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Kinesiotaping for rotator cuff disease (Protocol)

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[Intervention Protocol]

Kinesiotaping for rotator cuff disease

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To determine the benefits and harms of kinesio taping in adults with shoulder pain due to rotator cuff disease.

BACKGROUND

Description of the condition

Point prevalence of chronic shoulder pain has been variously estimated between 7% and 25%, while its incidence is around 1 per 100 per year, peaking at 2.5 per 100 per year among individuals aged 42 to 46 years (Bjelle 1989; Chard 1991). Abnormalities of the rotator cuff increase with age, from an overall prevalence of 9.7% (29 of 299) in patients aged 20 years and younger to 62% (166 of 268) in patients aged 80 years and older (Teunis 2014). It also accounts for up 10% of all referrals to physiotherapists (Peters 1994).

Shoulder disorders significantly impact on the majority of daily life activities, including eating and dressing, and on working (Bennell 2007). In addition, shoulder pain is often associated with anxiety, depression and impaired ability to sleep, hence affecting mood and concentration (Cho 2013).

Numerous terms are used to describe disorders of the rotator cuff (for example, subacromial impingement syndrome, rotator cuff tendinopathy or tendinitis, partial or full rotator cuff tear, calcific tendinitis and subacromial bursitis) (Schellingerhout 2008). 'Rotator cuff disease' is proposed as an umbrella term to classify disorders of the rotator cuff, whether the cause is degeneration or acute injury, to cover different anatomical locations (Buchbinder 1996; Whittle 2015), and we will use this term in this review.

Rotator cuff disease, such as subacromial impingement and rotator cuff tendinopathy, are considered to be the most common causes of chronic shoulder pain (Burbank 2008). Other less frequent causes of shoulder pain include frozen shoulder, shoulder instability and shoulder joint osteoarthritis (Burbank 2008). For example, shoulder impingement accounts for 44% to 65% of shoulder complaints during general practice consultations (Van der Windt 1996), and it is an associated economic burden on healthcare systems (Virta 2012).

The occurrence of rotator cuff disorder is associated with jobs that are highly repetitive such as hairdressing (Mitchell 2005), activities that require forceful exertion or awkward postures, or have a high psychosocial job demand (Van Rijn 2010), or some sports (e.g. overhead athletes) (Ellenbecker 2010; Page 2011). The rotator

cuff pain manifests in the midrange of motion (between 40° and 120°), often causing a painful arch during active abduction (Kessel 1977). Pain over the shoulder area, frequently irradiating along the ipsilateral arm, is one of the symptoms more frequently reported by patients, along with restriction in shoulder range of motion (ROM) and impeded activities of daily living (Bayam 2011). High baseline pain, disability, and previous episodes are associated with an unfavourable outcome (Littlewood 2013). It is proposed that early recognition and adequate treatment may reduce the risk of this disorder becoming a chronic condition (Kessel 1977; Khan 2013).

Conservative treatments for rotator cuff pain management include electro-physical therapies (e.g. laser, shock wave therapy), manual mobilisation, exercise and taping (Escamilla 2014). These interventions could diminish costs related to more invasive treatments and absences from work (Ketola 2013; Khan 2013; Vas 2005).

Description of the intervention

Taping has been used for a long time to prevent and treat sports injuries as it provides protection and support to the joint or muscle or both during the movement (Williams 2012). The conventionally used tape is rigid while the recently introduced kinesio taping is an elastic, adhesive, latex-free taping made from cotton, without active pharmacological agents and is water resistant (Kase 2003). Kinesio taping was developed by a Japanese chiropractor, Dr Kenso Kase, in the 1970s; he described it as a natural way to relieve pain (Kase 2003). According to its inventor, kinesio taping offers several advantages over other conventional taping. Firstly, it aims to give a free range of motion in order to allow the body's muscular system to heal itself biomechanically. Secondly, the kinesio taping can be virtually applied to any joint or musculoskeletal region, it is easy to apply, non-allergenic and with relatively low cost (Kase 2003). At present, it is marketed by various companies under different brand names, often in a variety of colours. These qualities and aggressive marketing made kinesio taping an increasingly popular intervention amongst elite athletes who use it to try and prevent injuries (Williams 2012). Kinesio taping has also gained momentum as a potential rehabilitative intervention among the general public and health professionals in the last decade, even though sound scientific proof of its validity has been lacking.

Based on the recent systematic reviews for rotator cuff disorder, the evidence related to the efficacy of conservative interventions compared with surgery is inconclusive due to low-quality studies (Coghlan 2008; Saltychev 2015; Tashjian 2013). As surgery has higher costs and carries a risk of complications, conservative interventions seem to be the best option to recommend as the first choice treatment for shoulder pain (Saltychev 2015). Two recent reviews focused on conservative interventions for rotator cuff disease concluded that the effects of manual therapy and exercise may be similar to those of glucocorticoid (steroid) injection and surgery (namely, arthroscopic subacromial decompression), but this is based on low-quality evidence (Page 2016a). Only therapeutic ultrasound and low level laser therapy showed some benefit over placebo (Page 2016b). Kinesio taping was not included in these previous reviews.

How the intervention might work

Kinesio taping was designed to simulate the qualities of human skin, and it has roughly the same thickness as the skin (Kase 2003). Manufacturers claim that kinesio taping provides benefits by facilitating the body's natural physiologic and healing processes with sensory stimulation and mechanical support: aiding muscle and positional stimulus through the skin, aligning fascial (connective) tissues, creating more space by lifting the soft tissues above the area of pain or inflammation, assisting drainage of lymph, fluid exuding from a sore or inflamed tissue, by directing fluid toward the duct, and providing sensory stimulation and mechanical support without restricting the body's range of motion, differently from a conventional rigid tape (Kase 2003).

These benefits are supposed to depend on the amount, as well as on the stretch direction, of the applied tape (Kase 2003). Kinesio taping can be applied producing different shapes (e.g. 'Y', 'I', 'web'), according to the shape and size of the affected muscle. Application methods differ with the therapeutic aim. When the tape is used to inhibit or restore muscle function, it is applied from its insertion to the origin to limit the muscle performance (Djordjevic 2012) or from its origin to the insertion to enhance muscle activity (e.g., forearm grip strength) (Mohammadi 2014). Conversely, when the tape is used to promote lymphatic drainage, it is applied in the fan format directing lymph fluid towards less congested parts of the lymphatic system inorder to try and reduce swelling. The arms of the fan direct lymphatic flow towards the anchor facilitating drainage (e.g. to help reduce swelling after a mastectomy) (Pekyavas 2014).

Theoretically, these mechanisms of these actions might reduce pain from rotator cuff disease. Authors claim that kinesio taping might: 1) improve shoulder strength, range of motion and proprioception (the sense of the relative position of body segments in relation to other body segments) (Williams 2012); 2) improve proprioceptive feedback and correct alignment during movement, to help promoting the stability of the shoulder blade (Kaya 2011; Mottram 1997); 3) allow free movements of arms without pain (Host 1995); and 4) prevent acute injuries and the evolution to a chronic condition and impairments (Myers 2000). There is little evidence to supprt these claims.

Why it is important to do this review

Kinesio taping is one of the conservative treatments proposed for rotator cuff disease. Clinicians have adopted it in the rehabilitation

treatment of painful conditions, even if firm evidence of its benefits are not yet well established.

Previous reviews focused on injury prevention in healthy subjects (Kamper 2013; Williams 2012) or considered participants with a wide spectrum of conditions relate to the musculoskeletal system focusing on different joints at the same time (Kalron 2013; Lim 2015; Montalvo 2014; Morris 2013; Mostafavifar 2012; Parreira 2014). In the latter case, data were not pooled, due to clinical heterogeneity, and the small number of retrieved studies focused on a specific condition, limiting conclusions. In recent years, an increasing number of RCTs on kinesio taping use for shoulder pain have been published with conflicting results (Djordjevic 2012; Kaya 2011; Sahin 2016; Simsek 2013; Thelen 2008).

Thus, there is conflicting evidence from randomized trials of the benefits of kinesio taping in people with rotator cuff disease, and an evidence gap given that the trials in this population have not been adequately systematically reviewed previously.

OBJECTIVES

To determine the benefits and harms of kinesio taping in adults with shoulder pain due to rotator cuff disease.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised controlled clinical trials (with methods of allocating participants to treatment that are not strictly random, e.g. using alternation, date of birth, or some similar method of allocation) will be selected.

Types of participants

We will include adults with rotator cuff disease as defined by the authors (e.g. using terminology such as subacromial impingement syndrome, rotator cuff tendonitis or tendinopathy, supraspinatus, infraspinatus or subscapularis tendonitis, subacromial bursitis, or rotator cuff tears), for any duration.

We will include studies with participants with unspecified shoulder pain provided that the inclusion criteria are compatible with a diagnosis of rotator cuff disease. We will also include studies of participants with mixed shoulder disorders (e.g. shoulder girdle fractures, dislocation and previous surgery, adhesive capsulitis, full thickness rotator cuff tear), if these participants are a minority of the study population (i.e. less than 20%), or if we can retrieve the data for participants with rotator cuff disease separately from the trialists.

We will exclude trials that include participants with a history of significant trauma or systemic inflammatory conditions such as rheumatoid arthritis, osteoarthritis, hemiplegic shoulders, or pain in the shoulder region as part of a complex myofascial pain condition, or those with adhesive capsulitis (frozen shoulder), shoulder instability, and rotator cuff arthropathy.

Types of interventions

Experimental intervention: kinesio taping (KT) with or without standardised co-interventions (such as supervised or home exercises), provided that co-interventions were given equally to both experimental and control groups. We will include any number of kinesio taping applications or for any length of time of kinesio taping application.

We will compare the experimental intervention (kinesio taping) to:

- sham taping;
- other conservative interventions (e.g. conventional taping, physical therapies, exercise, glucocorticoid injection, oral medication, or other interventions).

Types of outcome measures

We will not consider outcomes as part of the eligibility criteria. In fact, a recent review evaluating outcome assessment in rehabilitative interventions found considerable variation of the reporting of outcome measures in clinical trials (Gianola 2016).

Major outcomes

- Overall pain (mean or mean change measured by visual analogue scale (VAS), numerical or categorical rating scale).
- Function: Where trialists reported outcome data for more than one function scale, we will extract data on the scale that was highest on the following a priori defined list: (1) Shoulder Pain and Disability Index (SPADI); (2) Croft Shoulder Disability Questionnaire; (3) Constant-Murley Score; (4) any other shoulder-specific function scale.
- Pain on motion: measured by VAS, numerical or categorical rating scale, regardless of the type of clinical evaluation e.g. on resisted movements, at the endpoint of pain-free active shoulder ROM, with active movements, caused by a clinical diagnostic test for rotator cuff disease (e.g. empty can test of Jobe).
- Active range of motion (AROM): extent of active shoulder abduction or elevation of the shoulder without pain, measured in degrees or other scales (e.g. functional target distance).
- Global assessment of treatment success as defined by the trialists (e.g. proportion of participants with significant overall

improvement), or measured by specific tools (e.g. Global Perceived Effect, GPE (Kamper 2010)).

- Quality of life as measured by generic measures (such as components of the Short Form-36 (SF-36)) or disease-specific tools).
- Adverse events: number of participants experiencing any adverse event (e.g. skin reactions, including severe or painful rash, itching, dermatitis, local ulceration or exfoliation, and enlarged glands).

Minor outcomes

- Other measures of pain: such as, pain at night and pain at rest.
- Other measures of range of motion (ROM): external rotation and internal rotation measured in degrees or other scales (e.g. hand-behind-back distance in centimetres). If authors reported outcome data for both active and passive ROM measures, we will extract the data on active ROM only.
- Muscle strength: strength of any muscle of shoulder measured by digital hand dynamometer, isokinetic peak torque, or other.
- Withdrawals or drop outs: proportion who withdrew from treatment due to adverse events or other reasons.

The tape will generally stay on for three to four days. In KT therapy, more than one application can be accepted; consequently we will consider all trials independently from the number of applications of KT and define as 'therapeutic cycle' the time between the first application and the removal of the last KT application planned in each trial. For the meta-analysis, we will consider the last available measurement within 30 days from the end of the therapeutic cycle.

Search methods for identification of studies

Electronic searches

The following electronic databases will be used to identify relevant studies published from database inception to the present:

- Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library;
- MEDLINE via Ovid;
- Embase via Ovid;
- PEDro (Physiotherapy Evidence database) via http://www.pedro.org.au/;
- CINAHL plus (Cumulative Index to Nursing and Allied Health Literature) via EBSCOhost.

The electronic search strategy for CENTRAL and MEDLINE is outlined in Appendix 1.

Ongoing trials and protocols of published trials will be searched in the clinical trials register maintained by the US National Institutes of Health (http://clinicaltrials.gov) and the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organization (http://www.who.int/ictrp/en/). The reference lists of included trials and relevant review articles retrieved will be reviewed to identify other potentially relevant trials. No date or language restrictions will be applied.

Searching other resources

The reference lists of included articles will be searched to ascertain if any relevant trials have not been identified by the electronic searches. Kinesio taping manufacturers will be contacted to identify additional unpublished trials.

Data collection and analysis

Selection of studies

Two review authors (SG, GC) will independently select the citations identified in the literature search on the basis of title and abstract, discarding those not meeting the inclusion criteria. All potentially relevant articles will be retrieved for an assessment of the full text. The assessment of eligibility will be conducted independently by two review authors. If any doubt arises that a study meets the inclusion criteria, a consensus meeting will be held to resolve disagreements concerning the inclusion of RCTs, and another review author (AA) will be consulted if disagreements persist. We will document excluded studies in the 'Characteristics of excluded studies' table and will provide an individual reason for exclusion.

Data extraction and management

We will use a data collection form for study characteristics and outcome data, which will be piloted on at least one eligible RCT. Two review authors (SG, GC) will extract independently study characteristics from included studies. We will extract for each study the following characteristics:

1. Methods: design, start date and total duration, setting and withdrawals from the study.
2. Participants: number, mean or median age with a dispersion measure, sex, shoulder pathology and systemic conditions.
3. Interventions: kinesio taping application methods (characteristics, direction related to function, stretch, shape and size of the strips, target muscle, number and duration of applications, provider), comparisons, concomitant therapies and/or medications.
4. Outcomes: list of relevant outcomes assessed, definitions used, values of means and standard deviations at baseline and at all time points and/or change from baseline measures for continuous outcomes, and frequencies for categorical outcomes.

5. Characteristics of the design of the trial as outlined below in the Assessment of risk of bias in included studies section.

6. Notes: funding and notable declarations of conflict of interest of trial authors.

Two review authors (SG,GC) will independently extract all outcome measures data from included studies. We will resolve disagreements by consensus or by involving a third person (AA). Two review authors (SG,GC) will transfer data into the Review Manager (Review Manager 2014). We will double-check that data is entered correctly by comparing the data presented in the systematic review with the study reports. We will note in the 'Characteristics of included studies' table if outcome data was not reported in a usable way.

A priori decision rules to assist in selecting which data to extract in the event of multiple outcome reporting are the following:

- Where authors reported outcomes for more than one pain at movement score, we will extract data on the scale highest on the following list: (1) visual analogue or rating scale; (2) any other pain score;
- According to the recent systematic review about the quality of measurement properties per questionnaire (Huang 2015), where authors reported outcomes for more than one disability scale, we will extract data on the scale that is highest on the following list: (1) The Western Ontario Rotator Cuff Index (WORC) (Kirkley 2003); (2) Shoulder Pain and Disability Index (SPADI) (Roach 1991); (3) The Simple Shoulder Test (SST) (Godfrey 2007); (4) Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (Hudak 1996); (5) Constant Score (Constant 1987); (6) any other function scale;
- Physiotherapy studies have small sample sizes and use patient-reported outcomes, such as pain, that have high between-subject variability. Consequently, imbalances between groups are possible at baseline, even with adequate randomizations. Moreover, the effects are often very small in this field. Consequently, differences between groups are difficult to detect. For these reasons, if a study reports both change and its SD, and final value and its SD, we will use change from baseline values rather than final values (Banerjee 2008). If studies report only final values and SD, we will use the available measures.

Assessment of risk of bias in included studies

Two review authors (SG,GC) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions (*Higgins 2011a). We will resolve any disagreement by discussion or by involving another author (AA). We will assess the risk of bias according to the following domains.

1. Random sequence generation (selection bias).
2. Allocation concealment (selection bias).
3. Blinding of participants, and care providers (performance bias).
4. Blinding of outcome assessment for self-reported outcomes such as pain, function, global assessment, quality of life (detection bias).
5. Blinding of outcome assessment - objective outcomes (detection bias).
6. Incomplete outcome data for each treatment group (attrition bias).
7. Selective outcome reporting (reporting bias).
8. Other bias: group similarity at baseline (selection bias).

We will grade each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for our judgment in the 'Risk of bias' table. We will summarise the 'risk of bias' judgements across different studies for each of the domains listed. The two review authors (SG,GC) will resolve discrepancies in judgment by discussion and will ask a third review author (AA) to make the final judgment if they cannot reach a consensus.

For our major outcomes, we will consider blinding of participants and outcome assessors separately when necessary. In physiotherapy trials, blinding of participants and outcome assessors is crucial for patient-reported outcomes due to their subjective nature. However, blinding of participants is not always possible to achieve as participants are aware if they receive a given treatment (e.g. kinesio taping or physical exercises) unless they receive a sham therapy (e.g. kinesio taping compared to sham kinesio taping). Nevertheless, we will describe if methods to blind participants and outcome assessors are reported. If blinding is adequate, we will judge studies to be at low risk of bias. If no description is given, we will contact the study authors for more information, and if we do not receive a response, we will assign a judgment of unclear risk of bias. If blinding is not present, or is not possible because of the nature of intervention, we will judge the study to be at high risk of bias because it is possible that the lack of blinding might influence the results.

Analogously, we will consider the impact of missing data for the following major outcomes (overall pain and function). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

We will present the figures generated by the 'risk of bias' tool to provide summary assessments of the risk of bias.

Measures of treatment effect

For the primary and secondary outcomes, we will assess the treatment effects using the risk ratio (RR) for dichotomized outcomes and the mean difference (MD) for continuous outcomes with their corresponding 95% confidence intervals (CIs). However, when different scales are used to measure the same conceptual outcome (e.g. pain, disability), standardised mean differences (SMD) will be calculated. SMDs will be back-translated to a typical scale (e.g. 0 to 10 for pain) by multiplying the SMD by a typical among-person standard deviation (e.g. the standard deviation of the control

group at baseline from the most representative trial) (Schünemann 2011).

For pain, a negative effect size will indicate that kinesio taping is more beneficial than the comparison therapy, meaning that participants have better pain relief. For the other outcomes such as ROM, a positive effect size will indicate that kinesio taping is more beneficial than the comparison therapy, meaning that participants have a greater ROM.

In the 'Effects of interventions' results section and the 'Comments' column of the 'Summary of findings' table, we will provide the absolute per cent difference, the relative per cent change from baseline, and the number needed-to-treat for an additional beneficial outcome (NNTB) and number needed to treat for an additional harmful outcome (NNTH) (the NNTB or NNTH will be provided only when the outcome shows a statistically significant difference).

For dichotomous outcomes, the NNTB or NNTH will be calculated from the control group event rate and the relative risk using the Visual Rx NNT calculator (Cates 2008). The NNTB or NNTH for continuous measures will be calculated using the Wells calculator (available at the CMSG Editorial office).

For dichotomous outcomes, the absolute risk difference will be calculated using the risk difference statistic in RevMan software (Review Manager 2014), and the result expressed as a percentage.

For continuous outcomes, the absolute benefit will be calculated as the improvement in the intervention group minus the improvement in the control group, in the original units, expressed as a percentage.

The relative per cent change for dichotomous data will be calculated as the risk ratio - 1 and expressed as a percentage. For continuous outcomes, the relative difference in the change from baseline will be calculated as the absolute benefit divided by the baseline mean of the control group, expressed as a percentage.

Unit of analysis issues

The units of randomizations and analysis in the included trials will be the individual participant. Exceptionally, people may present with bilateral shoulder pain, which may be randomised to a single treatment for each shoulder. Therefore, a trial including people with bilateral shoulder pain may present results for shoulders rather than individuals, a potential unit of analysis issue.We will still include such studies with the potential unit of analysis issues. If people with bilateral shoulder pain are included, a sensitivity analysis will be undertaken.

Dealing with missing data

a) Individuals missing from the reported results of primary studies

For included studies, we will note any discrepancy between the number randomised and the number analysed in each treatment group, reporting the percentage of lost to follow-up in each group and reasons for attrition. Where data are missing, we will contact the corresponding authors of included studies by written correspondence (e.g. emailing or writing to corresponding author(s)) to retrieve any available unreported data. If information on missing individuals is not provided, we will perform available case analysis, commenting on the possible impact of missing data on the results. If more than 10 studies are included, we will explore the impact of including studies with missing individual data on the conclusion of the meta-analysis by performing a sensitivity analysis.

b) Missing summary data for an outcome

If a study does not provide usable summary measures for an outcome it will be included in the review but excluded from the meta-analysis. Implications of its absence will be discussed. For studies that report a mean difference but no standard deviation (SD), the latter will be computed from other statistics - such as, standard errors, confidence intervals, t-value or P-values - whenever possible. If standard deviations cannot be calculated, and random missingness can be assumed, they will be imputed (Higgins 2011b). For each outcome, we will impute missing SDs as the pooled SD from all other trials in the same meta-analysis by treatment group. This is, both for fixed- and random-effects models, an easy method of analysis and it is less biased than excluding studies with missing standard deviations (Furukawa 2006). If the proportion of trials missing variability data for a particular outcome is high (> 30%), we will conduct analyses using only available data, and implications will be discussed in the text.

Assessment of heterogeneity

Clinical and methodological heterogeneity will be assessed in terms of participants, interventions, outcomes and study characteristics for the included studies. This will be conducted by observing the data extraction tables.

Statistical heterogeneity will be evaluated using forest plots, the I^2 statistics and the estimate of the between-study variance (τ^2) (Higgins 2003; Higgins 2009). The interpretation of an I^2 value of 0% to 40% might 'not be important'; 30% to 60% may represent 'moderate' heterogeneity; 50% to 90% may represent 'substantial' heterogeneity; and 75% to 100% represents 'considerable' heterogeneity (Deeks 2011).

Assessment of reporting biases

We will use funnel plots to explore the likelihood of reporting biases when at least 10 studies are included in the meta-analysis. First, we will assess funnel plot asymmetry visually, integrating visual inspection with the use of formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by

Egger (Egger 1997), and for dichotomous outcomes, we will use the test proposed by Harbord (Harbord 2006). If asymmetry is suggested by visual assessment or detected by tests, we will discuss possible explanations (such as publication bias, poor methodological quality, true heterogeneity, artefact or chance) and consider implications for the review findings (Sterne 2011).

We will consider the possibility of small-study bias on review findings. In the presence of small-sample bias, the random-effects estimate of the intervention is more beneficial than the fixed-effect estimate (Sterne 2011).

We will assess the risk of bias due to selective outcome reporting by comparing outcomes the trial investigators intended to measure with outcomes reported in trial reports. We will review protocols or clinical trial registries to determine intended outcomes. Otherwise, we will compare outcomes reported in the 'Results' section to those described in the 'Methods' section.

We will also examine studies to verify if they have been analysed on an intention-to-treat (ITT), per protocol or available case basis.

Data synthesis

We will undertake meta-analyses only where this is meaningful, i.e. if the treatments and comparators, participants and the underlying clinical question are similar enough for pooling to make sense (low clinical and methodological heterogeneity). If this is the case, we will use either a fixed-effect or random-effects model on the basis of careful consideration of the extent of statistical heterogeneity (Higgins 2003) and whether it can be explained by available features, including the size of the studies. If high heterogeneity ((I^2 > 75%) is detected and cannot be reduced by accounting for methodological or clinical features among trials, the results will not be combined but will be presented as a narrative synthesis.

If dichotomous outcomes, such as side effects, are very rare and at least one study has no events, we will perform the meta-analysis using a generalized linear mixed model, allowing the inclusion of studies with no events (Stijnen 2010). If continuous outcomes have a highly skewed distribution, we will consider transformation before pooling. If we pool studies using the SMD, the Hedges' bias-correction will be used by default to adjust for small-sample bias (Hedges 1981). We will use 95% CIs throughout.

We will analyse the data using Review Manager 5.3 (Review Manager 2014). Where necessary, we will perform meta-regression or other analyses using the software R (R software) and the package metaphor (Viechtbauer 2010) (which are not supported in Revman).

Regardless of whether available homogeneous data are sufficient to allow review authors to quantitatively summarise the data, we will assess the overall quality of the evidence for each outcome. To accomplish this, we will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

For each outcome, the quality starts at high when high-quality RCTs provide results; quality is reduced by one level when each of the quality considerations above are not met:

High-quality evidence:

Consistent findings have been noted among at least 75% of RCTs with no limitations on study design; with consistent, direct and precise data; and with no known or suspected publication biases. Further research is unlikely to change 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.

Summary of findings tables

Where there are sufficient data, we will create 'Summary of findings' tables using the following outcomes:

- Active range of motion (AROM): extent of active shoulder abduction/elevation of the shoulder without pain, measured in degrees or other scales (e.g. functional target distance).
- Overall pain (mean or mean change measured by visual analogue scale (VAS), numerical or categorical rating scale).
- Function. Where trialists reported outcome data for more than one function scale, we will extract data on the scale that was highest on the following a priori defined list: (1) Shoulder Pain and Disability Index (SPADI); (2) Croft Shoulder Disability Questionnaire; (3) Constant-Murley Score; (4) any other shoulder-specific function scale.
- Pain on motion measured by VAS, numerical or categorical rating scale, regardless of the type of clinical evaluation e.g. on resisted movements, at the endpoint of pain-free active shoulder

ROM, with active movements, caused by a clinical diagnostic test for SIS (e.g. empty can test of Jobe).

- Global assessment of treatment success as defined by the trialists (e.g. proportion of participants with significant overall improvement), or measured by specific tools (e.g. Global Perceived Effect, GPE (Kamper 2010)).
- Quality of life as measured by generic measures (such as components of the Short Form-36 (SF-36)) or disease-specific tools).
- Number of participants experiencing any adverse events (e.g. skin reactions, including severe or painful rash, itching, dermatitis, local ulceration or exfoliation, and enlarged glands).

The tables will include the main comparisons described in the Types of interventions as follows:

- kinesio taping use versus sham taping
- kinesio taping use versus other interventions (e.g. exercise)

Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be carried out for the following subgroups only if sufficient studies are retrieved in the data collection process, as it is unlikely that the investigation of heterogeneity will produce useful findings unless a substantial number of studies are identified (Deeks 2011).

1. Number of applications of kinesio taping: one versus two or more applications

In kinesio taping therapy, consecutive applications can be performed (Kase 2003), therefore we will try to understand if applying the kinesio taping more than once (i.e. prolonging the KT treatment for more than three to four days) is more beneficial, similar to using high-dose for medicines.

2. Target population: 'overhead' people (e.g. athletes, workers) versus general population.

Individuals who are at risk of developing impingement syndrome include athletes (e.g. baseball players), assembly-line workers, warehouse workers, and others who perform repetitive work with the arms raised above shoulder height. In those individuals, the shoulder pain may be more severe than in the general population. In fact, athletes and overhead workers have a different pattern of scapular kinematics than the general population (Timmons 2012).

We will restrict subgroup analysis to pain and function outcomes. We will conduct a statistical test for heterogeneity across subgroup results and compute an I^2 statistic. We will use the random-effects models to analyse the variation in the mean effects in the different subgroups using meta-regression techniques - if the number of studies in the meta-analysis are adequate. Acknowledging that subgroup comparisons are observational, we will use caution in the interpretation of subgroup analyses.

Sensitivity analysis

We plan to carry out the following sensitivity analysis: studies with missing data for participants will be excluded to allow investigation of their impact on the results of the meta-analysis.

We will conduct sensitivity analysis to investigate the effects of risks of bias. We will assess the effect of including studies with unclear or high risk of the following biases on subjective outcomes (pain, function, quality of life, treatment success) by:

- removing studies with lack of or unclear random sequence generation or adequate allocation concealment to assess the potential effect of selection bias;
- removing studies with lack of or unclear participant-blinding to assess the potential effect performance and detection bias.

Interpreting results and reaching conclusions

Where there is no firm evidence of the effect or if the effect is lacking we will emphasize this in our conclusions. We will base our conclusions only on findings from the quantitative or narrative (if a meta-analysis is not sensible) synthesis of included studies. We will avoid making recommendations for practice and our implications for research will suggest priorities for future research and outline what uncertainties remain in the field.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies for CENTRAL and MEDLINE

Search strategy for CENTRAL:

1. MeSH descriptor: [Shoulder Pain] explode all trees
2. MeSH descriptor: [Shoulder Impingement Syndrome] explode all trees
3. MeSH descriptor: [Rotator Cuff] explode all trees
4. MeSH descriptor: [Bursitis] explode all trees
5. ((shoulder* in All Text or rotator* in All Text) and (bursitis in All Text or impinge* in All Text or tendonitis in All Text or tendonitis in All Text or tendinopathy in All Text or pain* in All Text))
6. "rotator cuff " in All Text
7. #1 or #2 or #3 or #4 or #5 or #6
8. tap* in All Text
9. kinesio* in All Text
10. #8 or #9
11. #7 and #10

Search strategy for MEDLINE (Ovid):

1. shoulder pain/
2. shoulder impingement syndrome/
3. rotator cuff/
4. exp bursitis/
5. ((shoulder$ or rotator cuff) adj5 (bursitis or or impinge$ or tendinitis or tendonitis or tendinopathy or pain$)).mp.
6. rotator cuff.mp.
7. or/1-6

8. (tap$ or kinesiotap$ or kinesio$)
9. randomized controlled trial.pt.
10. controlled clinical trial.pt.
11. randomized.ab.
12. placebo.ab.
13. drug therapy.fs.
14. randomly.ab.
15. trial.ab.
16. groups.ab.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
18. exp animals/ not humans.sh.
19. 9 not 10
20. 7 and 8 and 19

CONTRIBUTIONS OF AUTHORS

SG conceived, wrote and coordinated the protocol, will carry out the search, conduct screenings, extract data and complete the risk of bias assessment;

AA wrote the protocol and will perform the statistical analyses, contribute to screening, extract data and assess of risk of bias in case of doubt or disagreement;

GC wrote the protocol and will carry out the search, conduct screenings, extract data and complete the risk of bias assessment;

LL revised the protocol and will provide input for writing the discussion;

LM conceived the protocol and provided statistical advice, will provide input for writing the discussion;

MGV is the guarantor of the review, provided statistical advice, will provide input for writing the discussion;

All authors approved of the final protocol.

DECLARATIONS OF INTEREST

None known

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External sources

- No sources of support supplied