that guidance to patients should be tailored to the patient's particular history, examination and assessment of the nature of their particular cause of the NSLBP and Sciatica | Thank you for your comment. The recommendation on self-management states that advice and information should be tailored to needs and |

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| Association | | | | presentation, not merely as a stand alone or primary therapeutic approach. | capabilities of people with non-specific low back pain with or without sciatica. |
| United Chiropractic Association | Short | general | general | Section 1.2.2 – Exercise – This recommendation, particularly the group aspect of this programme, will be a challenging change in practice because of a concern over foreseeable waiting times. We are concerned that this recommendation must take into account a timely and appropriate implementation based on the patient's history, examination and assessment of the nature of their particular cause of the NSLBP and Sciatica presentation. If this clinical due diligence cannot be accomplished within the NHS due to waitlist, then allied healthcare alternatives delivered in a timely manner should be considered to avoid unnecessary chronicity. | Thank you for your comment. NICE guidelines are created to improve the standard of care, based on evidence. Difficulties with implementation do not warrant not striving for the highest standard of care. NICE guidelines only cover settings in which NHS funded care is received, therefore we are unable to make recommendation concerning other healthcare alternatives. |
| United Chiropractic Association | Short | general | general | Section 1.2.3-1.2.4 – Orthotics – We are concerned that the recommendation of sacroliliac belts/ foot orthotics be considered as an ancillary support if the correct use of said items assists in improving the functional stability and integrity of the spine and its adjacent structures. | Thank you for your comment. The GDG agreed that there was no evidence suggesting foot orthotics/ sacroliliac belts were of benefit to people with low back pain with or without sciatica, and recommended against their use. The GDG were therefore unable to recommend their use as an ancillary support. |
| United Chiropractic Association | Short | general | general | Section 1.2.6 – Traction – We are concerned that the recommendation of traction be considered as an ancillary procedure if the correct implementation of said therapy assists in improving the functional stability and integrity of the spine and its adjacent structures. | Thank you for your comment. The GDG found that there was very limited evidence of benefit for traction as a single therapy, and therefore could not recommend it as an ancillary procedure. |
| United Chiropractic Association | Short | general | general | Section 1.2.7 – Manipulation/ Mobilisation / Soft Tissue Techniques – We are concerned that the clinical efficacy of spinal manipulation has not been shown to be any less effective than is the case with respect to the current guideline CG88. We are concerned that this recommendation may imply that, only in addition to exercise in a multi-modal treatment package would spinal manipulation be considered valuable, clinically indicated, and cost-effective. This is simply not appropriate in all cases. Dependent upon the initial presenting criteria, and the nature of the NSLBP and Sciatica problem, clinically effective care with spinal manipulation may be indicated PRIOR to exercise being tolerated. Due consideration should be in the hands of the clinician to | Thank you for your comment. The GDG agreed that the evidence reviewed did not provide sufficient evidence of benefit of manual therapies compared to sham to recommend their use in isolation. However, evidence from its use in combination with other treatments and from the MBR review, did show more benefit.<br>The recommendation has been reworded following stakeholder feedback. It now reads: consider manipulation for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy. |

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| | | | | determine the order/ frequency of manipulation, progressing to a multi-modal treatment package when clinically appropriate. | This recommendation was based on evidence from two studies of treatment packages including the aforementioned components (see chapters 9, 12 and 17). The GDG agreed that based on the evidence, manual therapy could not be recommended as an independent intervention. |
| United Chiropractic Association | Short | general | general | Section 1.3.2 – Radiofrequency Denervation – We are concerned that proceeding to a referral level of this intervention may be premature if an appropriate trial of conservative spinal manipulative therapy has not been undertaken. Considering the clinical effectiveness of spinal manipulation therapy, as indicated and recommended in CG88, surely in addition to other non-surgical interventions, SMT should be considered prior to radiofrequency denervation referral. Of course, if this intervention is found not to be effective in the patient, appropriate referral can be recommended. | Thank you for your comment. Referral for radiofrequency denervation has been recommended for a specific group of people with chronic non-specific low back pain. With reference to your comment, non-surgical treatment should have not worked for this group of people before such referral is considered. Please see section 23.6 (Recommendations and link to evidence) for details. |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | General | General | **Conflict of Interest**<br>Previous NICE guidance for low back pain was followed by considerable controversy. Some criticisms were directed at the GDG and in particular at the balance of specialities represented.<br><br>It would seem appropriate that the most stringent precautions should be taken to avoid any appearance of conflict of interest. In the operation of the previous GDG, members who were involved in providing a specific treatment left the room and took no part either in the discussion or in the decision relating to that treatment. With the exception of pharmacological treatments this does not appear the case with the current guideline development. | Thank you for your comment. We were mindful of the comments that were received following consultation and publication of CG88. At the beginning of development discussions were held with the GDG regarding conflicts of interest and the appropriateness of declaring work in private practice. It was agreed in accordance with the conflicts of interest policy relevant at the time of development, that this was not viewed as a conflict that would require members to withdraw from decision making. Members of committees are recruited because of their specialist knowledge of topics and therefore they should be involved in the relevant discussions. However for transparency any member who provided private practice would declare this (appendix B). |

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| | | 42-65<br><br><br><br>137-154<br><br><br><br><br>**155-182** | | This would be of particular relevance in the situations where the expert opinion of the GDG was used as a factor for decision making.<br><br>**Specific areas where a conflict of interest may be present are:**<br><br>**23 Radiofrequency denervation for facet joint pain**<br><br>Five members of the GDG are professionally associated with pain services, but remained present during the discussion and decision making. This permits the perception of potential conflict of interest.<br><br>**2.6 Total Lumbar Disc replacement**<br><br>Two members of the GDG were spinal surgeons but were not excluded from discussion and recommendation process. This permits the perception of conflict of interest.<br><br>**27. Spinal Fusion**<br>There are two spinal surgeons on the GDG who took part in the discussion and the decision making. This permits the perception of a conflict of interest. | |
| United Kingdom Spinal Societie | Full 2 | 56 | 15 | It is not clear why GDG chose to use the expert opinion of the group for an estimate of the duration of the therapy. In a systematic review published in 2010 (1), five RCT's were included in the analysis for radio frequency denervation of facet joints in a placebo model | Thank you for your comment.<br>A systematic review was also conducted for this guideline and this included the studies identified in the systematic review that you have cited. Both reviews show the average pain score obtained at |

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| s Board and British Orthopaedic association | | | | following positive response to medial branch block. They reported evidence favouring denervation in short term outcomes (4 weeks). They report evidence of no improvement in the intermediate term (one to six months) or in the long term (six months). In a single cohort study of repeated denervation treatments, a publication in 2004 (2) indicated average duration of relief of 10.5 months for a first injection, 11.6 months for a second injection, 11.2 months for a third injection and nine months for a fourth injection. Gofeld 2007 (3) in a ten year perspective audit noted 68 percent "success" at 12 months and 30 percent at 24 months. Cohen 2010 (4) reported in their single nerve block paradigm a 42 percent successful outcome at three months (8 of 19).<br><br>The GDG may wish to review the availability of evidence of duration of treatment effect before relying on consensus opinion. If published evidence is preferred then the treatment would not be cost effective on the new model.<br><br>It has been suggested (da Rocha 2014, 5) that prolonged relief from a medial branch block is evidence that facet joint pain is <u>not</u> the cause of the symptoms and actually prolonged relief would be a contra indication to subsequent denervation. It would be greatly appreciated if the GDG would consider providing guidance on the evidence for an apparent prolonged response to medial branch block being an indication of active facet joint pain, given the duration of the local anaesthetic agents most commonly employed. This is a significant factor as the GDG have recommended a denervation procedure in patients with prolonged | different time points after radiofrequency denervation. These studies were used in the model; however they did not report on the duration of pain relief.<br>We have edited the model write up to explain that other studies on duration of effectiveness were considered and that the study by MacVicar was considered the most reliable study.<br>The study by Schofferman et al (2004) is a retrospective chart review including only patients for whom the initial procedure was successful but then benefits were subsequently dissipated and at least one additional radiofrequency denervation was performed. This study is selecting people in whom the procedure is less likely to be successful in the long run as all of them had a repeat procedure. The study by Gofeld et al. (2007) does not report the mean pain score at baseline and at follow up; also they report the median pain relief duration, while we are interested in the mean. The median would not take into account the outliers (possibly on the higher end) and therefore could reduce the overall duration. The study by Cohen et al. (2010) was considered unreliable due to the small sample size (n=19).<br><br>Denervation would only be offered to those who experienced relief from medial branch blocks and in whom the pain has subsequently returned. The assumption that prolonged relief from medial branch blocks equates to another mechanism for pain other than pain arising from the facet joints (as proposed by Rocha), whilst an interesting premise, remains theoretical. Studies of repeated medial branch blocks (by Manchikanti et al (2008) for example) suggest that facet joint pain remains the mechanism following prolonged relief. |

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| | | | | response to a local anaesthetic injection but have at present not based this in evidence. The GDG might wish to provide this evidence in the light of different opinions in the literature.<br><br>References:<br><br>1. Henschke et al. Injection therapy and denervation procedures for chronic low back pain: a systematic review. European Spine Journal (2010) 19:1425-14449.<br>2. Schofferman and Kine. Effectiveness of repeat radio frequency neurotomy for lumbar facet pain. Spine. 29 (21): 2471-2473.<br>3. Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints: 10-year prospective clinical audit. Pain Physician 2007;10: 291–99<br>4. Cohen SP, Williams KA, Kurihara C, et al. Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology 2010: 113: 395–405<br>5. da Rocha ID, a Cristante AF, Raphael Martus Marcon RM, Oliveira RP, Letaif OB, de Barros Filho TEP. Controlled medial branch anesthetic block in the diagnosis of chronic lumbar facet joint pain: the value of a three-month follow-up. CLINICS 2014;69(8):529-534 | |

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| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 59 | 29 | **23.6 Recommendations and link to evidence**<br><br>Consistency of Approach to Evidence<br>There is inconsistency in the evaluation of the evidence for this therapy as compared to all other therapies. In the second paragraph in the section trade-off between clinical benefits and harms, a trend is reported and has the appearance of being given weight. No trend is reported in any other treatment. | Thank you for your comment. Although the GDG were aware of non-clinically significant trends, this did not bare weight when making decisions about recommendations, and therefore this sentence has been removed to avoid confusion. |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 59 | 29 | It is recorded “the GDG noted that one would not expect any treatment related pain to occur beyond four months”. This appears an opinion of the expert group rather than based on evidence. It may be appropriate for the GDG to consider that in other circumstances injury related neuropathic pain may be persistent and indeed require management in its own right. | Thank you for your comment. As stated in section 4.5 of the full guideline, when clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The GDG were aware of Kornick 2004, which reported a complication rate of 1%. As adverse events are often poorly reported, the GDG used this knowledge to inform their decision making. This has been added into the LETR to avoid confusion. |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 59 | 29 | There are two remarks that in the expert opinion of the GDG the adverse event rate of 5 percent was “higher than expected”. This mitigation of the reported complications by expert opinion is not repeated elsewhere in the guidance and is an inconsistency in the use of evidence in the guidance overall. | Thank you for your comment. As stated in section 4.5 of the full guideline, when clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The GDG were aware of Kornick 2004, which reported a complication rate of 1%. As adverse events are often poorly reported, the GDG used this knowledge to inform their decision making. This has been added into the LETR to avoid confusion, |

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| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 59 | 29 | **23.6 Other considerations**<br>The GDG have proposed clinical features which may be helpful in identifying patient suitable for denervation. This proposal represents the only place in the overall guidance document where clinical advice on identification is proffered, and may be held to represent an area where the treatment of evidence and analysis is distinctly different for one treatment than others in the guidance. The consensus document referred to was constructed on the Delphi principal and no evidence of the sensitivity or specificity of these clinical findings were available in the original publication. Published investigations of specificity and sensitivity have demonstrated little utility of the features investigated (6,7,8). The GDG may wish to consider providing evidence for the use of this paradigm.<br><br>6. Schwarzer AC, Aprill C, Derby R, Fortin JD, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine. 1994;15:1132–1137<br>7. Manchikanti L, Pampati V, Fellows B, Baha GA. The inability of the clinical picture to characterize pain from facet joints. Pain Physician. 2000;3:158–166.<br>8. M. J. Hancock, C. G. Maher, J. Latimer, M. F. Spindler, J. H. McAuley, M. Laslett, and N. Bogduk Systematic review of tests to identify the disc, SIJ or facet joint as the source of low back pain. Eur Spine J. Oct 2007; 16(10): 1539–1550 | Thank you for your comment. The LETR details clinical features which may be helpful in determining which patients may be suitable for this intervention although the GDG accept that reliably identifying patients with facet joint pain is challenging and the evidence to support this identification is conflicting. For this reason this full level of detail is not included in the recommendation, which states that it should be considered in people in whom the main source of pain is thought to come from structures supplied by the medial branch nerve. |

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| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 120 | 24 | **24.Epidural Injections**<br>It has been recommended that epidural injections of local anaesthetic and steroid in people with acute sciatica be considered. In the preamble it is made clear that all routes of administration are included and specifically nerve root block. However, it is possible that commissioners and others reading the brief version of the guidance will not appreciate this and fail to commission appropriately. This is perhaps made more likely as nerve root block and epidural have separate OPCS codes and, therefore, appear separately in SUS and HES data. The CRG are requested to consider a form of words clarifying the scope of their recommendation. | Thank you for your comment. We were unable to demonstrate, given the available evidence, that image guided epidurals, or that one route of epidural administration was superior to another. A research recommendation was written to address this uncertainty, but we are unable to be more specific in the recommendation. Your comment will be considered by NICE where relevant support activity is being planned. |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 152 | 33 | **26.6 Recommendations and links to evidence**<br>**Trade Off between Clinical Benefits and Harms**<br><br>First paragraph, the GDG note that anterior lumbar interbody fusion is not commonly performed "due to a perceived lack of effectiveness". This statement appears supported only by the collected expert opinion, which may have been coloured by a trial against fusion with BAK cages which were subsequently demonstrated to have unsatisfactory results.<br><br>An unmatched cohort series of 150 anterior fusions and 150 postero-lateral fusions indicated superiority of anterior fusion over instrumented postero-lateral fusion in function and return to work (9). The GRADE quality rating in surgical trials is usually low because of the inevitable risk of bias owing to the lack of blinding. The GDG may wish to consider the value of lower quality | Thank you for your comment.<br><br>The GDG was concerned about the use of BAK cages to achieve anterior lumbar interbody fusion in the control group of the Gornet 2011 trial. The GDG was aware that anterior procedures in the lumbar spine for back pain are not commonly performed in the UK setting, and that the BAK cages technique shows a low fusion rate and would not be considered appropriate for a stand-alone anterior fusion in clinical practice. For this reason, as most of the evidence in favour of disc replacement in the review came from the Gornet 2011 trial, the GDG wished to stress that such evidence should be regarded with caution. This has now been clarified in section 26.6 (Recommendations and link to evidence). The comparison of different spinal fusion routes was outside the scope of the guideline.<br>Regarding the quality rating of included studies, the protocol for this, and all intervention reviews in the |

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| | | | | evidence in surgical studies to inform the expressed opinion.<br><br>The GDG expressed concern over the risk of patient harm from surgical intervention and quote figures from one study with 80 participants in the disc replacement arm, noting that it was not powered to detect harm. This imprecision must be in both directions however, the risk of an excess of serious complications by chance in a small group is higher. Many of the studies referred to by the GDG were included in the systemic review by Wei in 2013 (10). This systemic review examined the reported complications in five randomised controlled trials comprising of 1081 total disc replacement operations. The complication rate reported was 5.8 percent and in the 500 fusion patients of the same trials, the complication rate was 10.8 percent. In this review the re-operation rate was 5.2 percent for total disc replacement and six percent for spinal fusion.<br><br>It is acknowledged that spinal surgery is a major intervention and will carry a significantly greater risk of patient harm than conservative management. These data were considered in the original NICE guidance IP 306. It is suggested that the GDG may wish to re-consider their presentation and evaluation of the risk of complications.<br>References:<br>9. Greenough et al, Instrumented Postero-Lateral Lumbar Fusion; results and comparison with anterior interbody fusion. Spine 1998; 23:479-486.<br>10. Wei et al | guideline included both RCTs and observational studies where RCT evidence was lacking. In this review 2 cohort studies were included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent as stated in the methods, section 4.3.2.<br><br>The GDG were aware of the Hellum 2011 study, which reported the serious adverse events related with disc replacement, in particular 1 lower leg amputation and 4 cases of considerable blood loss out of 80 participants. It was the GDG concern that this was a high rate of adverse events in a study not powered to detect harm, but believed that this high adverse event rate was reflective of the risks observed in practice. This is detailed in the LETR (section 26.6). Wei et al (2013) was not included in our review as all primary studies included in the systematic review were available and included in this review. Some of the included studies were conducted in populations that were not relevant to our review protocol, however the relevant studies were included and did inform the recommendation. |

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| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 152 | 33 | **Quality of Evidence**<br><br>The GDG note that the GRADE quality rating of the evidence was low to very low. This was driven by a high risk of bias. It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass.<br><br>Given the paucity of evidence and the inevitably low GRADE evaluation of randomised surgical trials there is a strong case for reviewing evidence from other sources. There has been an increase over time of the use of spinal surgical registries in a number of specialities including spinal surgery. The use of such data with a properly structured methodology (STROBE) has been investigated by a number of authors and its use has been supported (11-16).<br><br>The GDG may wish to consider evidence from the Swedish Spine Registry which covers 42 of 45 Spine Centres in Sweden. The 2012 report (ref 17) indicates that total disc replacement provides better outcomes in most modalities than spinal fusion. The data in the registry is sufficiently detailed to permit evaluation of the influence of pre-operative functional scores. They also note that the RCT as a technique for comparison with other fusion techniques might be possible. Not stated in this report is the consideration that to achieve a satisfactory GRADE quality rating, the comparator in such a trial would have to be stand alone anterior fusion | Thank you for your comment. The protocol for this, and all intervention reviews in the guideline included both RCTs and observational studies where RCT evidence was lacking. In this review 2 cohort studies were included. GRADE quality rating informs the overall confidence in the evidence due to factors including risk of bias, and therefore ratings for outcomes where blinding is more problematic are still downgraded. It is noted that double blinded trials are less common in surgery, however this is also true of other interventions included in the guideline and the approach to evidence quality appraisal and consideration is consistent as stated in the methods, section 4.3.2.<br><br>The GDG were aware of the availability of spine registries, however when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best available evidence was used to inform the review question. Observational data was used within the review, but no published analysis of registry data was identified to inform the review, and evidence was available from the included studies. Furthermore, the GDG highlighted that many spine registries are filled on a voluntary basis, and therefore are at very high risk of selection bias. |

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| | | | | otherwise blinding would be impossible with one operation done from the front and the other from the back.<br><br>The 2014 report of the Swedish Spinal Registry (18) evaluates the results of surgery for degenerative disc disease at one year, two years and five years. These surgeries are fusions of various types and disc replacement (16 percent). Considering the evidence review undertaken by the GDG, outcomes of total disc replacement may be considered not inferior to those of spinal fusion and so these results have validity. The change in EQ5D score from pre-operative to one year follow up was 0.32. The improvement at two years was 0.3 and at 5 years 0.29. Thus surgical procedures resulted in approximately a third of a Qualy in improvement per year for five years. Pain on the VAS scale reduced from 6.2 pre operatively to 2.7 at one year, 2.9 at two years and 3.3 at five years. ODI results are available for two years only, with a reduction from 44 pre operatively to 23 at one year and 24 at two years. Registries have the additional advantage of representing surgery in the real world, with normal health care provision and normal surgical teams.<br><br>The GDG are invited to consider whether in the absence of the possibility of high quality studies on the GRADE quality rating, data from spinal registries should be included in the evidence base.<br><br>References:<br>11 .Benson K1, Hartz AJ. A comparison of observational studies and randomized, | |

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| | | | | controlled trials. N Engl J. Med. 2000 Jun 22;342(25):1878-86.<br><br>12 Concato J, Lawler EV, Lew RA, Gaziano JM, Aslan M, Huang GD. Observational methods in comparative effectiveness research. Am J Med. 2010 Dec;123(12 Suppl 1)<br>13 Concato J1, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000 Jun 22;342(25):1887-92.<br>14 Colditz GA. Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. Crit Rev Food Sci Nutr. 2010;50 Suppl 1:10-2.<br>15 Jacobs WC et al. Spine surgery research: on and beyond current strategies. Spine J 2012.<br>16 Phillips et al. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine 2013.<br>17 http://www.4s.nu/pdf/Report_2012_swespine_englishversion.pdf<br>ISBN: 978-91-979924-5-9<br>18 http://www.4s.nu/pdf/Report_2014_Swespine_Engl_ver_141204.pdf<br>ISBN: 978-91-88017-00-0 | |
| United Kingdom Spinal Societies Board and | Full 2 | 152 | 33 | **Trade-off between net clinical effects and costs**<br><br>The GDG notes that two studies were considered for the economic evaluation. One study (Johnsen 2014) demonstrated cost effectiveness against multi- | Thank you for your comment. The inconsistency of the terminology for the multidisciplinary rehabilitation in Johnsen 2014 has been amended and is now consistent across the review. We have amended the LETR in response to your comment. |

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| British Orthopaedic association | | | | disciplinary rehabilitation. The evidence extract describes this as a three element MBR programme. In paragraph two, the GDG then note that comparator interventions might not be cost effective themselves. However, in the evaluation of multi-disciplinary bio-psychosocial rehabilitation in another part of the guidance, the 3 element MBR is noted to be a cost effective intervention. There appears to be a contradiction here.<br><br>There does not appear to be a rationale for preferring the analysis using the FS6D over the EQ5D. | When choosing outcomes, EQ-5D scores are to be preferred over SF-6D according to the NICE Reference Case and therefore, the analysis using EQ5D data was used in the base-case analysis. The SF-6D was reported as a one-way sensitivity analysis and was therefore presented to the GDG as an additional consideration of uncertainty. Changes have been made to the LETR to clarify this. |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 152 | 33 | **Patient Choice**<br><br>It is clear that any form of spinal surgery for axial lumbar spine pain is a much larger intervention with significant risk of complications. As such it is appropriate that total disc replacement should be considered only after an inadequate response to an appropriate NBR (CPPP). All health care delivery is patient centred and is undertaken in partnership with the patient themselves. It is perhaps inappropriate that the choice of an effective treatment should be denied to patients without their involvement. The uptake of a surgical option after full and open discussion of potential benefits and potential risks is a decision which should be made by patients. It is requested that the GDG consider whether patient choice should take a higher priority.<br>Other considerations<br><br>and governance might be sufficient reason to modify the recommendation and allow patient choice. | Thank you for your comment. Patient choice is integral to all NICE guidelines and should apply across all recommendations. This is stated in section 4.5.4 and inside the cover page, highlighting that: "The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources". However, having reviewed the evidence for disc replacement the GDG agreed that the risks of harms associated with the surgical procedure outweighed the potential benefits and the GDG decided it was appropriate to recommend against the use of disc replacement for non-specific low back pain. |

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| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 152 | 33 | **Other Considerations**<br><br>The GDG note that total disc replacement in the lumbar region is effective. It notes the risk of complications associated with major surgery.<br><br>It is plain that the risk of complications is potentially correlated with the experience of the surgeon and of the multi-disciplinary team. Lumbar total disc replacement is a specialised procedure, directly commissioned by NHS England. The potential for complications might be addressed by performing such surgery only under the auspices of a specialised surgical centre.<br><br>The audit and governance all surgical procedures are of great importance, especially with regard to patient satisfaction, patient outcomes and complications. All specialised spinal surgery is now mandated to be entered on the British Spine Registry. In this regard, what has been termed “special arrangements for clinical governance, consent and audit for this procedure” might be expressed as entry into the British Spine Registry, which would also permit research.<br><br>The GDG may wish to consider whether improved safeguards, audit | Patient choice is integral to all NICE guidelines and should apply across all recommendations. This is stated in section 4.5.4 and inside the cover page, highlighting that: “The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources”. However, having reviewed the evidence for disc replacement the GDG agreed that the risks of harms associated with the surgical procedure outweighed the potential benefits and the GDG decided it was appropriate to recommend against the use of disc replacement for non-specific low back pain.<br>Based on the evidence reviewed, suggesting that the risks of harms associated with the surgical procedure outweighed the potential benefit, the GDG agreed it was appropriate to recommend against the use of disc replacement for non-specific low back pain. The GDG is unable to comment about how changes in audit and governance may affect the outcomes of surgery. |
| United Kingdom Spinal Societies Board | Full 2 | 178 | 36 | **27.6 Recommendations and Link to Evidence**<br><br>Trade-off between Clinical Benefits and Harms<br>The GDG note evidence formed one large study indicating clinical benefit of spinal fusion over usual | Thank you for your comment. Data from spinal registries was not used to inform this review as the GDG agreed when setting the protocol that studies design would be restricted to RCTs in the first instance, and then observational studies if there were limited evidence available, to ensure the best |

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| and British Orthopaedic association | | | | care. They also note a number of studies collectively indicating broad equivalence between spinal fusion and MBR programmes.<br><br>The GDG noted that the GRADE quality rating of the evidence was low to very low. This was driven by a high risk of bias. It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass.<br><br>Given the paucity of evidence and the inevitably low GRADE evaluation or randomised surgical trials there is a strong case for reviewing evidence from other sources. There has been an increase over time of the use of spinal surgical registries in a number of specialities including spinal surgery. The use of such data with a properly structured methodology (STROBE) has been investigated by a number of authors and its use has been supported (11-16).<br>The GDG may wish to reconsider evidence from the Swedish Spine Registry which covers 42 of 45 Spine Centres in Sweden. The 2014 report of the Swedish Spinal Registry (18) evaluates the results of surgery for degenerative disc disease at one year, two years and five years. These surgeries are fusions of various types and disc replacement (16 percent). The change in EQ5D score from pre-operative to one year follow up was 0.32. The improvement at two years was 0.3 and at 5 years 0.29. Thus surgical procedures resulted in approximately a third of a Qualy in improvement per | available evidence was used to inform the review question. Observational data was used within the review, but no published analysis of registry data was identified. Furthermore, on consideration of this suggestion, the GDG highlighted that many spine registries are filled on a voluntary basis, and therefore are at very high risk of selection bias. |

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| | | | | year for five years. Pain on the VAS scale reduced from 6.2 pre operatively to 2.7 at one year, 2.9 at two years and 3.3 at five years. ODI results are available for two years only, with a reduction from 44 pre operatively to 23 at one year and 24 at two years. Registries have the additional advantage of representing surgery in the real world, with normal health care provision and normal surgical teams.<br><br>The GDG are invited to consider whether in the absence of the possibility of high quality studies on the GRADE quality rating, data from spinal registries should be included in the evidence base.<br><br>References<br>11 Benson K1, Hartz AJ. A comparison of observational studies and randomized, controlled trials. N Engl J. Med. 2000 Jun 22;342(25):1878-86.<br><br>12 Concato J, Lawler EV, Lew RA, Gaziano JM, Aslan M, Huang GD. Observational methods in comparative effectiveness research. Am J Med. 2010 Dec;123(12 Suppl 1)<br>13 Concato J1, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000 Jun 22;342(25):1887-92.<br>14 Colditz GA. Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. Crit Rev Food Sci Nutr. 2010;50 Suppl 1:10-2.<br>15 Jacobs WC et al. Spine surgery research: on and beyond current strategies. Spine J 2012. | |

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| | | | | 16 Phillips et al. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine 2013.<br>18<br>http://www.4s.nu/pdf/Report_2014_Swespine_Engl_ver_141204.pdf<br>ISBN: 978-91-88017-00-0 | |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 178 | 36 | **Patient Choice**<br><br>It is clear that any form of spinal surgery for axial lumbar spine pain is a much larger intervention with significant risk of complications. As such it is appropriate that spinal fusion should be considered only after an inadequate response to an appropriate NBR (CPPP). All health care delivery is patient centred and is undertaken in partnership with the patient themselves. It is perhaps inappropriate that the choice of an effective treatment should be denied to patients without their involvement. The uptake of a surgical option after full and open discussion of potential benefits and potential risks is a decision which should be made by patients. It is requested that the GDG consider whether patient choice should take a higher priority. | Thank you for your comment. Patient choice has been considered by the GDG. All patient treatment decisions would be discussed with the patient. Please see the introduction on page 4 of the short version about patient decisions, and the linked 'Your Care' web page. |
| United Kingdom Spinal Societies Board and British Orthopa | Full 2 | 178 | 36 | **Other Considerations**<br><br>It the GDG note the existing guidance on non-rigid stabilisation recommending "normal arrangements for clinical governance, consent and audit for this procedure". Non-rigid stabilisation as a technique has fallen out of favour in spinal surgery owing to a substantial re-operation rate and less satisfactory long | Thank you for your comment. The GDG were aware of the existing IP guidance and have been in communication with the IPG team.. Both IPG321 and IPG387 recommend special arrangements for the procedures covered and therefore are not considered to conflict with the recommendation that fusion should only take place in the context of an RCT. |

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| edic association | | | | term results. The GDG is requested to consider whether by effectively recommending against fusion surgery that a large patient population may then be subjected to a recrudescence of less satisfactory technique.<br><br>The GDG note the existing guidance on trans-axial interbody lumbosacral fusion (IPG387) and lateral **(**including extreme extra and direct lateral) interbody fusion IPG321. The GDG are requested to consider whether their advice is internally consistent with recommending against the majority of fusions but permitting these forms of fusion which have a significantly lower evidence base. | |
| United Kingdom Spinal Societies Board and British Orthopaedic association | Full 2 | 178 | 36 | **Research Recommendation**<br><br>The GDG recommend "a large multi-centre randomised trial with sufficient power to answer these important questions". It is inherent in the design of trial between surgical and non-surgical care that there can be no blinding of the patient or of the investigator. This risk of bias cannot be eliminated as the undertaking of sham surgery under general anaesthesia is outside the ethical compass. This will inevitably result in a low GRADE evaluation for randomised surgical trials<br><br>The GDG also suggest within the trial investigating possible predictors of response. It is clear that the trial size would be significantly larger than the Oxford Stabilisation Trial (Fairbank et al). The Fairbank study came under the auspices of the MRC, cost £1.8 million and took 9 years. The study included 349 subjects and | Thank you for your comment.<br>The GDG believe that a good quality trial can be undertaken in surgery and the difficulties of blinding should not be an obstacle to such trials being undertaken<br><br>The review of the evidence did not suggest that this should be routinely considered on the NHS. As detailed in section 4.5.1 of the Methods chapter, when areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research. The GDG is unable to comment about the funding of further trials, but the feasibility is considered in the writing of the research recommendation.<br><br>Based on the evidence reviewed, showing no consistent benefit of spinal fusion over comparator treatments and potential harm, the GDG agreed it was appropriate to recommend against the use of |

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| | | | | achieved a GRADE quality rating of low due to risk of bias. As the risk of bias cannot be eliminated it seems extremely unlikely that funding could be obtained for any such further study and indeed it would appear difficult to justify such a use of research resources.<br><br>It is plain that the risk of complications is potentially correlated with the experience of the surgeon and of the system. Lumbar fusion is a specialist procedure. The potential for complications might be addressed by performing such surgery only under the auspices of a specialist spinal surgeon.<br><br>All specialised spinal surgery is now mandated to be entered on the British Spine Registry. In addition the entry of lumbar spinal fusion into the British Spine Registry would provide a thorough evaluation of the outcomes, the important predictive factors, the complications and the cost effectiveness of the procedure. With the increasing evidence for the utility of registries, this might meet the requirement for further evaluation and research in an effective but achievable manner.<br><br>The GDG may wish to consider whether improved safeguards and the improved audit, research and governance which is available through the registry might be sufficient reason to modify the recommendation and allow patient choice.<br><br>The GDG may also choose to refer to the National Spinal Taskforce report (2013) | spinal fusion for non-specific low back pain unless as part of a randomised controlled trial.<br><br>Regarding registries, We are unable to make a recommendation that data should be submitted to a registry, but have added a statement to the 'evidence and link to recommendations' section to state that the GDG suggest if done within an RCT data should be submitted to a registry.<br><br>The GDG is unable to comment about how changes in audit and governance may affect the outcomes of surgery.<br><br>Although the GDG were aware of other research, this guideline is based only on the findings of the analysis conducted by NICE. |

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| | | | | **COMMISSIONING SPINAL SERVICES – GETTING THE SERVICE BACK ON TRACK**<br>recommendations on Research and Development which for ease of reference are listed below.<br>These apply particularly to Spinal fusion and TDR<br><br>**5.2 RESEARCH AND DEVELOPMENT**<br>Research is at the centre of NHS activity. The capacity of the NHS to deliver high quality studies in collaboration with NIHR has been considerably enhanced since the advent of CLRN's. This report has identified a number of areas of spinal clinical activity where the evidence base for interventions is poor or incomplete. This should inform Industry, research leads and grant givers. Spinal surgery uses a wide range of Med Tech implants and devices. Development of industry-funded studies is a priority. The research design for most of these studies is likely to be a cohort study, but in some cases RCT's are feasible. Existing examples are the Magec study of an implant for treating early onset scoliosis that can be lengthened in the clinic, avoiding many distressing general anaesthetics. The development of commercially funded device research is a priority for NIHR. In recent years an increasing and appropriate focus has developed on the evidence base underpinning medical interventions. This has been classified in terms of its strengths and weaknesses with double blind RCTs being regarded as the gold standard for most interventions. NICE has recognised that in some surgical areas this is neither always feasible nor the most appropriate method.<br>It is also relevant that from concept through ethical approval and procedure performance to gain sufficient numbers to adequately power a trial, a minimum of two | |

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| | | | | year follow-up, data collation, processing, write-up, submission, re-editing, publication and dissemination usually takes a decade.<br>As a result, when attempting to introduce new technology, there is frequently a minimal or absent historical evidence base. It is perceived that in the current financial climate this will be taken as justification not to support innovation in UK spinal surgery. The life expectancy of advice before it is superseded is short. This reduces the incentive for companies to support this type of research.<br>In addition many procedures that are currently being undertaken have a limited evidence base but as perceived by the authors of this report, seem from impression or cohort studies to be of possible potential value. It is unlikely that all of these will in the short term be assessed on an RCT basis. The alternatives are to discontinue commissioning these or to require the proponents to optimise their assessment process using recognised outcome measures and engage in studies for a defined period to justify or deny continued use. If the invitation to participate in such a process is rejected, then continued financing would reasonably be questioned.<br>It is recognised that in the current financial climate surgeons are unlikely to be permitted the time (by Trusts) to set up such a process properly with the necessary independent assessment of outcome. It is suggested that a process should be developed with HTA, clinical trials units and RDS to draft trial design, obtain ethical approval (if necessary for what is an audit of current practice), assess outcomes independently, | |

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| | | | | collate the data and present and publish the results in collaboration with their surgical colleagues.<br>Within a three to five year time frame this should place all procedures on a more robust evidence base. To discontinue familiar current procedures on the basis of an absence of evidence to date would be to spurn a readymade opportunity both to identify procedures that may be of value and also to waste a potential lever to improve outcome assessment.<br>Many of these studies require networks of surgeons. Commissioners should look at a provider network in terms of its research capacity as an essential part of quality assessment.<br>**RECOMMENDATION:**<br>The Department of Health should ensure that NIHR and the new Academic Health Science Networks are receptive to the introduction of new spinal technology with input from the Spinal Surgical Societies, relevant Statutory Bodies (MHRA, NICE MTAC) and ABHI Spinal group to allow appropriate and timely innovation. | |
| United Kingdom Spinal Societies Board and British Orthopaedic association | general | General | General | **Consistency of Approach to Evidence**<br><br>Between the treatments considered there appear to be differences in the way the evidence is approached during the discussion and decision making process.<br><br>**Multimodal Therapy**<br><br>In a number of recommendations it is suggested that some treatments be offered as part of a multimodal treatment package. The format or delivery of such a package is not defined within the guidance. It is not clear whether this is a package which might be | Thank you for your comment. The term 'multimodal' has been amended. The recommendations now refer to 'a treatment package including exercise with or without psychological therapy' and 'a treatment package including exercise with or without manual therapy', to make the format and content more transparent. These recommendations are based on evidence from studies that used a treatment package consisting of these components, which can be found in chapters 9, 12 and 17.<br><br>It is beyond the scope of this review to specify who should deliver an intervention, the review focussed on whether or not interventions are clinically and |

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| | | | | delivered by a single individual, for example manipulative therapy delivered by a "psychologically informed therapist" with discussion and advice on other self-management techniques, or a package delivered by more than one person. Clearly the involvement of another practitioner would have significant effects on costs and cost effectiveness and might indeed alter the recommendation.<br><br>No evidence has been brought forward concerning such a multi modal package.<br><br>Further guidance on the definition of multi-modal package, by whom it should be delivered and an assessment of the evidence base would be greatly appreciated. | cost-effective and was based on the best available evidence identified according to the review protocol. |
| University Hospitals Birmingham NHS Foundation Trust | Full 2 | 54, 59,64. | 7 figure 1 | The guideline states that injection therapy should be considered for suspected facet joint pain. Key features associated with suspected facet joint pain are listed in page 64. Would the GDG consider adding this list to the recommendations section (point 31) on page 59 or associated with the algorithm on page 54. | Thank you for your comment. We have considered this and have added a bullet point to the recommendation to give further guidance: "the predominant source of pain is believed to originate from structures supplied by the medial branch nerve.." |
| University Hospitals Birmingham NHS Foundat | general | 603<br><br>5 | 37<br><br>19-22 | Could the GDG confirm that "psychological therapies" as part of multimodal treatment packages can be undertaken within a therapy led service (e.g. Cognitive behavioural informed physiotherapy) as opposed to conducted by a psychologist/ cognitive behavioural therapist. | Thank you for your comment. Psychological therapies should be offered by an appropriately trained specialist. |

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| ion Trust | | | | | |
| University Hospitals Birmingham NHS Foundation Trust | general | 671<br><br>7 | "Other considerations"<br><br>1-5 | CG173 (Neuropathic pain- pharmacological management) is referenced within Pharmacology section "other considerations" (Full, version 1) but not within recommendations or short version. Clinicians comment that patients presenting for possible spinal surgery with sciatica have often not fully explored such analgesia and this may be overlooked. Could key points from CG173 be included within this new guideline or clear reference be included within the guideline recommendations. | Thank you for your comment. We have now added a recommendation to cross-refer to CG173 for the pharmacological management of sciatica. |
| University Hospitals Birmingham NHS Foundation Trust | Short | 7 | 25-26 | The guidelines state that epidural injections should not be used for neurogenic claudication in people who have spinal canal stenosis. Although not utilised for treatment purposes within our Trust, could the GDG comment on the use of epidural injection for diagnostic purposes; for example, to inform differential diagnosis if there is ambiguity regarding neurogenic claudication versus vascular diagnosis, if the patient is unsure whether they wish to proceed with surgery or to gauge the likely effect of surgery/ prognosis. | Thank you for your comment. The GDG did not evaluate evidence for any injection procedure as a diagnostic intervention, and therefore cannot comment on the use of epidural injection for diagnostic purposes. |
| University Hospitals Birmingham NHS Foundation Trust | Short | 7 | 25-26 | The guideline has stated that a caudal epidural can be used for disc bulge but not canal stenosis. Further clarification to aid implementation is called for | The recommendation is for epidurals to be considered in acute sciatica which may be caused by disc prolapse but also by degenerative stenosis. The recommendation for spinal stenosis refers to the symptoms of neurogenic claudication. |
| University Hospitals Birming | Short | 8 | Line 12-13 | Whilst we recognise that there is no place for spinal fusion surgery in the management of non-specific lower back pain, could the GDG comment on specific lower back conditions for which spinal fusion could still be considered, for example, | Thank you for your comment. Section 27.6 (Recommendations and link to evidence, 'Other considerations paragraph') states that the GDG acknowledged there were causes of low back pain for which spinal fusion might be an appropriate |

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| ham NHS Foundation Trust | | | | spondylolisthesis. Such omission creates the impression that there is no place for spinal fusion surgery at all. | treatment. These causes of low back pain, including spondylolisthesis, are beyond the scope of this guideline and the GDG was unable to comment on them. However the reviewed evidence for non-specific low back pain showed that potential harms outweighed potential benefits and for this reason spinal fusion was recommended only in the context of a randomised controlled trial in this population. |
| University of York | Full 1 | 229 | Table 76 | EXERCISE<br>In Table 76, there is an error relating to the top entry: "With sciatica – Pain (VAS 0-10) ≤ 4 months". This is a single trial also reported in Appendix K on Page 60, Figure 219, Albert 2012, which has incorrectly stated the mean scores. From the original paper, Pain (VAS 0 -10 and ≤ 4 months) mean and standard deviation are actually 1.5 (SD=2.1) and 2.3 (SD=2.7) for exercise vs. sham respectively, with p=0.06 for the difference between groups. This will affect the GRADE, as no there is no longer statistical significance. | Thank you for your comment. Following discussion with the GDG, this study has now been excluded from the review due to the sham arm being another form of exercise and therefore did not meet the review protocol. There is no longer any evidence in the review for the comparison between exercise and sham exercise. |
| University of York | Full 1 | 297 | 27 | EXERCISE<br>The GDG states that, "In people with low back pain and sciatica a clinical benefit of biomechanical exercise compared with placebo for pain intensity was demonstrated in evidence from 1 study at ≤4 months (low quality; n=170) but not at > 4 months (moderate quality; n=170)." This statement refers to a trial, Albert 2012, which has data incorrectly stated the mean group scores for ≤ 4 months, (Appendix K, page 60, Figure 219). From the original paper, the mean pain scores (VAS 0-10 and at ≤ 4 months) and standard deviations are actually 1.5 (SD=2.1) and 2.3 (SD=2.7) for exercise vs. sham respectively. This difference is no longer statistically significant, as the original paper quotes a p-value of 0.06 for the difference between groups. | Thank you for your comment. Following discussion with the GDG, this study has now been excluded from the review due to the sham arm being another form of exercise and therefore did not meet the review protocol. |
| University of York | Full 1 | 303 | 7 | EXERCISE<br>The GDG states that, "The only sham-controlled evidence identified for this review was for biomechanical exercise, 1 | Thank you for your comment. Following discussion with the GDG, the Albert (2012) study has now been excluded from the review due to the sham arm being |

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| | | | | study of individual exercise and 1 study of groups in people with low back pain and sciatica reported benefits in favour of exercise." However neither study showed statistically significant differences, the first (Albert 2012) because of an error in data entry, which needs to be corrected as per the original paper, which reported a non-significant difference over the short term (P<0.06). The Albert 2012 also shows sham exercise outperforming true exercise for the period > 4 months. | another form of exercise and therefore does not meet the review protocol. Furthermore, the Smith (2001) study has been moved to the self-management review after a reconsideration of the interventions. The LETR has been updated to reflect these changes and we apologise for the error in classification and reporting. |
| University of York | Full 1 | 303 | 7 | EXERCISE<br>In the Trade-off between clinical benefits and harms, The GDG noted, "that there was some evidence of benefit for all exercise types compared to sham." The very limited evidence described does rely on the only largish trial (Albert 2012, n=170), however this has had short term data incorrectly entered, and sham outperforms exercise over the longer term (>4months). The remaining trials are very small trials, which does show one comparison of exercise vs. sham as being statistically significant, but all trials have a high or very high risk of bias, and all analyses but one are LOW GRADE. | Thank you for your comment. . Following discussion with the GDG, the Albert (2012) study has now been excluded from the review due to the sham arm being another form of exercise and therefore does not meet the review protocol. The LETR has been updated to reflect that there is now no evidence for exercise compared to sham. However, the GDG considered that in the absence of any evidence of exercise compared to sham, and the difficulties associated with creating a sham exercise intervention, that the evidence of benefit compared to usual care and other interventions still justified a recommendation for exercise. |
| University of York | Full 1 | 491 | general | ACUPUNCTURE<br>The GDG states, "There was also no clinical difference demonstrated for function using a range of measures (very low to high quality; 4 studies; total n = 717)." Actually based on the large Haake 2007 trial, for example, analyses of functional change is statistically significant for 749 patients over ≤4 months (Figure 677) and also for 753 patients > 4 months (Appendix K, Page 155, Figures 677 and 678 respectively). Note that Figure 678 incorrectly provides the wrong sign to the Haake trial, as its result is a positive one, not negative as reported, so this should be corrected here and elsewhere. This is another example of when data is corrected in studies that are sufficiently powered, there is clear support that acupuncture outperforms placebo/sham. | Thank you for your comment. The data for function outcomes has been checked again and amended made to the Brinkhaus 2006 data. The data for Leibing 2002 was accurately reported as change scores and therefore no changes were made for this study. The GDG have revisited this updated evidence and concluded that the evidence still does not indicate a clinical benefit of acupuncture over sham. |

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| University of York | Full 1 | 491 | 26-28 | ACUPUNCTURE<br>The GDG states, "Similarly, high quality evidence showed no clinically significant difference (vs. sham) for pain severity in both the short and long term (7 studies, n = 1359; and 4 studies, n = 1159 respectively)." This is somewhat ambiguous, as there are statistically significant differences for both short and long term, which is proof of principle that acupuncture is more than the sham controls. While the current draft shows that neither is reaching the MCID of 1.0 (on the VAS 0-10 scale), an error in the short term meta-analysis (Appendix K, Page 153, Figure 667 - the Brinkhaus trial has been incorrectly reversed in its effect), when corrected, shows a difference: -1.03, (95%CI: -1.53 to -0.54)], which is greater than the MCID of 1.0. This is a reversal of key data, which can be taken into account when the GDG consider revisions to the Draft. | Thank you for your comment. None of the pain severity outcomes reach clinical benefit based on the MID of 1 for the VAS scale (0-10). The data included within the meta-analysis in figure 667 has been checked again, the data from Brinkhaus 2006 has been amended. However, the revised meta-analysis still does not reach clinical benefit with a mean difference of -0.80. Statistical significance is not used to determine clinical importance of an effect size as this relates only to whether a difference is due to chance or not. This is consistent with best practice guideline methodology. |
| University of York | Full 1 | 492 | 20-22 | ACUPUNCTURE<br>For a *Mixed population (with or without sciatica)* the trial referred to is the Thomas trial of acupuncture for low back pain (Thomas et al BMJ, 2006). The Draft has not reported the trial showed clinically relevant and statistically significant (P=0.003) improvements at two years post randomisation, as well as good evidence of cost-effectiveness (Ratcliffe et al BMJ 2006). This trial was set in primary care in the UK which means that data from this trial is highly relevant to the GDG's interpretation of the longer term data on acupuncture vs. usual care. | Thank you for your comment. The data extracted for this trial is at the time-point of 12 months as specified in the protocol. It was agreed a priori by the GDG that where multiple longer term (greater than 4 months) time points are reported, those closest to 12 months will be extracted consistently across reviews. |
| University of York | Full 1 | 493 | 7 | ACUPUNCTURE<br>The GDG's statement regarding "the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects" needs to be applied equitably across all the reviewed interventions. As has been documented above, the evidence on acupuncture vs. sham/placebo is as good as or even better than several of the recommended interventions vs. sham/placebo, including | The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they are not feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or |

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| | | | | exercise, manual therapy, psychological therapies and epidurals for sciatica. | usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to first demonstrate a treatment effect separate from the non-specific treatment effects. |
| University of York | Full 1 | 493 | 7 | ACUPUNCTURE<br>In the Trade-off section, Acupuncture versus placebo/sham in low back pain without sciatica, the GDG states, " For the placebo/sham -controlled evidence in the low back pain population, the GDG agreed that no clinical benefit was seen for pain or function."<br><br>15A) The Draft's evidence on longer term benefits (> 4 months) of acupuncture vs. sham is provided by a meta-analysis of four trials with 1159 patients shows acupuncture is statistically significantly reduces pain compared to sham [-0.33, (95%CI: -0.60 to -0.06)].(Page 153, Line 720, Figure 668). In terms of the quality of this evidence, this meta-analysis is defined as HIGH GRADE (Page 472), which by definition means that "Further research is very unlikely to change our confidence in the estimate of effect". (Page 50, Line 7)<br><br>15B) For short term reductions in pain (≤ 4 months), the acupuncture is again statistically significantly better than sham (Page 153, Line 719, Figure 667). However the Brinkhaus 2006 trial in this Figure is incorrectly signed (the sign should be switched to show a positive effect), a re-analysis will find that not only is the difference between acupuncture and sham that is statistically significant, it also exceeds the minimum clinical difference of one point [new analysis: -1.03, (95%CI: -1.53 to -0.54)] . This correction will also improve the quality of the evidence as defined by the GRADE. None of the other therapies mentioned above that are recommended by NICE provide such strong evidence of specific intervention effects over and above contextual or placebo effects. | Thank you for your comment. To determine clinical benefit the GDG agreed that the mean difference needs to reach the MID of 1 on a 10 point VAS scale, therefore -0.33 would not be considered clinically beneficial. Figure 667 has been checked and amended for data taken from Brinkhaus 2006, however the mean difference is -0.80, therefore not showing clinical benefit. |

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| University of York | Full 1 | 494 | 7 | ACUPUNCTURE<br>For the section, Acupuncture versus usual care (or waiting list) in low back pain without sciatica and in low back pain with or without sciatica (mixed population) The GDG states that, "Benefit was also observed in pain and function at ≤4 months, identified from a large body of evidence. The benefits for pain were not sustained beyond 4 months." This is not correct from the actual evidence, as the Thomas trial (published in the BMJ in 2006), found statistically significant (P<0.003) and clinically relevant benefits of acupuncture vs. usual care at 24 months. Moreover this trial was set in primary care in the UK, and provided evidence that acupuncture is highly cost-effective (Ratcliffe et al 2006). | Thank you for your comment. The data extracted for Thomas 2006 was at 12 months. It was agreed a priori by the GDG that where multiple longer term (greater than 4 months) time points are reported, those closest to 12 months will be extracted, as stated in the protocol. Therefore the data for 24 months wasn't included in this review. |
| University of York | Full 1 | 495 | 7 | ACUPUNCTURE<br>In the Trade-off between net clinical effects and costs, the GDG noted that, "there was insufficient evidence of an overall treatment-specific effect to support a recommendation for acupuncture" and in the Summary, "there was still not compelling and consistent evidence of a treatment-specific effect for acupuncture."<br><br>17A) However there is better evidence on acupuncture vs sham than several of the interventions recommended in the draft. There is proof of principle that acupuncture vs. sham has statistically significant and clinically relevant reductions in pain over the short term (≤ 4 months) (Appendix K, Figure 667), and statistically significant benefits are also observed over the longer term (> 4 months) (Appendix K, Figure 668), a level of benefits not achieved by the other interventions. [The clinical relevance of the pain data for ≤ 4 months in the comparison of acupuncture vs. sham only becomes apparent on a re-analysis, as the Draft inadvertently is in error for one of the trials – Brinkhaus et al 2006 – which has been incorrectly entered, see Appendix K, Figure 667), and when correctly entered and re-analysed will show a clinically relevant improvement in pain with a MCID > 1.0 on a VAS | Thank you for your comment. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly.<br>The GDG determined clinical significance based on MIDs rather than statistical significance (please see chapter 4 for more detail on this). The error mentioned for Brinkhaus 2006 in forest plot 667 has been amended and the GDG have reviewed the amended meta-analysis. Since the mean difference is now 0.8, it still doesn't meet the MID of 1 to achieve clinical significance.<br>All other errors mentioned have been checked and amendments made where necessary. However the GDG observed that the evidence was still conflicting for acupuncture versus sham, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up. |

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| | | | | scale of 0-10.] Many other errors relating to the acupuncture data are identified below, all of which when corrected will show acupuncture in an improved light.<br><br>17B) It should be noted that a number of statistically significant effects for acupuncture vs. sham/placebo are reported over the longer term, see Appendix K, including Fig 668 (pain), Figure 692 (quality of life), Figure 693 (quality of life, physical component), Figure 695 (pain), Figure 699 (function), Figure 702 (function), Figure 705 (psychological distress).<br><br>17C) The main reason for the inconsistency across all therapies is the small sample sizes of included trials. This is an inherent problem across the field of low back pain research. Furthermore, some of the inconsistency has occurred as a result of errors in the Draft (see elsewhere for details), which when corrected will be found to reduce the inconsistency, especially for the sham/placebo comparisons. When taking into account that most studies in this Draft are underpowered, it is the acupuncture-related meta-analyses that stand out as providing higher quality data with larger sample sizes, and where sufficiently well powered, statistically significant benefits beyond placebo effects.<br><br>17D) The difference between acupuncture and sham has also been shown in the most rigorous of independent studies (Vickers AJ, et al. Arch Intern Med. 2012;172:1444–53 and Vickers AJ & Linde K. JAMA. 2014;311:955–6) in which an individual meta-analysis of only high quality trials of acupuncture for chronic pain, including back pain, found statistically significant differences in outcome between acupuncture and sham (P<0.001), differences that could not be ascribed to bias. | The Vickers IPD meta-analysis was not included in the original review due to it pooling populations with low back pain with/without sciatica and low back pain only, as well as pooling across time points. However, we admit that the data for the relevant studies could have been extracted and used in the meta-analysis. We have subsequently undertaken a sensitivity analysis to demonstrate the difference in the review had the data from the IPD meta-analysis been used. This is presented alongside the forest plots in sections K.9.1 and K.9.2, demonstrating no difference to the conclusions made. |

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| University of York | Full 1 | 496 | 7 | ACUPUNCTURE<br>The GDG states that, "The evidence for pain and function was informed by several studies and substantial heterogeneity was observed in the meta-analyses." This is not always true, as a number of meta-analyses had $I^2$ of 0%, including analyses comparing acupuncture with sham/placebo for which there were statistically significant differences, as shown for example in Appendix K, Figure 662 (quality of life), Figure 668 (pain), and Figure 673 (function). | Thank you for your comment. This statement has been changed to 'The evidence for pain and function was informed by several studies with a number of meta-analyses showing substantial heterogeneity.' |
| University of York | Full 1 | 496 | 7 | ACUPUNCTURE<br>The GDG considered "that other treatments reviewed in the guideline had specific and clinically important treatment effects, beyond contextual effects, although acknowledged that for treatments where no sham comparison was available it was not possible to distinguish specific and non-specific effects."<br><br>Taking the evidence equally into account for each intervention reviewed in the Draft, acupuncture performs at least as well if not better than many others, including exercise, manual therapies, psychological therapies and epidurals for sciatica. For example,<br>• the total number of trials, total participants and mean number of participants for acupuncture vs. sham are documented as 11 trials, 1971 participants and mean of 179, whereas exercise vs sham comprise of 5 trials, 374 patients, and mean of 75, manual therapy vs sham comprise of 7 trials, 697 patients, and mean of 97 for epidurals for sciatica vs sham comprise of 4 trials, 443 patients, and mean of 111;<br>• of the 11 trials of acupuncture, 7 are assed as "low risk of bias", none of the five trials of exercise vs. sham are "low risk", two out seven manual therapy trials are "low risk", and none of the epidurals for sciatic are "low risk";<br>• a summation of quality of evidence GRADE scores, when comparing acupuncture vs. sham, 16 out of 48 meta- | Thank you for your comment. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Unlike acupuncture where a sham intervention is possible, the GDG agreed it is much harder to achieve this for exercise. On revisiting the 'sham exercise' evidence that was included in the draft guidance, the GDG agreed that none of the included sham interventions could be considered as true forms of 'sham exercise' (one was a psychological therapy and the other was an alternate form of exercise), therefore these have now moved to another comparison or excluded as appropriate according to the review protocol. Therefore the revised guideline will no longer have any evidence for exercise versus sham. Consequently, the GDG have had to base their decision on the evidence against usual care in the absence of a reliable sham (following standard methodology).<br>The GDG agreed that there was not enough evidence from the reviews of the interventions offered in isolation for either manual therapies or psychological therapies to base a recommendation on (consistent with acupuncture). However there was additional evidence for each of these interventions in |

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| | | | | analyses are assessed as HIGH GRADE, whereas none of the 5 meta-analyses of exercise vs. sham are HIGH GRADE, for manual therapy vs sham 4 out of 19 are HIGH GRADE, and none of the epidurals for sciatica vs sham. | combination and from the review of 'MBR' interventions which provided enough evidence to warrant these interventions to be considered only as part of a package of treatment. The combinations reviewed did not support the same recommendation to be made for acupuncture.<br>When reviewing the evidence for epidural injections the GDG was able to identify a subset of people in whom epidurals showed clinical benefit; people with acute sciatica, whereas this was not possible from the acupuncture evidence review. Therefore the recommendation made for epidural injections is for this subset of people with sciatica only. Furthermore, the GDG were mindful of the limited availability of treatment options for people with acute severe sciatica. |
| University of York | Full 1 | 496 | 7 | ACUPUNCTURE<br>The GDG "noted the lack of effect of acupuncture on pain outcomes in the sham-controlled trials". However as has been documented in this set of Comments, there is more evidence for acupuncture on pain outcomes than has been shown for other interventions. There is indeed some inconsistency, which can largely be explained by the small sample sizes in many sham-controlled acupuncture trials. However inconsistency is problematic for most of the interventions that are recommended in this Draft. | Thank you for your comment. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different which impacts the decisions made by the GDG. Where evidence reviews lack sham comparisons because they aren't feasible (e.g. see the updated evidence in chapter 9), the GDG has had to make decisions of clinical effectiveness accordingly. |
| University of York | Full 1 | 496 | 7 | ACUPUNCTURE<br>The GDG "discussed whether the passive nature of acupuncture treatment might promote dependence on the procedure or possibly discourage self-management or participation in activity and exercise." This line of reasoning has been countered by the ATLAS trial (MacPherson et al, Annals of Internal Medicine, 2015) which found that self-efficacy at 6 months was significantly improved in patients in the acupuncture arm compared to those in the usual care arm, and that increased self-efficacy was associated with | Thank you for your comment. The issue of possible dependence of acupuncture has now been removed from the guideline. |

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| | | | | statistically significant reductions in chronic neck pain at 6 months and 12 months. | |
| University of York | Full 1 | 496 | 7 | ACUPUNCTURE<br>For the GDG, "The majority view of the group was to recommend 'do not offer' acupuncture". From an evidence-based point of view that takes into account the errors documented above and below, and applying a consistent interpretation across interventions, the GDG would be justified in revising its majority view and consider a recommendation of acupuncture. The rationale is that not only is there substantial evidence that acupuncture outperforms a sham/placebo (when the appropriate and sufficiently powered evidence is aggregated) but also there is sufficient evidence on acupuncture vs. usual care along with cost-effectiveness data relevant to primary care in the UK. A principle underlying evidence based medicine is to provide a fair comparison between interventions, and if operated with respect to acupuncture, would lead to the GDG to be justified in considering a recommendation of acupuncture for low back pain. | Thank you for your comment. Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. However the GDG observed that the evidence was still conflicting for acupuncture versus sham, with some small effects seen for SF-36, HADS, healthcare utilisation and responder criteria outcomes, which were not maintained in long term follow-up which resulted in the GDG leaving the recommendation unchanged.<br>The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to first demonstrate a treatment effect separate from the non-specific treatment effects. |
| University of York | Full 1 | 601 | 20-22 | COMBINED PHYSICAL AND PSYCHOLOGICAL PROGRAMMES<br>The GDG states that, "no clinical benefit was observed for people with low back pain with / without sciatica when cognitive behavioural approaches was compared to sham or usual care or waiting list controls for the majority of reported outcomes" The recommendation of combined physical and psychological programmes is therefore in marked contrast to the expectation of the GDG that an intervention should demonstrate evidence beyond context effects, given the | Thank you for your comment. The GDG placed more weight on the comparison between an intervention and placebo/sham whenever a placebo/sham was available and it was feasible to do so.<br><br>In the case of psychological therapies, we agree there was no evidence of benefit for cognitive behavioural approaches compared to sham, usual care or waiting list controls except for one function outcome and therefore insufficient evidence to |

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| | | | | GDG's point regarding "the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects."(Page 493, Line 7) | recommend psychological therapies as a treatment in isolation. However the GDG discussed that cognitive behavioural approaches are unlikely to be provided in isolation and that the improvement of pain and function are not primary aims of this type of interventions. Evidence from their use in combination with other treatments, and from the review of multidisciplinary biopsychosocial rehabilitation programmes informed a recommendation to consider psychological therapies only as part of a package of treatment.<br><br>The review of multidisciplinary biopsychosocial rehabilitation programmes informed the recommendation for combined physical and psychological programmes (CPP). The GDG agreed a sham was not feasible for such a complex intervention. The GDG had therefore to base the recommendation on the best evidence available. Although the GDG acknowledged that the evidence was mixed, the GDG felt that CPP should be recommended on the basis of CPP showing benefit over waiting list, single and combined interventions, alongside evidence from single intervention chapters. |
| University of York | Full 1 | 736 | 1 | COMBINED PHYSICAL AND PSYCHOLOGICAL PROGRAMMES<br>The GDG has noted, "that there was very little evidence for usual care comparisons (with combined physical and psychological programmes) and no studies were identified that could be classified as a placebo/sham comparison." The GDG previously stated that the Draft has taken a view "equally across interventions reviewed in this guideline."(Full version, Part 1, page 494) Therefore for consistency, the evidence for combined physical and psychological programmes can usefully be compared to acupuncture, and | Thank you for your comment. The GDG placed more weight on the comparison between an intervention and placebo/sham whenever a placebo/sham was available and it was feasible to do so.<br><br>In the case of combined physical and psychological programmes (CPP) the GDG agreed a sham was not feasible. The GDG had therefore to base the recommendation on the best evidence available. Although the GDG acknowledged that the evidence was mixed, the GDG felt that CPP should be |

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| | | | | the rationale for not recommending acupuncture can be reviewed. | recommended on the basis of CPP showing benefit over waiting list, single and combined interventions, alongside evidence from single intervention chapters and economic evidence.<br><br>In the case of psychological therapies, there was no evidence of benefit for cognitive behavioural approaches compared to sham, usual care or waiting list controls except for one function outcome and therefore insufficient evidence to recommend psychological therapies as a treatment in isolation. However evidence from its use in combination and the MBR chapter supported the recommendation of psychological therapies to be offered as part of a treatment package including exercise, with or without manual therapy. This is detailed in section 15.7 Recommendations and link to evidence. |
| University of York | general | general | general | It is noted that an unexpected large number of errors have been found in the acupuncture section, and all found so far have that have been re-analysed suggest a strengthening of the evidence base in support of a positive recommendation on acupuncture for low back pain. | Thank you for your comment. Amendments to the acupuncture evidence review have been made and the GDG has reviewed the updated evidence. Where the suggested errors were lack of understanding of the analysis methods, we have provided explanations to clarify. However, the GDG observed that the evidence was still conflicting for acupuncture versus sham, with only small effects seen for a few outcomes, which were not maintained in long term follow-up. Therefore it was agreed that there was no consistent evidence of benefit compared to sham to recommend acupuncture. |
| Warwick Clinical Trials Unit | Full 1 | 19 | 12 - 18 | The guideline identifies the importance of red flags for screening for serious causes of back pain. Whilst how to screen out serious causes is out of scope the GDG should be aware that a systematic review of red flags for malignancy and fracture suggest that these are largely uninformative. | Thank you for your comment. We have added the reference of the report referred to in appendix P. |

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| | | | | Downie A, Williams CM, Henschke N, Hancock MJ, Ostelo RW, de Vet HC, Macaskill P, Irwig L, van Tulder MW, Koes BW, Maher CG. Red flags to screen for malignancy and fracture in patients with low back pain: systematic review BMJ. 2013 Dec 11;347:f7095. doi: 10.1136/bmj.f7095.<br><br>Here the reader is directed to Appendix P for a list of red flags. Appendix P actually reproduces a guide to appropriate referral to specialist services produced by NICE in 2001. We have been unable to locate this on the NICE website and confirm if it has been reviewed since then. It is not listed on page 21 as part of related NICE guidance.<br><br>We have concerns that this guidance may no longer be valid; and at the very least it needs to be easily accessible on the NICE website so people can appraise quality of the guidance. The GDG might here wish to consider a link to more recent NICE guidance on the recognition of, and referral for, suspected cancer. https://www.nice.org.uk/guidance/ng12 | |
| Warwick Clinical Trials Unit | Full 1 | 20 | 26 | Reference 200 appears to relate to a study on red flags rather than supporting anything in the previous sentence. | Thank you for your comment. This was a typing error that has now been corrected. |
| Warwick Clinical Trials Unit | Full 1 | 41 | 23-25 | We are concerned that a general view has been taken to assess outcomes using just two times points; closest to four months and closest to one year<br><br>Using a four month time window for assessing outcome for trials of treatments for acute low back pain is essentially meaningless. It is much shorter term outcomes that will be of direct patient relevance; except for those intervention focussed on prevention of disability. The GDG does not seem to have put themselves in a position appraise the potential short term benefits of a range of treatments for people with acute low back pain. | Thank you for your comment. We acknowledge that the choice of what time point to report outcomes at may lead to differences in the overall conclusions. For this reason when setting the protocols, the GDG agreed that two time points would be considered rather than one, to capture short and long term effects. Time points reported have to be limited in order to enable the review to be manageable and interpretable across interventions. Therefore the GDG agreed that <4 months and 1 year were the most appropriate for the majority of reviews. For questions where longer term follow-up was considered important to capture, outcomes were also |

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| | | | | For interventional procedures for chronic pain this approach can lead to the problem that if only immediate post-procedure values are available these may interpreted as indicating results at four months.<br><br>There is a further fundamental problem for both acute and chronic pain when considering pharmacological treatments for relief of pain symptoms. It is, in fact the short term data that may be most relevant to advising patients whether taking a few pain killers for their back pain is worthwhile – not the long term data on what happens if these drugs are taken for prolonged periods. | considered at later time points (e.g. reviews of surgical interventions).<br>Where outcomes were only reported at less than 4 months (e.g some of the pharmacological interventions) these were included <4 month time point and the actual time reported was noted in the evidence tables so that shorter follow-ups were captured as relevant. Therefore the GDG considered that short term benefits of treatments, where appropriate, were captured. The GDG also felt that it was important to note whether effects were maintained in the long term. When setting the protocol, they therefore considered that longer term follow-up data was still important to capture if available. However, all the evidence reviewed in the Pharmacological treatment chapter reported outcomes at ≤ 4 months.<br>When setting the protocols, it was also agreed that there was no reason to believe acute and chronic low back pain should be treated differently. Therefore these populations were pooled for analysis and only analysed separately if heterogeneity was observed in the data which may have been explained by duration of pain. If all evidence was for one of these subgroups that was also considered in the recommendations. |
| Warwick Clinical Trials Unit | Full 1 | 370 | 1 | The UK BEAM trial has been included as evidence in the combination manual therapy adjunct (Table 158), but not in the exercise therapy adjunct. First, it is not clear why manual therapy as an adjunct has been considered, but exercise therapy as an adjunct has not (this is inconsistent). Moreover, it is not clear why one arm of the UK BEAM has been deemed suitable (combined exercise and manipulation), whilst the exercise arm has not. In all three arms, the interventions were adjuncts to best usual care. In the questions on exercise the UK BEAM trial is listed neither in included nor excluded studies. Given the size and quality of | Thank you for your comment. The exercise adjunct arms of the UK BEAM trial have now been added to the exercise review. |

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| | | | | UK BEAM, including it under these questions may have changed conclusions and so why it was omitted needs to be clear. | |
| Warwick Clinical Trials Unit | Full 1 | 452 | 12 | Recommendation 12 suggests the use of manual therapy techniques only as part of a multi-modal package. So far as we can see in the guidance what constitutes a multi-modal package of care is not described; nor was the evidence for such packages appraised. For this recommendation to be helpful, the GDG needs to spell out the composition of the multi-modal intervention that is recommended. This needs to include indications of both content and dose of these interventions. The dose delivered is important as the best data showing a positive effect from manual therapy from RCTs with substantially more than the six sessions of physiotherapy care typically available from the NHS. To recommend an inadequate dose of manipulation, mobilisation or soft tissue techniques will mean that patients may fail to gain any of the potential benefits from this treatment approach. It should be noted here that the effects sizes found in trials of manual therapy are, at best, modest. The 2011 Cochrane review of spinal manipulative therapy for chronic LBP, for example, estimated the SMD for a short term effect to be 0.22 (95% CI 0.07 to 0.36). This is far below the threshold of an SMD of 0.5 specified in the methods for this guideline. The GDG do not appear to have explained why they have chosen to use a lower threshold here for recommending treatment.<br><br>We note that the GDG have not taken the opportunity to identify systematic reviews of adverse events from manual treatment and thus are simply relying on their opinion when considering the potential risk of this treatment approach. It is unacceptable for the GDG to use their awareness of case reports of serious adverse events as a basis for recommendation. We agree that risk of adverse events needs to be considered for all interventions. The appropriate source for data on this subject would be a systematic review | Thank you for your comment. The term 'multi modal' has now been changed following stakeholder feedback. Therefore the revised recommendation now reads: consider manual therapy for managing non-specific low back pain with or without sciatica, but only as part of a treatment package including exercise with or without psychological therapy, where manual therapy is defined as manipulation, mobilisation or soft tissue techniques, for example massage.<br>The GDG was unable to recommend a specific dose of the intervention from the evidence examined in the review.<br><br>Regarding adverse events, the GDG considered those reported in the trials included in the review. Adverse events were common, minor and transient. They mainly consisted of muscle soreness for a few days after treatment. Furthermore, none of the studies included in the review reported serious events attributable to manual therapy. Although we are unable within the resources of the guideline to undertake additional reviews for adverse events for each intervention, GDG clinical expertise is also used to inform on this aspect. The GDG were aware of serious but very rare adverse events that may be related to spinal manipulation and this was taken into account in writing the recommendation. The paper by Carnes et al was not included in the review because the population was not restricted to people with low back pain and sciatica in the trials included.<br><br>We recognise that the evidence does not support manual therapy alone as superior to sham. Therefore |

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| | | | | of observational studies. See, for example, Carnes et al Adverse events in manual therapy: a systematic review. Manual therapy 2010; 15: 355-363 that gives numeric estimates for the incidence of serious adverse events from both observational studies and RCTs.<br><br>We consider there is an inconsistency in how the evidence has been interpreted here. The evidence presented supports the hypothesis that manual therapy can be superior to usual care. It does not, however, support the hypothesis that it is superior to sham therapy. If, as the GDG opine elsewhere that therapist delivered interventions need to be shown to be superior to sham (which would require a change in the wording of the research question) to be recommended then they should not be recommending manual therapy. | the GDG made a recommendation for manual therapy only when part of a treatment package of exercise with or without psychological therapy which was informed by evidence from manual therapies used in combination with other treatments, and also evidence within the review of multidisciplinary biopsychosocial interventions. |
| Warwick Clinical Trials Unit | Full 1 | 603 | 37 | Recommendation 18 suggests the use of psychological therapies only as part of a multi-modal package. So far as we can see in the guidance what constitutes a multi-modal package of care is not described; nor the evidence for such packages appraised. For this recommendation to be helpful the GDG needs to spell out what a multi-modal intervention would consist of. This needs to include indications of style, content and dose. Delivering an ineffective psychological intervention, or a watered down version of a proven intervention may well not achieve the beneficial effects the GDG are hoping for.<br><br>We note here our conflict in that one of the key papers referred to be GDG was a study done at this unit of a particular group intervention package that would not lend itself to being subsumed into an unspecified 'multi-modal intervention'.<br><br>We are most disappointed that GDG did not find the data from this trial (Lamb 2010), conducted in the UK sufficiently persuasive to suggest that this intervention should be | Thank you for your comment. Recommendation 1.2.13 has now been reworded to clarify and the term 'multi-modal' is no longer used. The recommendation now reads as follows: Consider psychological therapies using a cognitive behavioural approach for managing non-specific low back pain with or without sciatica but only part of a treatment package including exercise with or without manual therapy Regarding the Lamb trial (Lamb 2010b), it was not possible to include outcomes at 3 years as it was agreed at protocol stage that outcomes would be reported at up to 4 months and at 1 year. These were agreed as appropriate timepoints to assess effectiveness of interventions. Evidence from this study has been considered and it did not show clinical benefit to a change in pain and function. The improvement in terms of quality of life (SF-12 physical and EQ-5D in the short and longer term) was noted by the GDG. |

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| | | | | considered as an option. It has shown clear benefits on pain, function and quality of life at four and 12 months and the within trial cost-utility analysis shows that represents good value for money. Furthermore, although not included in the data extractions here it has effects sustained for up to three years. It is an intervention that would be easily deliverable in the NHS. We request that the GDG re-visit their discussion on this paper and consider if this a treatment option, delivered as designed, they would people living with back pain.<br><br>We note again here that there is some evidence for effectiveness of psychological interventions but little for their efficacy. It is not possible from the data presented to separate the contextual effects related to the intervention, including group effects from the actual effect of the modality being tested. | Effectiveness is used here as a broad term to include efficacy and we will clarify this in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). We agree that without evidence against sham it is not possible to separate intervention effect from the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. However, as discussed the recommendations are based on the best evidence available for each intervention, and on this basis it was agreed there is not sufficient evidence to recommend psychological therapies as an intervention in isolation of other treatments. |
| Warwick Clinical Trials Unit | Full 1 | 666 | 34 | Recommendation 24. We were surprised by the recommendation to consider weak opioids (with our without paracetamol) for managing acute non-specific low back pain. The GDG agreed that the efficacy of opioid for low back pain could not be determined. They then proceed to offer this as an option based on a paper by Innes where they conclude that a paracetamol/codeine combination is equivalent to ketorolac. It is not possible to conclude equivalence from this study that was designed as a superiority study. The data in the Forest plot no 948 are the differences in pain scores six hours after an initial dose of study medications. As described in the paper the pain scores improved substantially in both groups with the effects peaking around 2.5 hours. It is highly likely that there will have been little or no actual analgesic effect from either preparation at six hours. Whilst no statistically significant differences were seen in any of the short term outcomes, this study was not designed to show equivalence and cannot be interpreted as such. For this conclusion to be drawn it is necessary for an equivalence margin to have been pre-specified and a per protocol analysis performed. To conclude equivalence it is necessary to | Thank you for your comment. The GDG were mindful of the limited evidence base for this recommendation, including the limitations of some of the study follow-up time points, however they acknowledged the need for a treatment option for the subset of people who are unable to take NSAIDs. The recommendation has therefore been modified to specify this and reads as follows: Where an NSAID is contraindicated, not tolerated or has been ineffective consider weak opioids (with or without paracetamol) for managing acute non-specific low back pain only. |

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| | | | | measure outcomes just on people who are exposed to the intervention. With the six hour outcomes it is likely there is insufficient drug present for any possible effects to be seen. There are some additional data included in the paper on one week outcomes not presented to the GDG. These again show no statistical difference. However, as 16 participants had withdrawn prematurely because of analgesic inefficiency it is not possible to draw any conclusion about equivalence as a per protocol analysis is not provided. We suggest that is recommendation should be withdrawn. Consequentially recommendation 22 should also be removed.<br><br>That this study that provided six hour outcomes that are presented in the data synthesis as four month outcomes illustrates a possibly fatal flaw in the approach used by the GDG to assessing the short term effect on pain of analgesic medications. We suggest that this whole section needs revisiting to ascertain if there are short term benefits to be gained from analgesics. | |
| Warwick Clinical Trials Unit | Full 1 | 667 | | Recommendation 27. Might there be merit in explicitly stating the drug groups of interest here? Or, indeed, subsuming this recommendation into recommendation 26 which then becomes:<br><br>Do not offer selective serotonin reuptake inhibitors, serotonin– norepinephrine reuptake inhibitors, tricyclic antidepressants, or gabapentinoids for managing non-specific low back pain. | Thank you for your comment. The drug classes included when looking at evidence for anticonvulsants were gabapentinoids and other anticonvulsants. However the only available evidence for other anticonvulsants was for topimarate. Therefore the GDG did not develop a more specific recommendation for this area to avoid confusion regarding other anticonvulsants not included in the review. It was thus considered best to have a general recommendation for anticonvulsants. |
| Warwick Clinical Trials Unit | Full 1 | 736 | 1 | Recommendation 29. We consider that this is unclear. It is not clear from the recommendations what physical therapies should be part of the programme. Although explained in linking evidence to recommendations it is also not clear in the recommendations which psychological approaches should be used. As with other therapist delivered interventions there is | Thank you for your comment. Physical interventions reviewed included specific exercise modalities, mobilisation and massage. There was not enough evidence to recommend one type of physical therapy over another, therefore this has not been specified in the recommendation. However, the GDG agreed that |

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| | | | | a need to specify dose. A brief intervention is unlikely to achieve the effect sought and so an indication of minimum dose delivered is needed. | any physical interventions should be tailored to the individual.<br><br>Regarding the preference for cognitive behavioural approaches, the GDG noted that most of the evidence for the psychological component of the programmes included a cognitive behavioural approach. Evidence in favour of CBA was also included the combination section of the psychological therapies review. The wording of the recommendation has now been edited to reflect this.<br><br>Regarding the dose of the intervention, the GDG acknowledged that there was heterogeneity in the intensity of interventions where clinical benefits were observed. It was not possible to conclude the most appropriate dose or frequency of intervention sessions. The GDG agreed that the dose of the intervention should be decided individually and progress should be carefully reviewed. |
| Warwick Clinical Trials Unit | Full 1 | 764 | 5 | Recommendation 29 does not appear to have been included in the algorithm. It needs to be included in Box A. Indeed the whole recommendation could be subsumed into recommendation 1.2.1 on self-management. The two recommendations are overlapping on the need to promote normal activities: becoming<br><br>Provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their non-specific low back pain with or without sciatica, including:<br><br>• information on the nature of non-specific low back pain and sciatica<br>• encouragement to continue with, or return to, normal activities as far as possible | Thank you for your comment, this change has been made in the remodelled algorithm. |

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| | | | | • promotion and facilitation of a return work | |
| Warwick Clinical Trials Unit | Full 2 | 59 | 29 | We suggest that the GDG are clearer on the severity score used to inform consideration of referral. If a visual analogue score is to be used then its bounds and units should be defined. In practice many patients find these difficult to complete and clinicians are poorly equipped to use them. It may sound very basic but it may not always be straightforward to have a correctly laid out 10cm VAS and ruler. We suggest that a score of five or more on an orally delivered numerical rating scale is more practical. This will not be how data were collected within trials; but there is sufficient confusion in the literature on how pain scores are actually collected that this need not be a bar to making pragmatic and practical suggestions on how to assess pain.<br><br>We note on detailed inspection of the model that that inception node is based on a pain score of >4. If what the GDG have in mind here is that a numerical rating scale is used then this maps onto a score of five or more this is not a problem. If however, the model is actually based on a visual analogue score of >4 and people with score of 4.1 to 4.9 have been included then it cannot inform a decision on the use of a score of five more for referral. We are not clear on the justification for cut points of either four or five. This all needs checking and clarifying. | Thank you for your comment. The GDG has considered your suggestion. However, we're unable to be prescriptive about the scale used due to different scales being applied in the trials as the evidence reviewed does not enable this.<br><br>The decision to use >4 was based on the inclusion criteria for the studies included in the review. There were a range of minimal pain levels used as entry requirements, but none were lower than 4. The average was 5, as stated in the LETR. The GDG have agreed for clarity to reword this to 5 or more. |
| Warwick Clinical Trials Unit | Full 2 | 59 | 29 | Recommendation 31. The available data from clinical trials indicate that radiofrequency denervation has promise as an intervention in selected populations. The GDG have highlighted the weakness in the available clinical evidence and in patient selection. On careful examination of the data presented for effect of radiofrequency ablation on pain presented to the GDG we have identified substantial concerns in the analyses and approach to inclusion of data. Our view is that these might have led to the GDG making a recommendation that is not adequately supported by the available data.(see separate comment on Figure 1117). | Thank you for your comment. Following stakeholder feedback, errors in the radiofrequency analysis have been corrected, however did not change the results of the overall analysis.<br>It also did not change the results of the economic model and the base case has remained the same as before. The GDG are aware of the Cochrane review, which although found no high-quality evidence, did in fact find moderate evidence for a large effect size in both short and long term outcomes, when pulse frequency is discounted. Regarding the on-going trial |

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| | | | | Others looking at the same data have not considered the evidence supports the use of radiofrequency denervation. We draw the GDG's attention to a Cochrane review, published after the GDG had drafted their recommendations, concluded.<br>*'The review authors found no high-quality evidence suggesting that RF denervation provides pain relief for patients with CLBP. Similarly, we identified no convincing evidence to show that this treatment improves function'*<br><br>Maas ET, Ostelo RW, Niemisto L, Jousimaa J, Hurri H, Malmivaara A, van Tulder MW. Radiofrequency denervation for chronic low back pain. Cochrane Database Syst Rev. 2015 Oct 23;10:CD008572. doi: 10.1002/14651858.CD008572.pub2.<br><br>In contrast to some other interventions a plausible sham procedure is possible means that any apparent effect is more than just the contextual effect. However, any decision to recommend a care pathway that includes the option of nerve root ablation needs to consider the whole context within which it is delivered. The GDG are clearly of this view as this is the one question for which they requested a new economic model. It is the output of this model that then becomes the driver for a decision to include a recommendation to consider referral for radiotherapy ablation.<br><br>We have concerns about the applicability of the base case model to the question at hand. (see our comments relating to Appendix N). We think that an appropriately defined base case model would produce a cost per QALY of around £18,651. This may be higher since the model had used clinical effectiveness data that may, as presented, be | you highlight, we are unable to include studies that are not yet published so cannot consider this data.<br><br>We have responded to your concerns on the economic model in your comments relating to Appendix N and we have explained there that we do not think the base case of the model should be changed. However we have clarified some additional limitations in the Appendix. |

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| | | | | overestimating the potential clinical effect of radiofrequency denervation.<br><br>The GDG are clearly concerned the evidence for this recommendation is weak. We suggest that clinical data and the economic model need reviewing in light of our concerns and the decision is revisited by the GDG.<br><br>Here we draw the GDG's attention to other interventions they have considered where therapist delivered interventions, compared with usual care, achieve values for a cost per QALY of a small fraction of the cost in this model from within trial analyses. These studies also show effect sizes (compared to usual care) similar to that seen against sham procedures for radiofrequency ablation. The net effect of this recommendation to consider making a referral will, of course be much smaller and only a minority of people will have the opportunity to benefit.<br><br>The GDG have chosen not to give wholehearted support to any of these therapist delivered interventions (except exercise). To choose to support radiofrequency denervation that will achieve a smaller overall clinical effect at a much higher cost per QALY is not sustainable. We also note that the GDG has concerns about the overall costs to the NHS of providing the service. This makes even a cautious 'consider' decision most unwise.<br><br>We are aware of one ongoing trial of radiofrequency treatment running in Holland (ISRCTN17868852). Based on timings of this study it is possible this will provide additional data to inform the final decision on this point | |
| Warwick Clinical Trials Unit | Full 2 | 59 | 29 | Recommendation 32. We support this recommendation; but does it also need to clarify that there is a pain score of five or more on a 0 – 10 numerical rating scale prior to the intervention? | Thank you for your comment. We have considered this, but recommendation 31 specifies that referral for assessment for radiofrequency denervation should be considered for with chronic non-specific low back |

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| | | | | | pain with suspected facet joint pain when non-surgical treatment has not worked for them, and they have moderate or severe levels of back pain (rated as greater than 5 on a visual analogue scale, or equivalent). Therefore, all patients relevant to recommendation 32, having radiofrequency denervation after a positive response to a diagnostic medial branch block, will have already had a pain severity score of 5 or more in order to be referred for treatment. |
| Warwick Clinical Trials Unit | Full 2 | 59 | 29 | There is a pressing need for further research in the role of radiofrequency denervation. Specifically, research is needed to test the overall effectiveness and cost-effectiveness of the model currently proposed here. We urge NICE to request the NIHR HTA programme to prioritise this in its commissioned call. | Thank you for your comment. The following research recommendation has been developed by the GDG for radiofrequency denervation; **'**What is the clinical and cost effectiveness of radiofrequency denervation for chronic low back pain in the long term?' |
| Warwick Clinical Trials Unit | Full 2 | 120 | 24 | Recommendation 33. We have failed to identify how the evidence presented relates to this recommendation. The GDG agreed that the evidence for epidurals was conflicting. They seem to be basing this recommendation on the observation that these might reduce incidence of surgery in people being considered for surgery. This observation may be relevant in a context where surgery is being considered but is not relevant in other circumstances. So far as direct evidence of effectiveness is concerned the most informative part of the data extraction are Figures 1136 and 1137 in appendix K 17. Here the meta-analysis shows a short term effect on pain of steroid plus anaesthetic vs anaesthetic alone is 0.52 (95% CI -1.04 to -0.00) for a transforaminal approach and -0.70 (95% CI -1.33 to 0.07) for a caudal approach when image guided respectively. For long term outcomes these are 0.20 (-0.37 to 0.77) and -0.60 (-1.24, 0.04). For non-image guided compared to placebo Figure 1193 is the most informative. Here the short term effect on pain is -0.19 (95% CI -1.09 to 0.71). In Figures 1205 and 1206 the result for the one included study comparing non image guided steroid + anaesthetic compared to anaesthetic alone where the | Thank you for your comment. The GDG acknowledged that evidence for epidurals is conflicting. However, they noted that clinical benefit was observed against placebo/sham when the local anaesthetic was combined with steroid in people with acute sciatica. The GDG felt there was sufficient evidence to warrant a 'consider' recommendation for epidurals with steroid and local anaesthetic for this subset of people taking into consideration the limited treatment options available for sciatica. Unlike the epidural review, it was not possible to distinguish a subset of people in whom acupuncture showed benefit. Additionally, with the consistently conflicting evidence and the many treatment options available for low back pain, the GDG agreed not to recommend acupuncture in a NHS setting. |

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| | | | | diagnosis was unclear; here effect sizes for short and term leg and back pain were -0.31 ( 95% CI -1.21 to 0.61), - 0.10 (95% -0.93 to 0.73), -0.50 ( (-1.36 to 0.36), and -2.0 (-8.12 to 4.12). In none of these analyses is the effect statistically significant.<br><br>By way of contrast we would draw the GDG's attention to tables 667/8 that present pain scores for effect on pain severity for acupuncture when compared to sham of low back pain on a VAS. For the short term results the effect is -0.80 (95% CI -1.36 to -0.25) and for long term results the effect size is -0.33 (95% CI -0.60 to -0.25). We consider it crucially important that the GDG is consistent in approach to interpretation of the data when they are making their decisions. Failure to do this will lead to this guideline losing face validity and running the risk of reputational harm to NICE. These two decisions appear to be inconsistent.<br><br>The GDG's decision has also been informed by the within trial cost effectiveness analysis in the study reported by Price et al (the clinical paper is Arden et al). We invite the GDG members to read this report for themselves as they may find it informative. An importance weakness of this study is that it relied upon a clinical diagnosis of sciatica rather than there being confirmed radiological evidence of nerve root compression. Although, radiological confirmation may be less important when considering epidural injection than if surgery is being considered. The headline cost per QALY figures are that cost to purchasers were £354,171 per QALY under the trial protocol and £167,145 per QALY if only one injection was given. An alternative approach to assessing costs to provider came to costs per QALY of £44,701 and £25,745 respectively. The GDG have used the lowest of these figures arguing that only single injections will be needed for the majority of people receiving epidural steroids who will have acute sciatica. This trial included around a third of participants with acute sciatica. Although the trial was seriously | |

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| | | | | underpowered for sub-group analyses, comparisons have been made between response to treatment of those with acute and chronic sciatica. If anything the evidence here appears to support the hypothesis that people with chronic sciatica will gain more benefit from epidural steroids. Overall the intervention was ineffective; any trend for an enhanced effect in the chronic group will reduce even further the possibility of effectiveness in the acute group. We think the GDG are seriously misinterpreting the data here and that there can be no cost-effectiveness argument for supporting the use of epidural steroids.<br><br>We do not think the decision to recommend epidural injections for people with acute sciatica is based on robust clinical and cost-effectiveness data.<br><br>Price C, Arden N, Coglan L, Rogers P. Cost-effectiveness and safety of epidural steroids in the management of sciatica. Health Technol Assess. 2005 Aug;9(33):1-58, iii. | |
| Warwick Clinical Trials Unit | Full 2 | 120 | 24 | Research recommendation 6; We do not agree that this is a relevant research question. We are not convinced that the evidence supports the effectiveness of either of these interventions. There is an important research question on the effectiveness and cost effectiveness of epidural steroids for people with acute sciatica and radiological evidence of disc prolapse. The cost effectiveness analysis of any such study would need to include the costs of imaging to identify those who may be eligible. | Thank you for your comment. This research recommendation was based on the existing guidance in the UK suggesting epidurals should be given under image-guidance based on safety grounds. However the epidurals review did not show much difference in the clinical effectiveness between image-guided and non-image guided epidurals. Bearing in mind the additional costs to the NHS for imaging when delivering image-guided epidurals, the GDG agreed that a recommendation for future research should be drafted. |
| Warwick Clinical Trials Unit | Full 2 | 219 | 5 | Recommendation 38.<br>Here there seem to be some evidence for short term benefits from decompression surgery that are not maintained in the long term. The benefits, as for all recommendations in this | Thank you for your comment.<br>The evidence reviewed showed that discectomy provided good prognosis and long-term pain relief in people suffering from sciatica. Sciatic symptoms tend |

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| | | | | guideline, are modest. We think that the guidance needs to more clearly linked to the potential short term benefits, the apparent absence of long term benefits and risk of serious adverse events. This recommendation also needs to recognise that surgical de-compression is only a treatment option when there is radiological evidence of compression. There may also be time window here for when surgical decompression is likely to be most effective. Suggesting this approach for those with very long standing symptoms of sciatica may be raising unrealistic expectations. At the other extreme we doubt that surgery is a sensible option for most people with acute sciatica that may well largely resolve in the short term irrespective of treatment. Setting the pros and cons of surgery for individual patients is, we think, beyond scope of this guideline. Also we think that before there is a surgical consultation that there should be evidence of surgically treatable lesion. We therefore suggest editing the recommendation to something like:<br>'Consider referral to a spinal surgeon for possible spinal decompression for people with persistent sciatica when non-surgical treatment has not improved pain or function and there are radiological findings congruent with their sciatic symptoms'. | to improve naturally with time without treatment; however, the GDG felt that earlier symptom resolution with surgical intervention should be an option. It was therefore recommended that spinal decompression is considered for a subgroup of people with sciatica who had failed to respond to conservative management of their symptoms. This is detailed in section 28.6 (Recommendations and link to evidence).<br><br>The GDG discussed the need of imaging prior to spinal decompression and observed that prior imaging was an inclusion criteria for all the studies included in the review. The GDG was also aware that operating without concordant imaging would carry a significant risk of harm, because such patients would be exposed to the risks of surgery and general anaesthetics with little chance of any benefit. The GDG therefore decided it was appropriate to restrict the use of spinal decompression in people in whom radiological findings are concordant with sciatic symptoms.<br>The wording of the recommendation has now been updated as follows: Consider spinal decompression for people with sciatica when non-surgical treatment has not improved pain or function and in whom radiological findings are concordant with sciatic symptoms. |
| Warwick Clinical Trials Unit | General | General | General | We are well aware of the amount of work needed to collate, assess and interpret the evidence for a NICE guideline. This scope of this particular guideline is extensive including acute and chronic pain as well as both back pain and radicular pain. We consider it is vital that the massive contribution of the technical team to developing this guidance is recognised. | Thank you for your comment. |
| Warwick Clinical | General | General | General | In many parts of the evidence extraction where we have examined sections in detail we have identified errors in what is reported. This is likely to be an inevitable consequence of | Thank you for your comment. We apologise for any errors that were identified. The consultation process for this draft guideline allows for the amendment of |

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| Trials Unit | | | | the massive task given to the technical team in trying to synthesise this dataset. We suggest that in areas where there are high stakes decisions, or where the final guidance might be challenged, that a careful check of all material is made. Errors identified after final publication that undermine guidance may cause reputational harm to NICE | identified errors and we will ensure a careful check to avoid errors in the published guideline. |
| Warwick Clinical Trials Unit | General | General | General | NICE defines effectiveness in its Glossary as 'The extent to which an intervention produces an overall benefit under usual or everyday conditions'. Weight is given in some parts of this guidance to comparisons with sham interventions. Sham interventions may not be representative of usual or everyday conditions. Whilst scientifically interesting, in studies of complex interventions, to assess efficacy when compared to sham interventions it may not always be relevant to assessing effectiveness. We suggest that the focus in this guideline should be towards assessment of effectiveness rather than assessment of efficacy. Although, as the NICE manual recognises this distinction can be difficult in studies of complex intervention.<br><br>That efficacy and effectiveness studies can come to different conclusions is explicitly recognised in the manual when it considers NICE interventional procedures guidance. A procedure can meet an efficacy bar and be approved as an interventional procedure but fail to meet an effectiveness bar and not be part of a clinical guideline.<br><br>This is a difficult area. We think that it is important that the approach used within this guidance needs to be clearly described and applied consistently throughout the guidance. | Thank you for your comment. Effectiveness is used here as a broad term to include efficacy and we have clarified this in the glossary. All of the reviews do look to determine both (using 'effectiveness' as a broad term to cover both situations). However the GDG agreed that proof of benefit compared to placebo/sham needed to be demonstrated before usual care comparisons could be given weight given that these are subject to bias of the non-specific effects that arise out of the process of treatment (such as the effects the therapeutic context might have) rather than directly from the active treatment components. The GDG were careful to ensure consistency in their decision making across the evidence reviews. However, the level of evidence included for comparisons against sham in each evidence review is different. Where evidence reviews lack sham comparisons because they aren't feasible, the GDG has had to make decisions of clinical effectiveness accordingly. Comparisons to other treatments or usual care are also taken into consideration in all reviews where available. However, where placebo or sham is available, this has been given priority in the review process to first demonstrate a treatment effect separate from the non-specific treatment effects. |
| Warwick Clinical Trials Unit | general | 502 | 177 | In many ways a minor point, but indicative of the challenge the technical team have had in trying to synthesise this evidence base is how the UK BEAM trial is credited. It is incorrectly attributed to a conference abstract by Moffett | Thank you for your comment. The Ernst and Moffett papers have now been excluded and edits to the other references mentioned have been made where relevant. |

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| | | | | (375). It should be credited to the UK BEAM trial team (current reference 533 attributed to Underwood). Current reference 47 attributed to Brearley should be attributed to UK BEAM trial team. Reference 128 Ernst identifies comments to the BMJ about the trial and provides not data and should not be associated with the study.<br><br>On page 275 in the trial by Lamb (ISRCTN 54717854) one of the UK BEAM papers is incorrectly linked to this study. Interestingly here a sub-group analysis paper by Underwood is linked to the trial but for the UK BEAM data a similar paper by Underwood is not. Consistency of approach his needed.<br><br>Whilst not fundamental to the development of the guidance if these sorts of errors are repeated more widely it may reduce end-users confidence in guidance. These are, of course obvious to us as these are studies with which we are very familiar. | |
| Yawye | GENERAL | GENERAL | general | The guideline draft seems to describe inadequate way to perform the acupuncture:<br><br>"*The needles are either manipulated to produce a particular 'needle sensation', or stimulated electrically (electroacupuncture) for up to 20 minutes. Some practitioners also use moxa, a dried herb which is burned near the point to provide heat. A course of treatment usually consists of six or more sessions during which time, if a response occurs, pain relief gradually accumulates"*<br><br>We have found that is absolutely definition for western acupuncture which sometimes calls dry needle. We do not agree this definition. For non-western acupuncture, the correct definition is<br><br>" a form of alternative medicine and a key component of traditional Chinese medicine (TCM) involving thin needles inserted into the body at acupuncture points. … The method | Thank you for your comment. The introduction is intended only to set out the clinical issue and uncertainty and provide a brief description of the intervention. The GDG believe it is appropriate to leave this statement unchanged. |

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| | | | | used in TCM the most widely adopted in the US, is rarely used alone but rather as an adjunct to other forms of treatment" [1]<br><br>It is absolutely true if someone using acupuncture alone, professional acupuncturist will not consider that is adequate way. | |
| Yawye | GENERAL | GENERAL | GENERAL | Furthermore, GDG in the draft perhaps may not recognise that in USA if people are not qualified as acupuncturist, even they use dry needle which only needle alone is breached USA law. The difference between using acupuncture alone or not is not just different personal view, it has already widely involved legal debates in USA. Since majority of acupuncturist against people using needle alone to treat as acupuncture treatment, many states of USA has closed door to allow physicians without training to touch acupuncture needle. Therefore, GDG must make very clearly that whether the needle was used alone or connecting other interventions. The latter one is accepted method for acupuncture. Otherwise is inadequate or sham acupuncture. We advice that any trial studies intended to use needle alone should be considered inadequate acupuncture treatment and should not be included for meta analysis. | Thank you for your comment. All studies included in chapter 13 were included based on their suitability according to adherence to the review protocol (please see appendix C.9), and were seen and approved by the GDG members and the co-opted acupuncturist. Full details of what the interventions involved are available in the evidence tables in appendix H. |
| Yawye | GENERAL | GENERAL | general | Furthermore, from our clinic observations, at the time people who were received acupuncture treatments are more likely to come back looking alternative medicine and less like to back to see GP. For instance most of our return patients when they have any pain rather than NLBP they will be first looking DIY to care by themselves and then if failed they will visit acupuncturist again. Most of returning clients with any sort pain are more likely to select one off treatment rather than a course of treatment from acupuncture. Therefore the cost of sensitivity for Prof Thomas should have included not just 24 month, but more than 2 year, 5 year and even 10 years such as Mr D Wonderling did for acupuncture for headache[2]. It should be | Thank you for your comment. As stated in response to your comments, based on the evidence reviewed we are unable to recommend acupuncture due to inconsistent evidence of benefit compared to sham. |

[1] https://en.wikipedia.org/wiki/Acupuncture
[2] http://www.bmj.com/content/bmj/328/7442/747.full.pdf

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| | | | | aware that acupuncture treatment is not single intervention but it is introducing a multiple interventions via needle and people received more benefit beyond needling. For instance, they will start to take more excises to reduce recurrence of NLBP. That is GDG should use intervention coverage over 10 years which maximum willingness to pay can be less £5000 for a QALY | |
| Yawye | GENERAL | GENERAL | GENERAL | From our observation those returning NLBP clients because of recurrence or persistent for long period is about less than 15% in our NLBP patients pool. From epidemiological records, there is no good data or consistent data to show long persistent rate or recurrent rate. Overall, the prevalence of persistent NLBP for one year is about 21%.[3] Therefore, Prof Thomas' QALYS based on from 24 month benefit which is for persistent NLBP, cannot be generalised for the entirely NLBP population directly. For the above reason, we can understand that even all of NLBP are from persistent patients and even all of acupuncturists are not outstand experts for acupuncture, the cost effective is still existed. And trade off for 5-6 is still required which no matter the patients NLBP how serious is. In Summary, the effective of cost effective for acupuncture is very high and even acupuncture is under inadequate hand or inadequate management it is still showing cost effective. However, if NHS have had optimal way to use right acupuncturist and take optimal number of sessions from acupuncture, the cost effective will be much higher. GDG should take those situations into the guideline. | Thank you for your comment.<br>We could only comment on the results of the studies based on the assumptions they made. We could not assess how the incremental cost effectiveness ratio varies if we change parameters. |
| Yawye | GENERAL | GENERAL | GENERAL | We do not accept that GDG has serious systematic bias but we do find several decision GDG has not take into account in real world and then resulted to many possible inadequate decisions. For example. GDG says<br><br>"*The quality of evidence informing the usual care and other active comparisons ranged from high to very low. The high rating was only observed in outcomes with a sham comparator. In the outcomes with a usual care comparison, lack of patient* | Thank you for your comment. In the acupuncture review, we searched for and included studies which compared against sham, usual care, waiting list, no treatment and other interventions. Evidence against all of these comparators is considered by the GDG when developing recommendations where available. However any evidence for comparisons against placebo/sham has been be given priority in order to determine the treatment effect is over and above any |

[3] Pain physician 2000 3(2) page : 5 studies from 1983 to 1999

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| | | | | *blinding was the primary reason for a significant risk of bias for subjective outcomes and the quality rating was downgraded accordingly. In addition blinding of the treating therapist was not achieved in many trials due to the nature of the sham technique employed."*<br><br>That is clearly evidence that GDG is only enhancing the quality of meta analysis rather than quality of RCTs. But real life is that if quality of acupuncture was not adequate tested during trial intervention, all of results no matter how good they designed , it will be cabbage in and cabbage out. For instance, GDG moved out three studies for meta analysis: among of them :Grant 1999 and Muller 2005 did not have placebo and then they treat them high bias. From our quality control score of acupuncture[4] , both studies have reached high grade and we would consider that is wrong to take them out. Furthermore, GDG was not consistently using above criteria to make quality of study. Another example, Thomas 2005 did not have any sham or placebo but they still treated her study good study. Perhaps, the question is not From Prof Thomas concept she does not think without sham or placebo the trial is not good. For this reason GDG should consider too focus on the sham to avoid selection bias. | contextual or placebo effects. This was determined a-priori before the evidence was reviewed, and is stated in the methods of the guideline. |
| Yawye | GENERAL | GENERAL | GENERAL | Perhaps there three main Questions for GDG could not find answer therefore, they are not happy to recommend acupuncture is that :<br><br>1. "*The GDG considered that other treatments reviewed in the guideline had specific and clinically important treatment effects, beyond contextual effects, although acknowledged that for treatments where no "sham" comparison was available it was not possible to distinguish specific and non-specific effects. The majority view of the group was to recommend "do not offer" acupuncture.* | Thank you for your comment. All the included studies for this review were seen and approved by the GDG including the co-opted acupuncturist. Therefore all the forms of acupuncture included in this review were considered acceptable forms of acupuncture.<br>The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects |

[4] See appendix I

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| | | | | 2. *"The GDG discussed that if there was a specific treatment effect, this would be likely to be mediate through pain reduction"*<br>3. "*The GDG considered the potentially considerable cost impact for the NHS if acupuncture was recommended and this would need to be underpinned by a strong evidence base of clinical and cost-effectiveness, which the GDG did not feel had been demonstrated*"<br><br>We would make following comments by reversed order.<br><br>1. For question 3, logical, if someone to sue that other is wrong, he has a burden of proof. In our case, new member of GDG tried to U turn which they have same problem that they should bring strong evidence to prove whether the cost effective was wrong - which it is not case because they used the same study - or whether it is currently NHS with substantial change - which is not true. In contract, we have done our analysis, it has shown that if we do sensitivity analysis based coverage more year from two to 10 or based on determining optimal number of sessions for acupuncture, the threshold of cost is definitely lower than £20,000 per QALY. That meets the NICE criteria[5].<br>2. For question 2, our simple comment is that 10 out 30 studies have used as real acupuncture, rest of them were tested by inadequate acupuncture method. Therefore, effect of specific effect of acupuncture cannot be demonstrated. Unless before we can make sure that all sham | above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis.<br>Although acupuncture was cost-effective based on the analysis carried out for this review, the GDG considered the clinical effectiveness alongside cost-effectiveness. Due to the conflicting evidence for acupuncture compared to sham, the GDG agreed there was insufficient evidence to confirm the treatment effects were not beyond placebo effect. Therefore, they agreed not to recommend acupuncture in a NHS setting. |

[5] NICE: Generally, we consider that interventions costing the NHS less than £20,000 per QALY gained are cost effective. Those costing between £20,000 and £30,000 per QALY gained may also be deemed cost effective, if certain conditions are satisfied..

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| | | | | acupunctures are placebo acupuncture and all placebo acupunctures are real placebo which are not inadequate acupuncture or not hidden treatments.<br>3. For question 1, our comment is that since no one know the exactly reason caused pain in LNBP, it therefore, is hardly or impossible to use acupuncture to determine what is specific effect due to treatment, especially no one know exactly mechanism for acupuncture to relief the pain. Logical, we cannot use unknow A to prove unknow B. Furthermore, it is common agreement like other intervention, *where no "sham" comparison was available* for acupuncture as well therefore, ony one to make sham or placebo control for acupuncture is inadequate for the study | |
| Yawye | GENERAL | GENERAL | GENERAL | There are strong common agreement that there is no sham needle or no sham acupuncture. We agree with out colleague such as from ATCM and BACc. The GDG statement:<br>" *comparison with sham acupuncture showed no consistent clinically important effect, leading to the conclusion that the effects of acupuncture were probably the result of non-specific contextual effects."*<br><br>That is big mistake. We believe many our colleagues' comments have made against this statement. However we do not agree that GDG was negligent or unfair to make such wrong statement because as evidence based medicine principle and inconsistent results from acupuncture, GDG should agree with all international researchers to see whether there is any placebo effect. Even there is strong against opinion for taking placebo or sham as control, there are still several good reasons to use placebo as control in order to understand about acupuncture. Otherwise, there is no way to start or it will be un-ethic to say yes or no. | Thank you for your comment. The GDG recognise that there is controversy around the possibility of delivering an effective inert sham treatment for acupuncture. On discussion the GDG took the view that the included studies had included a variety of sham controls with a varied capacity to elicit physiological effects but that consistently acupuncture did not deliver clinically important effects above those shams. This was the case for both penetrating and non-penetrating shams. The GDG were of the view that the sham comparisons were essentially credible on that basis. |

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| | | | | However, after more than 3000 RCTs for acupunctures and more than 50 RCTS for NLBP, it is time for GDG to consider whether there is any gain from the study and whether it is time to stop them at all.<br><br>We do not agree the opinion that all of studies with sham/placebo control are no useful because they minimized effective of acupuncture. From 25 studies we can have original paper, we have found study with sham or placebo can give us some useful idea about quality of placebo and real effect of treatment. That is based on if we can take nocebo or hidden treatment into account. Due to time restriction we cannot present our new method or give NICE how to make balance between effective of treatment and effective detecting placebo[6].<br><br>For the above reason, we highly recommend NICE not to take withdraw action until the question of sham needle is real sham or real placebo resolved. There is no need to take a new trial but it is essential to take a good analysis again. | |
| Yawye | GENERAL | GENERAL | GENERAL | "Not recommended acupuncture", Professor Mark Baker, clinical practice director for NICE, said "*This is because there is not enough evidence to show that it is more effective than sham treatment*." Emeritus professor David Colquhoun, a pharmacologist at University College London, who is the strongest person against using acupunctures at all, says " the *difference between acupuncture and no acupuncture was on average – over all the studies assessed – equivalent to a 10-point difference on a 100-point scale commonly used by* | Thank you for your comment. When including evidence for this review, the GDG did not discriminate between the types of acupuncture included in the trials. All trials included were subject to meeting the review protocol criteria (appendix C.9). Therefore, it will not possible for the GDG to make a recommendation favouring Chinese acupuncture without having specifically separately reviewed evidence for this form of acupuncture. |

[6] We are working a formula with LSTHM to find out alternative calculation to use existing RCTs data under following 5 possible function in sham or placebo needle: The formula as simple presentation: A=acupuncture. Possible one: If B=placebo and A=B, then acupuncture =placebo; Possible two: If B=placebo + nocebo+ hidden treatment and A=B, acupuncture =placebo + nocebo +hidden effect. Possible three if nocebo = 0 and A=B, then acupuncture = placebo + hidden treatment. Possible four; If placebo < nocebo A=B , then acupuncture = nocebo + hidden treatment. Possible five : If placebo=nocebo, B=hidden treatment, A=B, then acupuncture = hidden treatment. Of course, if it is case that nocebo = > placebo, and A=B, acupuncture cannot be treated as placebo. There is another possible that if A is inadequate A and A=B , nocebo > placebo then inadequate A = weaker effective from acupuncture + nocebo

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| | | | | *scientists to assess pain*." "– as appears to be the case – most placebo effects are quite small, then patients don't get much benefit from it anyway. They might get some psychological boost, but it doesn't cure their pain effectively; and that boost is not worth the dishonesty." he says. "Patients are steered toward therapists who may be acting irresponsibly. Some acupuncturists make a series of absurd claims, claiming to treat everything from hay fever to depression, infertility, tinnitus and 'children's health'. Such acupuncturists," he says, "offer nothing more than hope in exchange for a great deal of cash." We do not want blame them because both of them might have seen western acupuncture or inadequate one. We believe anyone who have really understood acupunctures, such as those authors: Coan, Grant, Molsberger, Weiss, and Witt, that they all consider if with high quality of acupuncture we should show a big gap between sham after taken nocebo into account and real one at the same time[7] [8].[9] [10] For above reason, we strongly recommended NICE should give clearly message to public that Acupuncture referred in guideline is mainly to the western medical acupuncture and there is no consistent evidence to deny effective of traditional acupuncture. | |
| Yoga Biomedical Trust | General | general | general | Answer to Question 3<br><br>NICE is faced with a dilemma. Recognised organisations have implemented competing and incompatible criteria for certification of yoga therapists for LBP and sciatica. And there is currently insufficient scientific knowledge to choose between them. The existing trials do | Thank you for your comment. It is beyond the scope of this review to specify who should deliver an intervention, the review focussed on whether or not yoga was clinically and cost-effective and was based on the best available evidence identified according to the review protocol.<br>There was no evidence to specify which type of exercise was most beneficial, therefore we have recommended that people's specific needs, preferences and capabilities into account when choosing the type of exercise. |

[7] Edit: Are the effects of acupuncture specific or nonspecific and response. PAIN 152 (2011) 952-958
[8] Enck P et al: New Insight into the placebo and nocebo responses. Neuron 59 7:195-206
[9] Edit: clinical meaningful nocebo effect in acupuncture? J Clinic epidemiology 2014 67 -1275-1376
[10] Planes S et al: The nocebo effect of drug PRP 2016 4(2) 1-15

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| | | | | show beneficial effects of yoga, but they fail to distinguish among types of yoga, inclusion and exclusion criteria of subjects, and (generally) between nsLBP and sciatica[1]. Since clients with herniated disc can be harmed by inappropriate yoga, these deficiencies are serious.<br><br>These are very real challenges to the implementation of the proposed Guidelines. If the Guidelines are to recommend yoga for LBP, they need to indicate how to find a suitably-qualified yoga teacher. At least 3 organisations in the UK train and certify teachers to work with LBP – Yoga Campus, Yoga Biomedical Trust and the Healthy Back Institute. The first two of these include LBP as part of their overall training to be a yoga therapist, competent to treat a wide range of medical conditions; whereas the Healthy Back Institute gives a specialised course to equip yoga teachers to treat LBP but not other conditions. The Complementary and Natural Healthcare Council recognises only those with the full therapist training, and therefore excludes the Healthy Backs teachers. However, the Healthy Backs course is the only one, whose yoga regime for LBP has been validated by an RCT listed in the Guidelines. Which of these qualifications should the NICE Guidelines recommend? | |

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| | | | | The situation is even more complex because the Yoga Biomedical Trust system is the only one for which an RCT has demonstrated safety and efficacy in the treatment of sciatica (Monro, 2015). The trial of Sherman et al (2011) specifically excluded sciatica. The York Trial (Tilbrook et al, 2011) did not specifically exclude sciatica but included leg pain in neither the baseline characteristics nor the outcome measures; and their published yoga regime states:<br><br>*'This yoga programme was designed for those with general non-specific (non-serious) low back pain.'*<br>http://www.yogaforbacks.co.uk/yoga-for-healthy-lower-backs-course/#wrap<br><br>The demarcation between nsLBP and LBP with sciatica and herniated disc is ill defined in current clinical practice. Early herniated disc in its early stages and between acute episodes usually lacks significant neuropathy and gets classed as nsLBP, even though it is at greater-than-normal risk of exacerbation and requires modified yoga regimes for safety. Previous trials of yoga for nsLBP probably included cases of this type, and failed to detect adverse effects through lack of assessment techniques sensitive to small changes in sciatica. Such uncertainties in the detection of herniated disc render | |

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| | | | | the selection of a suitable yoga therapist even more challenging.<br><br>This dilemma could be resolved by provisionally accepting all three of the above qualifications (as well as certain others), on the condition that clinical audit is incorporated into their practice. If any of them turned out to be less effective than the others, or to be having adverse effects, it would be discontinued unless or until suitable adjustments had been made.<br><br>We have developed a software system 'CALBA', which is suitable for this purpose. It provides a coherent, phased approach to management of LBP, with assessment at the core, but including monitoring, referral to therapists, and the construction of a database for evaluation and research. The analytical core is CALBA (Computer Assisted Low Back Assessment, http://www.calba.net), a sophisticated program that takes a detailed case history, produces an assessment of the patient's condition and carries out the post-assessment monitoring. The public interface is www.yogatherapy.org, which reports the assessment and monitoring results to the client and therapist, provides advice on lifestyle and therapy tailored to the client's condition, and also where clients, | |

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| | | | | professionals and therapists are registered, clients are directed to appropriate therapists, and records of treatments and outcomes are stored and analysed.<br><br>The analysis part of the system is not yet sufficiently validated but the case history-taking and monitoring parts are already fully functional and reliable, and could be utilised from the time that the Guidelines are published. They would facilitate the characterisation of LBP patients, selection of suitable therapists, and clinical audit. In addition to providing clinical audit for quality control, the monitoring results would be fed back to the patients and their therapists, thus helping adjustments to be made to the therapy regime in response to changes in the LBP and also motivating the patient to continue practising.<br><br>The cost of this service has been tentatively set at £50 for a package consisting of the initial assessment, 3 months of daily or weekly monitoring and appropriate reports to the patient, therapist and doctor. | |
| Yogafor backs | Short | Gen eral | Genera l | The NICE Press Statement of 24th March 2016 with<br><br>regard to the draft guidelines mentioned 'yoga' – | Thank you for your comment. The GDG noted that there was some evidence of benefit for all exercise types compared to usual care or other active comparators, but no clear evidence for one type being superior to another. The GDG felt that the variability in comparators and study designs made it |

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| | | | | '*The draft guideline recommends exercise, in all its forms (for example, stretching, strengthening, aerobic or yoga), as the first step in managing low back pain*.'<br><br>This seems to be a clear and confident evidence-based recommendation that 'appropriate group yoga' should be recommended as a 'first step in managing low back pain'.<br>As this NICE Committee deemed it appropriate to mention the word 'yoga' in a relatively short press statement document, we therefore very strongly recommend that the word 'yoga' should also be mentioned in the short guideline.<br><br>At a time when the general public are receptive to the word 'yoga' and due to yoga's holistic health promotional aspects, we feel that this short guideline, which GPs and the general public will tend to read more than the long version, should definitely include a clear and encouraging 'signposting' to 'yoga'. There are some yoga courses already offered within NHS settings. Not all patients will be motivated enough to commit to attending an evidence-based group yoga course, but we welcome the fact that this signposted and/or referral choice will be available. | difficult to clearly determine which form of exercise was most beneficial. Therefore, the recommendation was written to cover the range of exercise modalities that demonstrated benefits rather than for a specific exercise modality. |
| Yogafor backs | Full | Gen eral | Genera l | We can Help with Integration and Implementation of an Evidence-based Yoga for Back-Care Exercise Programme.<br>NICE ask us to comment on how we can help with implementation of the guidelines and 'good practice projects'. This NICE recommendation supporting 'yoga' will have been significantly influenced by the robust UK 313-participant clinical research trials | Thank you for your comment. This has been passed on to the implementation team.<br><br>The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the |

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| | | | | carried out by The University of York (H. Tilbrook et al *Annals of Internal Medicine*, Cox et al *Complementary Therapies in Clinical Practice* and LH Chuang et al *Spine Journal* research papers) evaluating the effectiveness and cost-effectiveness of our group 'Yoga for Healthy Lower Backs' 12-week self-management course. Thanks to the randomised controlled trial research funding charity Arthritis Research UK, this unique and specific evidence-based programme is currently available taught by highly experienced and trained UK professionals.<br><br>The Yoga for Healthy Lower Backs Institute is a nationally-accredited training school set up as a social enterprise with high standards and governance. There are several hundred experienced teachers throughout the UK trained via a nationally-accredited 'Yoga for Healthy Lower Backs Teacher Training Course', who are able to deliver the specific evidence-based standardized 12-week course, according to a comprehensive Teachers Manual along with the evidence-based Students Manual, Relaxations CD, home practice sheets, hand-outs, outcome measure collation, patient and referrer information, registration process, and more. Registered teachers have knowledge of Red and Yellow Flags, how and when to refer on/back, how to individualise the yoga poses and sequences appropriately for individual lower back conditions and other 'biopsychosocial' needs, and these teachers are fully-supported by peers, mentors and the Institute (as well as their original yoga teacher training associations). | recommendation is not specific to any one exercise modality, we are unable to highlight this specific programme in the recommendation. |

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| | | | | As a body of professional yoga teachers (some of whom are already health professionals, e.g. GP, physiotherapists, occupational therapists, osteopaths), we would be like to continue to transfer knowledge from the original trial (keeping to the evidence base with our fully-documented, well-structured and fully-resourced 'generalizable' course. We would be extremely interested in working with others to help to integrate our unique and specific, UK-evidence-based 'Yoga for Healthy Lower Backs' yoga programme into mainstream health and social care and in fact we are already currently working towards this in several areas of the UK, e.g. Cornwall, Devon, Merseyside, Sheffield, NHS Innovations North East.<br><br>Due to its specificity and strong effectiveness and cost-effectiveness evidence-base, the 'Yoga for Healthy Lower Backs' course is already being signposted to by UK health professionals. More integration is being worked on. The research's 'knowledge transfer' (of the fully-resourced, fully-documented, quality assured yoga programme) is developng well, but more could be done. Post-research, this 12-week course is still performing well with good evidence of positive outcomes.<br><br>In order to help those with low back pain and health professional referrers, we would welcome NICE's help to build confidence and awareness and in turn we would be extremely interested in helping to develop best practice for integrating this yoga programme, particularly as in peer-reviewed research (*LH Chuang* | |

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| | | | | *et al*) it was found that offering the 12-week 'Yoga for Healthy Lower Backs' course (evaluated in The University of York / Arthritis Research UK randomized control trial) could result in cost-savings for the UK economy, the NHS, society, workplaces, and councils. It was shown that this yoga would be cost-effective compared to physiotherapy packages and hospital clinic rehabilitation programmes.<br><br>In our original University of York research, GPs referred patients to the 12-week group yoga course and we anticipate that offering this yoga course in Primary Care community-based settings will help save Secondary Care costs.<br><br>An NHS back pain physiotherapist specialist says "*Having experienced this course first-hand, if I were to have back pain, then this is absolutely what I would do*." Chair of British Council for Yoga Therapy says "*This is an excellent course focussing on long-term back care. Recommendation by NICE endorses not only yoga's effectiveness, but also its cost-effectiveness at a time when NHS funds need to be used in the best way possible. 'Yoga for Healthy Lower Backs' courses are taught by over 400 very experienced self-employed teachers nationwide*."<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme | |

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| | | | | designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. We could potentially train more existing NHS health professionals in how to deliver this programme.<br><br>As, to our knowledge, there is no other yoga programme with this much evidence that is being offered up in the same way as in the research itself, we thank this NICE Committee for helping us to create awareness of our educational and social enterprise 'knowledge transfer' project work. | |
| Yogafor backs | Full | Gen eral | Genera l | Cost-Effectiveness and Reduction in Work Absenteeism (and see Comment 2 above for further information)<br>At a cost of £292 (currently slightly cheaper in the private sector, whilst we are still rolling out the programme), it was shown in published research (*LH Chuang et al Spine Journal*) that the 'Yoga for Healthy Lower Backs' programme would be cost-effective for the NHS (when compared to physiotherapy packages or hospital rehabilitation programmes).<br>It was found to be a dominant treatment for society. | Thank you for your comment. This study was included in the review of economic evidence and it was used to inform recommendations as reported in the linking evidence to recommendation section 9.6.<br><br>The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the recommendation is not specific to any one exercise |

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| | | | | Offering the 12-week 'Yoga for Healthy Lower Backs' course significantly reduced absenteeism from work over the 12 months studied (3.83 days off work in the yoga group, compared to 12.24 in the control 'usual care' group). It was shown that employers could save a mean of £817 p.a. per employee offered the 12-week course (based on average UK salary and after paying for the cost of the course and course self-management educational resources).<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. | modality, we are unable to highlight this specific programme in the recommendation. |
| Yogafor backs | Short | 4 | 14 | We request a change to the wording in the Exercise section to:-<br>'Consider a group exercise programme (biomechanical, mind–body – for instance, | Thank you for your comment. The evidence for yoga has been reviewed in the mind-body group of interventions, which are listed in the current wording of the recommendation. The review did not look at evidence comparing different types of mind-body |

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| | | | | appropriate evidence-based yoga - or a combination of approaches, which could include aerobic) as a first step to managing low back pain. Consider that there are other additional benefits to group exercise.'<br><br>Firstly and most importantly, please mention the word 'yoga' to give the general public and referrers the clear message that there is a body of evidence to support 'yoga' for helping people to help themselves to improved back and general health. (Also see Comment No. 1 above.)<br>Currently, it only says 'mind/body', which we feel is a rather vague term, whereas the body of evidence supports 'yoga' (considerably more than the other mind/body exercise that has been included, i.e. Tai Chi).<br><br>We would be happiest if the wording were 'specialised yoga' or 'appropriate evidence-based yoga' for clarity, but understand that this might increase the word-count unnecessarily.<br><br>Secondly, it would also be helpful to add the phrase 'as a first step to managing low back pain' as mentioned in the press statement. It is often unhelpful to the patients (outcomes and psychological stress) to have their condition become chronic by any delay in this advice.<br><br>Thirdly, in view of the fact that the Committee considered that there were other benefits to group exercise that should be considered when making this | group interventions to each other, therefore no specific type of such intervention (for example yoga) can be specified in the recommendation.<br><br>The GDG found no difference between group and individual exercise in terms of clinical evidence. There was no economic analysis of group exercise directly compared with individual exercise, as there was no evidence for this comparison, however each type of exercise intervention was analysed where cost effectiveness data was available. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care. Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the cost effectiveness evidence, the GDG concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. The GDG are aware that some patients may not fully engage with group exercise, however do state in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise, in order to promote engagement. Please note that all exercise included in the exercise review is supervised exercise. Unsupervised exercise has been considered as self-management and can be found in the self-management review in Chapter 8.<br><br>The GDG noted that there was some evidence of benefit for all exercise types compared to usual care or other active comparators, but no clear evidence for one type being superior to another and benefits were |

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| | | | | recommendation, we recommend adding the second sentence to encourage uptake of treatments that will be likely to contribute to 'long-term self-management' (compared to 'long-term reliance' on health professionals). P. 306 of the long version mentions 'group exercise' and it should therefore mention the word 'group' here.<br><br>Regarding our suggestion of word editing as above - We feel there seems more evidence supporting 'yoga' compared to 'aerobic exercise', and that the long-note version of the guidelines mentions that 'aerobic exercise' could be incorporated into an exercise programme (but that there was not much specific evidence about aerobic exercise if it were the only form of exercise (p.306), i.e. we feel perhaps it should not be a specific recommendation or possibly not even mentioned in order not to mislead readers of this important short guideline).<br><br>Representatives from The Yoga for Healthy Lower Backs Institute, The British Wheel of Yoga (governing yoga body for Sport England and Sport & Recreation Alliance UK, the latter was formerly the CCPR) and The British Council for Yoga Therapy feel strongly that the word 'yoga' should be mentioned in the short version guideline document that patients and GPs will be most likely to read.<br><br>Thank you very much for including the word 'yoga' in the short version of the guideline. | seen inconsistently across critical outcomes. The GC felt that the variability in comparators and study designs made it difficult to clearly determine which form of exercise was most beneficial. The evidence compared to usual care did show that exercise is likely to be of value, however, the GC agreed that there was insufficient evidence that one form of exercise was superior to another. Therefore, a recommendation for a specific exercise modality, such as for example mind-body exercise, was not supported from the current evidence base. |
| Yogafor backs | Short | 4 | 14 | At a time when the Department of Health seems to be working towards health and social care budgetary | Thank you for your comment. The wording of the recommendation reflects that this guidance applies to settings in which NHS funded care is received. |

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| | | | | integration (i.e. shared community projects), we find it could be potentially unhelpful to say<br>'within the NHS ...'<br>For this reason and to allow a wider spread of provision, we suggest this phrase could be left out.<br><br>It is not just group exercise programmes within the NHS that can be helpful. The UK researched 'Yoga for Healthy Lower Backs' 12-week course was designed to help people to self-manage for the long-term by giving patients a self-help toolkit (H. Tilbrook et al, H Cox et al, LH Chuang et al research papers) and it is currently mainly offered within the private sector.<br><br>Perhaps this sentence is meant to refer to when a patient is actually experiencing an acute flare-up (?), but in that case, it would seem sensible to still recommend exercise but not necessarily immediately, unless the exercise programme was carefully designed for this, i.e. start as soon as the acute phase is settling down. If this is what is meant, please consider altering the sentence to the following:-<br><br>'Consider a well-structured, group exercise programme overseen by a health professional'<br>(Also see above comment for this sentence.) | The GDG found no difference between group and individual exercise in terms of clinical evidence. There was no economic analysis of group exercise directly compared with individual exercise, as there was no evidence for this comparison, however each type of exercise intervention was analysed where cost effectiveness data was available. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care. Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the cost effectiveness evidence, the GDG concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. The GDG are aware that some patients may not fully engage with group exercise, however do state in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise, in order to promote engagement. Exercise is recommended for people with a specific episode or flare-up of low back pain with or without sciatica. Please note that all exercise included in the exercise review is supervised exercise. Unsupervised exercise has been considered as self-management and can be found in the self-management review in Chapter 8. |
| Yogafor backs | Short | 4 | 11 | '- information on appropriate supervised exercise programmes that encourage long-term self-management' | Thank you for your comment. The self-management recommendation states that people with low back pain with or without sciatica should be encouraged to continue with normal activities at all steps of the |

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| | | | | Please importantly add the above sentence to the list in the Self-management section. It is advantageous to referrers, patients and budgets, if patients learn to self-manage for the long-term and this is a missed opportunity if GPs are not recommended to mention this advice.<br>Many GPs and patients and some academics spoken to feel that this would be a helpful addition to better reflect the long-note version and in order to actively encourage long-term positive outcomes.<br>It is not just group exercise programmes within the NHS, in 1.2.2 Exercise section, that can be helpful. The UK researched 'Yoga for Healthy Lower Backs' 12-week course was designed to help people to self-manage for the long-term by giving patients a self-help toolkit (H. Tilbrook et al, H Cox et al, LH Chuang et al research papers). Good 'signposting' to evidence-based exercise programmes should be encouraged (and our 'Yoga for Healthy Lower Backs Institute' is actively working on this). | treatment pathway, Please note that unsupervised exercise has been considered as self-management (Chapter 8), while all exercise included in the exercise review (Chapter 9) is supervised exercise.<br><br>With regards to group exercise, the GDG found no difference between group and individual exercise in terms of clinical evidence. There was no economic analysis of group exercise directly compared with individual exercise, as there was no evidence for this comparison, however each type of exercise intervention was analysed where cost effectiveness data was available. Although there was limited cost effectiveness evidence for individual exercise, group mind body exercise was shown to be cost effective compared to usual care. Furthermore, although group mixed exercise was more costly and less effective compared to cognitive behaviour approaches, the GDG considered that group mixed exercise may be cost effective compared to usual care. Therefore, after reviewing the cost effectiveness evidence, the GDG concluded that group exercise would incur fewer costs than individual exercise and consequently recommended group exercise. The GDG are aware that some patients may not fully engage with group exercise, however do state in the recommendation that people's specific needs, capabilities and preferences should be taken into account when choosing the type of exercise, in order to promote engagement. |
| Yoga for backs | Short | 5 | 24 | 'Consider a combined physical and psychological programme (preferably in a group context, that takes into account a person's specific needs and capabilities) for people with persistent non-specific low back pain or sciatica.' | Thank you for your comment. The physical component of combined physical and psychological programmes could include specific exercise modalities, mobilisation, or massage. The evidence included in the review did not support one specific physical element. Furthermore, the GDG considered |

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| | | | | Please consider additionally adding 'yoga' into this category (at least in the long-note version), as it is naturally suited to address the physical and psychological aspects of low back pain within one combined approach.<br><br>Yoga seems particularly good at working with those with Yellow Flags (as identified via the STarTBack tool).<br><br>Please note and/or mention in the long-note version of the guideline, that this could be a well-structured evidence-based yoga programme (for instance 'Yoga for Healthy Lower Backs' that teaches people to take back control of their 'biopsychosocial' health for the long-term). | evidence for combined physical and psychological programmes alongside the evidence from the other individual non-invasive intervention reviews in the guideline. The exercise review (Chapter 9) showed insufficient evidence that one form of exercise was superior to another. Therefore, a recommendation for a specific exercise modality, such as for example mind-body exercise or yoga more specifically, was not supported from the current evidence base. |
| Yogafor backs | Short | 5 | 5 | There seem to be a lot of guideline headings that say DO NOT. Might it be possible to delete some of these headings or to put some of the DO NOTs in a separate section? Those who skim-read will just see the headings and, for instance, may think that Acupuncture is recommended. | Thank you for your comment. The recommendations are ordered in terms of the order of review chapters, the patient pathway and order that treatments might be considered. Editing of the recommendations has been undertaken to best ensure that the intention of recommendations is clear and not misinterpreted. |
| Yogafor backs | Short | 6 | 5 | ***'Return-to-work programmes***<br>1.2.15 Promote and facilitate return to work or normal activities of daily living for people with non-specific low back pain with or without sciatica, for instance, by signposting to evidence-based well-structured exercise for back-care programmes.'<br><br>We would recommend adding the latter phrase 'for instance, by signposting to evidence-based well-structured exercise for back-care programmes' to this sentence (as above). | Thank you for your comment. The GDG agreed not to recommend specific return to work programmes as there was no strong evidence in the review for any specific programme. This evidence therefore does not support the suggested rewording.However, considering the broader evidence highlighting benefits of enabling people to return to work or their usual activities, the GDG agreed that a consensus recommendation should be made for this to be encouraged as part of all treatment for people with low back pain and/or sciatica.<br><br>In this guideline the economic perspective adopted is the NHS and PSS perspective, therefore we did not include the cost of time off work into economic considerations. |

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| | | | | Reasoning:- Many Councils and workplaces are providing employees with just a 2-hour long session on back pain advice and this would not appear to be adequate to bring about lifestyle or behavioural change.<br><br>The 'Yoga for Healthy Lower Backs' 12-week yoga programme has been shown (in published research mentioned in the guideline - LH Chuang et al) to significantly reduced work absenteeism over the 12 months studied from a mean of 12.29 (control 'usual care' plus The Back Book) compared to 3.83 (12-week yoga course). This was shown to equate to employer savings of £817 per employee offered the 12-week fully-resourced course (including the cost of the once-off course at £292 per person and based on average UK salaries). | |
| Yogafor backs | Short | 8 | 18 | Multi-Modal Treatment Package.<br>It is worth noting that a yoga back-care programme (such as the 'Yoga for Healthy Lower Backs' programme) would be likely to offer such a multi-modal approach within one combination treatment package. Perhaps the guideline could mention this, at least in the long-note version. | Thank you for your comment. The term 'multimodal' has now been amended. The recommendations now refer to 'a treatment package including exercise with or without psychological therapy' and 'a treatment package including exercise with or without manual therapy', to make the format and content more transparent. These recommendations are based on evidence from studies that used a treatment package consisting of these components, which can be found in chapters 9, 12 and 17.The exercise review (chapter 9) showed insufficient evidence that one form of exercise was superior to another. Therefore, a recommendation for a specific exercise modality, such as for example mind-body exercise, was not supported from the current evidence base, however yoga, or other mind-body exercises may be one of the forms of exercise that are considered. |
| Yogafor backs | Long | 202 | 20 | We have consulted with other yoga professionals and organisations, who feel strongly that these guidelines | Thank you for your comment. Yoga was considered as a modality of mind-body exercises, defined in the |

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| | | | | should help patients and referrers to understand what yoga is and what kind of yoga might be most useful. We would therefore request a short description of 'yoga' somewhere within this mind/body section. We suggest the following could be used:-<br><br>'Yoga in its therapeutic format (as opposed to gym industry stretching or some 'general yoga' classes) is a holistic health and fitness discipline that positively influences the multiple layers of a person's being, i.e. the physical, emotional, mental. Yoga is generally multi-modal, as it includes postural awareness, mindfulness, biomechanical exercise, relaxation/breathing skills, MSK education through subtle joint and muscle alignment awareness, and the enhancement of positive mental states. Importantly, it offers an enjoyable self-empowering package of long-term care that enables simple lifestyle and behavioural changes.'<br><br>It is worth noting that the type of evidence-based yoga that would be likely to be taught within a UK medical setting will need to be tailored to its cultural setting, as well as needing to be user-friendly for beginners, for instance, it will mention general philosophical themes, but will also speak about joints / muscles / relaxation. | chapter introduction as 'any exercise intervention that includes a combined physical, mental and spiritual focus, often with connection to metaphysical and cultural philosophies'. As the review did not compare different mind body exercises to each other, we do not think any further detail is required. |

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| Yogafor backs | Long | Gen eral | Genera l | Additional Research Here to Inform the Guideline, regarding Low Back Pain Patient Costs compared to Non-Back Patient Costs.<br>We believe the research mentioned below is relevant, as it shows GPs, referrers and commissioners how important it is to implement these guidelines.<br><br>'London School of Economics and Political Science looked at data from the General Practice Research Database, including records of diagnoses and pain relief prescriptions for chronic low back pain. In total they looked at data on 64,167 patients with back pain and a further 52,986 patients who were pain-free between 2007 and 2009.<br><br>The records showed that the total health care costs for patients with back pain were double those for patients without back pain.<br>On average the financial burden of caring for a patient with low back pain in the 12 months following their diagnosis was £1074 compared with just £516 for a typical person without back pain.<br><br>Almost 3/5 (58.8%) of the cost difference was due to additional GP consultations, with another 1/5 (22.3) due to referrals to secondary care and the remainder accounted for by the cost of pain medications.<br><br>The researchers noted that the findings do not take into account the indirect costs associated with low back pain, nor the expense of over-the-counter medications or lack of adherence to treatment.<br><br>*Spine Journal* 2013' Report on Arthritis Research UK website (link below).<br>http://www.arthritisresearchuk.org/news/general- | Thank you for your comments. This has been passed onto the implementation team. |

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| | | | | news/2013/january/uk-study-shows-high-cost-of-treating-back-pain.aspx | |
| Yogafor backs | Long | 217 | 1 | In Table 71, the type of yoga used in within the Helen Cox et al paper (Complementary Therapies in Clinical Practice 2010) which was a pilot trial to determine appropriate main trial recruitment methods for the main H. Tilbrook randomized control trial, is currently incorrect.<br>It should read<br>'Yoga for Healthy Lower Backs' instead of 'viniyoga'.<br><br>This University of York small trial used the same 12-week yoga programme, the same resources and was taught by one of the same 12 yoga teaching professionals who taught for the H. Tilbrook trial. | Thank you for your comment. More details on the intervention arereported as per the original paper in Appendix H, section H.5. This has now been corrected in the full guideline. |
| Yogafor backs | Long | 291 | 1 | Economic Evidence Profile<br>For the LH Chuang et al cost-effectiveness 2012 paper, which contributes significantly to the health economic data for group exercise, please put<br>'Yoga for Healthy Lower Backs' instead of just 'yoga'.<br>This will help to identify which type of yoga programme informed this University of York trial.<br>We feel strongly that this should be mentioned here.<br>Thank you.<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme | The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the recommendation is not specific to any one exercise modality, we are unable to highlight this specific programme in the recommendation. |

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| | | | | designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. | |
| Yogafor backs | Long | 201 | 1 | Under 'Other Considerations' within this Self-Management section, we feel the guidelines should definitely mention something like:- 'it is helpful for health professionals to think about signposting to self-management back-care group exercise programmes' (as mentioned in the short guideline p.4 Line 11 Comment 6). | Thank you for your comment. The self-management review focussed on programmes that were solely self-management education or advice interventions, or advice to rest/stay active. Unsupervised exercise was included within this review rather than the exercise review as the GDG agreed that it was more appropriately defined as self-management if there was no supervision involved. There was no evidence to support a group setting for self-management unsupervised exercise programmes specifically and therefore this has not been added as an example within the 'other considerations' section. |
| Yogafor backs | Long | 155 | | We wondered why the Karen Sherman et al 2005 yoga trial had been included in the Self-Management section and not the H. Tilbrook et al 2011 (Annals of Internal Medicine) yoga trial. In the Tilbrook trial, 156 participants were offered a 12-week self-management yoga course and these UK GP patients were followed up for one year (as in the Sherman trial); to see how they had fared 9 months after completing the taught yoga course; patients received a student manual, 4-track relaxations CD, home practice sheets, hand-outs | Thank you for your comment. Unsupervised exercise was included within the self-management review, rather than the exercise review as the GDG agreed that it was more appropriately defined as self-management if there was no supervision involved. This is detailed in section 8.6 Recommendations and link to evidence, The Sherman 2005 trial has been included in both the self-management chapter (comparison advice to stay active versus yoga; advice to stay active versus exercise) and in the exercise chapter (comparison yoga versus exercise; yoga versus advice to stay active; exercise versus |

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| | | | | to enable them to self-manage for the long-term; Arthritis Research UK funded this research in order to provide a yoga package of care (called the 'Yoga for Healthy Lower Backs' programme) to enable people to take control of their back health for the long-term.<br><br>If appropriate, please add this H. Tilbrook 2011 trial (and mention 'Yoga for Healthy Lower Backs' as the type of yoga) within this table. | advice to stay active). The Tilbrook trial compared yoga to waiting list; as the yoga sessions were supervised, this trial has been placed in the exercise chapter. |
| Yogafor backs | Long | 160 | 1 | In Table 35 We feel the H. Tilbrook 2011 trial could be mentioned as a self-management combination approach also, as, similarly to the ATeam Alexander Technique trial and others mentioned in this table, the yoga trial offered 156 patients self-management education via a 12-week course along with educational resources to enable lifelong practice of simple yoga techniques in daily life and the research followed up participants for 12 months.<br>Possibly the Karen Sherman yoga trial should also be added to this Table 35. | Thank you for your comment. Unsupervised exercise was included within the self-management review, rather than the exercise review as the GDG agreed that it was more appropriately defined as self-management if there was no supervision involved. This is detailed in section 8.6 Recommendations and link to evidence, The Tilbrook trial compared yoga to waiting list; as the yoga sessions were supervised, this trial has been placed in the exercise chapter. Elements included in the concurrent treatment, such as back pain educational booklet (the back book) and advice to continue their usual care (not specified) were extracted and are reported in Table 73 (exercise chapter, section 9.3.3) |
| Yogafor backs | Long | 197 | 33 | The H. Tilbrook 2011 trial could fit in with the 'Unsupervised Exercise' brief regarding self-management (See previous comment No. 15) | Thank you for your comment. Unsupervised exercise was included within the self-management review, rather than the exercise review as the GDG agreed that it was more appropriately defined as self-management if there was no supervision involved. This is detailed in section 8.6 Recommendations and link to evidence, The Tilbrook trial compared yoga to waiting list; as the yoga sessions were supervised, this trial has been placed in the exercise chapter. Elements included in the concurrent treatment, such as back pain educational booklet (the back book) and advice to continue their usual care (not specified) |

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| | | | | | were extracted and are reported in Table 73 (exercise chapter, section 9.3.3) |
| Yogafor backs | Long | 220 | | Tilbrook entry in the table could usefully have extra information added as per the other trials (see the Bentzen entry on p. 205). Please add the following information.<br><br>'Duration of Pain = Mean of 10 years. Had presented to GP within last 18 months with low back pain'<br><br>'Duration of Treatment = 3 months treatment followed by 9 months self-management with the aid of manual, relaxations compact disc, home practice sheets, hand-outs' | Thank you for your comment. This table is a summary of included studies. More detailed information is reported in Appendix H, section H.5, |
| Yogafor backs | Long | 257 | 2 | In Table 95, it mentions many identification names of yoga and yet it fails to mention the identification name of the yoga programme used in one of the most significant trials (the UK-based, University of York H. Tilbrook and its recruitment methodology pilot trial H. Cox). Please add<br>'Yoga for Healthy Lower Backs'<br>to all the H. Tilbrook (313 participants) and H. Cox results within the table on pages 257-261, that is 1st, 2nd, 3rd, 4th, 5th, 6th, 11th, 12th, 13th, 14th entries within this Table.<br>Thank you.<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of* | The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the recommendation is not specific to any one exercise modality, we are unable to highlight this specific programme in the recommendation. |

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| | | | | *Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. | |
| Yogafor backs | Long | 291 | 1 | Economic evidence profile Table 123<br>We feel it is important for identification purposes to mention<br>'Yoga for Healthy Lower Backs'<br>as we and others could not easily find the word 'yoga' and this is the name that best describes the yoga studied in this 'Spine Journal' Cost Evaluation paper (LH Chuang et al linked to H. Tilbrook et al).<br><br>We believe this is especially important as this research perhaps provides the most significant contribution to the body of evidence for the cost-effectiveness for group exercise programmes.<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of* | The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the recommendation is not specific to any one exercise modality, we are unable to highlight this specific programme in the recommendation. |

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| | | | | *Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. | |
| Yogafor backs | Long | 297 | 11 | Please note that there were some costs included for yoga teacher class fees within the LH Chuang et al paper.<br>We would be happy to help with breaking down the 'Yoga for Healthy Lower Backs' course fees, mentioned as being £292 per person per 12-week course (which includes a mat, manual, relaxations CD, home practice sheets, hand-outs, registration process, outcome gathering, teacher training). | Thank you for your comment. We aren't able to use these details at this stage. |
| Yogafor backs | Long | 300 | 7 | You identify other yoga (hatha and Iyengar) in the rest of this section, so please also add 'Yoga for Healthy Lower Backs here as follows:-<br>'In the people with low back pain with or without sciatica, evidence from 2 studies (Yoga for Healthy Lower Backs) suggested a benefit in terms quality of life on EQ-5D | The term 'yoga for healthy' backs was not specifically stated in the evidence tables in the appendices, but has been used in the 'summary of included studies' table in the full guideline. A full description of the programme used in the paper has been provided in the evidence table relating to this study. As the recommendation is not specific to any one exercise modality, we are unable to highlight this specific programme in the recommendation. |

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| | | | | for group mind-body exercise when compared with usual 8 care at the short term'.<br><br>Please note - the name 'Yoga for Healthy Lower Backs' was purposefully used as a heading in the '*Annals of Internal Medicine'* published paper for identification purposes (as recommended by an EU guideline low back pain specialist) in order to distinguish this specific, appropriate, structured group yoga programme designed specifically for chronic / episodic / recurring low back pain, as compared to general yoga classes. It will be helpful to inform guideline readers, if this identification name is used where relevant (in a similar way to which the guidelines uses the words ' MacKenzie, Feldenkrais and STarTBack). This specific yoga is taught by well-qualified and highly-trained Yoga for Healthy Lower Backs Institute Registered yoga teachers (trained via several different schools and methods), who have had additional extensive training in how to deliver the same evidence-based 'Yoga for Healthy Lower Backs' 12-week course. | |
| Yogafor backs | Long | 304 | | If physiotherapists were to teach a 12-week yoga programme as used in the H. Tilbrook trial, they would have to be trained, whereas the 'Yoga for Healthy Lower Backs' Institute registered teachers have already taken it upon themselves to invest in this training. One would need to add in time for record-keeping, registration forms, resource purchasing, venue hire, between class support, pre-class/ post-class support, course preparation time for individualisation, course set-up time, course hand-out costs and preparation. The Yoga for Healthy Lower Backs Institute regards the | Thank you for your comment. The consideration about physiotherapists delivering the intervention was the result of an analysis conducted in the study and it was not a consideration made by us.<br>In terms of reporting the intervention cost, we have to report what it was estimated in the published study.<br><br>In the Trade-off between net clinical benefits and costs section of this chapter, in paragraph 9.6 we do acknowledge the fact that future care costs may be saved, stating "If exercise programmes are effective, upfront costs may be offset by downstream cost |

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| | | | | original 2012 published trial figure of £292 to be a realistic 2016 cost per patient per fully-resourced course that will enable patients to self-manage and promote healthy lifestyle changes. It is being delivered at a slightly reduced cost currently within the private sector in order to enable the success of the 'yoga programme roll-out'.<br><br>It might be helpful to mention that when self-management educational programmes such as this are successful they have the potential to save considerable future Primary Care, Secondary Care and Social Care costs for many years into the future. Five years after beginning the yoga programme when contacting trial participants randomly for media purposes, they said things like '*this yoga enabled me to further pursue my career as a gardener by working at Kew'* and *'I was able to say to my consultant that I would not be needing surgery as I was 95% better (moving about more easily at home and in hobbies, no medications, less depressed, back at work) thanks to the Yoga for Healthy Lower Backs course and Arthritis Research UK'*. The yoga programme appears currently to be saving NHS costs by helping to decrease use of secondary care. | savings due to reduced healthcare utilisation or may be justified due to the benefits to the patient." |
| Yogafor backs | Appen dix H | 318 | H. Tilbroo k | It would be more accurate to say 'Participants recruited between July 2007 and July 2008 and identified for recruitment by searching GP databases, then in a second wave of recruitment (this second wave also recruited relatively small | Thank you for your comment. In the section 'recruitment/selection of patients' we report information on methods only, and not results details. Any further information on recruitment where relevant would be taken into consideration when assessing risk of bias assessment. |

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| | | | | numbers via advertisements in the local media)'<br><br>Please see 'Figure 1 Study Flow Diagram' in the *Annals of Internal Medicine* H. Tilbrook et al 2011 paper for evidence showing that<br>out of a total of 1093 patient applicants<br>only 98 applied via the media<br>compared to 995 potential research participants recruited via 39 UK GP surgeries<br>(please note these figures are pre-eligibility and randomisation. Total trial participants n=313). | |
| Yogafor backs | Long | 766 | | Within this Return to Work Programme Recommendation, we recommend you add the following (in the Introduction section or perhaps within the Other Considerations section).<br>'One randomized control trial (H. Tilbrook and LH Chuang) showed that offering a 12-week 'Yoga for Healthy Lower Backs' course (including elements such as exercise, postural awareness, back-care education, relaxation, breathing, psychological or positive mental attitude) reduced work absenteeism over the 12 months studied (a mean of 12.29 days off work in the usual care group compared to 3.83 in the yoga group).' | Thank you for your comment. The return to work review included studies on interventions/multidisciplinary programmes with a specified return to work focus, which was not the case for the Tilbrook 2011 and Chuang 2012 trials. Evidence from these two studies has been included in the exercise review (chapter 9). In this review, return to work was not an outcome pre-specified at protocol stage and this has therefore not been extracted.<br><br>Regarding return to work, the GDG did not recommend specific programmes as this was not supported by the evidence reviewed. However, considering the broader evidence highlighting benefits of enabling people to return to work or their usual activities, the GDG agreed that a consensus recommendation should be made for this to be encouraged as part of all treatment for people with low back pain and/or sciatica. |

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| | | | | Return to Work Programme's should therefore be signposting to evidence-based courses such as this yoga programme. | |
| Yogafor backs | Short (and Long) | 12 | 6 | Research Recommendations – Addition<br>The press statement began with mentioning how group exercise programmes (including yoga) should be viewed as a first step to managing low back pain. Please therefore recommend that more research should be done (or please give substantial implementation strategy advice) on finding good models for how to integrate community-based group mind/body exercise programmes within integrated health and social care systems.<br><br>Providing these programmes within Primary Care or a community setting will help save costs, will better suit patients, and will be likely to improve long-term outcomes (particularly as it can be helpful to de-medicalize non-specific chronic low back pain).<br><br>As intimated within the NHS Five Year Forward View, we believe, as others do, that more funds should be put into this kind of patient-empowering health-promotional community-based treatment option that will be likely to offer long-term positive outcomes (along with additional positive healthy outcomes regarding co-existing multi-morbidities) whilst additionally saving considerable short-term and long-term costs.<br><br>Patients appreciate yoga with its strong emphasis on physical and mental health as a combined treatment and we feel that this is an obvious recommendation to make regarding future research. Health professionals | Thank you for your comment. Research recommendations have been written in areas where the evidence base is lacking or there is considerable uncertainty on an area specifically reviewed within the guideline. The integration of community mind/body exercise programmes within health and social care systems was not something specifically reviewed, therefore we are unable to prioritise this as a research recommendation from the guideline.<br><br>We have passed this information to the NICE implementation team for their information however. |

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| | | | | are looking for longer-term health promotional courses that prevent costly, time-consuming and 'heart-sinking' re-presentations (a study showed that 75% of patients presenting to their GP with low back pain, re-present with back pain within 12 months). Courses that combine the physical and mental approaches (as yoga, by its very nature, does so well) will be likely to be the most effective for long-term outcomes. | |
| Yogafor backs | Gener al | | | Specific NICE Question 1 Do any recommendations represent a substantial increase in costs, and do you consider that the reasons given in the guideline are sufficient to justify this?<br>If the evidence-based 'Yoga for Healthy Lower Backs' programme (H. Tilbrook, H. Cox, LH Chuang papers) is to be integrated into the NHS, one should bear in mind that there has helpfully already been substantial prior UK human resources and financial *input (see answer to question 3 below) into the pre-implementation phase, e.g. the research itself, the six associated published papers and the academics involved, the training of the experienced yoga teachers, and multiple projects working towards transfer knowledge.<br><br>This yoga programme is well-structured, fully-resourced (12-class plans, students' manual, teachers' manual, relaxations CD, relaxation App, home practice sheets, | Thank you for your comments. This has been passed onto the implementation team. |

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| | | | | course hand-outs, registration process / outcome measure and other standardized course documentation), teachers are trained, supported and already teaching the programme. It is available now.<br><br>The guidelines mention 'group exercise' prominently. The body of evidence suggests 'yoga' should be considered and offered. We feel that the NHS and Social Care should be confident that we can offer up this yoga programme to the same standard and quality as in the research trial itself with good regulation and governance.<br><br>At a cost of under £292 per person for a once-off 12-week course, this represents good value for a long-term self-management course with other health promotional benefits.<br><br>Furthermore, published research showed that the 'Yoga for Healthy Lower Backs' programme would be cheaper than a package of physiotherapy or a hospital rehabilitation programme (LH Chuang et al) and that it was a dominant treatment for society.<br><br>London School of Economics and Political Sciences (see comment 12 above) found that back pain patients cost double that of non back pain patients, i.e. and average of £1074 versus £516 per year. This means that offering a £292 course could offer substantial | |

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| | | | | reduction in NHS back patient costs (especially if one views the overall NHS budget).<br><br>Combination or multimodal treatment packages, such as our yoga programme provides, would seem to not only offer the best value cost-wise, but would also potentially help patients the most (i.e. they would be less likely to become confused or disillusioned, which can happen when they are offered a physical treatment followed by a psychological treatment, or when they are given a scan report without any treatment). Group treatments that are not too general will work best, i.e. it is important to offer individualisation and real personalized support. | |
| Yogafor backs | Gener al | | | Specific NICE Question 2 Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.<br>We believe that offering up group exercise, which is the NICE 'first step to managing low back pain' recommendation may require a step-change of approach and yet it could be key to the success of implementing the new guidelines with regard to outcomes, cost-savings, societal impact and patient satisfaction.<br><br>It has become more and more common for those with persistent low back pain to demand secondary care | Thank you for your comment. This has been passed onto the NICE implementation team. |

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| | | | | services (scans, surgical interventions), as they may have felt this was necessary for good outcomes.<br><br>Offering something like the 'Yoga for Healthy Lower Backs' courses, with its patient-centred 'psychological and physical' combined approach that offers a long-term self-help toolkit is preferable. Patients attending this 12-week course are often surprised at how they can fairly easily learn how they can personally do something by themselves to lessen the duration, intensity and frequency of their back pain. They say that they wish they had known before that there was something like this yoga with its specificity and educative patient-empowering approach.<br><br>Patients need to know how and where to access such a course.<br><br>In the majority of the UK, it does not appear that there are enough group exercise programmes readily available within the NHS. In some areas, after an initial assessment, physiotherapists give out exercise hand-outs and patients are subsequently asked to go to the hospital clinic gym to perform these exercises 'with a health professional on hand to help'. This is not the same as a supervised, well-structured, fully-resourced group course, where everyone begins together and the exercise is specifically tailored to the individual (as in the 'Yoga for Healthy Lower Backs' 12-week course). | |

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| | | | | We believe that with the current difficult NHS financial challenges, many Departments and bodies are understandably protective of their own budgets. We know that the aim is to integrate health and social care budgets and that this has happened in some areas, which may help, if NICE recommends working in this way.<br><br>Regarding Budgets - For NICE recommended treatment options, such as a group exercise mind/body yoga courses, it would be best (for costs, patients and outcomes) to offer these up in the community or Primary Care, but unless there is true integration of budgets or more budgetary flow to enable these projects to succeed, it might be challenging. For this to work, there must be people at the top with a clear overview of the bigger picture who are prepared to make decisions for innovation, change and improvement.<br><br>More Funding at Primary Care level – we believe that it is crucial that funds are channelled here in order to prevent development of increased numbers of patients with long-term chronic conditions. This will save short and long-term costs.<br><br>For us at The Yoga for Healthy Lower Backs Institute, as a body of professional yoga teachers able to offer | |

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| | | | | the programme - it is proving challenging to encourage people to relinquish part of their budget to enable integration of this evidence-based course.<br>For existing back pain 'Any Qualified Providers' - many seem understandably reluctant to offer to share their NHS income with others and we as an Institute and social enterprise with self-employed teachers do not believe that it would behelp to set ourselves up in this way as an AQP provider. This route would be unlikely to enable good multidisciplinary team working, whereas becoming integrated into Primary Care or a Physiotherapy Department (or a Back Pain Care Pathway) would.<br><br>For UK GPs – those who know about this evidence-based 'Yoga for Healthy Lower Backs' programme seem keen to signpost to it, but are looking for guidance about how best to do this and how the funding works. In our experience, the majority of GPs would prefer to feel more confident in knowing how and where to refer to within the community / Primary Care, as many GPs say they see many (depressed and/or disabled) patients re-presenting in their surgeries several months or years later with the same non-specific back pain problems.<br><br>For UK Pain Clinics or Hospital Pain Management Departments – many are also keen to signpost those who have gone through the whole Secondary Care system and yet still have persistent pain to our yoga | |

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| | | | | programme, as they are confident that these people can benefit from our holistic empowering approach, but we and many in the actual Pain Clinics feel that our programme should appear earlier within the care pathway (i.e. 'as a first step' as NICE recommends).<br><br>For Councils / Adult Social Care – they need to be encouraged to work with the NHS to share budgets and offer programmes that will help them to help people to live happier and healthier lives. Muscular-skeletal conditions (and especially low back pain) is one of the top reasons for people developing long-term chronic conditions. | |
| Yogafor backs | Gener al | | | Specific NICE Question 3 What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)<br>We believe that signposting people earlier, rather than later, to self-management back-care programmes will offer short and long-term benefits (to patients / NHS / GPs / society / costs).<br><br>We at the Yoga for Healthy Lower Backs Institute represent an example of a national initiative with respect for maintaining quality and standards, respecting the evidence-base and with improvement, | Thank you for your comment. This has been passed onto the NICE implementation team. |

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| | | | | high quality knowledge transfer and good practice at its heart. As a social enterprise dedicated to maintaining standards and implementing the same 'Yoga for Healthy Lower Backs' used in clinical trials, we still have links with the original research body, York Trial Unit, Department of Health Sciences, The University of York. We also have links and support from our research funding body, Arthritis Research UK. As a 'best practice', innovative, evidence-based yoga programme for long-term back-care, we are supported by the British Wheel of Yoga (who, as the Sport England and Sports & Recreation Alliance UK yoga governing body, have accredited our Institute as a 'Recognized centre of excellence in training and standards'), British Council for Yoga Therapy (who have approved of our work and permitted us to be a member organisation of the association working towards improved UK yoga standards), and the UK charity BackCareUK.<br><br>Our 400 teachers are spread throughout the UK and we at the Institute are currently working on several UK-based projects, e.g. in Cornwall, Devon, NHS North East Innovations, Merseyside, Sheffield, with the aim of creating good models of ways of integrating the course into mainstream health and social care in order to make it more inclusive.<br><br>The 'Yoga for Healthy Lower Backs' 12-week programme is unique, as there is no other yoga | |

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| | | | | programme in the UK available with such good evidence-base (or perhaps internationally, as most other yoga research does not seem to have been able to transfer their knowledge widely and openly). The yoga was designed after considerable consultation with multiple yoga and other back-care specialists. It was designed to be appropriate for beginners and is taught with a gentle and gradually-progressing approach for those who might be restricted to begin with. Some other yoga might be inappropriate (too fast/still/strenuous or expect prior knowledge or the teacher might not be sufficiently trained) and so it makes it important to signpost / refer to this specially-designed course.<br><br>*Financial and Human Resource Input - Bear in mind, when considering using the 'Yoga for Healthy Lower Backs' programme that there has helpfully already been substantial prior UK financial (estimated at over £400,000) and human resources (100 health, academic, back pain, yoga, research; 400 yoga teachers) and time (11 years from trial design phase to now in 2016) input into the pre-implementation phase, e.g. the research itself, the six associated published papers and the academics involved, the training of the experienced yoga teachers, the multiple project work towards transfer knowledge. The guidelines mention 'group exercise' prominently and this 12-week 'Yoga for Healthy Lower Backs' course represents a well- | |

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| | | | | structured 'best practice' yoga course. Governance, regulation, quality assurance and standards have been worked on since the research itself, but certainly the course is uniquely delivered in the same way and to the same standard as in the research itself.<br><br>This yoga course is well-structured, fully-resourced (12-class plans, students' manual, teachers' manual, relaxations CD, relaxation App, home practice sheets, course hand-outs, registration process / outcome measure and other standardized course documentation).<br><br>The course is being taught with good outcomes now throughout the UK. The experienced and already trained yoga teachers (some of which are also physiotherapists, occupational therapists, GP Trainees) are trained via our intensive 'Yoga for Healthy Lower Backs' nationally-accredited course. They are supported and mentored whilst teaching the 12-week courses.<br><br>At a cost of under £292 per person for a once-off 12-week course, this represents good value for a long-term self-management course with other health promotional benefits.<br><br>With our published research findings showing that we reduced absenteeism from work by almost 70% and | |

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| | | | | knowing that 9 months after finishing the 3-month 'Yoga for Healthy Lower Backs' course, the majority of trial participants were still practising yoga at home the recommended twice a week.<br>These findings suggest that people found the yoga helpful, that they were able and happy to integrate it into their lives (noting that not only home yoga practice on the mat, but also postural or breathing awareness count as extra-curricular yoga practice), and that positive lifestyle and behavioural change had been encouraged for holistic long-term health and wellbeing.<br><br>We are measuring outcomes according to the Roland Morris Disability Questionnaire, Bournemouth Back Pain Scale, Visual Analogue Scale, Student Feedback Forms and have evidence that the course is performing very well, attendance rates have improved, and that NHS professionals have confidence to signpost to this specific yoga programme. To maintain quality, the same tutor, Alison Trewhela, who trained the initial 20 yoga teachers in how to deliver this programme for the original randomized control trial, is continuing to tutor the teacher training course and supporting the trained teachers.<br><br>Culm Valley Integrated Centre for Health at College GP Surgery in Devon is a shining example of multiple primary care initiatives and enabling patients to take back control of their health and wellbeing. We are | |

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| | | | | working with them regarding partial integration of our yoga programme with a forward view of full integration in the future.<br><br>Health Facilitators, or Health Champions, in Primary Care can help GPs with integration of, and/or signposting to, appropriate group exercise programmes in the community.<br><br>We would be very interested in field-testing the integration of group yoga and have developed good working relationships and health professional support, especially in Cornwall and Devon. We would welcome the opportunity to work with others to help our trained teachers to integrate this programme into the back pain care pathway in multiple areas of the UK whilst collaborating with others, e.g. with GPs, for best outcomes and patient satisfaction.<br><br>We would also be interested in training existing NHS staff, e.g. physiotherapists with a special interest in yoga via a suitably modified Yoga for Healthy Lower Backs Teacher Training course.<br><br>Please visit www.yogaforbacks.co.uk for more information. | |
| Yogafor backs | Gener al | | | New 2016 Research showing that yoga is as good as stretching-strengthening exercises, but potentially more appealing and enjoyable for patients. | Thank you for your comment. All searches were updated on 15 December 2015. No papers published after this date were considered. |

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| | | | | **Gothe NP, McAuley E:** Yoga Is as Good as Stretching-Strengthening Exercises in Improving Functional Fitness Outcomes: Results From a Randomized Controlled Trial. ***J Gerontol A Biol Sci Med Sci*; 2016 Mar;71(3):406-11**<br>"These findings have clinical implications as yoga is a more amenable form of exercise than strengthening exercises as it requires minimal equipment and can be adapted for individuals with lower levels of functioning or disabilities." | |
| Yogafor backs | Gener al | | | New 2016 Mindfulness Based Stress Reduction Research adds more strength to the evidence behind yoga's effectiveness, as the trial below mentions it includes Yoga (as do the majority of 'mindfulness' programmes and research). It should also be noted that Yoga sessions / classes will always include multiple 'Mindfulness' techniques, e.g. postural awareness, observation of the breath, attention to optimum mobility and joint alignment, calming of the mind / emotions and relaxation / meditation techniques.<br>We and representatives from other yoga organisations ask NICE to consider the above whenever discussing 'mindfulness', as yoga would incorporate the majority of these approaches, but would be likely to also add some useful philosophical education, which is very similar to CBT with its positive and realistic approach to each of life's 'moments'. Many would go so far as to say that mindfulness is the same as yoga.<br><br>1. Cherkin DC, Sherman KJ, Balderson BH, Cook AJ, Anderson ML, Hawkes RJ, Hansen KE, Turner JA:**Effect of Mindfulness-Based Stress Reduction vs Cognitive** | Thank you for your comment. All searches were updated on 15 December 2015. No papers published after this date were considered. |

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| | | | | **Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain: A Randomized Clinical Trial.***JAMA*; 2016 Mar 22-29;315(12):1240-9<br>"INTERVENTIONS: CBT (training to change pain-related thoughts and behaviors) and MBSR (training in mindfulness meditation and yoga) were delivered in 8 weekly 2-hour groups" | |
| Yogafor backs | Gener al | | | Because Yoga is a form of exercise that people relate well to, enjoy and would recommend to others, we believe that this should be taken into account when recommending treatment options, i.e. there should definitely be this patient choice of 'yoga' on offer.<br><br>Evidence for this -<br>Research (RCT 2011 in Archives of Int. Med.) comparing yoga classes versus stretching exercise classes, showed that 85% of those offered yoga classes would recommend yoga to others, compared to 54% of those offered stretching exercise classes.<br>"The percentage reporting they would definitely recommend the class to others was substantially higher in the yoga class (85% vs 54%; relative risk=1.6 [95% CI, 1.1-2.3]; *P*=.03)." (p.5)<br>**A Randomized Trial Comparing Yoga, Stretching, and a Self-care Book for Chronic Low Back Pain**<br>Karen J. Sherman, PhD, MPH; Daniel C. Cherkin, PhD; Robert D. Wellman, MS; Andrea J. Cook, PhD; Rene J. Hawkes, BS; Kristin Delaney, MPH; Richard A. Deyo, MD, MPH<br>*Arch Intern Med.* 2011;171(22):2019-2026. doi:10.1001/archinternmed.2011.524. | Thank you for your comment. Evidence from the Sherman 2011 has been included in the exercise review (chapter 9). Satisfaction with the programme was not an outcome that had been pre-specified at protocol stage; therefore, this has not been extracted. However, recommendation 1.2.2 on exercise states that people's specific needs, preferences and capabilities should be into account by the health professionals when choosing the type of exercise. The GDG agreed that it would be useful, and consistent with the evidence, to recommend an intervention that the person with back pain would be likely to participate in and that promotes self-management. This has been detailed in section 9.6 Recommendations and link to evidence. |

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| Yoga Studio International | Short | General | General | Dr. Monro Director of the YBT (Yoga Biomedical Trust) is Internationally recognised as an authority on the efficacy of Yoga Therapy for people with LBP, Sciatica and other Back conditions. He has been reseraching and working with people with back problems and Training Yoga Therapists in collaboration with Anatomy specialists and Orthopeadic Surgeons and Doctors for more than 20 years and has been developing a computerised risk assesment and monitoring tool which, when fully implemented may prove to be the most beneficial assessment/monitoring tool available - but will stil require trained therapists to be fully effective. | Thank you for your comment. |
| Yoga Studio International | Short | 1.1 | general | I trained as a Yoga Therapist at the Yoga Biomedical Trust In London (a course recognised by the CNHC) and have worked with people with non specific LBP, Sciatica and other back problems, including severe herniated disc problems for the past 15 Years. I have come to recognise that all methods of risk assessment are at best inprecise and that the most useful tool is the ability to listen to the patient in much more depth than that provided by the STarT back risk assessment tool. Unfortunately most GP's and NHS providers do not have necessary time available and that is where a commpetent, properly trained Yoga Therapist has an advantage. | Thank you for your comment. Risk factors or predictors of chronic, disabling back pain may not always be apparent to a health professional in the assessment of a patient. Evidence showed benefit in the use of STarT Back as a stratification tool at first point of contact, to inform shared decision-making about stratified management. This is detailed in section 6.6 (Recommendations and link to evidence). |
| Yoga Studio International | Short | 1.2.1 | Self Management | I would agree that clients need to be given the appropriate 'tools' for self management. That is why a yogic approach has many advantages, requiring little space, no particular tools and only time and a desire to improve the situation. | Thank you for your comment. |
| Yoga Studio International | Short | 1.2.2 | "Exercise" | Yoga, by its very nature is not ipsefacto a form of 'exercise' but an holistic practice involving body, mind and spirit (breath) and it is the combination of these that makes it a uniquely suitable practice for people with both LBP and Sciatic pain.Yoga Therapy as distinct from general yoga classes should be considered as a major NHS asset in the treatment of LBP with or without Sciatic pain. In order to facilitate this more properly trained therapist will be required. | Thank you for your comment. For the purposes of this review yoga was classified as a form of 'mind-body' exercise. Yoga classes and yoga therapy were not considered as distinct. |