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[Intervention Protocol]

Rigid dressings versus soft dressings for transtibial amputations

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ABSTRACT

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

To assess the benefits and harms of rigid dressings versus soft dressings for treating transtibial amputations.

BACKGROUND

Description of the condition

Lower limb amputation can result from non-traumatic causes (e.g. dysvascular disease, malignancy and congenital deficiencies) or traumatic causes (e.g. war injuries and work accidents) (Varma 2014; Ziegler-Graham 2008). Amongst these causes, dysvascular disease is most common and includes diseases such as diabetes and peripheral vascular disease (Varma 2014; Ziegler-Graham 2008). The incidence of lower limb amputation is estimated to be 24 per 100,000 in the USA (Moxey 2011), and 26 per 100,000 in the UK (Ahmad 2014). These estimates increase in people with diabetes, and estimates range from 410 to 3100 per 100,000 in the USA and from 147 to 248 per 100,000 in the UK (Moxey 2011). Trauma is the second most common cause of limb loss (Varma 2014; Ziegler-Graham 2008), and accounts for 16% of amputations in the USA (Tintle 2010), and 7% to 9% of amputations

in the UK (Perkins 2012). Approximately half of all lower limb amputations are transtibial (below the knee) amputations (Curran 2014; Fortington 2013; Kayssi 2015; Moxey 2010; Zayed 2014). Poor outcomes are commonly reported post-lower limb amputation. High mortality rates have been reported in patients with non-traumatic amputations, with almost 50% dying within one year and 70% dying within three years, mostly due to underlying co morbidities (e.g. heart failure, renal failure, cancer and chronic obstructive pulmonary disease) (Jones 2013). The rate of hospital readmission within 30 days ranges from 10% to 30%, with a large proportion readmitted due to wound complications and stump revisions (Curran 2014; Kayssi 2015; Ries 2015). In patients with traumatic amputations, half have been reported to have substantial disability at two-year and seven-year follow-up (MacKenzie 2004; MacKenzie 2005). Rehospitalisation rates were similar at less than 30%, with 34% developing wound infections and 15% requiring revision (Harris 2009). Consequently, the cost of acute and post-acute care of an initial episode of amputation is high, costing more

than USD 8.3 billion yearly in the USA (Ma 2014). In the UK, up to GBP 985 million is spent on care related to foot ulcers and amputations (Hex 2012).

Description of the intervention

Two main types of dressings can be applied after a transtibial amputation. These dressings include soft and rigid dressings. These dressings differ from local wound dressings (e.g. hydrogel dressings, negative wound therapy, honey, aloe vera) in that they are applied with a degree of compression in order to reduce stump swelling in preparation for prosthetic fitting in transtibial amputations (Choudhury 2001; Smith 2003). Soft dressings (e.g. elastic or crepe bandages) are the conventional choice of dressings due to their low cost and easy applicability (Choudhury 2001). However, rigid dressings have grown in popularity due to the belief that a hard exterior provides greater compression, greater reduction in swelling and hence faster wound healing and shorter time to prosthetic fitting (Churilov 2014; Nawijn 2005). Rigid dressings are the intervention of interest in this systematic review and include the following variations (Smith 2003);

Non-removable rigid dressings

These are multi-layered dressings made out of gauze pads and bandages, cotton/woollen/synthetic fibre stump socks and a plaster of Paris cast. Dressings are moulded up to the thigh level of the stump with the knee immobilised in full extension. The earliest report of their use is in 1961 (Baker 1977; Golbranson 1968). These dressings are sometimes combined with an immediate postoperative prosthesis (Johannesson 2010). Plaster of Paris casts are also sometimes replaced with a prefabricated plastic dressing held by neoprene and Velcro straps (Sumpio 2013).

Removable rigid dressings

These are similar to non-removable rigid dressings except they do not include the knee so it is free to flex. Use of a removable rigid dressing was first reported in 1979 (Wu 1979). The main advantages of a removable rigid dressing over a non-removable rigid dressing is that it allows frequent observation of the wound and does not require another cast to be made. If stump volume decreases, socks can be added to the cast and the cast placed back on the stump (Wu 1979). The removable rigid dressings may increase susceptibility to knee flexion contractures because the knee is not held in extension. In order to keep the knee extended and minimise the chances of knee flexion contractures, the use of pouches on patients' wheelchairs (Hughes 1998), or custom-made removable bivalved rigid shells have also been suggested (Duwayri 2012). Plaster of Paris casts are also sometimes replaced with a fibreglass/synthetic cast for a lighter cast (Duwayri 2012; Taylor 2008).

Immediate postoperative prostheses

These allow for early weight-bearing on the stump. These prostheses can vary in terms of their top or bottom parts. The top part surrounding the stump can come in either a custom-made plaster of Paris cast (Burgess 1968; Condon 1969; Folsom 1992), or prefabricated pneumatic air bladder/air splint (Pinzur 1989; Schon 2002), or prefabricated plastic dressing held by neoprene and Velcro straps (Ali 2013). The bottom part that is in contact with the ground can be either a metal cylinder (Pinzur 1989), or an adjustable aluminium pylon attached to an artificial foot (Ali 2013; Burgess 1968; Condon 1969; Folsom 1992; Schon 2002).

Others

These include combinations of the above (e.g. non-removable rigid dressings and immediate postoperative prostheses) or dressings and prostheses that are not yet described. These include the SteriShield Controlled Environment Unit (CEU) and semi-rigid dressings. The CEU consists of a sterile transparent pneumatic plastic cylinder, which allows the flow of warm filtered air through the system but does not allow weight-bearing (Ruckley 1986). Semi-rigid dressings consist of a bandage imbedded with Unna paste developed by a dermatologist in 1883 to treat ulcers. The Unna paste is made of zinc oxide, calamine, gelatin and glycerine and forms a semi-rigid inextensible dressing (MacLean 1994; Wong 2000).

How the intervention might work

The main postulated benefits of rigid dressings over soft dressings are:

- greater reduction in swelling via application of more consistent pressure around the stump (Duwayri 2012; Golbranson 1968); and
- greater protection of the stump from trauma due to the hard surface of a rigid dressing (Duwayri 2012; Wu 1979).

These factors are believed to lead to faster wound healing, reduced risk of wound infection/breakdown, reduced pain, shorter time to prosthetic fitting and reduced length of stay in the hospital (Churilov 2014; Schon 2002).

Why it is important to do this review

There is uncertainty about the most appropriate and effective type of dressings following transtibial amputations. Several reviews have been conducted to investigate the efficacy of rigid dressings in improving outcomes in transtibial amputations though only two were systematic reviews (Churilov 2014; Nawijn 2005). Of these two systematic reviews, one review was published more than a decade ago (Nawijn 2005), and one only investigated the efficacy

of rigid dressings on one outcome (i.e. time from amputation to prosthetic fitting) (Churilov 2014). Despite being the first meta-analysis to be conducted on the literature, Churilov 2014 drew the conclusion to support rigid dressings without consideration of the inconsistency and imprecision of the results from the studies included in the systematic review. Several amputee care guidelines have also recommended the use of rigid dressings for transtibial amputations (BACPAR 2012; US Dept of Veterans Affairs 2008), though these recommendations are largely based on poorly conducted randomised controlled trials (RCTs), observational studies, case-control studies and retrospective audits. Due to the scepticism surrounding the quality of evidence on rigid dressings and the belief that rigid dressings can lead to wound breakdowns in some patients with poor skin integrity, there remains wide variation in practice concerning dressings in transtibial amputations (Barnes 2014; Choudhury 2001). It is therefore important to conduct a comprehensive and rigorous systematic review to summarise recent evidence on the benefits and harms of rigid dressings in transtibial amputations.

OBJECTIVES

To assess the benefits and harms of rigid dressings versus soft dressings for treating transtibial amputations.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-RCTs. The latter includes studies with quasi-randomised allocation procedures, such as alternation, hospital record number or date of birth (Lefebvre 2011).

Types of participants

People of all ages with transtibial amputations due to all causes including dysvascular disease (diabetes, peripheral vascular disease), trauma and cancer.

Types of interventions

- Rigid dressings (intervention), which include non-removable rigid dressings, removable rigid dressings, immediate postoperative prostheses and others;

- soft dressings (comparison), which include crepe bandaging and elastic/compression bandaging.

Types of outcome measures

Timing of outcome measures

Outcomes could be obtained at any time point following amputation. We will group outcomes according to the time since amputation:

- short-term outcomes: outcomes obtained less than one month since amputation;
- medium-term outcomes: outcomes obtained between one to three months of amputation;
- long-term outcomes: outcomes obtained after three months of amputation.

We will present dichotomous and continuous outcomes as short-term, medium-term and long-term outcomes. We will present time-to-event outcomes at the median or mean follow-up reported by the authors. We will use our judgement as to whether statistical pooling within these outcomes is appropriate.

Primary outcomes

- Wound healing measured as time from amputation to wound healing and proportion of wounds healed;
- complications/adverse events measured as proportion of skin-related complications/adverse events (e.g. wound infections/breakdowns/stump revisions/further amputations/pressure areas), proportion of non skin-related complications/adverse events (e.g. deaths, chest infections, falls, pain) and severity of pain on the visual analogue scale.

Secondary outcomes

- Prescription of prosthetics measured as time from amputation to first prosthetic fit/cast;
- physical function measured as time to independent ambulation, proportion of participants mobilising independently and functional assessment scales (e.g. Functional Independence Measure scale);
- length of hospital stay measured as time from hospital admission to discharge;
- patient comfort measured with a validated scale used to measure patient's ease, comfort or satisfaction with the dressing;
- quality of life data measured with generic or wound-specific questionnaires;
- cost measured as any cost relating to dressings or other resources (e.g. personnel costs).
- swelling measured as girth measurements or any other measures of stump volume reported by study authors. (We note

that swelling is a potential surrogate outcome for other outcomes such as wound healing, physical function and length of hospital stay. Conclusions regarding efficacy of rigid dressings will not be based on swelling).

We anticipate that study authors will define wound healing in different ways (Gethin 2015). We will not try to enforce a single definition of wound healing across all trials but instead we will extract data according to each authors' definition of wound healing. We will also align our methods of data extraction and data analysis/synthesis of wound outcomes with previous Cochrane systematic reviews on wound healing for consistency (Dumville 2015a; Dumville 2015b). We have covered these methods further in the sections on [Data extraction and management](#), [Measures of treatment effect](#), [Unit of analysis issues](#) and [Data synthesis](#).

Search methods for identification of studies

Electronic searches

We will search the following electronic databases for relevant studies:

- the Cochrane Wounds Specialised Register (to present);
- the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, latest issue);
- Ovid MEDLINE (1946 to present);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (latest issue);
- Ovid Embase (1974 to present);
- EBSCO CINAHL Plus (1937 to present);
- Ovid AMED (1985 to present);
- PEDro (www.pedro.org.au) (to present).

We have presented the draft search strategy for CENTRAL in [Appendix 1](#). We will adapt this strategy to search the other databases we have listed above. We will combine the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2011). We will combine the Embase search with the Ovid Embase randomised trials filter terms developed by the UK Cochrane Centre (Lefebvre 2011). We will combine the CINAHL search with the randomised trials filter terms developed by the Scottish Intercollegiate Guidelines Network (SIGN 2015). We will not restrict studies with respect to language, date of publication or study setting.

Searching other resources

In order to identify further published, unpublished and ongoing studies, we will also:

- search the reference lists of relevant studies and reviews identified in prior searches;

- search the following clinical trial registries: ClinicalTrials.gov, [the World Health Organization \(WHO\) International Clinical Trials Registry Platform \(ICTRP\)](http://www.who.int/clinicaltrialsregistryplatform);
- use the Cited Reference Search facility on [ThomsonReuters Web of Science](http://www.thomsonreuters.com);
- contact relevant individuals and organisations for unpublished and ongoing studies;
- search the grey literature using [Open Grey](http://www.opengrey.org) and [Google Scholar](http://scholar.google.com).

Data collection and analysis

Selection of studies

Two review authors (LKK and LG) will independently screen titles and abstracts to determine eligibility of potential studies. We will resolve any disagreements through discussion and the third review author (LH) will arbitrate if there is still disagreement. We will obtain full-text publications of the potentially eligible studies and two review authors (LKK and LG) will independently screen these publications for inclusion. We will exclude studies that do not meet the inclusion criteria at this point. We will record the excluded studies and their reasons for exclusion in the 'Characteristics of excluded studies' table. If we require more information to determine the eligibility of studies, we will contact the investigators of relevant studies for more information. If there are disagreements regarding the eligibility of the full-text publications, we will consult a third review author (LH) to resolve these disagreements. We will complete a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow-chart to summarise this process (Liberati 2009). We will use the reference management software EndNote (EndNote 2014) to manage the records we retrieve in the selection process.

Data extraction and management

Two review authors (LKK and LG) will independently extract data on study characteristics and outcomes from the included studies using a data extraction form. The categories of data extracted will include:

- methods: study design, method of randomization, country of study, type of incision (skew flap or long posterior flap), care setting (acute/surgical or rehabilitation);
- participants: sample size (by group), number of dropouts (by group), inclusion criteria, exclusion criteria, baseline characteristics of participants (age, gender, traumatic or non-traumatic amputation and skin integrity (e.g. measured with the NPUAP Pressure Ulcer Stages/Categories), by group if provided);
- interventions: type of dressing, time to first application of dressing, duration of dressing (hours per day, days/weeks), comparator therapy;

- outcomes: primary outcomes (with definitions), secondary outcomes (with definitions), other outcomes (with definitions), timing of outcomes (short-term, medium-term or long-term with specific time frames);
- notes: publication status, funding of trials and conflicts of interest.

We will use a piloted data extraction form. We will resolve all disagreements by discussion or arbitration with the third review author (LH). One review author will enter the extracted data into Review Manager (RevMan) and a second author will cross-check the data to ensure accuracy (RevMan 2014). We will screen for potential duplicate publications by cross-checking authors' names, year of publication and journal titles. We will download and assess full-text copies of the studies if we remain uncertain whether or not the publication is a duplicate.

If several measures of a similar outcome (e.g. wound healing) are present in a study, we will extract all data and list them in a summary of study outcomes table, but we will only enter the preferred data type into the meta-analyses. The preferred data type will be time-to-event outcomes, followed by dichotomous outcomes and, lastly, continuous outcomes. Time-to-event outcomes (e.g. time from amputation to wound healing) and dichotomous outcomes (e.g. proportion of wounds healed) are preferred as these are likely to have more clinical relevance than continuous outcomes (e.g. wound size). Time-to-event outcomes are preferred over dichotomous outcomes as they allow more comparisons between studies with different follow-up time points and are less prone to selective outcome reporting bias, which can occur in studies with dichotomous outcomes since investigators can intentionally select time points that show the least or greatest difference between groups (Tierney 2007).

Assessment of risk of bias in included studies

Two review authors will independently rate the risk of bias in each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We will assess the risk of bias using the following domains (see Appendix 2):

- random sequence generation;
- treatment allocation;
- blinding of participants, care providers and outcome assessors;
 - incomplete outcome data;
 - selective outcome reporting;
 - other potential sources of bias (e.g. industry funding).

We will rate each potential source of bias as either high, low or unclear in each included study and will provide justification for our rating in the 'Risk of bias' table. If there is ambiguity, we will contact the study investigators for clarification. We will also summarise the overall risk of bias of all studies for each domain and

for each outcome so that the final results for outcome measures will be deemed as either at high, low or unclear risk of bias.

Measures of treatment effect

For time-to-event data (e.g. time from amputation to wound healing), we will calculate results as hazard ratios using the 'O-E' (observed minus expected events) and 'V' (logrank variance) statistics derived from number of events and times to events in control and interventions groups (Tierney 2007). If these statistics are not readily available, we will refer to further guidance (Tierney 2007), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). If study authors provide a mean or median time to outcomes and clearly state that all outcomes (e.g. wound healing) were achieved, we will pool these data in a meta-analysis as continuous data. If it is unclear that all outcomes were achieved, we will document but not pool the data. We will use the generic inverse variance method for all analyses in RevMan (RevMan 2014).

For dichotomous data (e.g. proportion of wounds healed), we will present results as risk ratios (RRs) with 95% confidence intervals (CIs). We will also calculate the number needed to treat for an additional beneficial outcome (NNTB) and number needed to treat for an additional harmful outcome (NNTH) from the risk difference for easier interpretability of results.

For continuous data (e.g. wound sizes, girth measurements, pain scores), we will calculate results as means or changes in mean scores with 95% CIs. If studies use different scales to measure the same outcome, we will report standardised mean differences with 95% CIs. If ordinal data are present, we will analyse these as continuous data.

Unit of analysis issues

If studies have more than one intervention group (e.g. non-removable rigid dressings and removable rigid dressings) or more than one control group (e.g. crepe bandaging and elastic bandaging), we will combine the groups such that we make only a single pairwise comparison, i.e. we compare data from both non-removable rigid and removable rigid dressing groups against data from crepe bandaging and elastic bandaging groups. The unit of analysis will be the participant. In the event that studies have participants with double amputations and treatment was carried out on both legs, we will adjust for intra-patient correlation (intra-cluster correlation) in the effect estimates of relevant outcome measures.

Dealing with missing data

If information is missing on the methods or results (e.g. data from drop-outs, data reported at baseline but not at follow-up, statistics such as standard deviations (SDs)), we will contact study investigators to request missing information. We will contact study investigators via email addresses provided in the publication or by

searching the staff directory of authors' affiliated organisations as stated in the publication. If we are unable to obtain the missing information, we will estimate the missing SD values according to methods described in the *Cochrane Handbook for Systematic Reviews of Interventions*, Section 16.1.3 (Higgins 2011b). We will perform sensitivity analyses to determine the influence of missing data on the results. We will discuss findings of the review based on the results of our sensitivity analyses.

Assessment of heterogeneity

Before combining studies in meta-analyses, we will check for clinical and statistical heterogeneity. We will base judgements about clinical heterogeneity on clinical reasoning after reviewing participant, intervention and outcome characteristics of studies. We will base judgements about statistical heterogeneity on the Chi² test and the I² statistic values (Higgins 2011a).

Assessment of reporting biases

We will minimise reporting biases by searching several databases and clinical trial registries. We will ensure that we do not enter data in duplicate publications twice into the meta-analysis. If there are more than 10 studies for each outcome, we will create funnel plots and look for signs of asymmetry. If there are fewer than 10 studies for each outcome, we will summarise the findings of the review based on the results of our sensitivity analyses.

Data synthesis

We will use RevMan to conduct our analyses (RevMan 2014). We will conduct a meta-analysis if the included studies do not demonstrate substantial clinical heterogeneity, i.e. participant, intervention and outcome characteristics of studies are similar enough to be pooled. Also, we will investigate statistical heterogeneity. We will conduct a meta-analysis if there is no substantial statistical heterogeneity, i.e. the Chi² test yields a P value greater than 0.1 and the I² statistic is less than 50% (Higgins 2011a). In deciding between a fixed-effect or a random-effects model, we will use a random-effects model if there is a sufficient number of included studies and the I² statistic value is greater than 0%. We will adopt the conservative approach of using a random-effects model with any signs of heterogeneity (i.e. I² statistic value is greater than 0%) due to the high risk of undetected heterogeneity which can occur with few included studies in a meta-analysis (Kontopantelis 2013).

'Summary of findings' tables

We will present the main results of the review in 'Summary of findings' tables using GRADEpro GDT (GRADEpro GDT 2015). These tables present key information concerning the quality of

the evidence, the magnitude of the effects of the interventions examined and the sum of the available data for the main outcomes (Schünemann 2011a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. The GRADE approach defines the quality of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The quality of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias (Schünemann 2011b). We plan to present the following outcomes in the 'Summary of findings' tables; wound healing, complications/adverse events, physical function, length of hospital stay, patient comfort, quality of life and cost.

Subgroup analysis and investigation of heterogeneity

We will investigate heterogeneity using the methods described in Section 9.6 of the *Cochrane Handbook* (Deeks 2011). We will perform subgroup analyses to determine whether the size of treatment effects are influenced by the following:

- type of rigid or soft dressings (e.g. non-removable rigid dressings vs crepe bandaging, removable rigid dressings vs crepe bandaging, non-removable rigid dressings vs elastic bandaging, removable rigid dressings vs elastic bandaging).

We will only perform subgroup analyses if there are a minimum of 10 studies included in the meta-analysis.

Sensitivity analysis

We will perform sensitivity analyses to determine if the results are robust to arbitrary decisions that we make during the review process. We also plan to assess whether these results differ when we only consider studies at low risk of bias versus studies of high and unclear risk of bias in specific methodological aspects of the study. These methodological aspects include:

- randomisation (true random versus quasi-random);
- concealed allocation (concealed versus non-concealed);
- blinding of assessors (blinding versus no blinding); and
- drop-out rate (greater than 15% versus less than 15%).

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* Indicates the major publication for the study

APPENDICES

Appendix 1. The Cochrane Central Register of Controlled Trials (CENTRAL) provisional search strategy

- #1 MeSH descriptor: [Amputation] explode all trees
- #2 MeSH descriptor: [Amputation Stumps] explode all trees
- #3 MeSH descriptor: [Amputees] explode all trees
- #4 MeSH descriptor: [Lower Extremity] this term only
- #5 ((transtibia* or trans-tibia*) near/3 amput*):ti,ab,kw
- #6 (“below knee” or below-knee) near/3 amput*):ti,ab,kw
- #7 ((low* next limb*) near/3 amput*):ti,ab,kw
- #8 ((low* next extremit*) near/3 amput*):ti,ab,kw
- #9 BKA:ti,ab,kw
- #10 amput* next stump*:ti,ab,kw
- #11 residua* next limb*:ti,ab,kw
- #12 {or #1-#11}
- #13 MeSH descriptor: [Bandages] explode all trees
- #14 MeSH descriptor: [Artificial Limbs] explode all trees
- #15 MeSH descriptor: [Casts, Surgical] explode all trees
- #16 MeSH descriptor: [Splints] explode all trees
- #17 ((rigid or plastic* or compress* or unna) near/3 (dressing* or bandage*)):ti,ab,kw
- #18 gauze:ti,ab,kw
- #19 (sock* near/5 (amput* or stump*)):ti,ab,kw
- #20 (prosth* near/3 (amput* or stump* or transtibia* or trans-tibia* or “below knee” or below-knee or low* next limb* or low* next extremit* or residua* next limb*)):ti,ab,kw
- #21 ((plaster or fibreglass or fiberglass or plastic* or surgical or synthetic*) near/3 cast*):ti,ab,kw
- #22 splint*:ti,ab,kw
- #23 {or #13-#22}
- #24 {and #12, #23} in Trials

Appendix 2. Cochrane 'Risk of bias' assessment tool

1. Was the allocation sequence randomly generated?

Low risk of bias

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.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

There is insufficient information about the sequence generation process provided to permit a judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

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 randomization); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

High risk of bias

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

Unclear

Insufficient information provided to permit a judgement of low or high risk of bias. This is usually the case if the method of concealment is not described, or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following:

- no blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding;
- blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
- either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following:

- no blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding;
- blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
- either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Either of the following:

- insufficient information to permit judgement of low or high risk of bias;
- the study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following:

- no missing outcome data;

- reasons for missing outcome data are unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
- missing outcome data are balanced in numbers across intervention groups, with similar reasons for missing data across groups;
- for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate;
- for continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is not enough to have a clinically relevant impact on the observed effect size;
- missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following:

- reason for missing outcome data are likely to be related to the true outcome, with either an imbalance in numbers or reasons for missing data across intervention groups;
- for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk is enough to induce clinically relevant bias in the intervention effect estimate;
- for continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is enough to induce a clinically relevant bias in the observed effect size;
- 'as-treated' analysis done with a substantial departure of the intervention received from that assigned at randomisation;
- potentially inappropriate application of simple imputation.

Unclear

Either of the following:

- insufficient reporting of attrition/exclusions to permit a judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided);
- the study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Either of the following:

- the study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way;
- the study protocol is unavailable but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following:

- not all of the study's prespecified primary outcomes have been reported;
- one or more primary outcomes is/are reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified;
- one or more reported primary outcomes was/were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);
- one or more outcomes of interest in the review is/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.

Unclear

Insufficient information provided to permit a judgement of low or high risk of bias. It is likely that most studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study either:

- had a potential source of bias related to the specific study design used;
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

CONTRIBUTIONS OF AUTHORS

LKK, LG and LH conceived the review. LKK co-ordinated the development of the protocol, and wrote the draft of the protocol with assistance from LH. LG provided feedback on the draft of the protocol. LKK, LG and LH approved the final version of the protocol before submission.

Contributions of the editorial base

Kurinchi Gurusamy (Editor) edited the protocol; advised on methodology, interpretation and content and approved the protocol prior to submission.

Gill Rizzello (Managing Editor) : co-ordinated the editorial process; advised on interpretation and content and edited the protocol.

Reetu Child (Information Specialist) designed the search strategy.

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LKK has no known conflicts of interest.

LG has no known conflicts of interest.

LH has no known conflicts of interest.

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