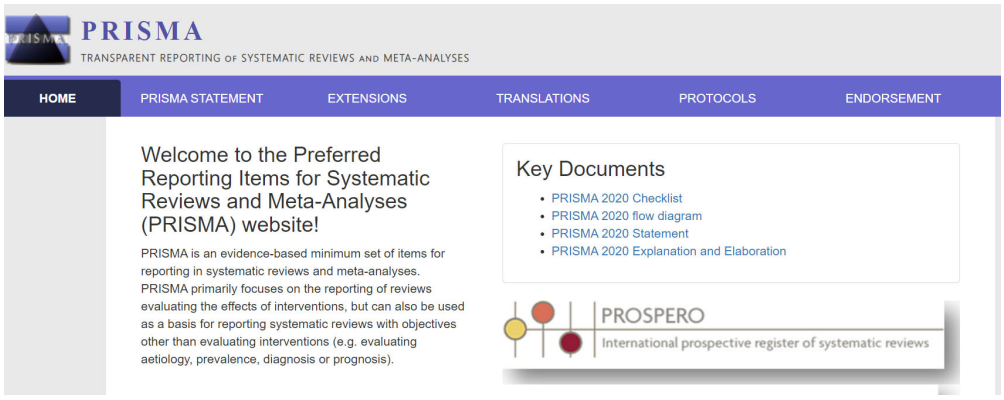
Systematic review reporting



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equator network

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Why is complete reporting of systematic reviews important?

Systematic reviews serve many critical roles for many types of users, including:

- patients, healthcare providers, researchers and policy makers

These roles include:

- Addressing questions that cannot be answered by individual studies
- Identifying problems that need addressing in future studies
- Generating or evaluating theories

Systematic reviews need to be:

- **Transparent**
- **Complete**
- **Accurate about:**
  - **WHY it was done**
  - **WHAT was DONE**
  - **WHAT was FOUND**

Page et al. 2021. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ n71.. doi:10.1136/bmj.n71

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Common aspects missing in reporting of systematic reviews

- Use of a protocol
- Eligibility criteria for publication status
- Years coverage of the search
- A full Boolean search logic for at least 1 database
- Methods for data extraction
- Methods for risk of bias assessment
- A primary outcome identified
- An abstract conclusion that incorporates study limitations
- Funding source

Page MJ, Shamseer L, Altman DG, Tetzlaff J, Sampson M, Tricco AC, et al. (2016) Epidemiology and Reporting Characteristics of Systematic Reviews of Biomedical Research: A Cross-Sectional Study. PLoS Med 13(5): e1002028. doi:10.1371/journal.

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The PRISMA 2020 statement: an updated guideline for reporting systematic reviews

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Updated items highlighted

A few key items will be discussed on the following slides

Table 1 | PRISMA 2020 item checklist

Section and topic	Item #	Checklist item	Location where item is reported
Title			
Title	1	Identify the report as a systematic review.	
Abstract			
Abstract	2	See the PRISMA 2020 for Abstracts checklist (table 2).	
Introduction			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
Methods			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesise results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesised results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	
Results			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram (see fig 1).	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesised results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
Discussion			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
Other information			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code, and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

Page et al. 2021. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ n71.. doi:10.1136/bmj.n71

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Example article*

BMJ 2021;372:m4825
http://dx.doi.org/10.1136/bmj.m4825

* pre- PRISMA2020, but still nicely illustrates many aspects of good SR reporting

OPEN ACCESS

Check for updates

Efficacy and safety of antidepressants for the treatment of back pain and osteoarthritis: systematic review and meta-analysis

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Additional material is published online only. To view please visit the journal online.
Cite this as: BMJ 2021;372:m4825
http://dx.doi.org/10.1136/bmj.m4825
Accepted: 3 November 2020

ABSTRACT

OBJECTIVE
To investigate the efficacy and safety of antidepressants for back and osteoarthritis pain compared with placebo.

DESIGN
Systematic review and meta-analysis.

DATA SOURCES
Medline, Embase, Cochrane Central Register of Controlled Trials, CINAHL, International Pharmaceutical Abstracts, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform from inception to 15 November and updated on 12 May 2020.

ELIGIBILITY CRITERIA FOR STUDY SELECTION
Randomised controlled trials comparing the efficacy or safety, or both of any antidepressant drug with placebo (active or inert) in participants with low back or neck pain, sciatica, or hip or knee osteoarthritis.

DATA EXTRACTION AND SYNTHESIS
Two independent reviewers extracted data. Pain and disability were primary outcomes. Pain and disability scores were converted to a scale of 0 (no pain or disability) to 100 (worst pain or disability). A random effects model was used to calculate weighted mean differences and 95% confidence intervals. Safety (any adverse event, serious adverse events, and proportion of participants who withdrew from trials owing to adverse events) was a secondary outcome. Risk of bias was assessed with the Cochrane Collaboration's tool and certainty of evidence with the grading of recommendations assessment, development and evaluation (GRADE) framework.

RESULTS
33 trials (5318 participants) were included. Moderate certainty evidence showed that serotonin-noradrenaline reuptake inhibitors (SNRIs) reduced back pain (mean difference −5.30, 95% confidence interval −7.31 to −3.30) at 3-13 weeks and low certainty evidence that SNRIs reduced osteoarthritis pain (−9.72, −12.75 to −6.69) at 3-13 weeks. Very low certainty evidence showed that SNRIs reduced sciatica at two weeks or less (−18.60, −31.87 to −5.33) but not at 3-13 weeks (−17.50, −42.90 to 7.89). Low to very low certainty evidence showed that tricyclic antidepressants (TCAs) did not reduce sciatica at two weeks or less (−7.55, −18.25 to 3.15) but did at 3-13 weeks (−15.95, −31.52 to −0.39) and 3-12 months (−27.0, −36.11 to −17.89). Moderate certainty evidence showed that SNRIs reduced disability from back pain at 3-13 weeks (−3.55, −5.22 to −1.88) and disability due to osteoarthritis at two weeks or less (−5.10, −7.31 to −2.89), with low certainty evidence at 3-13 weeks (−6.07, −8.13 to −4.02). TCAs and other antidepressants did not reduce pain or disability from back pain.

CONCLUSION
Moderate certainty evidence shows that the effect of SNRIs on pain and disability scores is small and not clinically important for back pain, but a clinically important effect cannot be excluded for osteoarthritis. TCAs and SNRIs might be effective for sciatica, but the certainty of evidence ranged from low to very low.

SYSTEMATIC REVIEW REGISTRATION
PROSPERO CRD42020158521.

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ABSTRACT

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Item 2 See the PRISMA 2020 for Abstracts checklist (Page et al., 2021)

Table 2 | PRISMA 2020 for Abstracts checklist*

Section and topic	Item #	Checklist item
Title		
Title	1	Identify the report as a systematic review.
Background		
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.
Methods		
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.
Synthesis of results	6	Specify the methods used to present and synthesise results.
Results		
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).
Discussion		
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).
Interpretation	10	Provide a general interpretation of the results and important implications.
Other		
Funding	11	Specify the primary source of funding for the review.
Registration	12	Provide the register name and registration number.

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ABSTRACT

2. Explicit statement of main objectives

1. Identify the report as a systematic review

4. Sources and dates specified

3. Inclusion and exclusion criteria

6. Methods used to present and synthesise the results

5. Methods used to assess risk of bias

ABSTRACT

OBJECTIVE
To investigate the efficacy and safety of antidepressants for back and osteoarthritis pain compared with placebo.

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Systematic review and meta-analysis.

DATA SOURCES
Medline, Embase, Cochrane Central Register of Controlled Trials, CINAHL, International Pharmaceutical Abstracts, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform from inception to 15 November and updated on 12 May 2020.

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DATA EXTRACTION AND SYNTHESIS
Two independent reviewers extracted data. Pain and disability were primary outcomes. Pain and disability scores were converted to a scale of 0 (no pain or disability) to 100 (worst pain or disability). A random effects model was used to calculate weighted mean differences and 95% confidence intervals. Safety (any adverse event, serious adverse events, and proportion of participants who withdrew from trials owing to adverse events) was a secondary outcome. Risk of bias was assessed with the Cochrane Collaboration's tool and certainty of evidence with the grading of recommendations assessment, development and evaluation (GRADE) framework.

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33 trials (5318 participants) were included. Moderate certainty evidence showed that serotonin-noradrenaline reuptake inhibitors (SNRIs) reduced back pain (mean difference −5.30, 95% confidence interval −7.31 to −3.30) at 3-13 weeks and low certainty evidence that SNRIs reduced osteoarthritis pain (−9.72, −12.75 to −6.69) at 3-13 weeks. Very low certainty evidence showed that SNRIs reduced sciatica at two weeks or less (−18.60, −31.87 to −5.33) but not at 3-13 weeks (−17.50, −42.90 to 7.89). Low to very low certainty evidence showed that tricyclic antidepressants (TCAs) did not reduce sciatica at two weeks or less (−7.55, −18.25 to 3.15) but did at 3-13 weeks (−15.95, −31.52 to −0.39) and 3-12 months (−27.0, −36.11 to −17.89). Moderate certainty evidence showed that SNRIs reduced disability from back pain at 3-13 weeks (−3.55, −5.22 to −1.88) and disability due to osteoarthritis at two weeks or less (−5.10, −7.31 to −2.89), with low certainty evidence at 3-13 weeks (−6.07, −8.13 to −4.02). TCAs and other antidepressants did not reduce pain or disability from back pain.

CONCLUSION
Moderate certainty evidence shows that the effect of SNRIs on pain and disability scores is small and not clinically important for back pain, but a clinically important effect cannot be excluded for osteoarthritis. TCAs and SNRIs might be effective for sciatica, but the certainty of evidence ranged from low to very low.

SYSTEMATIC REVIEW REGISTRATION
PROSPERO CRD42020158521.

7. Give the total number of included studies and participants and *summarise relevant characteristics of studies*

8. Present results for main outcomes, *preferably indicating the number of included studies and participants for each.* If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured)

9. Brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision)

10. Provide a general interpretation of the results and important implications

12. Provide the register name and registration number

11. Specify the primary source of funding for the review

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An example of a SR with key items MISSING

1. Identify the report as a systematic review (in abstract)

3. Inclusion and exclusion criteria

6. Methods used to present and synthesise the results

9. Brief summary of the limitations of the evidence included in the review

Abstract

Background: Despite increased utilization of conservative measures for displaced olecranon fractures in elderly patients, in whom operative fixation may be complicated by coexisting comorbidities and declining bone quality, the noninferiority of nonoperative management has yet to be proven. The purpose of this study was to review nonoperative management of displaced olecranon fractures in the elderly patient population.

Methods: A literature search of the PubMed database was performed using the term *olecranon fracture*. Papers included those with results for patients aged 65 years and older published between 1990 and 2018 in the English language. Data were pooled to analyze outcomes and complications of nonoperative management of olecranon fractures in the elderly patient population.

Results: Four eligible studies combined for a total of 69 patients with 70 fractures with an average age of 83.8 years (71-95 years), female predominance of 88%, and a mean follow-up of 12.4 months who underwent nonoperative management of displaced olecranon fractures. While only 25% of fractures went on to radiographic union, the mean Disabilities of the Arm, Shoulder, and Hand score was 16.9 (0-59.6), the mean arc of motion was 138°, and 92% of patients achieved excellent results. One-quarter (26%) of the patients experienced complications: radial head subluxation (1), skin sore (1), degenerative arthropathy (1), pain on movement (2), click in movement of the elbow (5), and local pain (8).

Conclusion: Displaced olecranon fractures in patients aged older than 70 years may be effectively managed with nonoperative measures to produce high satisfaction and functional range of motion.

Keywords: elbow, anatomy, fracture/dislocation, diagnosis, treatment, research and health outcomes, surgery, specialty, outcomes

11. Specify the primary source of funding for the review

12. Provide the register name and registration number

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METHODS

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METHODS

Item 5 Eligibility criteria

Eligibility criteria

We included randomised controlled trials that compared any antidepressant drug with placebo in participants with back pain (neck or low back pain with or without radicular symptoms) or hip or knee osteoarthritis, or both. Symptoms of any duration were included. Trials including drug combinations were eligible if the treatment contrast between groups was antidepressant versus placebo. The placebo comparator could be active (a substance that has no known effect on pain but might mimic the adverse effects of antidepressants) or inert (a substance that is not thought to have a therapeutic or adverse effect). We included reports published in peer reviewed journals as well as unpublished data posted on trial registry platforms (ClinicalTrials.gov and WHO International Clinical Trials Registry Platform). Trials that reported data on either pain, disability, or adverse events were included. No restrictions were placed on language or publication date. We excluded studies that included participants with serious spinal conditions (eg, fractures, cancer) and rheumatic conditions (eg, rheumatoid arthritis), unless these studies also included participants with back pain or hip or knee osteoarthritis, or a combination of these, and their data were reported separately. We considered studies to be eligible when participants received previous back or osteoarthritis surgery but excluded studies that evaluated immediate postoperative pain management (ie, surgery within past month). Abstracts from conferences were also excluded.

Specify
- the inclusion and exclusion criteria for the review and
- how studies were grouped for the syntheses

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METHODS

6. Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies

Items 6 & 7 Information sources and Search strategies

7. Present the full search strategies for all databases, registers and websites, including any filters and limits used

analyses (PRISMA) guidelines.[20] We searched Medline, Embase, Cochrane Central Register of Controlled Trials, CINAHL, International Pharmaceutical Abstracts, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform from inception to 15 November and updated the searches on 12 May 2020 (supplemental file 1). Two authors (GEF,

6. Specify the date when each source was last searched or consulted

Supplemental file 1. Search strategies

MEDLINE

1	antidepressants.mp. or exp Antidepressive Agents/
2	exp Antidepressive Agents, Second-Generation/
3	exp Antidepressive Agents, Tricyclic/
4	exp Amitriptyline/
5	exp Nortriptyline/
6	exp Desipramine/
7	exp Imipramine/
8	exp Doxepin/
9	exp Trimipramine/
10	exp Clomipramine/
11	exp Protriptyline/
12	Tetracyclic.mp.
13	exp Amoxapine/
14	exp Maprotiline/
15	exp Serotonin Uptake Inhibitors/
16	exp Citalopram/
17	Escitalopram.mp. Fluoxetine

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METHODS

Item 8
Selection process

8. Specify the methods used to decide whether a study met the inclusion criteria of the review, including :
how many reviewers screened each record and each report retrieved,
whether they worked independently, and if applicable,
details of automation tools used in the process.

MOK) independently screened records by titles and abstracts, and two authors (GEF, JZ) read full texts of potentially eligible studies to determine eligibility (see supplemental file 2 for a list of excluded trials with reasons). Any disagreements were resolved by consensus.

Supplemental file 2. List of excluded studies after full-text reading

ID	Author/registry identification	Year	Title	Reason for exclusion
1	Konno	2019	An Open-Label, 52-Week, Phase III Trial of Duloxetine in Japanese Patients with Chronic Low Back Pain	Wrong study design
2	Yue	2019	Clinical meaningfulness of duloxetine's effect in Chinese patients with chronic pain due to osteoarthritis: post hoc analyses of a phase 3 randomized trial	Wrong study design
3	Enteshari-Moghaddam	2019	Efficacy of duloxetine and gabapentin in pain reduction in patients with knee osteoarthritis	Wrong comparator
4	Itoh	2019	Efficacy of duloxetine for multi-site pain in patients with knee pain due to osteoarthritis: an exploratory post hoc analysis of a Japanese phase 3 randomized study	Conference abstract
5	Wang	2019	Maintenance of effect of duloxetine in Chinese patients with pain due to osteoarthritis: 13-week open-label extension data	Wrong study design

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METHODS

Items 9 & 10
Data collection process
and Data items

9. how many reviewers collected data from each report,
whether they worked independently

10b List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources)

Data extraction
Two authors (GEF, JZ) independently extracted data. Whenever possible, for each outcome we extracted post-treatment means, standard deviations, and number of participants in each group. When post-

approach. When data were not available in the published manuscript, we sought and, when available, extracted data on safety from the trial registry.

9. any processes for obtaining or confirming data from study investigators

number of participants in each group. When post-treatment scores were not reported, we extracted data according to the hierarchy of between group differences and corresponding 95% confidence intervals at follow-up and then pre-treatment to post-treatment within group change scores. When a study did not report standard deviations, we used estimation methods recommended by the Cochrane handbook for systematic reviews of interventions.[21] Cochrane's

10b ...
Describe any assumptions made about any missing or unclear information

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METHODS

Item 10
Data items

Outcomes

The primary outcomes were pain intensity and disability. Adverse events were a secondary outcome. Adverse events included the number of participants who experienced any adverse event (as defined by each study), experienced any serious adverse event (as defined by each study), and withdrew because of adverse effects.

Data synthesis and analysis

We classified follow-up times into two weeks or less, 3-13 weeks, 3-12 months, and more than 12 months. In studies with multiple time points, we extracted data from the time point closest to two weeks and three, six and 12 months. When trials had multiple treatment groups, we divided the number of participants in the placebo group by the number of treatment groups. For dichotomous outcomes, both the number of events and the sample size were divided by the number of treatment groups.[21]

10a List and define all outcomes for which data were sought.
Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.

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METHODS

Items 11 & 15
Risk of Bias and Certainty assessments

11. Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.

Risk of bias and certainty of evidence

Two reviewers (GEF, MOK) rated risk of bias of trials using the Cochrane Collaboration risk of bias tool.[23] Disagreements were resolved by consensus. We assessed the certainty of evidence using the grading of recommendations assessment, development and evaluation (GRADE) framework.[24] Certainty of evidence refers to the confidence that the true effect lies in a particular range.[25] The certainty of evidence was downgraded by one level if a serious flaw was present in the domains of limitations in study design, inconsistency, imprecision, and small study bias. We did not downgrade for indirectness because patients, interventions, and comparators were similar across comparisons (see supplemental file 3 for a description of the GRADE framework used). The certainty of evidence was then classified as high, moderate, low, or very low. High certainty means we are confident that the

15. Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.

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METHODS

Item 12 & 13 Effect measures and Synthesis methods

used by studies, and conversion procedures. Mean differences (95% confidence intervals) were calculated for continuous outcome measures, and risk ratios (95% confidence intervals) were calculated for dichotomous outcomes. Statistical heterogeneity in each meta-analysis was determined by means of the I^2 test. A random effects model was used across all comparisons.

12. Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.

For continuous outcomes, we calculated the mean difference between groups and the respective standard error in Comprehensive Meta-analysis V3 and entered these data in RevMan version 5.3 using the Generic inverse variance method to obtain forest plots. For dichotomous outcomes, we used the Mantel-Haenszel method in RevMan version 5.3.

13d. Describe any methods used to synthesise results and provide a rationale for the choice(s).
If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.

We grouped antidepressants based on their drug class. A pooled between group mean difference of 10 points (on a 0-100 scale) was considered by us to be the threshold for the smallest worthwhile effect for pain and disability.[30] Pooled mean differences between groups below this threshold were considered clinically unimportant. This threshold has been used in other reviews of drug treatments for back pain,[17 31 32] and it is also the recommended threshold for pain and disability in osteoarthritis.[33 34] We used funnel plots to test for small study effects when at least 10 trials were available within a comparison.[21] The Egger's test was used to investigate small study effects. For comparisons

13 a Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).

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An example of a SR with key items MISSING

10a List and define all outcomes for which data were sought.
Specify whether all results that were compatible with each outcome domain in each study were sought, and if not, the methods used to decide which results to collect.

12. Specify for each outcome the effect measure(s) used in the synthesis or presentation of results.

The present study was preregistered in the Open Science Framework (https://osf.io/z3btr/?view_only=8df0a2096e844c59a7547096812553bf). The systematic search was performed in January 2019 and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA, Supplemental Digital Content 1, http://links.lww.com/CJP/A641) 2009 checklist served as a guide for conducting the study. The key words related to the subject were selected on the basis of a comprehensive review of the literature. The electronic databases Cinahl, Medline, PubMed, PsycINFO, PSYNDEX, and SportDiscus were chosen.

Publications in English or German language were included regardless of publication date. The search terms used, either in isolation or in combination, were as follows: back pain, self-efficacy, psychometric, validation, reliability, quality, development. The detailed search strategy is available in the preregistration.

Screening and Selection Criteria (Inclusion/ Exclusion Criteria)

Inclusion and exclusion criteria were agreed upon by the authors of this study and were expressed in the preregistration (https://osf.io/z3btr/?view_only=8df0a2096e844c59a754709681255 3bf). The following inclusion criteria had to be met: (1) articles were written in English or German language, (2) adult patient population reporting acute or chronic back pain, (3) developmental, validation, or reliability measures on patient's pain-related self-efficacy.

Articles were excluded if any of the following were true: (1) language other than English or German; (2) articles did not involve any psychometric property information or developmental aspects on pain-related self-efficacy questionnaire; (3) articles did not cover pain-related content of self-efficacy; (4) commentary, meta-analysis, systematic review, case-study, study protocol, or editorial; and (5) articles involved animals, children or adolescents, cancer, opioid or drug use, pregnancy or postnatal women, and abstract screening was assessed independently and blindly by 2 assessors, with final arbitration on inclusion from both assessors. All disagreements were resolved through discussion. Full-text screening was carried out independently by both authors and final inclusion into the systematic review was agreed upon. Criteria were filled into prepared Tables using Microsoft Excel by one assessor and checked by a second assessor. Figure 1 provides an overview on the systematic search.

13d. Describe any methods used to synthesise results and provide a rationale for the choice(s).

14. Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).

15. Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.

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RESULTS

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RESULTS

Item 16
Study selection

Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram

Results

Overall, 2771 records were retrieved. Of these, 1930 records were screened after removal of duplicates and 1795 were excluded based on titles and abstracts. Of 131 potentially relevant trials screened for eligibility, 33 trials enrolling 5318 participants were included (fig 1). Most trials (n=28, 84.9%) used a parallel group design, whereas five (15.2%) used a crossover design with washout periods ranging from one week to two weeks.[35-39] Fourteen trials were sponsored

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RESULTS

New PRISMA flow diagram (Page et al. 2021)

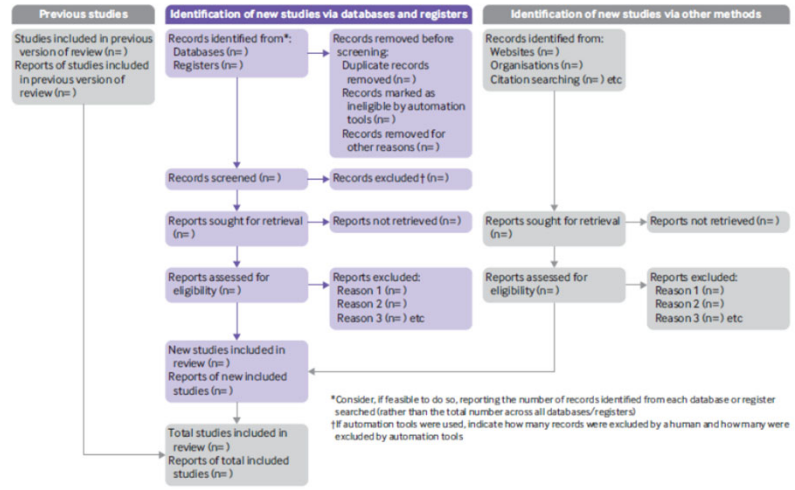

Fig 1 | PRISMA 2020 flow diagram template for systematic reviews. The new design is adapted from flow diagrams proposed by Boers,[55] Mayo-Wilson et al.[56] and Stovold et al.[57] The boxes in grey should only be completed if applicable; otherwise they should be removed from the flow diagram. Note that a "report" could be a journal article, preprint, conference abstract, study register entry, clinical study report, dissertation, unpublished manuscript, government report or any other document providing relevant information.

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RESULTS

Item 17 Study characteristics

Cite each included study and present its characteristics

Supplemental file 6. Characteristics of the included studies (n = 33)

Author year	Study design	Characteristics of participants	Interventions and dose regimens	Industry sponsorship (sponsor)	Source of data
Back pain (19 trials, 23 comparisons)					
Gould 2020[1]	Parallel group	**Condition**: Chronic low back pain (≥ 6 months) **Mean age (SD)**: intervention 55.6 (11.7), control 57.9 (10.9) **Neuropathic pain**: not mentioned **Depression**: No	**Drug (class)**: Desipramine (TCA) **Dose**: dose targeted to achieve a serum concentration of 5-60 ng/ml (20-60 mg/day) **Duration**: 12 weeks **Control**: Active placebo (Benztropine) 0.125 mg/day, single dose, for 12 weeks **Participants enrolled**: 142	No	Published
Schliessbach 2018[3]	Crossover	**Condition**: Chronic low back pain (≥ 3 months) **Mean age (SD)**: 54.4 (17.3) **Neuropathic pain**: Not mentioned **Depression**: No	**Drug (class)**: Imipramine (TCA) **Dose**: 75 mg/day **Duration**: single treatment **Participants enrolled**: 90 **Control**: Active placebo (Tolterodine) 1mg/day, single dose; single treatment **Rescue medication**: allowed **Washout period**: 1 week;	No	Published

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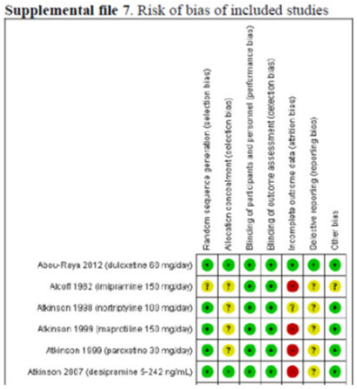
RESULTS

Item 18
Risk of bias in studies summary

Present assessments of risk of bias for each included study

For 26 of 33 trials, at least one domain was classified as high risk of bias (supplemental file 7). Twenty six trials were unclear in describing the methods used to conceal allocation and therefore were at unclear risk of selection bias. One trial was at high risk of performance bias owing to inadequate blinding of participants, and 13 were at unclear risk of performance bias. One trial was at high risk of detection bias owing to inadequate blinding of participants, and another 12 trials were at unclear risk of detection bias. Eighteen trials were at high risk of attrition bias. Five and 14 trials were at high and unclear risk of reporting bias, respectively.

Supplemental file 7. Risk of bias of included studies



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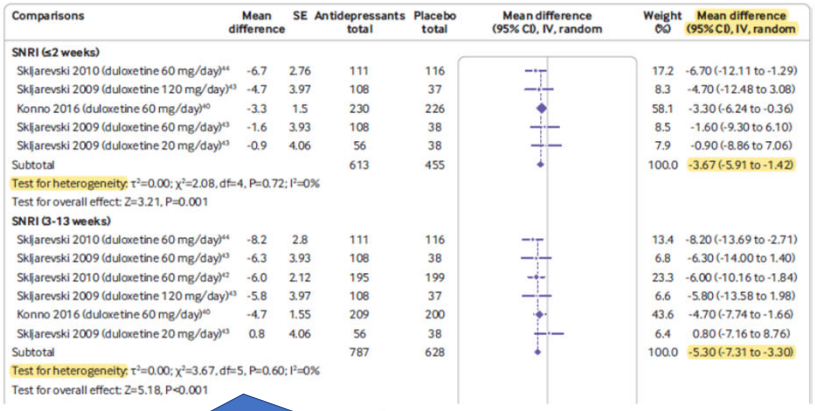
RESULTS

Items 19, 20b, 22
Results of individual studies, Results of syntheses, Certainty of Evidence

Moderate certainty evidence showed that SNRIs reduce pain at two weeks or less (mean difference −3.67, 95% confidence interval −5.91 to −1.42; three trials, 1068 participants) and 3-13 weeks (−5.30, −7.31 to −3.30; four trials, 1415 participants) (fig 2 and



19. For all outcomes, present, for each study:
(a) summary statistics for each group (where appropriate) and
(b) an effect estimate and its precision (e.g. confidence/credible interval),
ideally using structured tables or plots.

23. Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.

20b Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.

Table 1 | Summary of findings and certainty of evidence for pain

	Summary of findings		Certainty of evidence				
	No of participants (No of trials)	Mean difference (95% CI), 0-100	Study design	Inconsistency	Imprecision	Small study effects	Certainty of evidence
Back pain							
SNRI							
≤2 weeks	1068 (3)	−3.67 (−5.91 to −1.42)	Downgraded*	Not downgraded	Not downgraded	Not downgraded	Moderate
3-13 weeks	1415 (4)	−5.30 (−7.31 to −3.30)	Downgraded*	Not downgraded	Not downgraded	Not downgraded	Moderate

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Results

Four papers met inclusion and exclusion criteria after independent evaluation. One prospective cohort study,[12] 1 prospective randomized controlled trial,[9] and 2 retrospective cohort studies were included.[2,4] Eligible papers combined for a total of 69 patients with 70 fractures who underwent nonoperative management of displaced olecranon fractures with a mean follow-up of 12.4 months. Two publications defined displacement as >5 mm,[2,4] another defined displacement as >2 mm,[9] and the final study only included Mayo type 1 and type 2[12] olecranon fractures without severe displacement in their series, although the definition of severe displacement was not defined.[12] All

MISSING

16. Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram

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DISCUSSION

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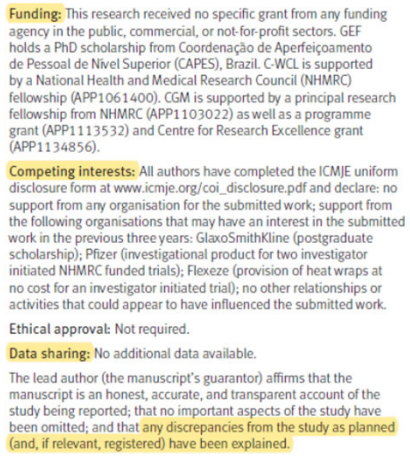
DISCUSSION

Items 24-27



Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. GEF holds a PhD scholarship from Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Brazil. C-WCL is supported by a National Health and Medical Research Council (NHMRC) fellowship (APP1061400). CGM is supported by a principal research fellowship from NHMRC (APP1103022) as well as a programme grant (APP1113532) and Centre for Research Excellence grant (APP1134856).

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; support from the following organisations that may have an interest in the submitted work in the previous three years: GlaxoSmithKline (postgraduate scholarship); Pfizer (investigational product for two investigator initiated NHMRC funded trials); Flexeze (provision of heat wraps at no cost for an investigator initiated trial); no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Not required.

Data sharing: No additional data available.

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

25 Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review

26 Declare any competing interests of review authors

27 Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review

24c Describe and explain any amendments to information provided at registration or in the protocol.

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Questions?

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