Muscle energy technique for non-specific low-back pain (Protocol)

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[Intervention Protocol]

Muscle energy technique for non-specific low-back pain

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to scrutinise the effectiveness of MET in the treatment of non-specific back pain with special emphasis on subjective pain parameters, functional status, or both compared with control interventions or untreated controls, respectively.

BACKGROUND

Clinical guidelines for low-back pain (LBP), developed by the National Institute for Health and Clinical Excellence (NICE 2009), define non-specific low-back pain as "tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain." The aetiology of low-back pain is poorly understood and authors and researchers have offered different opinions on the common cause of this complaint. Deyo and Weinstein (Deyo 2001) estimate that 85% of patients with isolated low-back pain cannot be given a precise patho-anatomical diagnosis. In a literature review, Vuori (Vuori 2001) states that 85% of the cases of LBP are unspecific and functional. Nachemson (Nachemson 1994) claimed that 97% of the lumbar spine problems are classified as "unspecific."

A systematic review of observational studies (van Tulder 1997) stated that no firm evidence for the presence or absence of a causal relationship between radiographic findings and non-specific low-back pain could be found. Bogduk (Bogduk 2009) argues that plain radiographs, magnetic resonance imaging (MRI) scans, or computed tomography (CT) scans are unable to reveal the cause of somatic pain in the majority of cases and that they carry the risk of erroneously positive interpretations. A purely biomechanical explanatory model for the development of LBP does not seem to be broad enough (Hestbaek 2003). Gilkey (Gilkey 2010) stated that back pain is multifactorial and different chains of causation make it very difficult to isolate risk factors. The recurrence rate of LBP is high. Studies state that 47% to 84% of individuals who have an episode of LBP will suffer a recurrence within one year (Stanton 2008). To this day, it is not possible to predict reliably who will develop back pain and what the reasons for that development are.

In clinical practice, non-specific low-back pain which is present for less than six weeks is classified as "acute." With a recovery rate of close to 90% within six to eight weeks, acute back pain has a great tendency to be self-limiting (Burton 2006; Waddell 2004). When back pain persists between six weeks and three months it is described as "subacute" and longer than three months as "chronic" (van Tulder 2006). Other authors (Cedraschi 1999; Dionne 2008) point out that patients with LBP typically suffer from changing, intermittent episodes of varying duration, and the "acute-subacute-chronic" classification is inadequate in classifying this episodic and intermittent condition.

Economic consequences of back pain are enormous. Only a small percentage of patients with chronic or episodic LBP account for a large fraction of healthcare expenditure. Various factors have been shown to be correlated with, or predictive of, chronic LBP, including the characteristics of the initial episode, pain, psychosocial issues and occupation (Neubauer 2006).

In addition to the economic impact of LBP on the individual and society, there is a further obvious impact on the individual. Researchers have reported changes in social behavior, retreat from activities of daily living life and reduced quality of life to be frequent features in people who suffer from back pain (Croft 1994).

Description of the intervention

Muscle Energy Technique (MET) is a commonly used treatment technique in osteopathy (Fryer 2009; Fryer 2010b) and manual therapy (Boyling 2005; Chaitow 2006). It was developed 50 years ago by Fred Mitchell Sr. and was then refined and partially modified by his son Fred Mitchell Jr. (Mitchell 1999; Mitchell 2001a; Mitchell 2001b). MET uses the voluntary contraction of the patient's muscle in a precisely controlled direction against a distinctly executed counter-force, which is applied by the operator.
MET can be used to:

- lengthen a shortened muscle;
- mobilise an articulation with restricted mobility;
- strengthen a physiologically weakened muscle;
- reduce localised oedema and passive congestion.

Several factors are claimed to be important for successful use of MET. These include an exact diagnosis, a precise positioning of the joint or tightened muscle by the therapist, an active and appropriately regulated muscle contraction by the patient against a defined resistance of the therapist, an accurate control of the modification in range of movement, and if necessary, repositioning of the joint at a new barrier of movement restriction.
Over the years, MET has undergone considerable modification. The classical concept focuses on an osteo-kinematic diagnosis and sees the tightened muscle in the context of a joint dysfunction (Mitchell 2001a), while newer concepts ignore the arthro-kinematic emphasis and see the primary application of MET in muscle tightness, spasms, and myofascial trigger points, with joint mobilisation as a consequence of muscle relaxation (Chaitow 2006).

How the intervention might work

The physiological mechanisms underlying the therapeutic effects of MET are unclear and may involve a variety of neurological and biomechanical mechanisms, including hypoalgesia, altered proprioception, motor programming and control, and changes in tissue fluid (Fryer 2010a). Lasting biomechanical changes to muscle property following MET have not been demonstrated, and changes to muscle extensibility and spinal range of motion may be related to mechanisms promoting hypoalgesia and an increase in stretch tolerance. Clincal studies suggest MET and related post-isometric techniques reduce pain and discomfort when applied to the spine (Wilson 2003) or muscles (Ballantyne 2003; Magnusson 1996). MET may have physiological effects, regardless of the presence or absence of dysfunction (Fryer 2004).

Why it is important to do this review

According to a study by Johnson and Kurtz (Johnson 2003), together with the soft-tissue technique and high-velocity low-amplitude thrusts, MET is one of the three most commonly used techniques applied by American osteopaths in a treatment. From the field of manual therapy, some studies (Cassidy 1992; Salvador 2005; Selkow 2009; Wilson 2003) have researched the effectiveness of MET and reported promising results. Given the fact that MET is a commonly applied therapeutic intervention for a common, relevant and expensive health problem for which a true gold standard is lacking, and that there is some evidence of its effectiveness, the effort of a comprehensive systematic review seems warranted.

OBJECTIVES

The objective of this review is to scrutinise the effectiveness of MET in the treatment of non-specific back pain with special emphasis on subjective pain parameters, functional status, or both compared with control interventions or untreated controls, respectively.

METHODS

Criteria for considering studies for this review

Types of studies

We will only include randomised clinical studies (RCTs) which are published in English, French, Spanish, Portuguese, Italian, Dutch or German . The studies must have been published or readily available (e.g., scholarly theses). For ongoing trials, the necessary data must be available on request.

Types of participants

We will include studies with adults (older than 18 years) with non-specific back pain, i. e., pain between the lumbo-pelvic region and the 12th rib. Trials including a mix of participants with (sub)acute and chronic symptoms will only be included if data for the (sub)acute and chronic samples are reported separately. Trials not reporting the duration of participants' symptoms will not be excluded but the impact of not clearly reporting the duration will be assessed in a subgroup analysis.

We will exclude studies which included participants with specific back pain (back pain with a specific cause, e.g., compression fracture, a tumour or metastasis, spondylitis ankylopetica, infection). Pregnancy is also a reason for exclusion.

Types of interventions

The intervention must be in accordance with the definition of the isometric form of MET. This includes the following.

1. Diagnosis of the restricted motion of a joint or shortened muscle
2. Positioning of the joint or muscle to engage the end range of restricted motion or stretch of muscle.
3. Voluntary gentle isometric contraction of the stretched muscle, away from the restricted range against resistance of the therapist.

We will include studies in which the trial authors describe this technique as a form of MET, but we will also consider techniques which were applied under a different name and which show a similarity to the described MET procedure. We will consider a technique with another name sufficiently similar to MET if the criteria listed under 1 to 3 are met. In cases where we are unclear if the reported technique can be considered similar to MET, we will attempt to contact the authors of the trial for more detailed information.The MET or similar-to-MET intervention must be performed by a manual therapist (e.g. osteopath, chiropractor, physiotherapist).

We will only consider studies where an effect size can be assigned to the MET intervention. Four types of comparisons are possible.

1. MET versus no treatment.
2. MET versus sham MET.
3. MET versus all other therapies.
4. MET plus any intervention versus that same intervention alone.

Types of outcome measures

Since low back pain is a symptom that requires reporting, we will consider patient-reported parameters and consequences of the condition on problem specific and generic measures of activities of daily living and quality of life in the first place for this review. In addition, we will also evaluate physiological measures such as range of movement.

Primary outcomes

- Pain measured by visual analogue scale (VAS), number rating scale (NRS) or McGill Pain Questionaire
- Results of functional disability questionnaires (Roland-Morris Disability Questionnaire (RMDQ), Oswestry-Disability Index (ODI) or another valid instrument)
- If available, scales of general well-being (for example, quality of life measured with the SF-36, SF-12, or EuroQuol).

We will report the timing of measuring outcomes separately as short-term (closest to four weeks), intermediate-term (closest to six months), and long-term (closest to one year).

Secondary outcomes

- Any kind of adverse events
- Change in medication
- Range of movement

Search methods for identification of studies

Electronic searches

We will perform a literature search on MET in the following electronic databases, from the beginning of the database to the present date:

- The Cochrane Central Register of Controlled Trials (CENTRAL), (Appendix 1)
- MEDLINE, (Appendix 2)
- EMBASE, (Appendix 3)
- CINAHL, (Appendix 4)
- PEDro, OSTMED-DR, OSTEOPATHIC WEBRESEARCH, GOOGLE SCHOLAR (Appendix 5)

Searching other resources

In addition to the listed databases, we will also screen databases of ongoing trials (metaRegister of Controlled Trials http://controlled-trials.com/mrct/). This search will be supplemented by a citation tracking of the identified trials and a manual search in the reference lists of all relevant papers which are not listed in the electronic database. Personal communication with experts in the field of MET will also be conducted to identify additional studies. The different searches will be performed between 03.01.2012 and 03.31.2012.

Data collection and analysis

Two review authors will independently conduct the following aspects of the review. None of the review authors is an author or co-author of one of the included trials.

Selection of studies

Two review authors will independently screen titles and abstracts of the results that are identified by the search strategy. Possibly eligible studies will be read in full text and independently evaluated for inclusion. In the case of disagreement, we will attempt to resolve it through discussion. If the disagreement persists, a third review author will be consulted. The search strategy will not be limited by language.

Data extraction and management

Two review authors will independently extract the data of the studies using a data extraction form. The following data will be extracted: author, year, country, study design, aim of the study, reported inclusion and exclusion criteria, drop-outs, number of treatments/period, measurement, number of patients, age (mean), gender, number of patients intervention/control, randomisation, blinding (patients), reported or observed side effects, index intervention, comparison/control interventions, reported results, study sponsorship, characteristics of treatment providers. The data extraction form is orientated to the data extraction form recommended by the CBRG and was piloted for this review in 2010.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias. With this data, we will evaluate and report the interobserver reliability (Kappa). We will use a consensus method to resolve disagreements. A third review author will be consulted if disagreement persists. If the article does not contain sufficient information on one or more of the criteria, we will contact the trial authors for additional information. If the authors cannot be contacted, or if the information is no longer available, the criteria will be scored as 'unclear.' We will use the updated Cochrane 'Risk of bias' tool from the *Cochrane Handbook of Reviews and Interventions* (Version 5.1, updated March 2011) (Higgins 2011) (Appendix 6) to assess the risk of bias. All criteria will be scored as "low risk", "high risk" or "unclear". Studies will be rated as having "low risk of bias" when at least six criteria are met and the study has no serious flaws (e.g., large drop-out rate). We will perform a sensitivity analysis to determine whether the overall results are the same when studies with different definitions of low or high risk of bias are analysed.

Measures of treatment effect

We will evaluate the studies regarding their clinical homogeneity (study population, treatment procedure, control group, timing of follow-up and measurement instruments). On the basis of these evaluations, and if the studies are clinically homogenous, we will pool the data for our outcome measures, pain, functional status and if possible, quality of life. These attempts will be made for short-, intermediate- and long-term follow-up. For pain, functional status, and quality of life, we will use a standardised mean difference (SMD) to combine studies that measure the same outcome but with different methods. With Review Manager 5.1, the results of each RCT will be plotted as point estimates with corresponding 95% confidence intervals (95% CI). We will report the results in a forest plot using a random-effects model. In the case that the studies are too heterogeneous, we will not perform a meta-analysis.

All analyses will be conducted separately for acute or sub-acute low-back pain versus chronic low-back pain.

Assessment of clinical relevance

Two review authors will independently score the clinical relevance of the included studies according to five questions recommended by the Cochrane Back Review Group (Furlan 2009). Each question will be scored positive (+) if the clinical relevance item was fulfilled, negative (-) if the item was not fulfilled and unclear (?) if data were not available. To assess minimal clinically important changes for LBP and function, we will use a 30% change on the VAS and NRS and two to three points (or 8% to 12%) on the Roland-Morris Disability Questionnaire or 10 for the Oswestry-Disability-Index for function (Bombardier 2001; Ostelo 2008). For the assessment of the clinical relevance the following questions will be investigated.

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

Unit of analysis issues

In cases where three or more interventions are evaluated in a single study, we will include each pair-wise comparison separately. In this case, the total number of participants in the MET intervention group will be divided out approximately evenly among the comparison groups.

Dealing with missing data

We will try to contact the correspondent author in cases where data are missing. Where data are reported in a graph and not in a table or the text, we will estimate the means and standard deviations from them. When standard deviations are not reported, we will estimate these from the CIs or other measures of variance, if possible. If the standard deviation for follow-up measurements is missing, we will use the standard deviation for that measure at baseline for subsequent follow-up measurements. Finally, if no measure of variation is reported anywhere in the text, we will estimate the standard deviation, based upon other studies with a similar population and risk of bias.

Assessment of heterogeneity

Assessment of heterogeneity takes place by calculation of I^2. We accept the recommendation in the *Cochrane Handbook of Reviews and Interventions* (Higgins 2011) which gives a rough guide for interpretation of I^2 (Higgins 2011): 0% to 40%, might not be important; 30% to 60%, may represent moderate heterogeneity; 50% to 90%, may represent substantial heterogeneity; 75% to 100%, considerable heterogeneity. We will not pool data from studies that are clearly heterogeneous.

Assessment of reporting biases

If we find enough studies, we will calculate a funnel plot to examine publication bias.

Data synthesis

Regardless of whether there are sufficient data available to use quantitative analyses to summarise the data, we will assess the overall quality of the evidence for each outcome. To accomplish this, we will use an adapted GRADE approach, as recommended in *Cochrane Handbook of Reviews and Interventions* (Higgins 2011) and by the updated CBRG method guidelines (Furlan 2009). The quality of the evidence for a specific outcome is based on the performance against five factors: study design and risk of bias, consistency of results, directness (generalisability), precision (sufficient data) and reporting of the results across all studies that measure that particular outcome. The quality starts at *high* when RCTs with a low risk of bias provide results for the outcome, and reduces by a level for each of the factors not met.

High quality evidence: there are consistent findings among at least 75% of RCTs with no limitations of the study design, consistent, direct and precise data and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results.

Moderate quality evidence: one of the domains is not met. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality evidence: two of the domains are not met. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality evidence: three of the domains are not met. We are very uncertain about the results.

No evidence: no RCTs were identified that addressed this outcome.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be used to evaluate the differences in effectiveness of 'true' MET and techniques with another name that show a similarity to the described MET procedure.

Sensitivity analysis

We will explore the robustness of the treatment effect using sensitivity analyses. In particular, we will use the results of the 'Risk of bias' assessment to exclude studies with a high risk of bias.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL Search Strategy

#1 MeSH descriptor Back Pain explode tree 1
#2 back
#3 MeSH descriptor Low Back Pain, this term only
#4 (lumbopelvic pain)
#5 (low next back next pain)
#6 (lbp)
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 muscle next energy next technique
#9 postisometric relaxation
#10 (isometric next contraction)
#11 (isometric stretching): ti, ab, kw
#12 (proprioceptive neuromuscular facilitation): ti, ab, kw
#13 (#8 OR #9 OR #10 OR #11 OR#12)
#14 (#7 AND #13)

Appendix 2. MEDLINE Search Strategy

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab,ti.
5. drug therapy.fs.
6. randomly.ab,ti.
7. trial.ab,ti.
8. groups.ab,ti.
9. or/1-8
10. (animals not (humans and animals)).sh.
11. 9 not 10
12. dorsalgia.ti,ab.
13. exp Back Pain/
14. backache.ti,ab.
15. (lumbar adj pain).ti,ab.
16. coccyx.ti,ab.
17. coccydynia.ti,ab.
18. sciatica.ti,ab.
19. sciatic neuropathy/
20. spondylosis.ti,ab.
21. lumbago.ti,ab.
22. exp low back pain/
23. lumbopelvic pain.mp.
24. or/12-23
25. 11 and 24
26. muscle energy technique.mp.
27. postisometric relaxation.mp.
28. post-isometric relaxation.mp.
29. isometric stretching.mp.
30. Muscle Stretching Exercises/
31. Isometric Contraction/

32. isometric contract*.mp.
33. proprioceptive neuromuscular facilitation
34. or/26-33
34. 25 and 34

Appendix 3. EMBASE Search Strategy (OVID)

1 Clinical Article/
2 exp Clinical Study/
3 Clinical Trial/
4 Controlled Study/
5 Randomized Controlled Trial/
6 Major Clinical Study/
7 Double Blind Procedure/
8 Multicenter Study/
9 Single Blind Procedure/
10 Phase 3 Clinical Trial/
11 Phase 4 Clinical Trial/
12 crossover procedure/
13 placebo/
14 or/1-13
15 allocat$.mp.
16 assign$.mp.
17 blind$.mp.
18 (clinic$ adj25 (study or trial)).mp.
19 compar$.mp.
20 control$.mp.
21 cross?over.mp.
22 factorial$.mp.
23 follow?up.mp.
24 placebo$.mp.
25 prospectiv$.mp.
26 random$.mp.
27 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
28 trial.mp.
29 (versus or vs).mp.
30 or/15-29
31 14 and 30
32 human/
33 Nonhuman/
34 exp ANIMAL/
35 Animal Experiment/
36 33 or 34 or 35
37 32 not 36
38 31 not 36
39 37 and 38
40 38 or 39
41 dorsalgia.mp.
42 back pain.mp.
43 exp LOW BACK PAIN/
44 exp BACKACHE/
45 (lumbar adj pain).mp.

46 coccyx.mp.
47 coccydynia.mp.
48 sciatica.mp.
49 exp ISCHIALGIA/
50 spondylosis.mp.
51 lumbago.mp.
52 or/41-50
53 muscle energy technique.mp.
54 postisometric relaxation.mp.
55 post-isometric relaxation.mp.
56 isometric stretching.mp.
57 isometric contract*.mp.
58 muscle isometric contraction
59 proprioceptive neuromuscular facilitation
60 53 or 54 or 55 or 56 or 57 or 58 or 59
61 40 and 52 and 60

Appendix 4. CINAHL Search Strategy

1 randomized controlled trial.pt
2 controlled clinical trial.pt
3 randomized.ab
4 randomly.ab
5 trial.ab
6 1 or 2 or 3 or 4 or 5
7 back pain.mj
8 low back pain.mj
9 lumbopelvic pain.ab
10 lumbopelvic pain.ti
11 7 or 8 or 9 or 10
12 muscle energy technique.ti
13 muscle energy technique.ab
14 postisometric relaxation.ti
15 postisometric relaxation.ab
16 post-isometric relaxation.ti
17 post-isometric relaxation.ab
18 isometric contract*.ti
19 isometric contract*.ab
20 proprioceptive neuromuscular facilitation.ti
21 proprioceptive neuromuscular facilitation.ab
22 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
21 6 and 11 and 22

Appendix 5. PEDro, OSTMED-DR, OSTEOPATHIC RESEARCH WEB, GOOGLE Scholar Search Strategy

PEDro

1 muscle energy technique.ti/ab. and lumbar spine, sacro-iliac joint or pelvis.bodypart
2 post-isometric relaxation.ti/ab . and lumbar spine, sacro-iliac joint or pelvis.bodypart
3. isometric contraction.ti/ab. and lumbar spine, sacro-iliac joint or pelvis.bodypart
4. proprioceptive neuromuscular facilitation.ti/ab. and lumbar spine, sacro-iliac joint or pelvis.bodypart

OSTMED-DR

1 "muscle energy technique".keyword or "post-isometric relaxation".keyword or "isometric contraction".keyword or "proprioceptive neuromuscular facilitation".keyword

OSTEOPATHIC RESEARCH WEB

1 muscle energy technique. all fields
2 post-isometric relaxation. all fields
3 postisometric relaxation. all fields
4 isometric contraction. all fields
5 proprioceptive neuromuscular facilitation. all fields

GOOGLE SCHOLAR

1 "muscle energy technique".all in title
2 "post-isometric relaxation".all in title
3 "postisometric relaxation".all in title
4 "isometric contraction" pain.all in title
5 "proprioceptive neuromuscular facilitation" pain .all in title

Appendix 6. Criteria for assessing risk of bias for internal validity (Higgins 2011)

Random sequence generation (selection bias)

Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence

There is a low risk of selection bias if the investigators describe a random component in the sequence generation process such as: referring to a random number table, using a computer random number generator, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots, minimisation (minimisation may be implemented without a random element, and this is considered to be equivalent to being random).

There is a high risk of selection bia*s* if the investigators describe a non-random component in the sequence generation process, such as: sequence generated by odd or even date of birth, date (or day) of admission, hospital or clinic record number; or allocation by judgement of the clinician, preference of the participant, results of a laboratory test or a series of tests, or availability of the intervention.

Allocation concealment (selection bias)

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment

There is a low risk of selection bias if the participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; or sequentially numbered, opaque, sealed envelopes.

There is a high risk of bias if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; or other explicitly unconcealed procedures.

Blinding of participants

Performance bias due to knowledge of the allocated interventions by participants during the study

There is a low risk of performance bias if blinding of participants was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of personnel/ care providers (performance bias)

Performance bias due to knowledge of the allocated interventions by personnel/care providers during the study

There is a low risk of performance bias if blinding of personnel was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of outcome assessor (detection bias)

Detection bias due to knowledge of the allocated interventions by outcome assessors

There is low risk of detection bias if the blinding of the outcome assessment was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding, or:

- for patient-reported outcomes in which the patient was the outcome assessor (e.g. pain, disability): there is a low risk of bias for outcome assessors if there is a low risk of bias for participant blinding (Boutron 2005)
- for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g. co-interventions, length of hospitalisation, treatment failure), in which the care provider is the outcome assessor: there is a low risk of bias for outcome assessors if there is a low risk of bias for care providers (Boutron 2005)
- for outcome criteria that are assessed from data from medical forms: there is a low risk of bias if the treatment or adverse effects of the treatment could not be noticed in the extracted data (Boutron 2005)

Incomplete outcome data (attrition bias)

Attrition bias due to amount, nature or handling of incomplete outcome data

There is a low risk of attrition bias if there were no missing outcome data; reasons for missing outcome data were unlikely to be related to the true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data were balanced in numbers, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size, or missing data were imputed using appropriate methods (if drop-outs are very large, imputation using even "acceptable" methods may still suggest a high risk of bias) (van Tulder 2003). The percentage of withdrawals and drop-outs should not exceed 20% for short-term follow-up and 30% for long-term follow-up and should not lead to substantial bias (these percentages are commonly used but arbitrary, not supported by literature) (van Tulder 2003).

Selective Reporting (reporting bias)

Reporting bias due to selective outcome reporting

There is low risk of reporting bias if the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way, or if the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

There is a high risk of reporting bias if not all of the study's pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Group similarity at baseline (selection bias)

Bias due to dissimilarity at baseline for the most important prognostic indicators.

There is low risk of bia*s* if groups are similar at baseline for demographic factors, value of main outcome measure(s), and important prognostic factors (examples in the field of back and neck pain are duration and severity of complaints, vocational status, percentage of patients with neurological symptoms) (van Tulder 2003).

Co-interventions (performance bias)

Bias because co-interventions were different across groups

There is low risk of bias if there were no co-interventions or they were similar between the index and control groups (van Tulder 2003).

Compliance (performance bias)

Bias due to inappropriate compliance with interventions across groups

There is low risk of bias if compliance with the interventions was acceptable, based on the reported intensity/dosage, duration, number and frequency for both the index and control intervention(s). For single-session interventions (e.g. surgery), this item is irrelevant (van Tulder 2003).

Intention-to-treat-analysis

There is low risk of bias if all randomised patients were reported/analysed in the group to which they were allocated by randomisation.

Timing of outcome assessments (detection bias)

Bias because important outcomes were not measured at the same time across groups

There is low risk of bias if all important outcome assessments for all intervention groups were measured at the same time (van Tulder 2003).

Other bias

Bias due to problems not covered elsewhere in the table

There is a low risk of bias if the study appears to be free of other sources of bias not addressed elsewhere (e.g. study funding).

HISTORY

Protocol first published: Issue 5, 2012

CONTRIBUTIONS OF AUTHORS

HF and GF wrote the background. HF drafted the protocol with help from the other authors. All authors read and approved the final version.

DECLARATIONS OF INTEREST

None of the authors has made or is involved in a clinical study which fulfil the inclusion criteria of this review. One of the authors, Gary Fryer, has been involved in several trials of MET, but none of his studies will be included in the review.

SOURCES OF SUPPORT

Internal sources

- No internal sources of support given, Not specified.

External sources

- No external sources of support given, Not specified.