CLINICAL PRACTICE GUIDELINES – HOW AND WHY?

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DECLARATIONS

- I am a full time pain specialist working in the NHS and private sector
- Member of the Evidence Analysis Committee - SIS
- Chair – NICE guideline on low back pain and sciatica 2016
- Chair – NICE guideline on rheumatoid arthritis 2017
- Chair – EFIC European low back pain guideline taskforce
- Expert advisor to the NICE Centre for Guidelines
- MSc student at Oxford University (medical statistics)

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BACK PAIN GUIDELINES

BACK PAIN: HISTORY

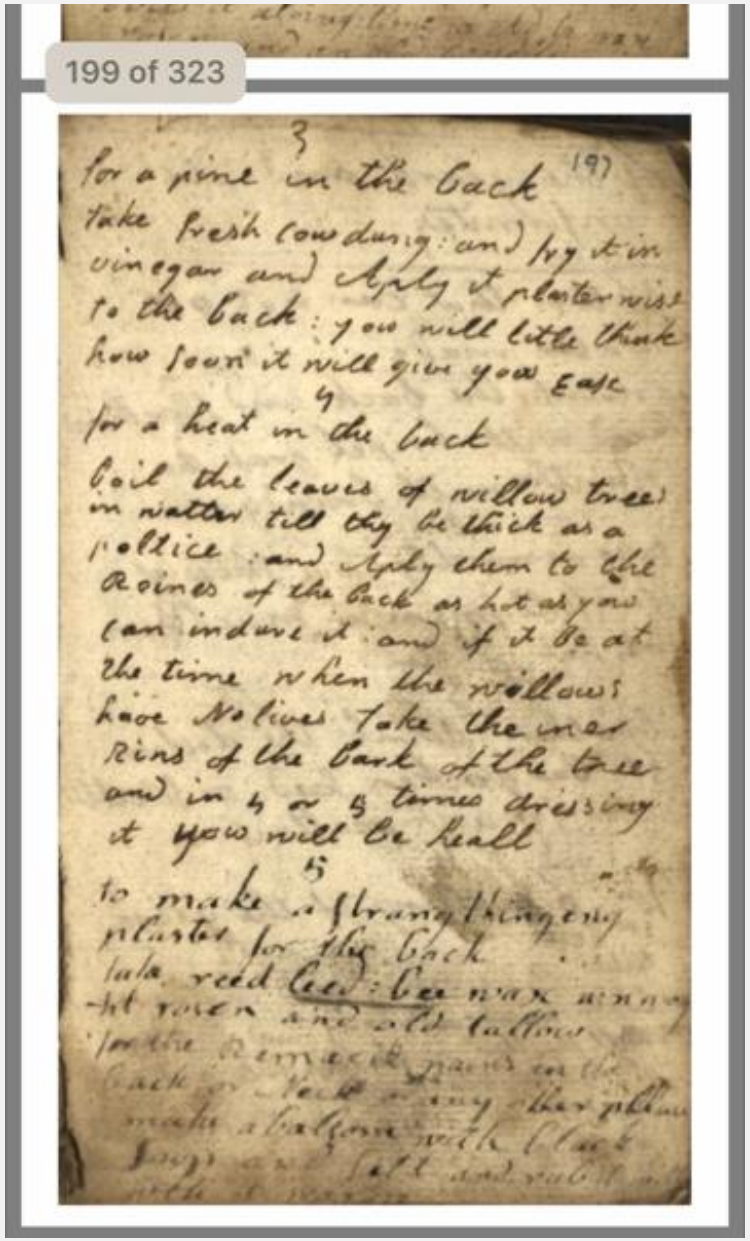
- Hippocrates (460 BC- 375 BC) : 'Ischiatic pain'

- Pliny (23-79 AD) 'Sexual Intercourse is good for lower back pain, for weakness of the eyes, for derangement and depression 28.155

- Galen (130 AD – 210 AD) : 'Socles, promising to set Diodorus' crooked back straight, piled three solid stones, each four feet square, on the hunchbacks spine. He was crushed and died, but he has become straighter than a ruler.'
  Book X1 – 120

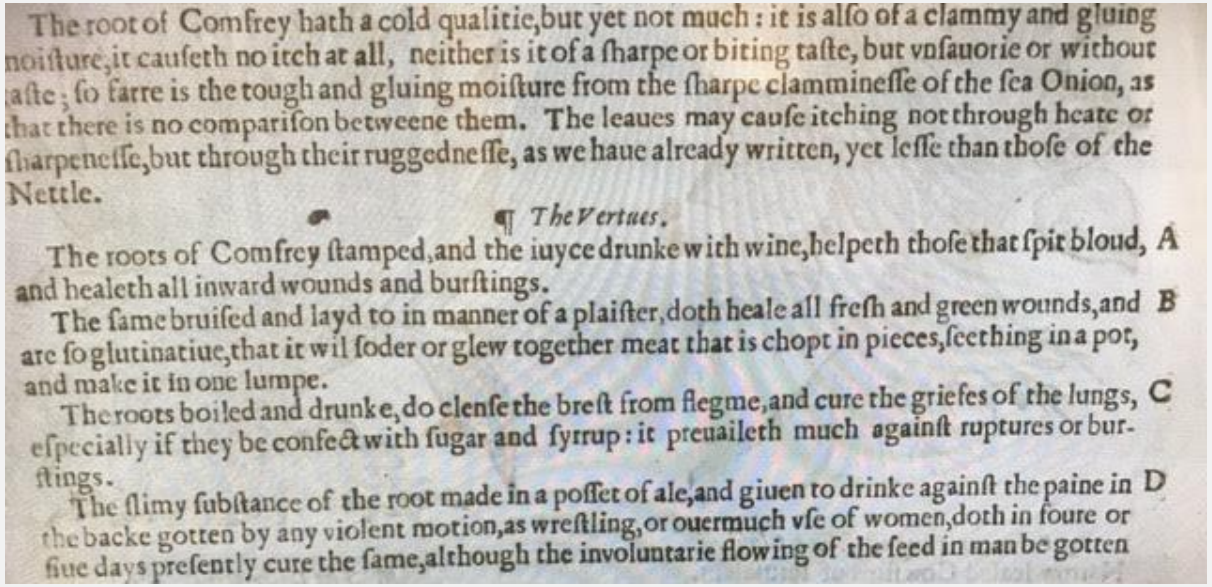
BACK PAIN: HISTORY

'For a pine in the back take fresh cow dung and fry it in vinegar and apply it plaster wise to the back: you will little think how soon it will give you ease.'



BACK PAIN: HISTORY

‘The slimy substance of the root made in a posset of ale, and given to drinke against the paine in the backe gotten by any violent motion, as wrestling or ouermuch use of women, doth in foure or five days presently cure the same, although the involuntarie flowing of the seed in man be gotten’



The root of Comfrey hath a cold qualitie, but yet not much: it is alſo of a clammy and gluing moiſture, it cauſeth no itch at all, neither is it of a ſharpe or biting taſte, but vnſauorie or without taſte; ſo farre is the tough and gluing moiſture from the ſharpe clammineſſe of the ſea Onion, as that there is no compariſon betweene them. The leaues may cauſe itching not through heate or ſharpeneſſe, but through their ruggedneſſe, as we haue already written, yet leſſe than thoſe of the Nettle.

¶ *The Vertues.*

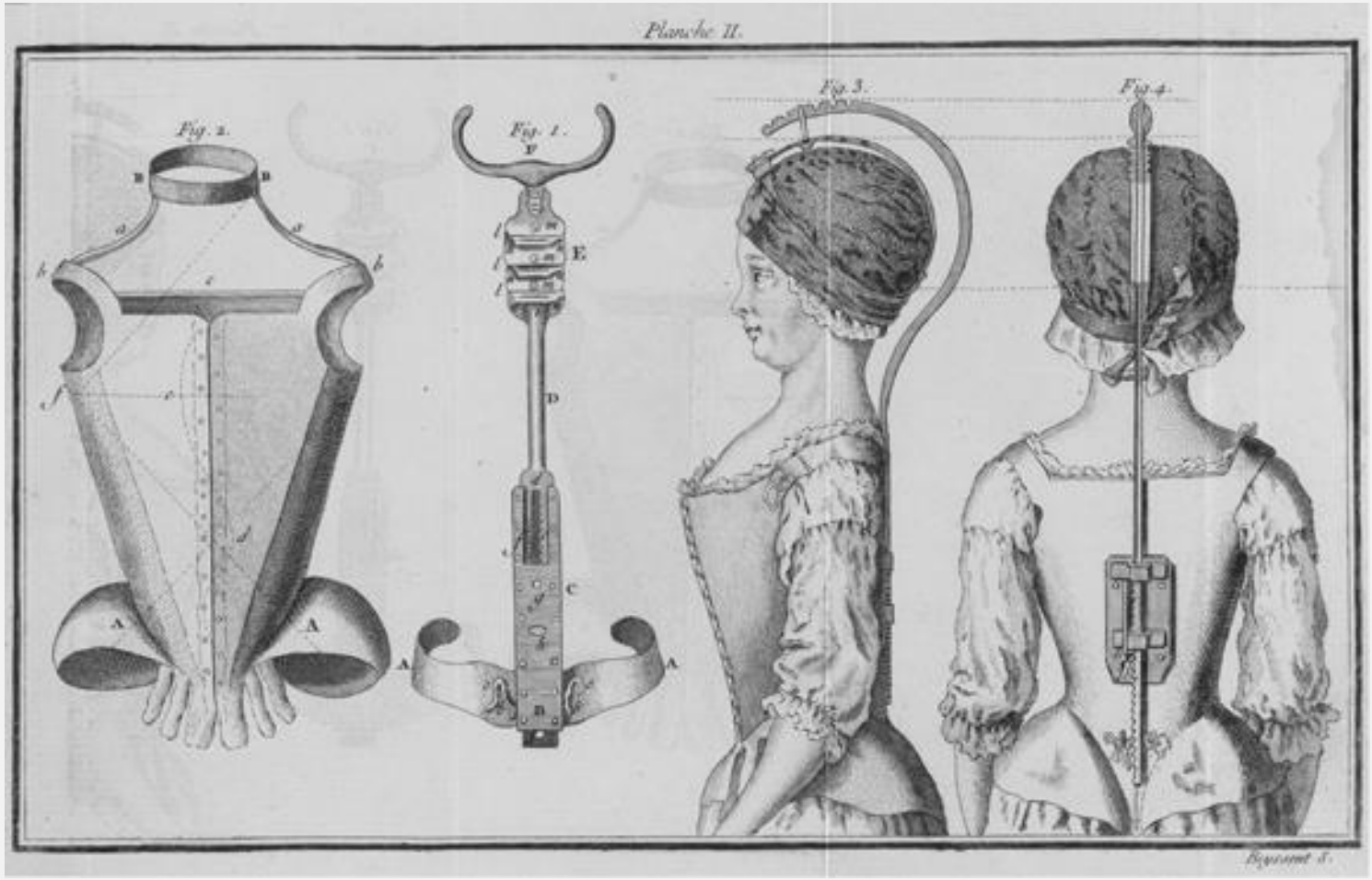
The roots of Comfrey ſtamped, and the iuyce drunke with wine, helpeth thoſe that ſpit bloud, A and healeth all inward wounds and burſtings.

The ſame bruiſed and layd to in manner of a plaiſter, doth heale all freſh and green wounds, and B are ſo glutinatiue, that it wil ſoder or glew together meat that is chopt in pieces, ſeething in a pot, and make it in one lumpe.

The roots boiled and drunke, do clenſe the breſt from flegme, and cure the griefes of the lungs, C eſpecially if they be confect with ſugar and ſyrrup: it preuaileth much againſt ruptures or burſtings.

The ſlimy ſubſtance of the root made in a poſſet of ale, and giuen to drinke againſt the paine in D the backe gotten by any violent motion, as wreſtling, or ouermuch vſe of women, doth in foure or fiue days preſently cure the ſame, although the involuntarie flowing of the ſeed in man be gotten

BACK PAIN: HISTORY



BACK PAIN: HISTORY

SNAKE-OIL LINIMENT

RELIEVES INSTANTANEOUSLY

AND CURES HEADACHE, NEURALGIA, TOOTHACHE, EARACHE, BACKACHE, SWELLINGS, SPRAINS, SORE CHEST, SWELLING of the THROAT, CONTRACTED CORDS and MUSCLES, STIFF JOINTS, WRENCHES, DISLOCATIONS, CUTS and BRUISES.

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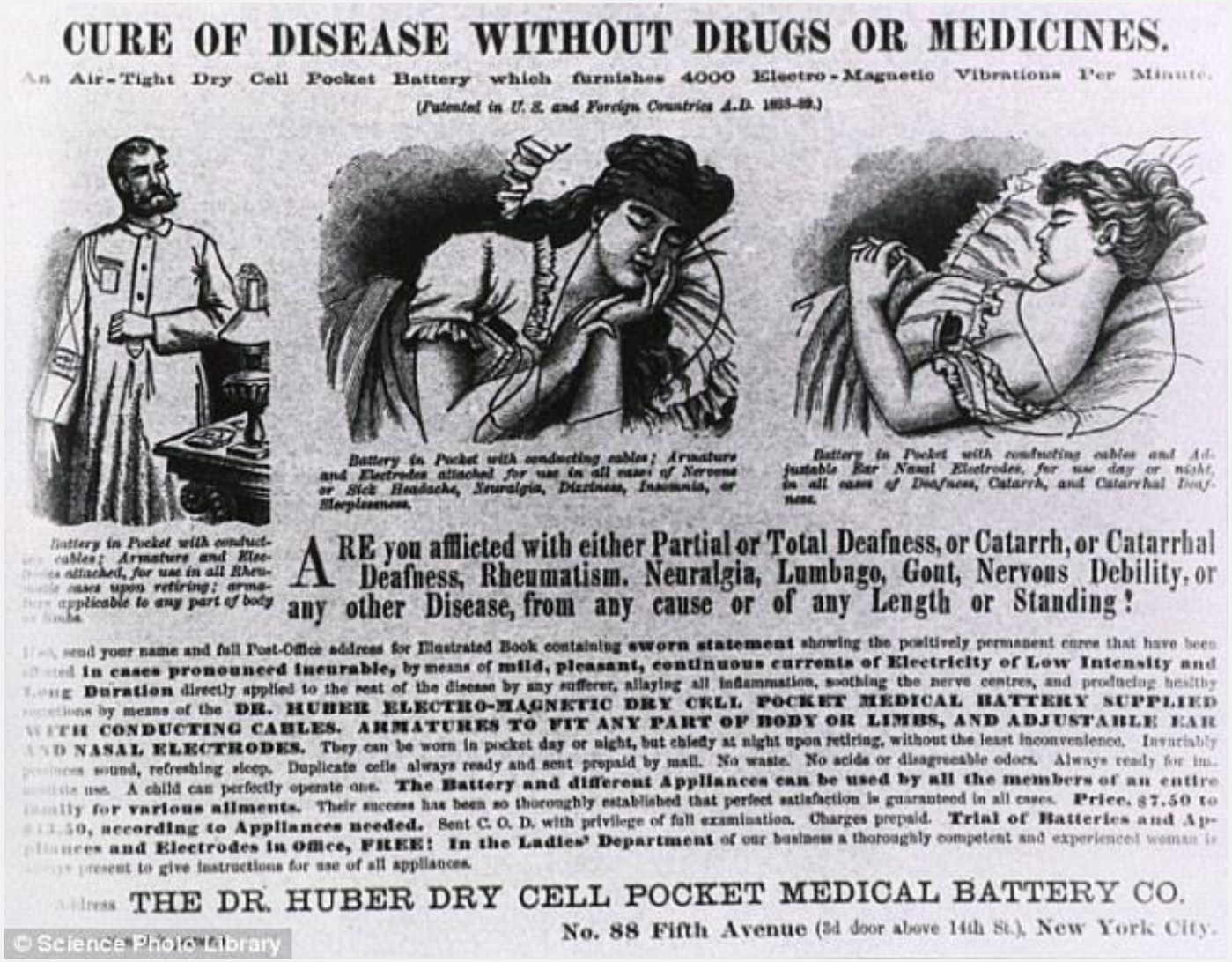
BACK PAIN: HISTORY



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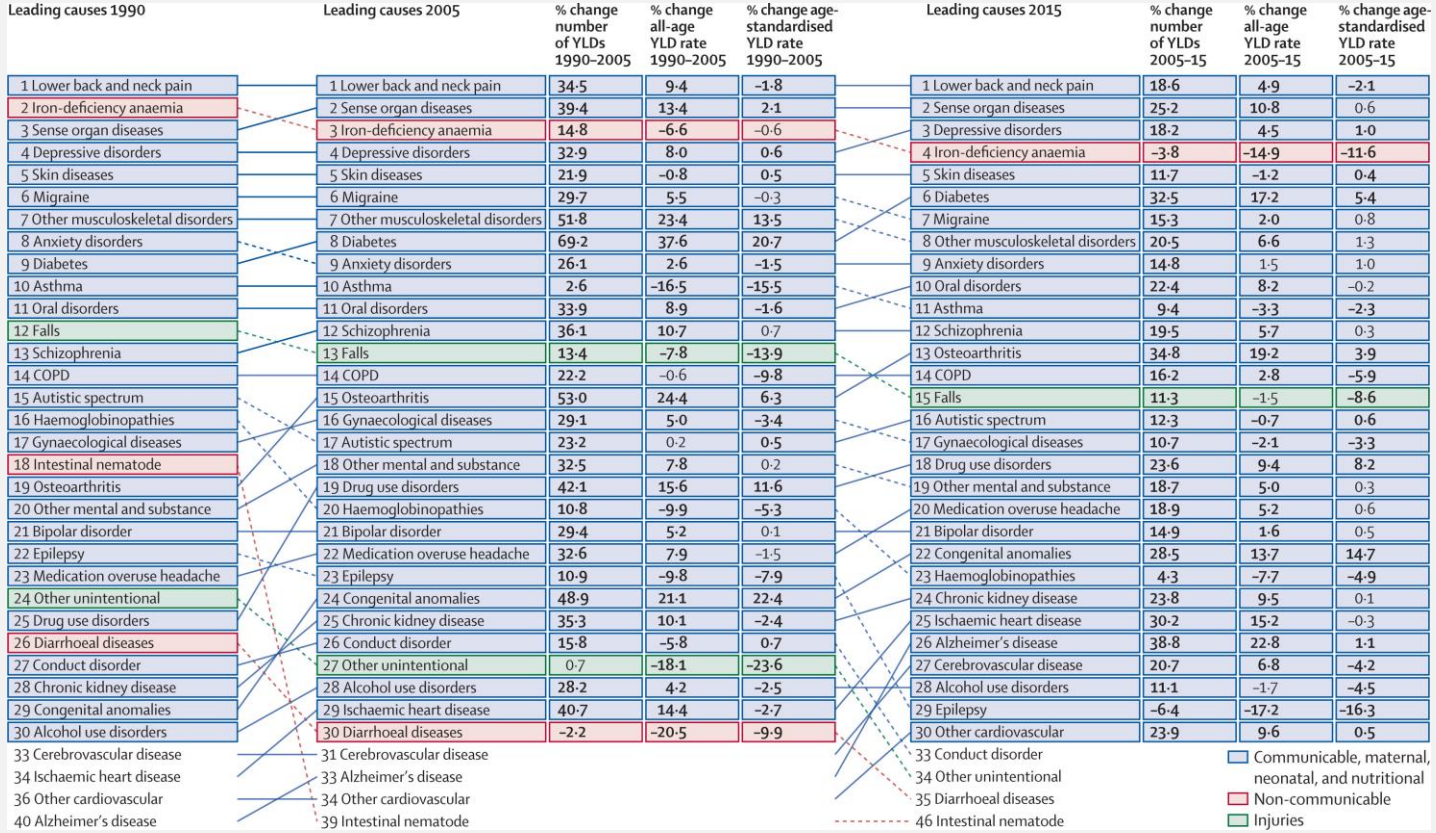
Rank[a]	Condition	Assigned Aggregated Condition Category	2013 Spending (Billions of Dollars), $	Annualized Rate of Change, 1996-2013, %
	All conditions		2100.1	3.5
1	Diabetes mellitus	Diabetes, urogenital, blood, and endocrine diseases	101.4	6.1
2	Ischemic heart disease	Cardiovascular diseases	88.1	0.2
3	Low back and neck pain	Musculoskeletal disorders	87.6	6.5
4	Treatment of hypertension	Treatment of risk factors	83.9	5.1

Dieleman et al. US Spending on Personal Health Care and Public Health, 1996-2013 JAMA 2016



The Lancet 2016 388, 1545-1602DOI: (10.1016/S0140-6736(16)31678-6

WHY DO WE NEED CLINICAL GUIDELINES?

'Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'

Field MJ, Lohr KN. Clinical practice guidelines: directions for a new program. Washington, DC: National Academy Press; 1990

- To make sense of 'Information overload' and to keep up to date
- To ensure that effective, evidence based interventions are prioritised
- To prevent waste and harm
- To reduce variations in practice
- To provide a rational basis for referral
- To highlight areas where there is scientific uncertainty

BACK PAIN GUIDELINES

Quebec Task Force 1987

- Radiological examinations reduced to a minimum
- Reassurance, encourage return to work
- Bed rest limited to a few days
- NSAIDs
- Pain > 3 months: consult multidisciplinary team
- Review psychosocial aspects of pain
- Physical rehabilitation
- Indications for surgery must always be specific

BACK PAIN GUIDELINES

I. The Norwegian Guideline (The Norwegian Back Pain Network, 2002)

II. New South Wales Guideline (New South Wales Therapeutic Assessment Group, 2002)

III. National Practice Guidelines for Physical Therapy in Patients with Low Back Pain (KNGF 2003)

IV. The New Zealand Guideline (New Zealand Guidelines Group, 2004)

V. The Australian Guideline (Australian Acute Musculoskeletal Pain Guidelines Group, 2004)

VI. European guidelines for the management of chronic nonspecific low back pain 2006

VII. The University of Michigan Guideline (University of Michigan Health System, 2010)

VIII. Low Back - Lumbar & Thoracic (Acute & Chronic) Guideline (Work Loss Data Institute, 2011)

IX. 2007/2009/2017 Diagnosis and Treatment of Low Back Pain: APC &APS

X. Low back and radicular pain: a pathway for care developed by the British Pain Society 2013

XI. 2015 Evidence-Informed Primary Care Management of Low Back Pain – Canada

XII. 2016 NICE low back pain and sciatica guideline.

XIII. 2017 Danish low back pain guideline.

BACK PAIN GUIDELINES

1. Identifying and refining the subject area.
2. Convening and running a guideline development group.
3. Assessing the evidence about the clinical question or condition, on the basis of systematic reviews.
4. Translating the evidence into a recommendation.
5. External review of the guideline.

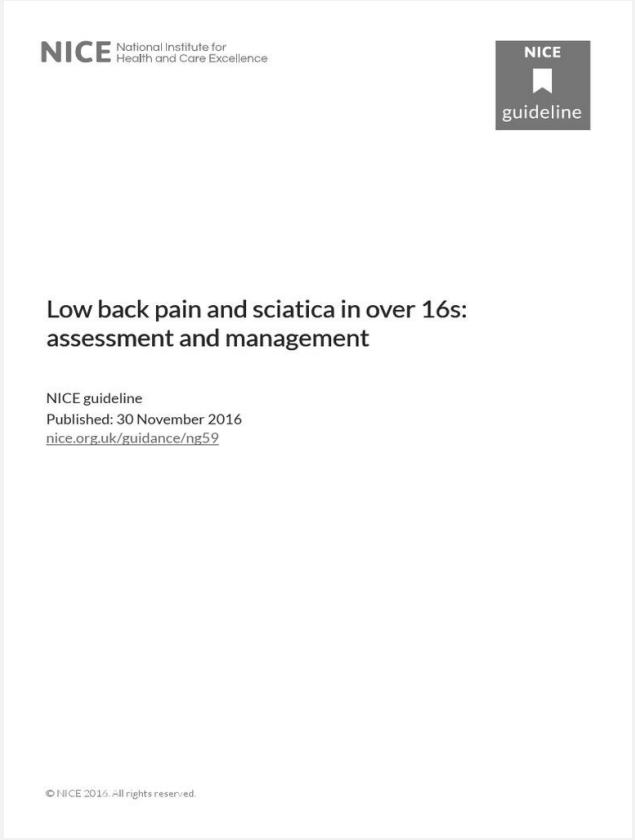
- Original/de novo systematic review and meta analysis
- Reviews of systematic reviews (+/- RCTs)
- Reviews of previous guideline recommendations

SYSTEMATIC REVIEWS

- ‘No high-quality evidence shows that XXXXXXX provides pain relief for patients with chronic low back pain’

- There was moderate quality evidence that XXXXXXX results in larger improvements in pain and daily function than usual care…..

NICE GUIDELINE NG59



NICE National Institute for Health and Care Excellence

NICE guideline

Low back pain and sciatica in over 16s: assessment and management

NICE guideline
Published: 30 November 2016
nice.org.uk/guidance/ng59

NICE GUIDELINE NG59

- Scope
- Guideline development group
- Formulating questions
- PICO
- Search and analysis
- Presentation to GDG
- GDG consensus

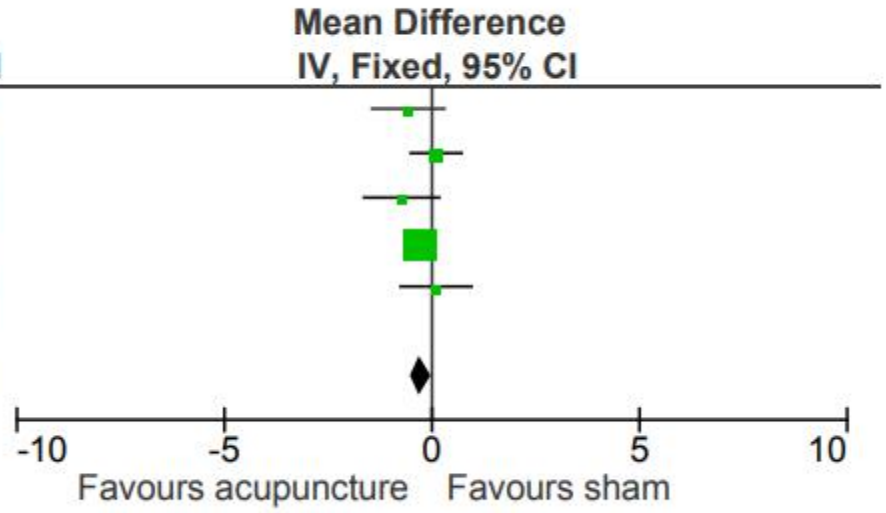
FOREST PLOT

Figure 694: Pain severity (VAS 0–10) > 4 months

Study or Subgroup	Acupuncture Mean	SD	Total	Sham Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Brinkhaus 2006A	3.92	2.92	137	4.49	3.04	68	8.2%	-0.57 [-1.44, 0.30]
Cherkin 2009 (SA)	3.5	2.7	147	3.4	2.7	152	16.6%	0.10 [-0.51, 0.71]
Cho 2013	2.79	2.44	57	3.52	2.53	59	7.6%	-0.73 [-1.63, 0.17]
Haake 2007	4.02	2.25	377	4.33	2.3	376	59.0%	-0.31 [-0.64, 0.02]
Leibing 2002	-1.7	1.8	40	-1.8	2.2	45	8.6%	0.10 [-0.75, 0.95]
Total (95% CI)			**758**			**700**	**100.0%**	**-0.26 [-0.51, -0.01]**

Heterogeneity: $Chi^2 = 3.63$, $df = 4$ ($P = 0.46$); $I^2 = 0\%$

Test for overall effect: $Z = 2.04$ ($P = 0.04$)



GDG DECISION MAKING

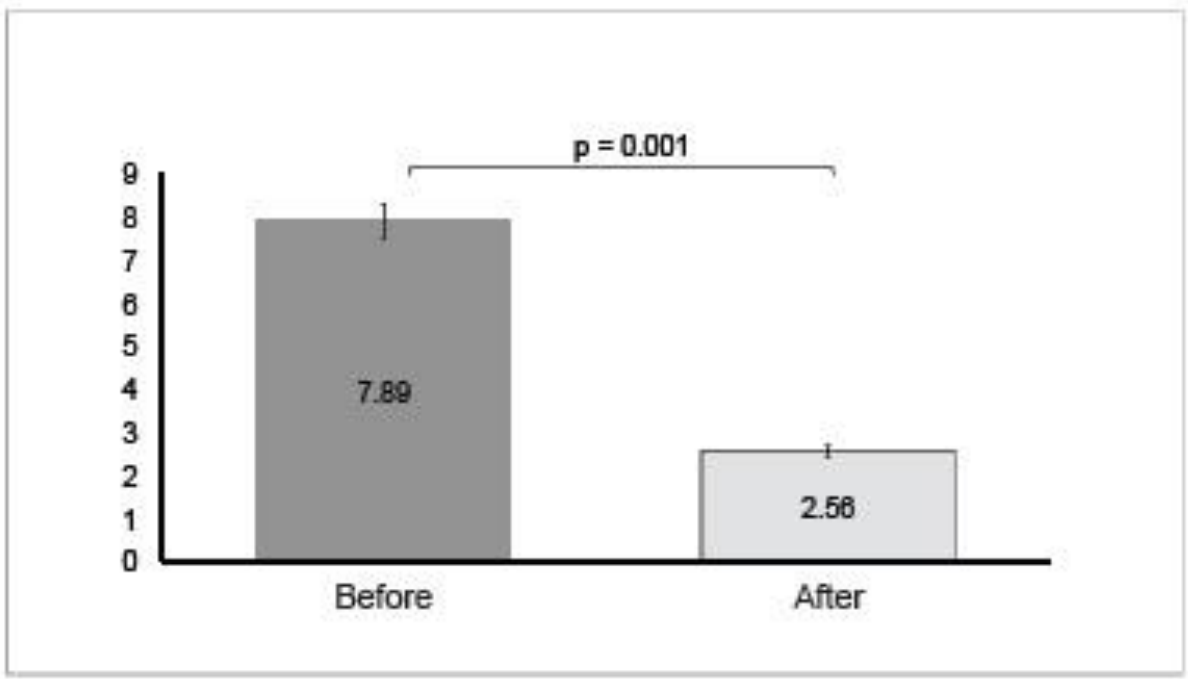
- Statistical significance of the primary efficacy analysis
- Magnitude of improvement in the primary efficacy outcome with treatment
- Results of responder analyses
- Treatment effect size compared to available treatments
- Rapidity of onset of treatment benefit
- Durability of treatment benefit
- Results for secondary efficacy endpoints
- Safety and tolerability
- Convenience
- Patient adherence
- Cost and cost effectiveness

Dworkin 2009

MINIMAL IMPORTANT DIFFERENCE

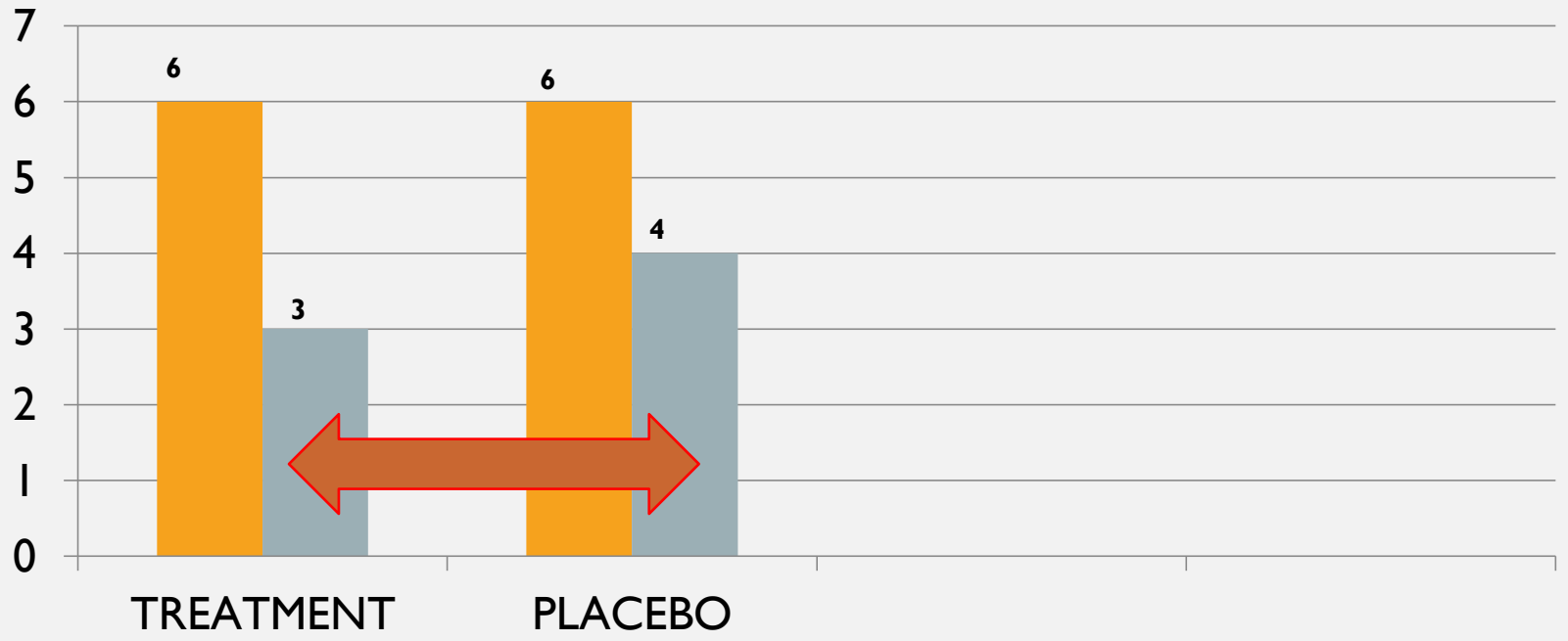
'The smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management.'

Jaeschke et al 1989



Graph 1 – Mean pain intensity reported by patients before and after Pilates treatment.

CLINICAL SIGNIFICANCE



MID

'It is crucial to recognize that criteria for clinically important changes in individuals cannot be extrapolated to the evaluation of group differences'

Dworkin R et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. PAIN 146 (2009) 238–244

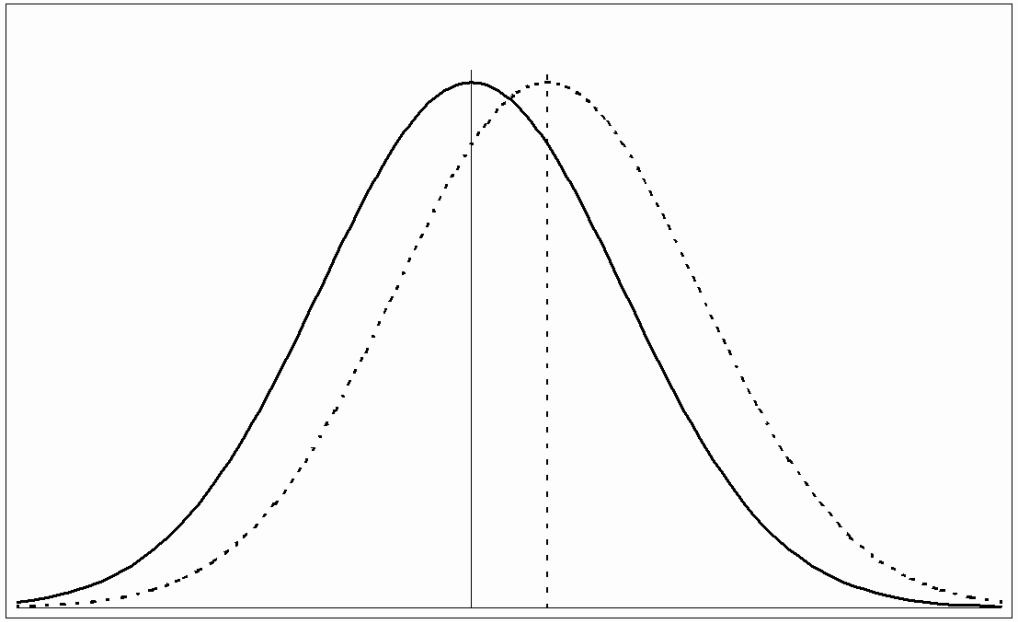
Table 2. Other characteristics of measures of the smallest worthwhile effect

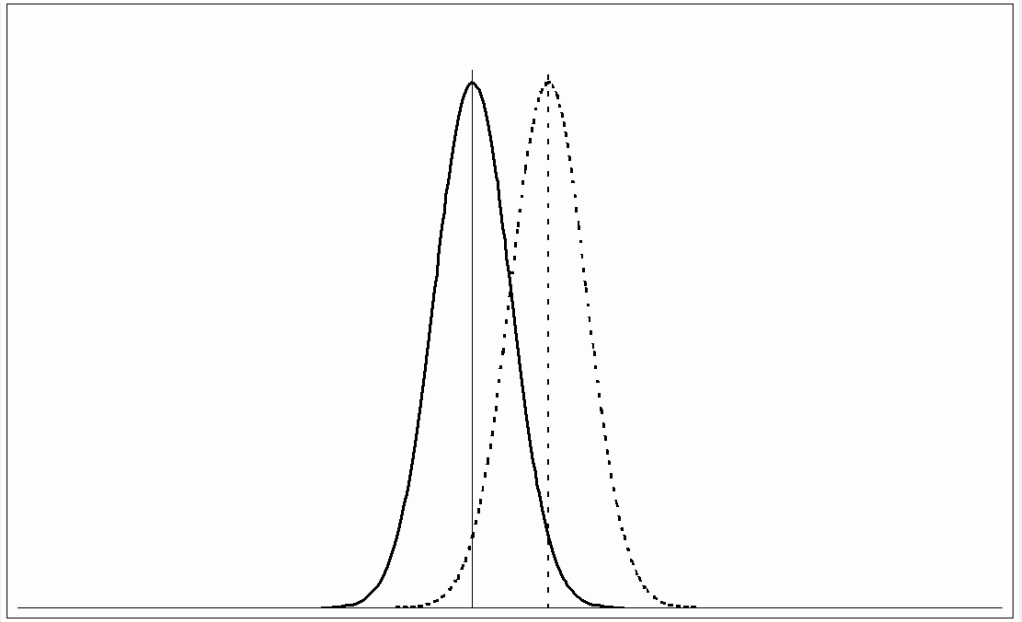
Study	Outcomes[a]	Terminology	Method[b]	Specific[c]	Between/within?[d]	Who decided?[e]
Beurskens et al., 1996 [5]	D, BP, MC	MCID	A	No	Within	Res
Bronfort and Bouter, 1999 [17]	D, QoL	MCID	A	No	Within	Res
Chansirinukor et al., 2005 [18]	D	MDC	D	No	Within	Res
Childs and Piva, 2005 [19]	D	MCID	A	No	Within	Res
Childs et al., 2005b [20]	BP	MCID	A/D	No	Within	Res
Coelho et al., 2008 [21]	D, BP	MCID	A	No	Within	Res
Copay et al., 2008 [22]	BP, LP, D	MCID/MDC/MCID[f]	A/D	No	Within	Res
Davidson and Keating, 2002 [23]	D, BP	MDC	A	No	Within	Res
Demoulin et al., 2010a [8]	D	MIC	A	No	Within	Res
Demoulin et al., 2010b [9]	D	MIC	A	No	Within	Res
de Vet et al., 2007 [24]	BP	MIC	A/D	No	Within	Res
Farrar et al., 2001 [25]	BP	CII[g]	A	No	Within	Res
Ferreira et al., 2009 [26]	MC	SWE	PS	Yes	Within	Pts
Fritz and Irrgang, 2001 [27]	D	MCID	A	No	Within	Res
Grotle et al., 2004 [28]	D, BP, QoL	MCID	A	No	Within	Res
Hagg et al., 2003 [29]	D, BP, Dep	MCID	A	No	Within	Res
Jordan et al., 2006 [30]	D	1.96 SEM/SEM/MCID	A/D	No	Within	Res
Kovacs et al., 2007 [31]	BP, LP, D	MDC/MCID	A/D	No	Within	Res
Lauridsen et al., 2006 [32]	D, BP	MCID	A	No	Within	Res
Mannion et al., 2006 [33]	D, BP	MCIC	A	No	Within	Res
Maughan and Lewis, 2010 [43]	D, BP, PSE	MCID	A	No	Within	Res
Oliveira et al., 2009 [41]	MC	SWE	PS	Yes	Within	Pts
Ostelo et al., 2004 [34]	D, MC	MDC	D	No	Within	Res
Ostelo et al., 2008 [35]	D, BP	MIC	Other	No	Within	Res
Riddle et al., 1998 [36]	D	MCID	A	No	Within	Res
Sheldon et al., 2008 [37]	D, BP	MCIC	A	No	Within	Res
Strand et al., 2002 [42]	D	MCIC	A	No	Within	Res
Stratford et al., 1998 [38]	D	MCID	A	No	Within	Res
van der Roer et al., 2006 [39]	BP	MCIC-O[h]/MCIC/MDC	A/D	No	Within	Res
Williams et al., 1998 [40]	D	MCID	D	No	Within	Res
Yelland et al., 2006 [7]	D, BP	MWR[i]	Other	Yes	Unclear	Pts

[a] D, disability; BP, back pain; MC, main complaint; QoL, quality of life; LP, leg pain; Dep, depression; PSE, pain self efficacy.
[b] A, anchor-based methods; D, distribution-based methods; PS, patient-centered survey.
[c] Was the estimate intervention-specific?
[d] Was the estimate of a between- or within-person difference?
[e] Who decided if the effect was large enough? Res, researchers; Pts, patients.
[f] Derived from effect sizes.
[g] Clinically important improvement.
[h] MCIC-Optimal cut-off point.
[i] Minimum worthwhile percent reduction.

EFFECT SIZE

$$\text{Effect Size} = \frac{[\text{Mean of experimental group}] - [\text{Mean of control group}]}{\text{Standard Deviation}}$$





EFFECT SIZE

- Example:

VAS Pain

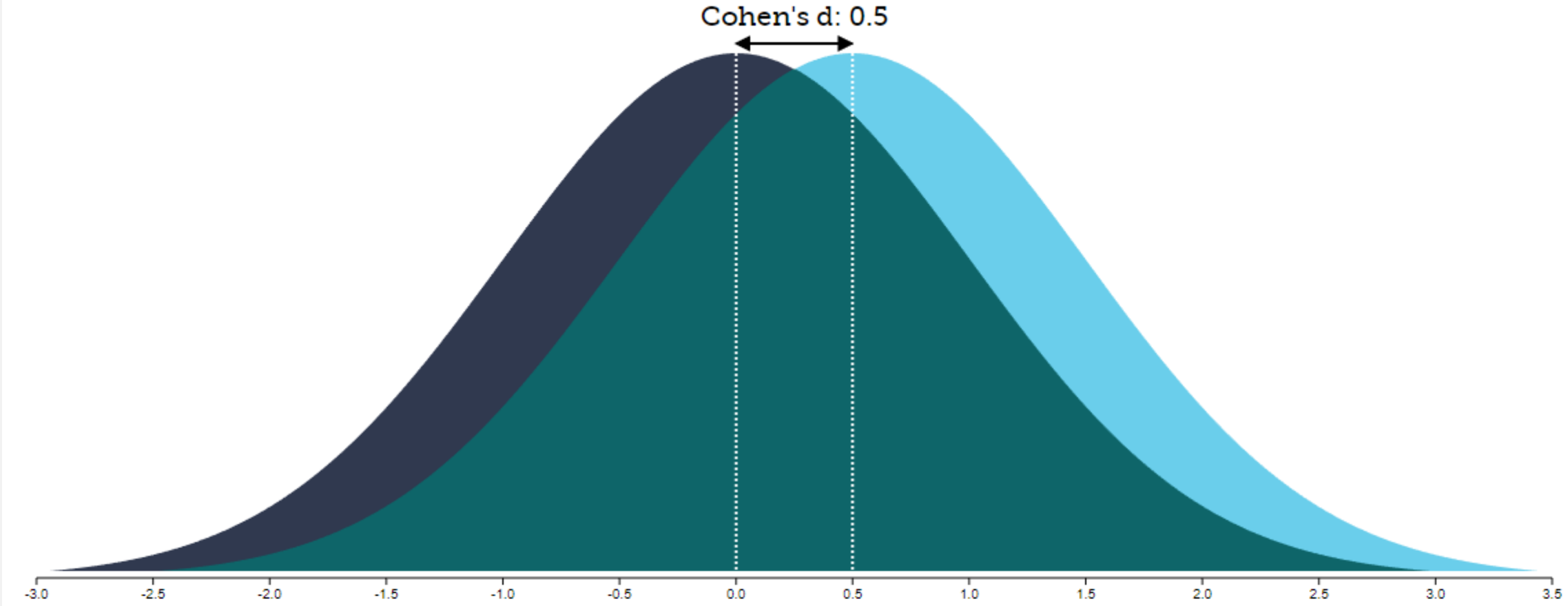
$$\frac{\text{4 (mean placebo group) – 3 (mean intervention group)}}{\text{2 (standard deviation)}}$$

Effect size = 0.5

(mean SD in 9076 subjects = 1.79)

EFFECT SIZE

- Small = 0.2/0.3
- Medium = 0.5
- Large = 0.8



Interpretation

69.15 %

Cohen's U_3

80.26 %

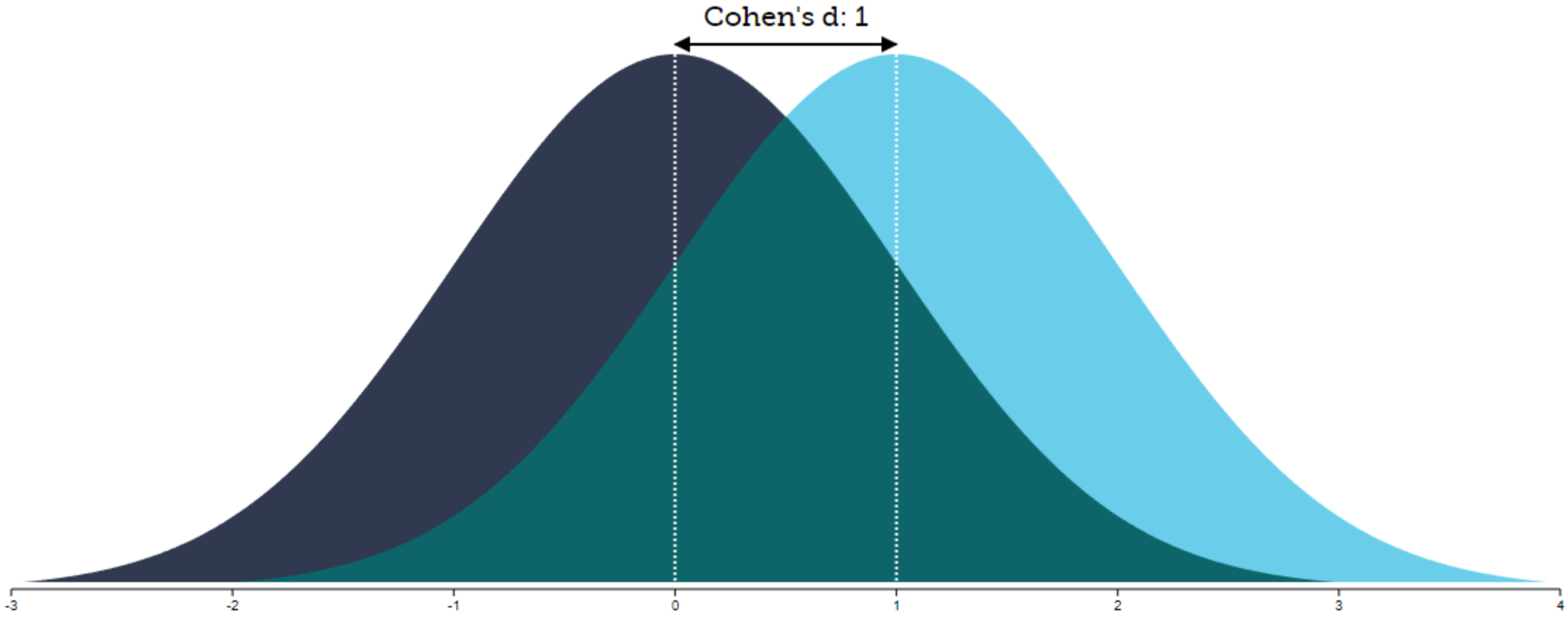
% Overlap

63.82 %

Probability of Superiority

6.01

Number Needed to Treat[1]



Interpretation

84.13 %

Cohen's U_3

61.71 %

% Overlap

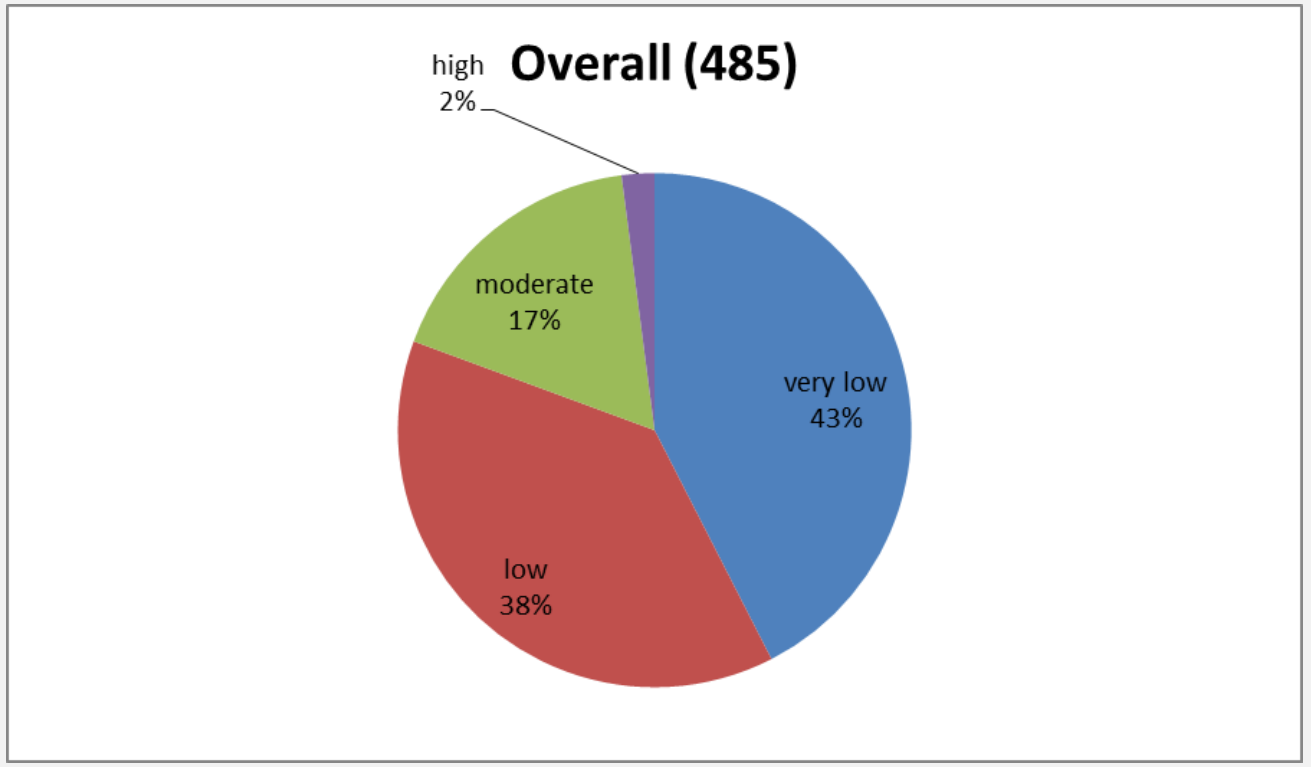
76.02 %

Probability of Superiority

2.76

Number Needed to Treat[1]

QUALITY



RECOMMENDATIONS

- DO NOT DO
- WEAK RECOMMENDATION
- STRONG RECOMMENDATION

TREATMENT A

- Statistically significant ☑
- Pain VAS short term effect size VS placebo = 0.43 (12: **3268**)
- Pain VAS long term effect size VS placebo ☒
- Pain VAS short term effect size VS usual care ☒
- Pain VAS long term effect size VS usual care ☒
- Function : +
- Cost effective N/A
- Harms ++

OPIOIDS

TREATMENT B

- Statistically significant ☑
- Pain VAS short term effect size VS placebo ☒
- Pain VAS long term effect size VS placebo ☒
- Pain VAS short term effect size VS usual care 0.26 (2: **82**)
- Pain VAS long term effect size VS usual care ☒
- Function : ++
- Cost effective ☑
- Harms -

YOGA

TREATMENT C

- Statistically significant ☑
- Pain VAS short term effect size VS placebo ☒
- Pain VAS long term effect size VS placebo ☒
- Pain VAS short term effect size VS usual care = 0.32 (6: **456**)
- Pain VAS long term effect size VS usual care ☒
- Function : +/-
- Cost effective N/A
- Harms -

CBT

TREATMENT D

- Statistically significant ☑
- Pain VAS short term effect size VS placebo = 1.16 (4: **167**)
- Pain VAS long term effect size VS placebo = 1.15 (3: **110**)
- Pain VAS short term effect size VS usual care ☒
- Pain VAS long term effect size VS usual care ☒
- Function : +/-
- Cost effective ☑
- Harms -

RADIOFREQUENCY

TREATMENT E

- Statistically significant ☑
- Pain VAS short term effect size VS placebo = 0.42 (8: **1760**)
- Pain VAS long term effect size VS placebo = 0.1 (5: **1458**)
- Pain VAS short term effect size VS usual care = 0.79 (8: **1334**)
- Pain VAS long term effect size VS usual care = 0.5 (3: **950**)
- Function : +/-
- Cost effective +/-
- Harms -

ACUPUNCTURE

TREATMENT F

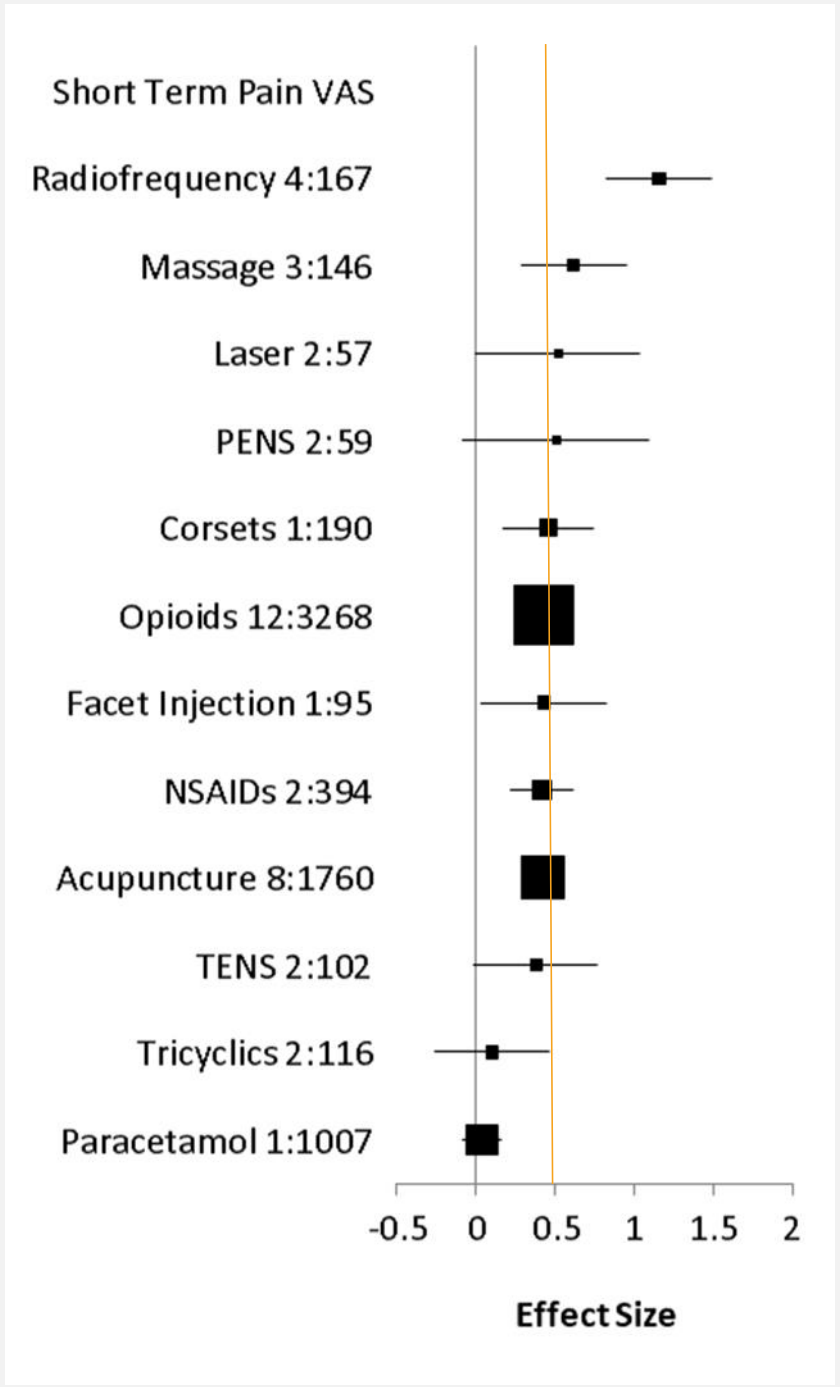
- Statistically significant ☑
- Pain VAS short term effect size VS placebo ☒
- Pain VAS long term effect size VS placebo ☒
- Pain VAS short term effect size VS usual care ☒
- Pain VAS long term effect size VS usual care = 0.68 (I: **264**)
- Function : +
- Cost effective ☒
- Harms ++

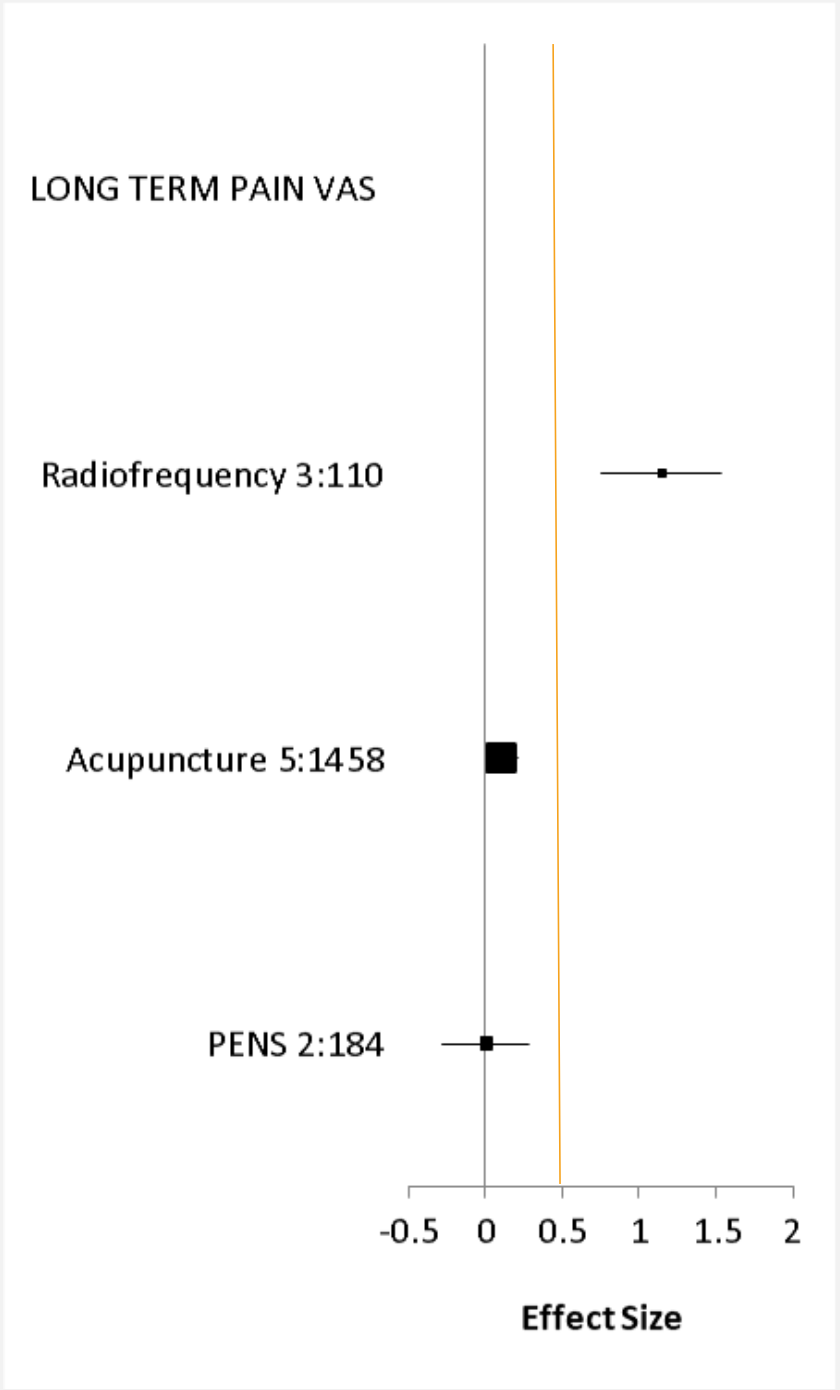
SPINAL FUSION

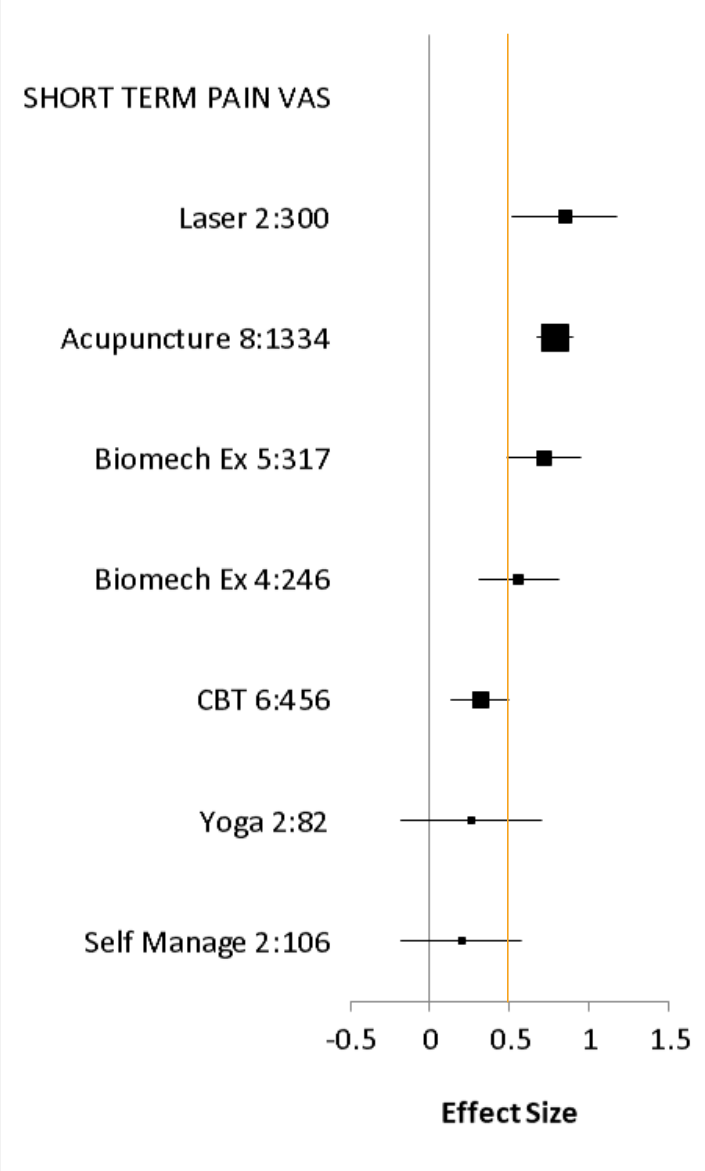
TREATMENT G

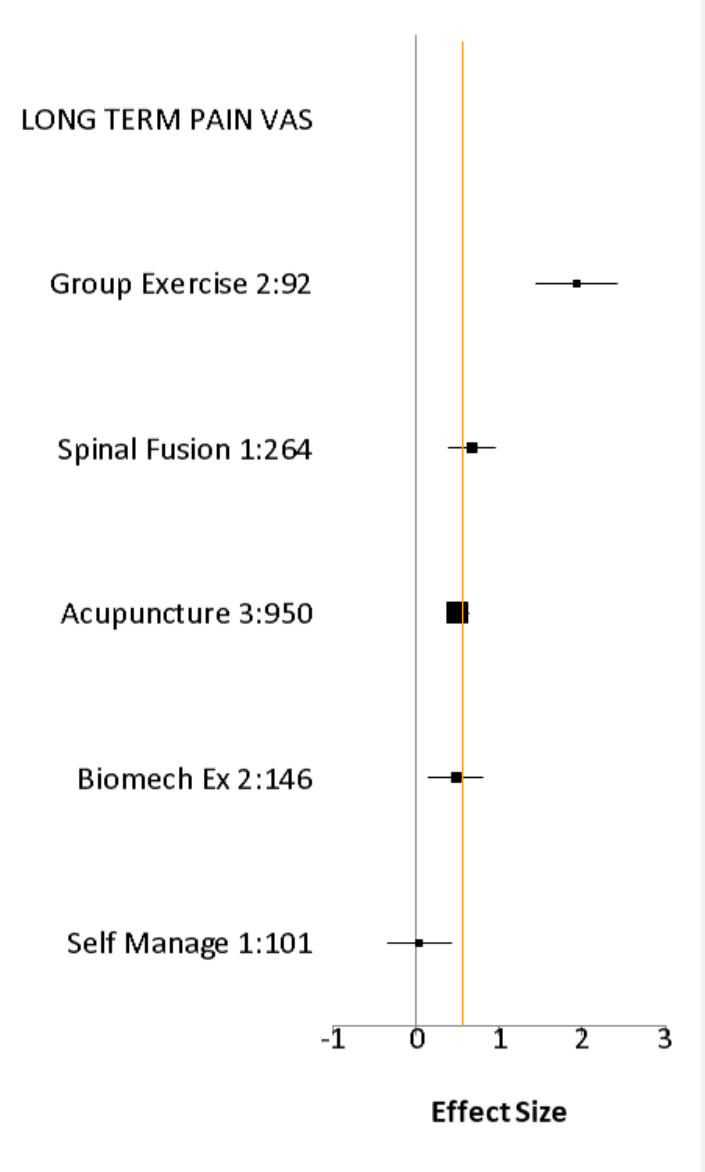
- Statistically significant ☑
- Pain VAS short term effect size VS placebo ☒
- Pain VAS long term effect size VS placebo ☒
- Pain VAS short term effect size VS usual care = 0.2 (2: **106**)
- Pain VAS long term effect size VS usual care = 0.04 (1: **101**)
- Function : -
- Cost effective N/A
- Harms -

SELF MANAGEMENT


Short Term Pain VAS
Radiofrequency 4:167
Massage 3:146
Laser 2:57
PENS 2:59
Corsets 1:190
Opioids 12:3268
Facet Injection 1:95
NSAIDs 2:394
Acupuncture 8:1760
TENS 2:102
Tricyclics 2:116
Paracetamol 1:1007
-0.5
0
0.5
1
1.5
2
Effect Size


LONG TERM PAIN VAS
Radiofrequency 3:110
Acupuncture 5:1458
PENS 2:184
-0.5
0
0.5
1
1.5
2
Effect Size


SHORT TERM PAIN VAS
Laser 2:300
Acupuncture 8:1334
Biomech Ex 5:317
Biomech Ex 4:246
CBT 6:456
Yoga 2:82
Self Manage 2:106
-0.5
0
0.5
1
1.5
Effect Size


LONG TERM PAIN VAS
Group Exercise 2:92
Spinal Fusion 1:264
Acupuncture 3:950
Biomech Ex 2:146
Self Manage 1:101
-1
0
1
2
3
Effect Size

Visual summary

Managing low back pain and sciatica

A brief overview the new NICE guidelines, from the perspective of a patient presenting in primary care.

Person with low back pain

With or without sciatica

Consider alternatives

Exclude specific causes of low back pain, for example:

Cancer | Infection | Trauma | Inflammatory disease | Cauda equina

Referral

✗ Imaging

Only consider imaging:

In specialist care

and

If likely to alter management

Assess likely recovery outcomes

The complexity and intensity of treatment may vary depending on how likely it is that the patient will have a good functional outcome

Consider using risk stratification –such as the **STarT Back** risk assessment tool

Possible indicators of poor outcomes

Fear / pain avoidance ▶ | Low mood ▶ | Job dissatisfaction ▶ | Ongoing litigation ▶

◀ Good — Likely outcomes — Poor ▶

Provide self management information

Information on nature of pain | Encouragement to continue activities

Self management is important for all patients, even those with acute symptoms and/or sciatica

Managing acute sciatica

- Neuropathic pain medication
- Epidural injections: Steroid + Local anaesthetic
- Spinal decompression

After acute symptoms of sciatica are controlled, it may be appropriate to (re)enter an excercise programme to manage underlying low back pain

To manage a specific episode

- Group exercise + Manual therapy
- Group exercise + Psychological therapy

Pain is persistent / treatment resistant

- Combined physical + psychological programme

Consider pain relief options

Paracetamol	NSAIDs*	Weak opioids
✗ Not effective alone	✓ Consider oral NSAIDs	✓ If NSAID ineffective / not tolerated / contraindicated

✗ Do not offer acupuncture

* NSAIDs = non-steroidal anti-inflammatory drugs