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The effectiveness and reporting standards of psychological interventions for improving outcomes after total knee replacement: a systematic review

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Abstract

Objectives: To assess the effectiveness and reporting standards of psychological interventions for improving outcomes after total knee replacement (TKR).

Design: The systematic review protocol was registered on the International Prospective Register of Systematic reviews (CRD42018095100). MEDLINE, EMBASE, and PsycINFO were searched from inception to up to 6th November 2018 with no language restrictions applied. Cohort studies and randomised controlled trials (RCTs) of psychological interventions assessing post-operative pain after TKR were included. Screening, data extraction and assessment of methodological quality was

performed in duplicate by two reviewers. The primary efficacy outcome was post-operative pain severity and the primary harm outcome was serious adverse events. Secondary outcomes included function, quality of life, and psychological wellbeing. Reporting standards were assessed using the TIDieR guidelines for intervention reporting.

Results: 12 studies were included (11 RCTs and one cohort), including 1003 participants. Psychological interventions comprised music therapy (four studies), reiki (two studies), guided imagery (one study), progressive muscle relaxation with biofeedback (one study), pain coping skills programme (one study), cognitive behavioural therapy (two studies), and a post-operative management programme (one study). Due to the high heterogeneity of interventions and poor reporting of harms data, it was not possible to make any definitive statements about the effectiveness or safety of psychology interventions for pain outcomes after TKR.

Conclusion: Further evidence about the effectiveness of psychological interventions for improving pain outcomes after TKR is needed. The reporting of harm outcomes and intervention fidelity is currently poor and would benefit from improvement. Future development of interventions would benefit from the inclusion of psychological theory, behaviour change mechanism, or targeting specific psychological traits linked with poor outcomes, such as anxiety, depression, and pain catastrophizing.

Strengths and limitations of this study

- Inclusion of RCTs and cohort studies to evaluate all available evidence and the identification of published protocols to highlight ongoing research likely to add to the evidence base.
- Evaluation of intervention reporting standards identified areas for improvement for future studies
- Limited opportunities for pooling of data in meta-analysis due to heterogeneity of included interventions.

Introduction

Total knee replacement (TKR) is the second most commonly performed elective procedure in the UK with nearly 100,00 procedures performed in annually [1 2]. TKR is performed to reduce pain and improve functional ability, predominately for people with osteoarthritis. TKR is a successful operation for many patients, with patient satisfaction ranging between 81-89% [3-5]. However, acute post-operative pain after TKR is common, with over half of patients reporting moderate-severe pain in the first three days post-operation [6]. In the longer-term, previous studies have demonstrated that up to 20% of patients experience unfavourable pain outcomes between 3 months and 5 years post-

operative [7-9]. Chronic pain has been shown to be the strongest predictor of dissatisfaction with TKR [7]. Pain after TKR is linked to decreased activity levels, which negatively impacts recovery, and can have a substantial adverse impact on quality of life and wellbeing [10]. In addition, treatment and investigations in relation to chronic pain come at an increased cost to the NHS [11]. Between 2003 and 2017 28,717 first revisions after primary knee replacement recorded on the National Joint Registry[1], often with little benefit for relieving pain[12]. The reduction and treatment of post-surgical pain after TKR is therefore a key focus of research to optimise outcomes and improve patient satisfaction.

Chronic pain after TKR is recognised to be multifactorial in aetiology, with causes including mechanical, biological, surgical and psychological factors [13-16]. In the field of chronic pain management, multidisciplinary approaches including multimodal combinations of analgesics, physical therapy, behavioural therapy, and psychological therapy have been shown to be superior to unimodal approaches such as analgesics only [17 18]. Conventionally, management of pain after surgery has focused on mechanical and biological aspects through the use of analgesic interventions and physiotherapy [19 20]. However, there is increasing awareness of the potential for psychological interventions to be implemented alongside surgery in the pre-, peri - or post-operative period to improve post-surgical outcomes. Psychological interventions may be of particular benefit to patients receiving TKR due to the role that psychological risk factors play in surgical outcomes. Previously conducted systematic reviews and prospective cohort studies have highlighted anxiety, depression, pain catastrophizing, and lack of active coping strategies as risk factors for the prediction of post-operative pain after TKR [21-24].

A previous meta-analysis and systematic review of psychological interventions alongside surgery, including orthopaedic procedures, found relaxation and guided imagery therapy to be effective in improving physical and psychological outcomes, including reduced post-operative pain levels and analgesic use [25]. However, this previous review predominantly included a range of surgical procedures when looking at the effectiveness of psychological interventions. This makes it challenging to draw specific conclusions about the utility of psychological interventions for patients recieving TKR. A systematic review of randomised controlled trials published in June 2018 with no published protocol found mixed evidence for the effectiveness of psychological interventions for improving outcomes after TKR and total hip replacement (THR)[26]. However, this review evaluated TKR and THR together, and therefore the findings are limited as these are two different surgical procedures with distinct indications and outcomes [27]. To date, no systematic review has been

conducted to evaluate the effectiveness of psychological interventions for patients undergoing primary TKR.

Potential challenges in evaluating the literature on psychological interventions are a lack of robust intervention reporting and heterogeneity in the use of psychological terminology. A previous analysis of randomised controlled trials found that only 29% of non-pharmacological interventions provided adequate completeness of intervention description [28]. Without thorough reporting, other researchers are unable to replicate or build on research findings, and synthesis of findings in systematic reviews and meta-analysis is difficult. Psychological interventions are complex and often involve varying intensity, doses, duration, and mode of delivery. Due to this complexity it is important that published studies provide clear descriptions of the content of the interventions to ensure that interventions can be replicated and results of any evaluations are transparent and open to full interpretation. To address this issue a checklist and guidance entitled TIDieR (Template for Intervention Description and Replication) was developed [29]. TIDieR provides the minimum recommended items for describing an intervention and can be used both in reporting of intervention evaluation and in systematic reviews of existing interventions. Including this assessment in systematic reviews of psychological interventions provides a structured, objective assessment of current reporting standards and identification of areas for improvement.

The primary aim of this systematic review was to assess the clinical effectiveness of psychological interventions for improving pain outcomes after TKR. The secondary aim was to evaluate the reporting standards of these interventions assessed against the TIDieR guidelines for intervention reporting.

Methods

This systematic review was prospectively registered on the international prospective register for systematic reviews (PROSPERO) on 27 April 2018 (registration number: CRD42018095100). Conduct of the systematic review followed guidance from the Cochrane handbook [30] and reporting was in accordance with the Preferred Reporting Items for Systematic Reviews [31]. The PRISMA checklist can be found in appendix 1.

Searches

Systematic literature searches were conducted using the OVID Gateway to access MEDLINE, EMBASE, and PsycINFO. Searches were conducted from inception to 6th November 2018, and no

language restrictions were applied. Search terms used are provided in Appendix 2. ISI Web of Science was used to check citations of key reviews and studies. Excluded studies included those reported only as dissertations or conference abstracts. Articles that were unobtainable and study protocols were also excluded.

Eligibility criteria

The following criteria were applied to determine eligibility of studies for inclusion in the review:

- Population: Adults undergoing primary TKR.
- Intervention: Any psychological intervention delivered pre-operatively, peri-operatively, or post-operatively to patients. Psychological interventions were defined as six categories: behavioural, cognitive, relaxation/mindfulness, group-based psychological support, social skills training, and psychotherapy/counselling.
- Control: Active treatment or control treatment (e.g. standard care, placebo, no treatment).
- Outcomes: Assessment of post-operative pain severity.
- Study type: Randomised controlled trial or cohort study.

Screening

All records identified through the searches were imported into Endnote X8 (Thomson Reuters) and duplicates removed. All articles were screened initially by one researcher (KW or VW), and articles that were clearly not relevant were excluded. Potentially eligible articles were screened at abstract and full text level by two reviewers independently (KW and VW). Screening results were then compared with any discrepancies discussed between the reviewers. If consensus could not be achieved, then a third independent reviewer was consulted (KV). Reasons for exclusion were recorded in Microsoft Excel.

Data extraction

Relevant data were extracted onto a standardised proforma by a researcher (KW, VW, or JR). Completed data extraction forms were then checked against the source article by a second reviewer (KW, VW, or JR). Extracted data included: study design, country, date, study population, content of the intervention, primary and secondary outcome data, measures used and data collection timepoints, information for assessment of risk of bias, and reporting standards measured against the TIDieR guidelines. If a study included TKR patients but did not provide disaggregated data, then a single email was sent to the corresponding author to enquire if this data was available. If no response was received or the data was not available then the study was excluded.

Outcomes

Following Cochrane guidance [30] this review had one efficacy and one harm primary outcome. The primary efficacy outcome was knee pain severity, measured at any timepoint after surgery. No limits were placed on the measures used to assess this outcome. The primary harm outcome was the occurrence of serious adverse events. Secondary outcomes included health-related quality of life, psychological wellbeing/status and reporting standards. Reporting standards for interventions were assessed using the TIDieR guidelines[29]. The TIDieR guidelines provide a template for minimum reporting standards for intervention description and replication. The 12-item checklist is applied on a presence/ absence basis with each item scored as yes, no, or partial. The guide provides additional detail on elaboration for each item, and examples of good reporting.

Risk of bias and reporting standards

Risk of bias for RCTs was assessed using the Cochrane risk of bias tool, which assesses risk of bias across six domains: selection, performance, detection, attrition, reporting and other [32]. Potential sources of bias for cohort studies was assessed using a non-summative scoring system that has been used previously in a systematic review within orthopaedics [33]. This checklist assessed bias due to selection, missing data, and confounding.

Strategy for data synthesis

At the protocol stage, meta-analysis was planned if an appropriate number of studies were identified with similar intervention and comparator groups, and comparable outcome data. If pooling of outcome data was not appropriate, a narrative synthesis was planned. Full details of the planned analysis strategy are provided in the PROSPERO record (CRD42018095100).

At analysis stage, opportunities for meta-analysis were limited by the heterogeneity in the content, duration, and intensity of the interventions. Therefore, a narrative synthesis was conducted.

PPI involvement

Patients or public were not involved in the design or conduct of this review.

Results

Searches identified 4680 articles, and 770 full text articles were assessed for eligibility. Twelve studies with a total of 1003 participants were eligible for inclusion (11 RCTs and one cohort studies) [34-45]. A PRISMA flow diagram is provided in Figure 1.

Study characteristics

An overview of study characteristics is provided in Table 1. Included studies were from USA (n= 7), Taiwan (n= 2), the UK (n=2), and China (n=1). The number of centres was reported for 11 studies: nine studies were conducted in a single-centre and two studies were conducted in two centres. Sample sizes for the included studies ranged from 30 – 308 participants, with a median of 65. Two studies included interventions delivered peri-operatively, five post-operatively, and five pre and post-operatively. Six studies conducted follow-up assessments during inpatient stay only (maximum 72 hours), one study five days post-operation, one study two months post-operation, and four studies 6 months post-operation. The most commonly used pain outcome measure was the pain visual analogue scale (n=5), other measures used were the pain visual analogue/numerical rating scale (n=4), the WOMAC pain scale (n=4), and the short-form McGill pain questionnaire (n=1). An overview of study findings is provided in Appendix 3. The primary harm outcome of serious adverse events was not reported in any of the included studies. Reporting of secondary outcomes was variable. Two studies reported on all secondary outcomes (function, health-related quality of life, and psychological wellbeing). The most commonly reported secondary outcome reported was knee function, included in five studies. Full details on secondary outcome reporting can be seen in appendix 4.

Table 1: Study characteristics

Publication, location, study design, date of study, number of centres	Randomised, Mean age, % female	Intervention category	Intervention treatment	Control treatment	Follow-up assessments	Pain assessment, adherence to treatment, losses to follow-up
Allred et al. 2010 USA RCT Dates not reported 1 centre	n=75 (39:36) 64:64 years 50:61%	Relaxation/ mindfulness	Listening to CD of easy listening music on headphones 20 mins before first ambulation and for 20 mins rest period after ambulation. Music had no lyrics, 60-80 bpm.	20 minute quiet rest period.	Post-operative day 1 - 20 mins before first physical therapy session, just before physical therapy, immediately after physical therapy, 20 minutes after physical therapy	Pain VAS 9 (6:3) did not receive intervention 19 (11:8) not included in analysis
Baldwin et al. 2017 USA 3-arm pilot RCT Dates not reported 1 centre	n=56 (25:19:12) Age not reported Gender not reported	Relaxation/ mindfulness	Reiki treatment during hospital stay - 1 hour treatment pre-operatively and 30 minute treatments at 24, 48, and 72 hours after surgery (if not already discharged).	Control 1: sham Reiki at same time points as intervention group. Control 2: 'Quiet time' at same time points as intervention group.	Pre and post each treatment session up to 72 hours after surgery	Pain VAS Adherence not reported 16 (7:7:2) at 48 hours, 35 (16:11:8) at 72 hours
Cai et al. 2018 China Pilot RCT June 2015 - Oct 2016 1 Centre	n= 111 (demographics provided on 100) 65:66 years 64:60%	Behavourial; Cognitive	Post-operative CBT-based 4 session programme of 30 mins each aimed at reducing kinesiophobia.	Usual care	4 weeks post-intervention and 6 months post-intervention	Pain NRS Adherence not reported 11 (5:6) not included in analysis
Chen et al. 2015 Taiwan RCT Dates not reported 1 centre	n=30(15:15) 66:70 years 67:67%	Relaxation/ mindfulness	Soothing piano and Chinese violin music played on a CD player through broadcast speakers. Played for 30 minutes in the pre-operative ward, 30 minutes in the surgical room	Usual care	On the ward after surgery	Pain VAS Adherence not reported 0 losses to follow-up

			waiting area, and 1 hour in post-operative recovery.			
das Nair et al. 2018 UK Feasibility RCT Dates not reported 2 centres	n= 50 (25:25) 65.7:66.7 years 56:36%	Behavourial; Cognitive	CBT-based intervention for anxiety, depression, and pain management. Up to 10 one hour sessions delivered in hospital or participant's home.	Usual care	4 months and 6 months post-randomisation	WOMAC pain score Adherence not reported 13:12 at 6 months
Jacobson et al. 2016 USA Pilot RCT 2011-2012 1 centre	n=82 (42:40) 66:64 years 54:70%	Relaxation/ mindfulness	Guided imagery: 19- to 21-minute audiorecordings designed for this project to promote functional outcomes after TKR and recorded with a soothing instrumental music background. Participants were instructed to listen to the CD every day for 2 weeks before and 3 weeks after surgery.	17- to 21-minute commercially available audiorecordings (e.g., poetry, short stories, essays) at same time points as intervention group.	Day of surgery, 3 weeks post-operative, 6 months post-operative	Pain VAS and WOMAC Pain scale 6 (5:1) received mixed intervention or discontinued intervention 24(13:11) excluded from analysis
Finlay et al. 2016 UK 5-arm RCT Dates not reported 1 centre	n=89(18:21:18:21:20) 68 years 65%	Relaxation/ mindfulness	Listening on headphones to 12-15 minutes of music track with no lyrics, once per day for 3 days after surgery. Four groups assigned music tracks with varying degrees of harmonicity and rhymicity.	Silent control group. Wore noise Cancelling headphones with no input.	Post-operative days 1 - 3	Pain VRS/NRS and Short-form McGill Pain questionnaire Adherence not reported 9 (2:3:0:1:3)
Notte et al. 2016 USA, Philadelphia Pilot RCT Dates not reported 1 centre	n=43 Age not given Sex not given	Relaxation / mindfulness	Reiki treatment 20 min treatment pre-op 30 min treatment after admission to PACU	Standard care, analgesia use	Before and after each reiki session No data on comparison arm for pain	Pain NRS Losses to follow-up not reported but 7 had surgery cancelled and 1 withdrew

			20 min treatment plus relaxing music on three post-op days in hospital			Adherence not reported
Losina et al. 2016 USA RCT Aug 2011 – Nov 2013 1 centre	N=308 66:67 60%	Cognitive / Behavioral	Enhanced postoperative management. Participants received 10 calls from navigators over the course of a 6-month post-TKA recovery period. Participants were helped to identify postsurgical objectives and motivational interviewing techniques were used to elicit statements of self-efficacy and aid the patient in developing specific strategies to achieve goals.	Usual care including inpatient physiotherapy, and outpatient physio after discharge.	Baseline, 3 months post-op, 6 months Postoperatively. Pain only reported as difference btw baseline and 6 months post-op	Pain WOMAC pain score Losses to follow-up: 21 (14 lost to follow-up and 7 withdrawn) 109 had ≥ 7 calls 23 had 5 or 6 calls 22 had <5 calls 134 had at least 1 call Adherence: 97% of patients had consistent navigator.
Riddle et al. 2011 USA Cohort Int: Apr – Sept 2009 Comp: Apr 2008 – Dec 2015 2 centres	N= 63 63.8:60.8 67:73.3%	Cognitive Relaxation / mindfulness	Pain coping skills training intervention comprising 8 sessions. 4 sessions prior to surgery and 4 sessions post-surgery - 2 in person sessions and 6 weekly telephone sessions.	Historical cohort, usual care	Post treatment questionnaires were collected on completion of the coping skills training which occurred on average, 67 (SD=18) days following surgery for intervention arm and 59 (SD=20) days for control.	Pain WOMAC pain score Losses to follow-up: 3 Adherence not reported

Simock et al. 2008 USA RCT June 2006 – March 2007 No. centres not reported, assumed to be 1.	N=30 67.3 years 60%	Relaxation / mindfulness	Patient selection music during surgery, on headphones.	White noise control on headphones.	Baseline, 3h, 6h, and 24h post-surgery	Pain VAS No losses to follow-up reported Adherence not reported
Wang et al. 2015 Taiwan RCT 2010 1 centre	N=66 72.6 years 65.15%	Relaxation / mindfulness	Biofeedback and progressive muscle relaxation during continuous passive motion therapy	Standard care during continuous passive motion therapy	1 day, 2 days, 3 days, 4 days, & 5 days post operatively Before and after CPM Therapy	Pain – pain intensity NRS CMP-elicited pain score Losses to follow-up: n=6 (4 intervention and 2 control). Adherence not reported.

Study quality

Risk of bias assessments for individual studies are displayed in figure 2 for RCTs and figure 3 for cohort studies.

INSERT FIGURE 2 AND FIGURE 3

Interventions

Eight studies were classified as relaxation/mindfulness and included music therapy (n=4), reiki (n=2), guided imagery (n=1), and progressive muscle relaxation with biofeedback (n=1). One study was classified as relaxation/mindfulness and cognitive, this included a pain coping skills programme. Three studies were classified as cognitive and behavioural and included cognitive behavioural therapy (CBT) based programmes (n=2) and a post-operative management programme comprising motivational interviewing to improve self-efficacy and goal attainment (n=1).

Music therapy

Four single-centre RCTs with 224 participants evaluated the effectiveness of music therapy for reducing acute post-operative pain during the inpatient stay after surgery[36 37 39 41]. All studies had high or unclear risk of bias for two or more domains, with blinding of participants and personnel being a high or unclear risk of bias for all studies. A 2-arm RCT with 75 participants which compared listening to a CD of easy listening music on headphones for 20 minutes before and after first post-surgical ambulation to a 20-minute quiet rest period found no differences in mean VAS pain score between groups at any timepoint [37]. A 2-arm RCT with 30 participants which compared listening to soothing piano and Chinese violin music through broadcast speakers for 30 minutes in the pre-operative ward, 30 minutes in the surgical room waiting area, and 1 hour in post-operative recovery to usual care found no differences in VAS pain score between groups on the ward after surgery [39]. A 5-arm RCT with 89 participants which compared listening to 12-15 minutes of instrument only music with varying degrees of harmonicity and rhythmicity on headphones once per day for three days post-surgery to wearing headphones with no input found no differences in NRS or VRS pain scores between groups on post-operative days 1-3 [41]. A 2-arm RCT with 30 participants which compared patient-selected music played on headphones during surgery to white noise found the intervention group reported lower mean VAS pain scores at 3 hours (1.5 (SD 1.4) vs 3.9 (SD 3.4); p=0.01) and 24 hours (2.4 (SD 1.7) vs 4.1 (SD 2.9); p=0.04) post-surgery [36].

Reiki

Two single-centre RCTs with 99 participants evaluated the effectiveness of Reiki for reducing acute post-operative pain after TKR [34 35]. Both studies were at high or unclear risk of bias for five out of seven domains. One 3-arm pilot RCT with 56 participants compared one hour of Reiki treatment pre-operatively and 30-minute treatments at 24, 48, and 72 hours after surgery to sham Reiki and 'quiet time', however, no statistical comparisons of VAS pain scores between trial arms was performed [34]. A 2-arm pilot RCT with 43 participants compared Reiki treatment to usual care, with the Reiki sessions lasting 20 minutes pre-operative, 30 minutes after admission to the postanesthesia care unit and 20 minutes on the first three days post-operative. Pain was assessed using an NRS before and after each treatment, however no comparisons were made between trial arms.

Guided imagery

One single-centre RCT evaluated the effectiveness of guided-imagery on outcomes post-surgery [42]. The study was at high or unclear risk of bias for three domains. The 2-arm RCT with 82 participants compared 19-21 minutes of audio-recorded guided imagery with soothing instrumental background music listened to every day for 2 weeks before surgery and 3 weeks after surgery to 17-21 minutes of commercially available audio-recordings (e.g. poetry, short stories, essays) at the same timepoints. Pain was assessed pre-operatively, on the day of surgery, 3 weeks post-surgery, and 6 months post-surgery using the WOMAC pain score and VAS pain score. No comparisons were made between trial arms.

Progressive muscle relaxation with biofeedback

One single-centre RCT evaluated the effectiveness of progressive muscle relaxation with biofeedback on pain during continuous passive motion therapy [45]. The study had unclear risk of bias for five domains. The 2-arm RCT with 66 participants compared 30 minutes of training on biofeedback-assisted progressive muscle relaxation skills on the day before surgery and during 30-minute sessions of continuous passive motion therapy twice daily for 5 days post-surgery to standard continuous passive motion therapy. Pain was assessed on days 1-5 after surgery before and after continuous passive motion therapy using an NRS pain score. The intervention group showed significantly lower NRS pain scores compared to the control group ($p<0.001$).

Pain coping skills programme

One two-centre cohort study involving 63 participants evaluated the effectiveness of a pain coping skills training programme on post-surgical pain [44]. The study was at unclear risk of bias for inclusion of consecutive patients. An 8-session pain coping skills programme with 4 sessions delivered pre-

operatively and 4 sessions delivered post-operatively (2 in person and 6 by weekly telephone sessions) was compared to a historical cohort receiving standard care. Pain was assessed after the completion of the programme using the WOMAC pain score. Participants in the intervention group had a mean improvement in WOMAC pain score of 6.9 (SD 4.7) compared to a mean improvement of 2.6 (SD 4.8) in the usual care group (p=0.017).

Enhanced post-operative recovery using motivational interviewing

One single centre RCT evaluated the effectiveness of an enhanced post-operative recovery programme to improve post-operative functional status [43]. The study was at high risk of bias for blinding of outcome assessment and selective reporting. In this 2-arm RCT with 308 participants, the intervention was an enhanced post-operative recovery programme comprising 10 telephone calls with a navigator over a 6-month post-operative period aimed at identifying post-surgical objectives and improving self-efficacy using motivational interviewing. The control group received usual care including inpatient physiotherapy and outpatient physiotherapy after discharge. Pain was assessed at baseline, 3-month post-surgery, and 6-months post-surgery using the WOMAC pain score. There were no differences between groups in mean WOMAC pain scores 6 months post-operation.

Cognitive behavioural therapy programmes

Two RCTs (one pilot and one feasibility) with 150 participants evaluated the effectiveness of CBT-based programmes [38 40]. Both studies were at low risk of bias for five domains, with one having unclear risk of bias for selective outcome reporting and other bias[38], and one with high risk of bias for blinding of participants and personnel and incomplete outcome data[40]. One 2-arm pilot RCT with 100 participants compared the used of CBT in reducing kinesiophobia post-surgery to standard care [38]. Four tailored sessions of 30 minutes each were delivered individually. Between group difference were found with reduction in pain NRS scores of 5.63 (SD 0.73) in the intervention group compared to 6.27 (SD 0.86) in the standard care group demonstrated at 6-month follow-up (p=0.003). One 2-arm feasibility RCT with 50 participants compared the use of a CBT-based programme for reducing anxiety and depression to standard care [40]. No between group differences in pain measured using the WOMAC pain score were found at 4 or 6-month follow-up, no between group difference in mood were found at 4 or 12-month follow up measured using the Beck Anxiety Inventory and Depression Inventory.

Intervention reporting standards

Table 2 documents the extent to which the included studies adhere to the TIDieR guidelines for reporting on interventions. Overall, all studies provided information on the name of the intervention, rationale for the intervention, procedures, and how the intervention was delivered. Nine of the studies provided information on the content of intervention and intensity of the intervention, with two studies providing partial details. Ten studies provided details on where the intervention was carried out. Nine studies provided information on who provided the intervention and their training with two studies providing partial details and one study providing no details. Reporting standards for tailoring, modifications, and fidelity/adherence were poor across all studies. Only one study provided information on tailoring and modifications to the intervention, and four studies provided information on fidelity/adherence (planned or actual).

Overall, although no studies provided information on all TIDieR domains, all studies provided details on at least seven out of 10 the domains, with most providing details on eight or more domains.

Table 2: TIDieR checklist summary

Study	Brief name	Why	What	Procedures	Who provided	How	Where	When and how much	Tailoring	Modifications	How well: planned	How well: actual	Overall score
Allred	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Partial	**8/12**
Baldwin	Yes	Yes	Partial	Yes	Yes	Yes	Yes	Yes	No	No	No	No	**7/12**
Cai	Yes	Yes	Yes	Yes	Partial	Yes	No	Yes	No	No	No	No	**7/12**
Chen	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	**8/12**
das Nair	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	**10/12**
Jacobson	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	**10/12**
Finlay	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	No	No	No	**8/12**
Notte	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	**8/12**
Losina	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Partial	Partial	**8/12**
Riddle	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	**8/12**
Simock	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial	No	No	No	No	**7/12**
Wang	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Yes	Yes	No	Yes	**10/12**

Ongoing research

Six published protocols for RCTs were identified in searches and three of these were for studies that would meet the inclusion criteria of the systematic review and have not yet been published. Two of these studies are focussed on psychological interventions delivered by physiotherapists for patients with high pain catastrophizing prior to TKR [46 47]. The other RCT will evaluate a theory-based telephone-delivered patient self-management support intervention to enhance adherence to exercise after TKR [48].

Discussion

This systematic review identified 12 studies that have evaluated the effectiveness of psychological interventions for improving pain outcomes after TKR surgery, with the predominant focus on mindfulness and relaxation. The largest group of interventions was music, and the majority of studies evaluated the effectiveness of interventions for reducing acute-postoperative pain. Pooling of data in meta-analysis was not possible due to the high heterogeneity between the interventions evaluated. Three studies did not compare outcomes between the intervention and control group and all RCTs had high or unclear risk of bias for at least two domains. Therefore, it was not possible to make any definitive statements on the effectiveness of psychological interventions for pain outcomes after TKR. However, some promising areas for future research were identified including the use of CBT in the reducing kinesiophobia [38] and pain coping skills programme[44]. The potential effectiveness of the pain coping skills programme which was found to be beneficial in a cohort study is, however, less clear as the recent publication of the RCT results show no benefit[49]. Suggestion has been made that this intervention would have more benefit for patients reporting persistent post-operative pain, rather than the population as a whole. Using the TIDieR guidelines as a framework, a need for improvements in the reporting of interventions were also identified, particularly on fidelity/adherence.

This systematic review has strengths and limitations which should be considered when interpreting the findings. The review was conducted following Cochrane guidance to ensure the methodology was robust and systematic [30]. In order to evaluate all available evidence, both RCTs and cohort studies were eligible for inclusion, and published protocols were identified to highlight ongoing research that is likely to add to the existing evidence base. Opportunities for pooling of data in meta-analysis were limited because of heterogeneity in the content, duration, and intensity of the interventions, and conclusions are therefore based on narrative synthesis. Secondary outcomes were poorly reported across studies with high heterogeneity in the measures used. The primary harm outcome of serious adverse events was inconsistently and poorly reported, an issue which is common in both trials of pain interventions [50 51] and psychological interventions [52 53], and therefore the safety of these interventions could not be evaluated. The unclear or high risk of bias ratings for many domains of the included studies highlights the need for more rigorous methodological conduct and reporting in studies on this topic. However, despite these limitations, this review provides a comprehensive overview of studies evaluating the effectiveness of psychological interventions for improving pain outcomes after TKR, and the findings have a number of methodological implications for future studies.

This review included both studies evaluating the effectiveness of psychological interventions on both short and long-term outcomes for pain, however the majority of included studies focussed on acute post-operative pain. Whilst ensuring optimal management of short-term pain is important, chronic pain is a substantial issue for TKR patients with up to 20% reporting long-term pain after surgery [7-9]. Chronic pain after TKR is associated with functional limitations and reduced activity levels and can have a substantial negative impact on wellbeing and quality of life [54-58]. Treatment and investigations in relation to ongoing pain after TKR also come at an increased cost to the NHS [11]. All the studies in this review delivered interventions pre-operatively, during the immediate post-operative recovery period, or both. It is therefore unclear if psychological interventions are more or less effective dependent on the timing of delivery. In addition, pain outcomes and mechanisms may differ between acute post-operative pain due to surgical recovery and chronic post-surgical pain, requiring different intervention approaches. Further robust research is needed to evaluate psychological interventions aimed at targeting chronic pain after TKR, in addition to during the immediate post-operative recovery period.

For all studies, harm outcomes were not reported. The assessment of harm outcomes, such as serious adverse events, within interventions is vital for patient safety. However, unlike pharmacological trial where monitoring and reporting of adverse events is mandatory, psychological interventions are rarely subject to the same scrutiny [52]. There is increasing recognition that harm may arise from psychological interventions and that these outcomes should be considered both at the development stage, as seen in dark logic models [59], and at the intervention reporting stage [60]. In 2004, the CONSORT group suggested 10 new recommendations for harm reporting in RCTs including explanations and examples of proper reporting [61]. Despite all RCTs included in this review being published after these recommendations, none have included harms data, demonstrating improvements are clearly needed in this area.

The purpose of this systematic review was to evaluate the effectiveness of psychological interventions specifically for improving pain outcomes after TKR. Many of the interventions included in the review have been the focus of broader, intervention-specific systematic reviews. For example, a systematic review and meta-analysis of peri-operative music interventions found that they reduced post-operative pain in surgical patients [62]. Interventions using cognitive behavioural modalities have been found to have small benefits for older adults with chronic pain [63]. Therefore, the wider literature suggests that some psychological interventions are effective at reducing pain

severity in mixed patient populations. However, our review highlighted the need for more robust RCTs with patients undergoing TKR.

The current evidence base is dominated by music interventions with only a small number of trials evaluating interventions based on psychological theory or including recognised behaviour change mechanisms[64], such as CBT and acceptance-based therapies, or interventions targeting particular psychological traits, such as anxiety, depression, or pain catastrophising, which are all linked to pain [21-24]. This makes it challenging to identify the 'active ingredients' of the interventions, or by which mechanisms these interventions may be able to effect change. However, more recent studies based on CBT targeting specific risk factors such as kinesiophobia and anxiety and depression are now emerging and demonstrate promising results. This indicates a more targeted and individually tailored approach to psychological interventions may be of greater benefit to the patient population. In addition, there are ongoing trials of psychological interventions, for example interventions targeting catastrophizing [46 47], which will add to the evidence base.

Reporting standards for all included studies as measured against the TIDieR guidelines were high for the rationale, content of the intervention, and procedure. However, 10 out of 12 studies did not include any information on tailoring or modifications, and only four out of 12 including adequate information on fidelity and adherence. While tailoring and modification may not have been relevant to many of the standardised interventions evaluated, fidelity and adherence are crucial for accurate interpretations of treatment effects. Psychological interventions are often complex and may involve multiple intervention components, dose intensities, and dose durations. In addition, many psychological interventions are designed with an individualised approach to accommodate particular individual needs and contexts [65 66]. Due to this complexity, accurate reporting of the implementation and adherence of psychological interventions is vital in order to fully understand the intervention effects and inform practice. Whilst the TIDieR guidelines provide a clear checklist for minimum information inclusion, including fidelity, they do not provide guidance on how to assess fidelity. To address this issue, additional guidelines have been published to guide fidelity reporting and improve transparency [67 68], however this results of this review demonstrate there are ongoing issues with the implementation of these guidelines.

Conclusion

This review highlights the need for more evidence about psychological interventions for improving pain outcomes after TKR. Given the high prevalence of acute and chronic pain after TKR, it is

important that interventions that may improve pain outcomes are evaluated in high quality RCTs. This review also highlights substantial ongoing issues in the reporting of interventions, particularly in relation to harm outcomes and intervention fidelity. Guidelines for the reporting of both harm and fidelity do exist and future interventions should implement these guidelines in order to improve reporting standards. Due to the pervasiveness of these problems, research in this area would also benefit from work exploring barriers to guideline implementation. Psychological interventions are broad, encompassing a wide variety of approaches with varying degrees of complexity and specificity. Future development of psychological interventions for TKR patients would benefit from being based on clearly identified psychological theory, behaviour change mechanisms, or targeting specific psychological traits linked with poor outcomes after TKR, such as anxiety, depression, and pain catastrophizing.

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Competing interests

No competing interests were declared by the authors.

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Data statement

No additional data are available. Extracted data is included within the manuscript and appendices.

Figure captions

Figure 1: PRISMA flow chart

Figure 2: Risk of bias summary table (RCTs)

Figure 3: Risk of bias summary table (cohort)

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Figure 1: PRISMA flow chart

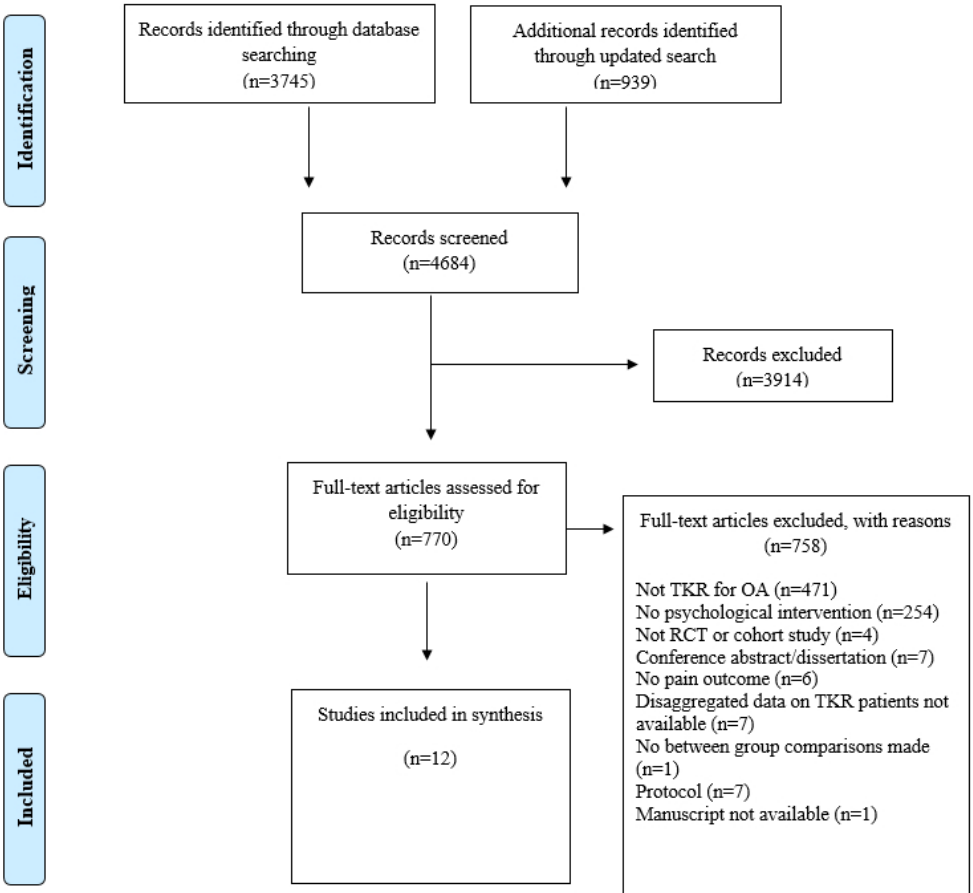


Figure 2: Risk of bias summary table (RCTs)

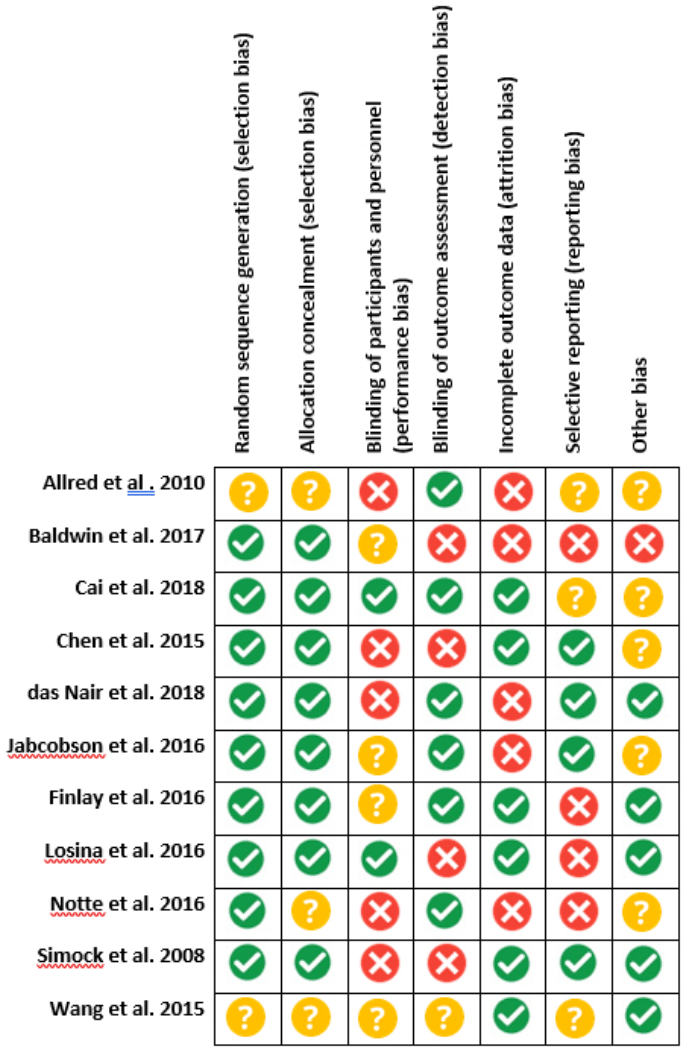
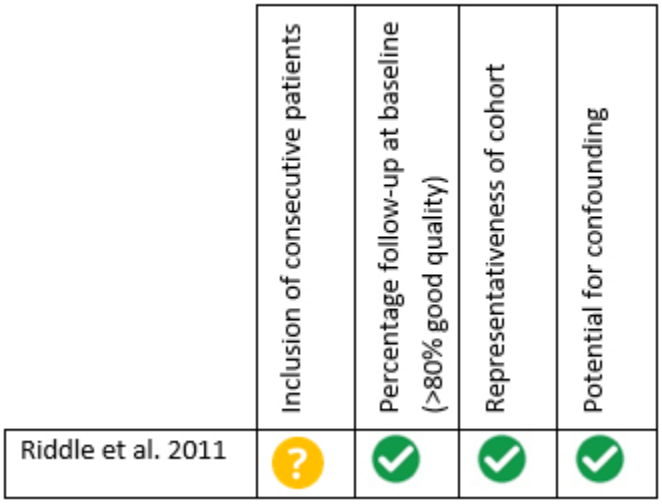


Figure 3: Risk of bias summary table (cohort)



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3, 4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4,5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Figures 2 and 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Appendix 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figures 2 and 3, pages 7-9
9Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10-13
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data; role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 For more information, visit: www.prisma-statement.org.

Appendix 2: Search terms

MEDLINE

Blom et al. 2016

1. exp preoperative care/
2. preoperative period.mp. or Preoperative Period/
3. pre-surg$.tw.
4. presurg$.tw.
5. before surg$.tw.
6. pre-operat$.tw.
7. preoperat$.tw.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7

1. Arthroplasty, Replacement, Knee/ or Arthroplasty, Replacement, Hip/
2. exp Arthroplasty, Replacement, Hip/ or exp Hip Prosthesis/ or hip replacement.mp.
3. exp Arthroplasty, Replacement, Knee/ or exp Knee Prosthesis/ or knee replacement.mp.
4. hip prosthesis.mp. or exp Hip Prosthesis/
5. knee prosthesis.mp. or exp Knee Prosthesis/
6. total hip.tw.
7. total knee.tw.
8. hip implant.mp.
9. knee implant.mp.
10. (knee$ adj5 (arthroplast$ or replacement$ or implant$ or prothes$)).mp.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10

1. survey.mp. or exp Data Collection/
2. randomized controlled trial.mp. or exp Randomized Controlled Trials/
3. prospective study.mp. or exp Prospective Studies/
4. observational study.mp.
5. Comparative Study/
6. exp EPIDEMIOLOGY/ or epidemiology.mp.

7. longitudinal study.mp. or exp Longitudinal Studies/

8. case control study.mp. or exp Case-Control Studies/

9. evaluation study.mp. or exp Evaluation Studies/

10. follow up study.mp. or exp Follow-Up Studies/

11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or10

Clarke 2016 – Cochrane protocol

24 exp osteoarthritis/ (42129)

25 osteoarthr$.tw. (41807)

26 (degenerative adj2 arthritis).tw. (1122)

27 or/24-26 (58230)

29 exp Psychotherapy/ (148827)

30 Psychotherap*.mp. (67432)

31 psychological intervention*.mp. (2453)

32 (psychological adj3 intervention*).mp. (3319)

33 (psychological adj3 therap*).mp. (1827)

34 (psychological adj3 treatment*).mp. (4155)

35 Psychology intervention*.mp. (42)

36 (psychology adj3 intervention*).mp. (98)

37 (psychology adj3 treatment).mp. (67)

38 (psychology adj3 therapy).mp. (133)

39 Behav* therap*.mp. (32942)

40 (behav* adj3 therap*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (35645)

41 behav* modification.mp. (3055)

42 activity scheduling.mp. (22)

43 assertiveness training.mp. (173)

44 aversion therap*.mp. (172)

45 covert sensitization.mp. (55)

46 behav* contracting.mp. (63)

47 behav* modification.mp. (3055)

48 biofeedback.mp. (8082)

49 feedback.mp. (99202)

50 contingency management.mp. (662)

51 conversion therap*.mp. (59)

52 distraction therap*.mp. (24)

53 exposure therap*.mp. (897)

54 abreaction therap*.mp. (1)

55 systematic desensitization therap*.mp. (11)

56 Eye Movement Desensitization Reprocessing.mp. (83)

57 EMDR.mp. (266)

58 implosive therap*.mp. (597)

59 pleasant events.mp. (73)

60 psychoeducation*.mp. (2540)

61 reciprocal inhibition therap*.mp. (6)

62 exp Mind-Body Therapies/ (40688)

63 relaxation techniques.mp. (773)

64 autogenic training.mp. (1123)

65 distraction.mp. (11204)

66 response cost.mp. (203)

67 guided imagery.mp. (484)

68 sleep phase chronotherap*.mp. (11)

69 social skills training.mp. (670)

70 social effectiveness.mp. (44)

71 cognitive behav* therap*.mp. (7951)

72 cognitive therap*.mp. (16063)

73 exp Cognitive Therapy/ (15383)

74 (cognitive adj3 therap*).mp. (20005)

75 CBT.mp. (4979)

76 Problem solving.mp. (28598)

77 rational emotive therap*.mp. (61)

78 reality therap*.mp. (307)

79 restructuring.mp. (10231)

80 role play.mp. (870)

81 schema*.mp. (9382)

82 self control.mp. (3319)

83 stress management.mp. (2688)

84 third wave therapies.mp. (1)

85 (acceptance adj3 commitment therap*).mp. (215)

86 ACT.mp. (194240)

87 behav* activation.mp. (1125)

88 compassion-focused.mp. (15)

89 dialectical behav* therap*.mp. (350)

90 diffusion.mp. (151584)

91 functional analytic psychotherapy*.mp. (18)

92 metacognitive therap*.tw. (31)

93 mind training.mp. (30)

94 mindfulness.mp. (1780)

95 (psychodynamic adj3 psychotherap*).mp. (824)

96 brief psychotherap*.mp. (413)

97 countertransference.mp. (3190)

98 Freudian.mp. (3387)

99 group therap*.mp. (3675)

100 Psychoanalytic Therapy/ (14142)

101 balint.mp. (496)

102 Jungian.mp. (734)

103 kleinian.mp. (149)

104 object relations.mp. (1049)

105 person centred therap*.mp. (8)

106 client centred therap*.mp. (16)

107 psychoanalytic therap*.mp. (14213)

108 alderian therap*.mp. (0)

109 dream analysis.mp. (32)

110 free association.mp. (635)

111 self analysis.mp. (244)

112 short term psychotherap*.mp. (219)

113 transference.mp. (7091)

114 humanistic therap*.mp. (12)

115 existential therap*.mp. (28)

116 experiential therap*.mp. (36)

117 process experiential.mp. (13)

118 gestalt therap*.mp. (169)

119 expressive therap*.mp. (49)

120 grief work.mp. (98)

121 rogerian.mp. (101)

122 non directive therap*.mp. (13)

123 supportive therap*.mp. (3101)

124 transactional analysis.mp. (361)

125 integrative therap*.mp. (169)

126 cognitive analytical therap*.mp. (3)

127 Counseling/ (27626)

128 counselling.mp. (17759)

129 eclectic therap*.mp. (25)

130 interpersonal therap*.mp. (249)

131 multimodal.mp. (17549)

132 transtheoretical.mp. (1117)

133 psychodynamic interpersonal therap*.mp. (30)

134 systemic therap*.mp. (7938)

135 conjoint therap*.mp. (68)

136 couples therap*.mp. (516)

137 marital therap*.mp. (1478)

138 relationship therap*.mp. (64)

139 emotion focussed therap*.mp. (1)

140 family therap*.mp. (8431)

141 integrative behavio?ral couple therap*.mp. (15)

142 narrative therap*.mp. (96)

143 personal construct.mp. (834)

144 socioenvironmental therap*.mp. (428)

145 solution focused brief therap*.mp. (29)

146 exp Psychology, Applied/ (188274)

147 Counsel*.mp. (89067)

148 directive counsel*.mp. (1340)

149 motivational interviewing.mp. (1791)

150 or/29-149 (934550)

Appendix 3: Overview of study findings

Study	Results summary
Allred et al. 2010	No difference in mean VAS pain score between intervention and control at any time points (p=.337). T1 (20 minutes before first physical therapy session) Intervention: 52.4 (SD 25.2) Control group: 46.4 (SD 25.7) T2 (just before physical therapy) Intervention: 36.5 (SD 23.8) Control group: 36.2 (SD 26.9) T3 (immediately after physical therapy) Intervention: 44.5 (SD 28.2) Control group: 48.0 (SD 27.7) T4 (20 minutes after physical therapy) Intervention: 41.2 (SD 25.8) Control group: 45.1 (SD 31.2)
Baldwin et al. 2017	No statistical comparisons made of the mean VAS pain score between the intervention group and control groups. 24 hours postintervention Intervention: 2.6 (SEM 0.2) Sham Reiki: 3.5 (SEM 0.6) Standard of care: 5.7 (SEM 0.8) 48 hours postintervention Intervention: 1.4 (SEM 0.4) Sham Reiki: 2.8 (SEM 0.5) Standard of care: 5.7 (SEM 0.6)

Cai et al. 2018	Between group effect improvement for mean pain NRS. 4 weeks Intervention: 6.23 (SD 1.03) Control: 6.52 (SD 0.77) 6 months Intervention: 5.63 (SD 0.73) Control: 6.27 (SD 0.86)
Chen et al. 2015	No difference in VAS pain score between intervention and control (p=.29). Intervention: 3.22 (SE 0.22) Control: 3.00 (SE 0.25)
das Nair	Feasibility study. No difference in mean pain scores at 4 or 6 month follow-up (p=0.40). 6 months Intervention: 7.5 (SD 2.3) Control: 6.5 (SD 3.6)
Jacobson et al. 2016	No statistical comparisons of mean WOMAC pain scores between intervention and control group. Day of surgery: Intervention: 7.8 (SD 3.1) Control: 8.2 (SD 3.8) 3 weeks post-operative: Intervention: 6.9 (SD 2.8) Control: 7.1 (SD 2.9) 6 months post-operative: Intervention: 2.7 (SD 3.1) Control: 3.5 (SD 3.3)
Finlay et al. 2016	No differences in NRS or VRS pain score between intervention and control group (no results provided).

Losina et al. 2016	No differences found in mean WOMAC pain score between intervention and control group. 6 months post-operative Intervention: 11 (95% CI 9, 14) Usual care: 11(95% CI 9, 14)
Notte et al. 2016	No statistical comparisons made of NRS pain scores between groups. Data presented in bar chart only.
Riddle et al. 2011	Mean WOMAC pain score improvement Intervention: 6.9 (SD 4.7) Control 2.6 (SD 4.8)
Simock et al. 2008	Intervention group had lower mean VAS pain score at 3 hours (p=0.01) and at 24 hours (p=0.04). 3 hours Intervention: 1.476 (SD1.39) Control: 3.876 (SD 3.44) 24 hours Intervention: 2.416 (SD 1.67) Control: 4.036 (SD 2.89)
Wang et al. 2015	Intervention group showed significantly lower CMP elicited NRS pain score (p<.001).

Appendix 4: Harm outcomes and secondary outcomes

	Serious Adverse Events	Function	Health-related quality of life	Psychological wellbeing / status
Allred et al. 2010	✗	✗	✗	✓ Anxiety VAS
Baldwin et al. 2017	✗	✗	✗	✓ State anxiety score
Cai et al. 2018	✗	✓ Hospital for special surgery knee rating scale	✗	✗
Chen et al. 2015	✗	✗	✗	✗
das Nair et al. 2018	✗	✓ WOMAC function	✓ ED-5D	✓ Beck anxiety inventory score
Jacobson et al. 2016	✗	✓ WOMAC function	✓ SF-36	✓ SF-36 mental health
Finlay et al. 2016	✗	✗	✗	✓ Profile of mood states
Losina et al. 2016	✗	✓ WOMAC function	✗	✗
Notte et al. 2016	✗	✗	✗	✗
Riddle et al. 2011	✗	✓ WOMAC disability scale	✗	✗
Simock et al. 2008	✗	✗	✗	✗
Wang et al. 2015	✗	✗	✗	✗

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The effectiveness and reporting standards of psychological interventions for improving short and long-term pain outcomes after total knee replacement: a systematic review

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The effectiveness and reporting standards of psychological interventions for improving short and long-term pain outcomes after total knee replacement: a systematic review

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Abstract

Objectives: To assess the effectiveness and reporting standards of psychological interventions for improving outcomes after total knee replacement (TKR).

Design: The systematic review protocol was registered on the International Prospective Register of Systematic reviews (CRD42018095100). MEDLINE, EMBASE, and PsycINFO were searched from inception to up to 9th May 2019 with no language restrictions applied. Randomised controlled trials (RCTs) assessing the effectiveness of psychological interventions for short and long-term post-operative pain after TKR were included. Screening, data extraction and assessment of

methodological quality was performed in duplicate by two reviewers. The primary effectiveness outcome was post-operative pain severity and the primary harm outcome was serious adverse events. Secondary outcomes included function, quality of life, and psychological wellbeing. Reporting standards were assessed using the TIDieR checklist for intervention reporting.

Results: 12 RCTs were included, with a total of 1299 participants. Psychological interventions comprised music therapy (five studies), guided imagery and music (one study), hypnosis (one study) progressive muscle relaxation with biofeedback (one study), pain coping skills programme (one study), cognitive behavioural therapy (two studies), and a post-operative management programme (one study). Due to the high heterogeneity of interventions and poor reporting of harms data, it was not possible to make any definitive statements about the overall effectiveness or safety of psychology interventions for pain outcomes after TKR.

Conclusion: Further evidence about the effectiveness of psychological interventions for improving pain outcomes after TKR is needed. The reporting of harm outcomes and intervention fidelity is currently poor and could be improved. Future work exploring the impact of intervention timing on effectiveness and whether different psychological approaches are needed to address acute post-operative pain and chronic post-operative pain would be of benefit.

Strengths and limitations of this study

- Inclusion of RCTs to evaluate all available evidence and the identification of published protocols to highlight ongoing research likely to add to the evidence base.
- Evaluation of intervention reporting standards identified areas for improvement for future studies.
- Limited opportunities for pooling of data in meta-analysis due to heterogeneity of included interventions.

Introduction

Total knee replacement (TKR) is the second most commonly performed elective procedure in the UK with nearly 100,00 procedures performed in annually [1 2]. TKR is performed to reduce pain and improve functional ability, predominately for people with osteoarthritis. TKR is a successful operation for many patients, with patient satisfaction ranging between 81-89% [3-5]. However, acute post-operative pain after TKR is common, with over half of patients reporting moderate-severe pain in the first three days post-operation [6]. In the longer-term, previous studies have demonstrated that up to 20% of patients experience unfavourable pain outcomes between 3 months and 5 years post-operative [7-9]. Chronic pain has been shown to be the strongest predictor of dissatisfaction with TKR[7].

Pain after TKR is linked to decreased activity levels, which negatively impacts recovery, and can have a substantial adverse impact on quality of life and wellbeing [10]. In addition, treatment and investigations in relation to chronic pain come at cost to the NHS [11]. Between 2003 and 2017 the National Joint Registry recorded 28,717 first revisions after primary TKR[1], often with little benefit for relief of pain[12]. The reduction and treatment of post-surgical pain after TKR is therefore a key focus of research to optimise outcomes and improve patient satisfaction.

Chronic pain after TKR is multifactorial in aetiology, with causes including mechanical, biological, surgical and psychological factors [13-16]. In the field of chronic pain management, multidisciplinary approaches including multimodal combinations of analgesics, physical therapy, behavioural therapy, and psychological therapy have been shown to be superior to unimodal approaches such as analgesics only [17-19]. Conventionally, management of pain after surgery has focused on mechanical and biological aspects through the use of analgesic interventions and physiotherapy [20 21]. However, there is increasing awareness of the potential for psychological interventions to be implemented alongside surgery in the pre-, peri - or post-operative period to improve post-surgical outcomes. Psychological interventions may be of particular benefit to patients receiving TKR due to the role that psychological risk factors play in surgical outcomes. Previously conducted systematic reviews and prospective cohort studies indicate that increased anxiety, depression, pain catastrophizing (magnification of the pain experience, rumination on the pain, feelings of helplessness), and a lack of active coping strategies as risk factors for increased post-operative pain after TKR beyond the acute recovery period[22-25].

A previous meta-analysis and systematic review of psychological interventions alongside surgery, including orthopaedic procedures, found that relaxation and guided imagery therapy were effective in improving physical and psychological outcomes, including reduced acute post-operative pain levels and analgesic use [26]. However, this previous review included a range of surgical procedures when looking at the effectiveness of psychological interventions, including abdominal, cardiac, and lumbar and spinal surgery. This makes it challenging to draw specific conclusions about the utility of psychological interventions for patients receiving TKR. A systematic review of randomised controlled trials published in June 2018 with no published protocol found mixed evidence for the effectiveness of psychological interventions for improving outcomes after TKR and total hip replacement (THR)[27]. However, this review evaluated TKR and THR together with one included study including TKR patients only, and therefore the findings are limited as these are two different surgical procedures with distinct indications and outcomes [28]. To date, no systematic review has been conducted to

evaluate the effectiveness of psychological interventions for patients undergoing primary TKR. Psychological interventions targeting pain may be of particular benefit to TKR patients due to the high incidence of chronic pain after surgery.

Potential challenges in evaluating the literature on psychological interventions are a lack of robust intervention reporting and heterogeneity in the use of psychological terminology. A previous analysis of randomised controlled trials found that only 29% of non-pharmacological interventions provided adequate completeness of intervention description [29]. Without thorough reporting, other researchers are unable to replicate or build on research findings, and synthesis of findings in systematic reviews and meta-analysis is difficult. Psychological interventions are complex and often involve varying intensity, doses, duration, and mode of delivery. Due to this complexity it is important that published studies provide clear descriptions of the content of the interventions to ensure that interventions can be replicated and results of any evaluations are transparent and open to full interpretation. To address consistency and transparency in reporting of interventions a checklist and guidance entitled TIDieR (Template for Intervention Description and Replication) has been developed [30]. TIDieR was designed for all types of intervention in health; it provides the minimum recommended items for describing an intervention to ensure replicability and can be used in reporting of interventions and in assessment of reporting quality. Using TIDieR to assess the reporting of psychological interventions provides a structured, objective assessment of current reporting standards and may help to identify areas for improvement.

The primary aim of this systematic review was to assess the clinical effectiveness of psychological interventions for improving pain outcomes after TKR. The secondary aim was to evaluate the reporting quality of these interventions assessed using the TIDieR checklist.

Methods

This systematic review was prospectively registered on the international register for systematic reviews (PROSPERO) on 27 April 2018 (registration number: CRD42018095100). Conduct of the systematic review followed guidance from the Cochrane handbook [31] and reporting was in accordance with the Preferred Reporting Items for Systematic Reviews [32] (PRISMA). The PRISMA checklist can be found in appendix 1.

Searches

Systematic literature searches were conducted using the OVID Gateway to access MEDLINE, EMBASE, and PsycINFO. Searches were conducted from inception to 9th May 2019, and no language restrictions were applied. Search terms used are provided in Appendix 2. ISI Web of Science was used to check citations of key reviews and studies. Excluded studies included those reported only as dissertations or conference abstracts. Articles that were unobtainable and study protocols were also excluded.

Eligibility criteria

The following criteria were applied to determine eligibility of studies for inclusion in the review:

- Population: Adults undergoing primary TKR.
- Intervention: Any psychological intervention delivered pre-operatively, peri-operatively, or post-operatively to patients. Psychological interventions were defined as six categories: behavioural, cognitive, relaxation/mindfulness, group-based psychological support, social skills training, and psychotherapy/counselling. Multimodal and complex interventions with psychological components were also considered eligible.
- Control: Active treatment or control treatment (e.g. standard care, placebo, no treatment).
- Outcomes: Assessment of post-operative pain severity (no time limit placed on assessment duration / follow-up).
- Study type: Randomised controlled trial.

Psychological interventions

Psychological interventions are defined as using specific principles and techniques hypothesised to improve psychological wellbeing or a reduction in symptoms associated with psychological difficulties[33], such as pain. Interventions eligible for inclusion included, but were not restricted to, cognitive-behavioural therapies; behavioural interventions; acceptance-commitment therapy; social skills training; relaxation therapies; mindfulness; psychodynamic; counselling; and interpersonal therapies. Excluded therapies included, but were not restricted to, didactic education or education designed to impart knowledge; pharmacological therapy; physiotherapy; spiritual healing (e.g. reiki); complementary and alternative medicine.

Screening

All records identified through the searches were imported into Endnote X8 (Thomson Reuters) and duplicates removed. All articles were screened initially by one researcher (KW or VW), and articles

that were identified as clearly not relevant were excluded. Potentially eligible articles were screened at abstract and full text level by two reviewers independently (KW and VW). Screening results were then compared with any discrepancies discussed between the reviewers. If consensus could not be achieved, then a third independent reviewer was consulted (KV). Reasons for exclusion were recorded in Microsoft Excel.

Data extraction

Relevant data were extracted onto a standardised proforma by a researcher (KW, VW, or JR). Completed data extraction forms were then checked against the source article by a second reviewer (KW, VW, or JR). Extracted data included: study design, country, date, study population, content of the intervention, primary and secondary outcome data, measures used and data collection timepoints, information for assessment of risk of bias, and reporting standards assessed by the TIDieR checklist. If a study included TKR patients but did not provide disaggregated data, then a single email was sent to the corresponding author to enquire if this data was available. If no response was received or the data was not available then the study was excluded.

Outcomes

Following Cochrane guidance [31] this review used one primary outcome for effectiveness and one for harm. The primary effectiveness outcome was knee pain severity, measured at any time-point after surgery. No limits were placed on the measures used to assess this outcome or on the follow-up duration period. The primary harm outcome was the occurrence of serious adverse events. Our definition of a serious adverse events was any untoward medical or psychological occurrence that met any of the following conditions:

- Resulted in death
- Was life-threatening
- Required inpatient hospitalisation or prolongation of existing hospitalisation
- Resulted in persistent or significant disability / incapacity
- Resulted in heightened levels of psychological distress from participants in the intervention

Secondary outcomes included health-related quality of life, psychological wellbeing/status and reporting standards. Reporting standards for interventions were assessed using the TIDieR guidelines and checklist[30]. TIDieR provides a template of minimum reporting standards for intervention description and replication. The 12-item checklist is applied on a presence/ absence basis with each

item recorded as yes, no, or partial. The guide provides additional detail on elaboration for each item, and examples of good reporting.

Risk of bias and reporting standards

Risk of bias for RCTs was assessed using the Cochrane risk of bias tool, which assesses risk of bias across six domains: selection, performance, detection, attrition, reporting and other [34].

Strategy for data synthesis

At the protocol stage, meta-analysis was planned if an appropriate number of studies were identified with similar intervention and comparator groups, and comparable outcome data. If pooling of outcome data was not appropriate, a narrative synthesis was planned. Full details of the planned analysis strategy are provided in the PROSPERO record (CRD42018095100).

At analysis stage, opportunities for meta-analysis were limited by the heterogeneity in the content, duration, and intensity of the interventions. Therefore, a narrative synthesis was conducted.

Patient and public involvement (PPI)

This research was conducted in a musculoskeletal research unit within which research priorities and delivery are identified and developed with ongoing patient and public involvement. This involvement takes place through the activities of the Patient and Public Partnership in Research (PEP-R) who have identified outcomes after knee replacement to be a key research area that they wish to see explored. Once the findings of this review have been published, the research team will work in collaboration with the patient involvement group to design dissemination approaches so that findings reach a wide audience.

Results

Searches identified 4898 articles, and 781 full text articles were assessed for eligibility. 12 RCTs with a total of 1299 participants were eligible for inclusion[35-46]. A PRISMA flow diagram is provided in Figure 1.

Study characteristics

An overview of study characteristics is provided in Table 1. Included studies were from the USA (n= 6), Taiwan (n= 2), the UK (n=2), China (n=1), and Malaysia (n=1). The number of centres was reported for 11 studies: nine studies were conducted in a single-centre, one study was conducted in

two centres, and one study was conducted in five centres. Sample sizes for the included studies ranged from 24 – 402 participants, with a median of 71. One study included interventions delivered peri-operatively, six post-operatively, and five pre and post-operatively. Four studies conducted follow-up assessments during inpatient stay only (maximum 72 hours), one study five days post-operation, five studies 6 months post-operation, and one study 12 months post-operation. One study collected outcome measures at the time of intervention only (post-operative physiotherapy) but did not state the timing post-operation. The most commonly used pain outcome measure was the pain visual analogue scale/numerical rating scale (n=9), other measures used were the pain visual analogue scale (n=4), the WOMAC pain scale (n=4), and the short-form McGill pain questionnaire (n=1). An overview of study findings is provided in Appendix 3. The primary harm outcome of serious adverse events was reported in one study only but was not defined. Reporting of secondary outcomes was variable. Two studies reported on all secondary outcomes (function, health-related quality of life, and psychological wellbeing). The most commonly reported secondary outcome reported was knee function, included in five studies. Full details on secondary outcome reporting can be seen in appendix 4.

Table 1: Study characteristics

Publication, location, study design, date of study, number of centres	Randomised, Mean age, % female	Intervention category	Intervention treatment	Timing of intervention	Control treatment	Follow-up assessments	Pain assessment, adherence to treatment, losses to follow-up
Allred et al. 2010 USA RCT Dates not reported 1 centre	n=75 (39:36) 64:64 years 50:61%	Relaxation/ mindfulness	Listening to CD of easy listening music on headphones 20 mins before first ambulation and for 20 mins rest period after ambulation. Music had no lyrics, 60-80 bpm.	Post-operative, in-hospital	20-minute quiet rest period.	Post-operative day 1 - 20 mins before first physical therapy session, just before physical therapy, immediately after physical therapy, 20 minutes after physical therapy	Pain VAS 9 (6:3) did not receive intervention 19 (11:8) not included in analysis
Cai et al. 2018 China Pilot RCT June 2015 - Oct 2016 1 centre	n= 111 (demographics provided on 100) 65:66 years 64:60%	Behavioural; Cognitive	Post-operative CBT-based 4 session programme of 30 mins each aimed at reducing kinesiophobia.	Post-operative, in-hospital	Usual care	4 weeks post-intervention and 6 months post-intervention	Pain NRS Adherence not reported 11 (5:6) not included in analysis

Chen et al. 2015 Taiwan RCT Dates not reported 1 centre	n=30 (15:15) 66:70 years 67:67%	Relaxation/ mindfulness	Soothing piano and Chinese violin music played on a CD player through broadcast speakers. Played for 30 minutes in the pre-operative ward, 30 minutes in the surgical room waiting area, and 1 hour in post-operative recovery.	Pre-operative and post-operative, in hospital	Usual care	On the ward after surgery	Pain VAS Adherence not reported 0 losses to follow-up
das Nair et al. 2018 UK Feasibility RCT Dates not reported 2 centres	n= 50 (25:25) 65.7:66.7 years 56:36%	Behavioral; Cognitive	CBT-based intervention for anxiety, depression, and pain management. Up to 10 one hour sessions delivered in hospital or participant's home.	Post-operatively	Usual care	4 months and 6 months post-randomisation	WOMAC pain scale Adherence not reported 13:12 at 6 months
Jacobson et al. 2016 USA Pilot RCT 2011-2012	n=82 (42:40) 66:64 years 54:70%	Relaxation/ mindfulness	Guided imagery: 19- to 21-minute audio recordings designed for this project to promote functional outcomes after TKR and recorded with a soothing instrumental music	Pre-operative and post-operative	17- to 21-minute commercially available audio recordings (e.g., poetry, short stories, essays)	Day of surgery, 3 weeks post-operative, 6 months post-operative	Pain VAS and WOMAC Pain scale 6 (5:1) received mixed intervention or discontinued intervention

1 centre			background. Participants were instructed to listen to the CD every day for 2 weeks before and 3 weeks after surgery.		at same time points as intervention group.		24(13:11) excluded from analysis
Finlay et al. 2016 UK 5-arm RCT Dates not reported 1 centre	n=89(18:21:18 :21:20) 68 years 65%	Relaxation/ mindfulness	Listening on headphones to 12- 15 minutes of music track with no lyrics, once per day for 3 days after surgery. Four groups assigned music tracks with varying degrees of harmonicity and rhythmicity.	Post-operative, in hospital	Silent control group: Wore noise Cancelling headphones with no input.	Pre-operative days 1 -3	Pain VRS/NRS and Short-form McGill Pain questionnaire Adherence not reported 9 (2:3:0:1:3)
Lee et al. 2019 Malaysia RCT Jan 2015 – Jan 2017 1 centre	N=24 (8:8:8) 65.6 : 65.3 : 67.9 87% : 87% : 100%	Relaxation / mindfulness	Pre-recorded hypnotic intervention. Pre-surgery session 35 minutes, listened to at least once pre-surgery. Post-surgery listened to at least one 24 hours after surgery.	Pre-operative and post-operative, in hospital	Minimal treatment effect and treatment as usual. Minimal treatment effect comprised psychoeducation, diaphragmatic breathing, recording of relaxing music	Baseline (NRS, HADS, PCS, treatment expectancy) Day 1 post-op two NRSs an hour apart, one before audio recording and one after Day 2 NRSs Day 3 NRSs Day of discharge (NRS, HADS, PCS), HYP and MET	Pain NRS for recent pain intensity and daily pain intensity Adherence not reported 1 lost to follow-up

					(same as background music in HYP group).	group asked how often they listened to recordings. 1 month – NRSs and BPI 3 months – NRSs and BPI 6 months – NRSs and BPI (1 to 6 month done by phone)	
Leonard 2019 USA RCT Dates not given 1 centre	N=32 (16:16) 53-80 : 45 – 87 years 75% : 68.8%	Relaxation / mindfulness	Music therapy during bicycling pedaling exercise post-operatively. Live music was played by a music therapist during PT supported pedaling exercise for 2 minutes, then pedaling alone with no music. Music included singing with paced guitar accompaniment. Songs were based on individual preference, and at a moderate / fast tempo.	Post-operative	Pedaling exercise with no music.	Baseline (1 min after flexion assessment), after each 2-minute intervention period (two periods).	Pain NRS Adherence not reported. No losses to follow-up reported.
Losina et al. 2016 USA RCT	N=308 66:67 60%	Cognitive / Behavioral	Enhanced postoperative management. Participants received 10 calls from navigators over the course of a 6-month post-TKA recovery	Post-operative	Usual care including inpatient physiotherapy, and outpatient	Baseline, 3 months post-op, 6 months Postoperatively.	WOMAC pain score Losses to follow-up: 21 (14 lost to follow-up and 7 withdrawn) 109 had ≥ 7 calls

Aug 2011 – Nov 2013 1 centre			period. Participants were helped to identify postsurgical objectives and motivational interviewing techniques were used to elicit statements of self-efficacy and aid the patient in developing specific strategies to achieve goals.		physio after discharge.	Pain only reported as difference btw baseline and 6 months post-op	23 had 5 or 6 calls 22 had <5 calls 134 had at least 1 call Adherence: 97% of patients had consistent navigator.
Riddle et al. 2019 USA RCT Jan 2013 – June 2016 5 centres	N=402 (130:135:137) 63.2 years 66%	Cognitive/ behavioural	Pain coping skills programme. Eight 50-minutes sessions delivered over a 2-month period, beginning 2 weeks prior to surgery and ending 6 weeks following surgery. One session in person, remaining sessions via telephone.	Pre-operative and post-operative	Arthritis education and usual care. Arthritis education delivered in the same format as pain coping skills programme.	Baseline, 2, 6, and 12 months after surgery.	WOMAC pain scale 73% patients received 5 or more sessions, reported as good adherence. Losses to follow up: 2 months – 19 intervention and 17 control 6 months – 20 intervention and 18 control

							12 months – 19 intervention and 15 control
Simock et al. 2008 USA RCT June 2006 – March 2007 No. centres not reported, assumed to be 1.	N=30 67.3 years 60%	Relaxation / mindfulness	Patient selection music during surgery, on headphones.	Peri-operative	White noise control on headphones.	Baseline, 3h, 6h, and 24h post-surgery	Pain VAS No losses to follow-up reported Adherence not reported
Wang et al. 2015 Taiwan RCT 2010 1 centre	N=66 72.6 years 65.15%	Relaxation / mindfulness	Biofeedback and progressive muscle relaxation during continuous passive motion therapy	Post-operative, in hospital	Standard care during continuous passive motion therapy	1 day, 2 days, 3 days, 4 days, & 5 days post operatively Before and after CPM Therapy	Pain intensity NRS CMP-elicited pain score Losses to follow-up: n=6 (4 intervention and 2 control). Adherence not reported.

Methodological quality

Risk of bias assessments for individual studies are shown in figure 2.

INSERT FIGURE 2

Interventions

Eight studies were classified as relaxation/mindfulness. These studies included music therapy (n=5), hypnosis (n=1), and progressive muscle relaxation with biofeedback (n=1). One study was multi-modal and included guided imagery and music (n=1). Three studies were classified as cognitive and behavioural and included cognitive behavioural therapy (CBT) based programmes (n=2) and a post-operative management programme comprising motivational interviewing to improve self-efficacy and goal attainment (n=1). One study was classified as combined relaxation/mindfulness and cognitive, this included a pain coping skills programme. The pain coping skills programme was a complex intervention including multi-modal components.

Music

Five single-centre RCTs with 256 participants evaluated the effectiveness of music therapy for reducing acute post-operative pain during the inpatient stay after surgery[37 38 40 42 47]. All studies had high or unclear risk of bias for two or more domains, with blinding of participants and personnel being a high or unclear risk of bias for all studies. Four studies had high or unclear risk of bias for selective reporting. A 2-arm RCT with 75 participants compared listening to a CD of 'easy listening' music on headphones for 20 minutes before and after first post-surgical ambulation to a 20-minute quiet rest period found no differences in mean VAS pain score between groups at any timepoint [38]. A 2-arm RCT with 30 participants which compared listening to soothing piano and Chinese violin music through broadcast speakers for 30 minutes in the pre-operative ward, 30 minutes in the surgical room waiting area, and 1 hour in post-operative recovery to usual care found no differences in VAS pain score between groups on the ward after surgery [40]. A 5-arm RCT with 89 participants which compared listening to 12-15 minutes of instrument only music with varying degrees of harmonicity and rhythmicity on headphones once per day for three days post-surgery to wearing headphones with no input found no differences in NRS or VRS pain scores between groups on post-operative days 1-3 [42]. A 2-arm RCT with 30 participants which compared patient-selected music played on headphones during surgery to white noise found the intervention group reported lower mean VAS pain scores at 3 hours (1.5 (SD 1.4) vs 3.9 (SD 3.4); p=0.01) and 24 hours (2.4 (SD 1.7) vs 4.1 (SD 2.9); p=0.04) post-surgery [37]. A two-arm RCT with 32 patients compared music therapist-delivered live

music during a five-minute physiotherapy pedalling exercise to no music found no mean difference in NRS pain scores between groups at the two-minute break timepoint and at the four minute endpoint after the pedalling exercise.

Guided imagery and music

One single-centre RCT evaluated the effectiveness of guided-imagery on outcomes post-surgery [43]. The study was at high or unclear risk of bias for three domains. The 2-arm RCT with 82 participants was multi-modal and compared 19-21 minutes of audio-recorded guided imagery with the addition of soothing instrumental background music listened to every day for 2 weeks before surgery and 3 weeks after surgery to a control group who received 17-21 minutes of commercially available spoken word audio-recordings (e.g. poetry, short stories, essays) at the same time-points. Pain was assessed pre-operatively, on the day of surgery, 3 weeks post-surgery, and 6 months post-surgery using the WOMAC pain score and VAS pain score. No comparisons were made between trial arms.

Hypnosis

One single-centre RCT evaluated the effectiveness of a pre-recorded hypnotic audio recording on outcome post-surgery[48]. The study was high or unclear risk of bias for four domains. The 3-arm RCT with 24 patients compared 35-minute pre-recorded hypnosis audio listened to at least one pre-surgery and at least once 24 hours post-surgery to minimal treatment effect (psychoeducation, diaphragmatic breathing, relaxing music) and treatment as usual. Pain was assessed using a pain NRS pre-operatively, daily until discharge, and then at 1 month, 3 months, and 6 months. Differences in mean pain ratings between the groups were small at 72 hours (1.77 vs 2.23 vs 2.59) and 6 months (1.4 vs 1.73 s 2.23).

Progressive muscle relaxation with biofeedback

One single-centre RCT evaluated the effectiveness of progressive muscle relaxation with biofeedback on pain during continuous passive motion therapy [46]. The study had unclear risk of bias for five domains and high risk of bias for blinding of outcome assessment. The 2-arm RCT with 66 participants was multi-modal and compared 30 minutes of training on biofeedback-assisted progressive muscle relaxation skills on the day before surgery and during 30-minute sessions of continuous passive motion therapy twice daily for 5 days post-surgery to standard continuous passive motion therapy. Pain was assessed on days 1-5 after surgery before and after continuous passive motion therapy using an NRS pain score. The intervention showed a significant between

group effect (p<0.001) with the intervention group reporting lower NRS pain scores compared to the control group on all five day.

Pain coping skills programme

One 5-centre RCT evaluated the effectives of a pain coping skills training programme for patients who catastrophize about pain before TKR[49]. The study was at high risk of bias for two domains, blinding participants and personnel and blinding of outcome assessment. The 3-arm RCT with 402 patients compared an eight-session pain coping skills programme to arthritis education and to usual care. The pain coping skills programme comprised eight 50-minute sessions over a 2-month period beginning 2 weeks before surgery and ending 6 weeks after surgery. One session was in person with remaining sessions via telephone. The programme was a complex multi-modal intervention and included sessions on cognitive restructuring, thought identification and challenging, self-calming and relaxation techniques, and activity management. Arthritis education following the same schedule, although without the psychological components. Pain was assessed by the WOMAC pain scale at baseline and 2, 6, and 12 months post-surgery. No differences were found in mean WOMAC pain treatment scores or group-by-time interaction.

Enhanced post-operative recovery using motivational interviewing

One single centre RCT evaluated the effectiveness of an enhanced post-operative recovery programme to improve post-operative functional status [44]. The study was at high risk of bias for blinding of participants and personnel, blinding of outcome assessment, and selective reporting. In this 2-arm RCT with 308 participants, the intervention was an enhanced post-operative recovery programme comprising 10 telephone calls with a navigator over a 6-month post-operative period aimed at identifying post-surgical objectives and improving self-efficacy using motivational interviewing. The control group received usual care including inpatient physiotherapy and outpatient physiotherapy after discharge. Pain was assessed at baseline, 3-month post-surgery, and 6-months post-surgery using the WOMAC pain score. There were no differences between groups in mean WOMAC pain scores at 6 months post-operation.

Cognitive behavioural therapy programmes

Two RCTs (one pilot and one feasibility) with 150 participants evaluated the effectiveness of CBT-based programmes [39 41]. Both studies were at low risk of bias for four domains, with one having unclear risk of bias for selective outcome reporting and other bias[39], and one with high risk of bias for blinding of participants and personnel, blinding of outcome assessment, and incomplete

outcome data[41]. One 2-arm pilot RCT with 100 participants evaluated use of CBT that aimed to reduce kinesiophobia (fear of movement) post-surgery when compared to standard care [39]. Four tailored sessions of 30 minutes each were delivered individually. Between group difference were found with reduction in pain NRS scores of 5.63 (SD 0.73) in the intervention group compared to 6.27 (SD 0.86) in the standard care group demonstrated at 6-month follow-up (p=0.003). One 2-arm feasibility RCT with 50 participants compared the use of a CBT-based programme of up to 10 one-hour sessions for reducing anxiety and depression to standard care [41]. No between group differences in pain measured using the WOMAC pain score were found at 4 or 6-month follow-up, no between group difference in mood were found at 4 or 12-month follow up measured using the Beck Anxiety Inventory and Depression Inventory.

Intervention reporting standards

Table 2 documents the extent to which the included studies adhere to the TIDieR guidelines for reporting on interventions. Overall, all studies provided the name of the intervention, rationale for the intervention, procedures, and how the intervention was delivered. Nine studies provided information about who provided the intervention and their training, with two studies providing partial details and one study providing no details. Ten studies provided details on where the intervention was carried out, and 11 studies reported on the timing and intensity of the intervention with one study provide partial details. Reporting of tailoring, modifications, and fidelity/adherence was generally poor: only one study provided information about both tailoring and modifications to the intervention, and only five studies provided information on fidelity/adherence (planned or actual) with one study providing partial details.

Overall, although no studies provided information relating to all TIDieR domains, all studies provided details on at least seven out of 10 the domains, with most providing details on eight or more domains.

Table 2: TIDieR study reporting checklist summary

Study	Brief name	Why	What	Procedures	Who provided	How	Where	When and how much	Tailoring	Modifications	How well: planned	How well: actual	Overall score
Allred	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Partial	**8/12**
Cai	Yes	Yes	Yes	Yes	Partial	Yes	No	Yes	No	No	No	No	**7/12**
Chen	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	**8/12**
das Nair	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	**10/12**
Jacobson	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	**10/12**
Finlay	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	No	No	No	**8/12**
Lee	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	**9/12**
Leonard	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	**9/12**
Losina	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Partial	Partial	**8/12**
Riddle	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	**10/12**
Simock	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial	No	No	No	No	**7/12**
Wang	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Yes	Yes	No	Yes	**10/12**

Ongoing research

Three published protocols for RCTs were identified in searches that would meet the inclusion criteria of the systematic review and have not yet been published. One study is focussed on cognitive/behavioural interventions delivered by physiotherapists for patients with high pain catastrophizing before TKR[50]. One RCT will evaluate a theory-based telephone-delivered patient self-management support intervention to enhance adherence to exercise after TKR[51]. The final study is focused on a pre-surgery group-based mindfulness training programme to improve post-operative pain[52].

Discussion

This systematic review identified 12 RCTs that have evaluated the effectiveness of psychological interventions for improving pain outcomes after TKR surgery, with the predominant focus on mindfulness and relaxation. The largest group of interventions was music, and the majority of studies evaluated the effectiveness of interventions for reducing acute-postoperative pain. Pooling of data in meta-analysis was not possible due to the high heterogeneity between the interventions evaluated. One study did not compare outcomes between the intervention and control group and all RCTs had high or unclear risk of bias for at least three domains. Therefore, it was not possible to make any conclusive statements about the overall effectiveness of psychological interventions for pain outcomes after TKR. However, some promising areas for future research were identified including the use of CBT to reduce kinesiophobia [39] and the use of progressive muscle relaxation during continuous passive motion therapy[46]. Use of the TIDieR checklist as a framework highlighted a need for improvements in the reporting of interventions, particularly in relation to fidelity/adherence.

This review included studies evaluating the effectiveness of psychological interventions on both short and long-term outcomes for pain. However, the majority of included studies focussed on acute post-operative pain. Whilst ensuring optimal management of short-term pain is important, chronic pain is a substantial issue for TKR patients with up to 20% reporting long-term pain after surgery [7-9]. Chronic pain after TKR is associated with functional limitations and reduced activity levels and can have a substantial negative impact on wellbeing and quality of life [53-57]. Treatment and investigations for patients who have ongoing pain after TKR come at a cost to the NHS that is above costs for those for whom there is no ongoing pain [11]. All the studies in this review delivered interventions pre-operatively, during the immediate post-operative recovery period, or both. We were unable to discern if psychological interventions are more or less effective dependent on the timing of delivery. In addition, pain outcomes and mechanisms may differ between acute post-operative pain due to surgical recovery and chronic post-surgical pain, requiring different intervention approaches. Further robust research is needed to evaluate psychological interventions aimed at targeting long-term or chronic pain after TKR, in addition to during the immediate post-operative recovery period.

Only one study in this review provided data on a harm outcome. The assessment of harm outcomes, such as serious adverse events, within interventions is vital for patient safety. However, unlike in trials of pharmacological treatments where monitoring and reporting of adverse events is mandatory, psychological interventions are rarely subject to the same scrutiny [58]. There is increasing

recognition that harm may arise from psychological interventions and that these outcomes should be considered both at the development stage, as seen in dark logic models [59], and at the intervention reporting stage[60]. In 2004, the CONSORT group suggested 10 new recommendations for harm reporting in RCTs including explanations and examples of proper reporting [61]. Despite all RCTs included in this review being published after these recommendations, only one included harms data. This demonstrates a need for improvement in reporting of harms related to psychological interventions.

The purpose of this systematic review was to evaluate the effectiveness of psychological interventions specifically for improving pain outcomes after TKR. Many of the interventions included in the review have been the focus of broader, intervention-specific systematic reviews. For example, a systematic review and meta-analysis of peri-operative music interventions found that they reduced post-operative pain in surgical patients [62]. Interventions using cognitive behavioural modalities have been found to have small benefits for older adults with chronic pain [63]. Therefore, the wider literature suggests that some psychological interventions are effective at reducing pain severity in mixed patient populations. However, our review highlighted the relative paucity of robust interventions focused on patients undergoing TKR.

The current evidence base is primarily focused on music interventions. Only a small number of trials evaluating interventions have been based on psychological theory or including recognised approaches to psychological and behavioural change[64], such as CBT and acceptance-based therapies, or interventions targeting particular psychological traits, such as anxiety, depression, or pain catastrophising, which are all linked to pain [22-25]. This makes it challenging to identify the 'active ingredients' of the interventions, or by which mechanisms these interventions may be able to effect change. However, more recent studies based on CBT to address specific risk factors such as kinesiophobia and anxiety and depression are now emerging and demonstrate promising results. This indicates that a more targeted and individually tailored approach to psychological interventions may be of greater benefit to the patient population. In addition, there are ongoing trials of psychological interventions, for example interventions that address catastrophizing[50], which will add to the evidence base.

Evaluation of reporting standards

Reporting standards for all included studies were assessed using the TIDieR checklist, with 10 out of the 12 studies published after these guidelines had become available. Reporting completeness

was high for intervention's rationale, content, and procedure. However, 10 out of 12 studies did not include any information on tailoring or modifications, seven out of 12 did not include adequate information on fidelity and adherence. While tailoring and modification may not have been relevant to many of the standardised interventions evaluated, fidelity and adherence are crucial for accurate interpretation of treatment effects. Psychological interventions are often complex and may involve multiple intervention components, dose intensities, and dose durations. In addition, many psychological interventions are designed to use an individualised approach that accommodates particular individual needs and contexts [65 66]. Due to this complexity, accurate reporting of the implementation and adherence of psychological interventions is vital in order to understand fully the intervention's effects and to inform practice. Whilst the TIDieR guidelines provide a clear checklist for minimum information inclusion, including fidelity, they do not provide guidance on how to assess fidelity. To address this issue, additional guidelines have been published to guide fidelity reporting and improve transparency [67 68], however this results of this review demonstrate there are ongoing issues with the implementation of these guidelines.

Strengths and limitations

This systematic review has strengths and limitations which should be considered when interpreting the findings. The review was conducted following Cochrane guidance to ensure the methodology was robust and systematic [31]. RCTs were eligible for inclusion, and published protocols were identified to highlight ongoing research that is likely to add to the existing evidence base. Opportunities for pooling of data in meta-analysis were limited because of heterogeneity in the content, duration, and intensity of the interventions, and conclusions are therefore based on narrative synthesis. Psychological interventions are often complex in nature and may contain multimodal components. To further explore this complexity, tools to aid in the disaggregation of intervention components and categorise levels of intervention complexity, such as iCAT (an intervention complexity assessment tool for systematic reviews) would be of benefit in future reviews. Secondary outcomes were poorly reported across studies with high heterogeneity in the measures used. The primary harm outcome of serious adverse events was inconsistently and poorly reported with only one trial including details on serious adverse events but no a priori definition, an issue which is common in both trials of pain interventions [69 70] and psychological interventions [58 71], and therefore the safety of these interventions could not be evaluated. The unclear or high risk of bias ratings for many domains of the included studies highlights the need for more rigorous methodological conduct and reporting in studies on this topic. However, despite these limitations, this review provides a comprehensive overview of studies evaluating the effectiveness of

psychological interventions for improving pain outcomes after TKR, and the findings have a number of methodological implications for future studies.

Conclusion

This review highlights the need for more evidence about psychological interventions for improving pain outcomes after TKR. Given the high prevalence of acute and chronic pain after TKR, it is important that interventions that may improve pain outcomes are evaluated in high quality RCTs. This review also highlights substantial ongoing issues in the reporting of interventions, particularly in relation to harm outcomes and intervention fidelity. Guidelines for the reporting of both harm and fidelity do exist and future interventions should implement these guidelines in order to improve reporting standards. Due to the pervasiveness of these problems, research in this area would also benefit from work exploring barriers to guideline implementation. Psychological interventions are broad, encompassing a wide variety of approaches with varying degrees of complexity and specificity. Future development of psychological interventions for people undergoing TKR would benefit from foundation on clearly identified psychological theory, behaviour change mechanisms, or targeting specific psychological traits linked with poor outcomes after TKR, such as anxiety, depression, and pain catastrophizing.

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Competing interests

No competing interests were declared by the authors.

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Data statement

No additional data are available. Extracted data is included within the manuscript and appendices.

Figure captions

Figure 1: PRISMA flow chart

Figure 2: Risk of bias summary table (RCTs)

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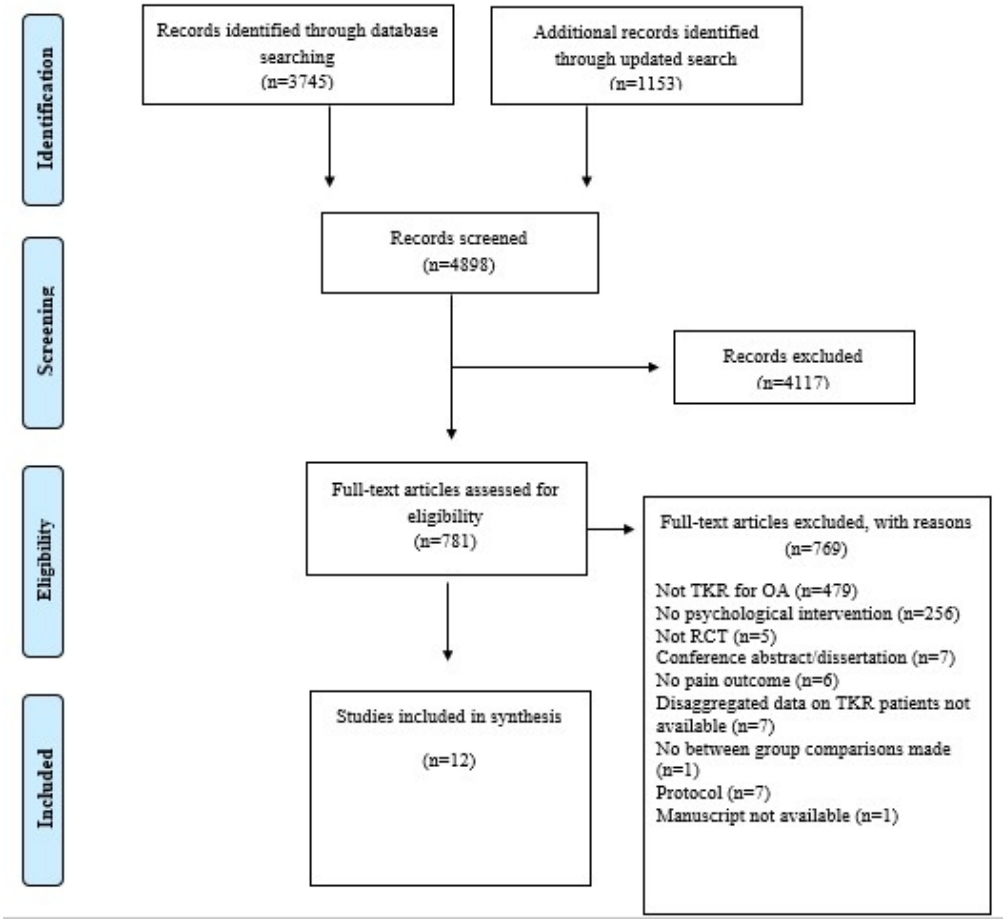
Figure 1: PRISMA flow chart



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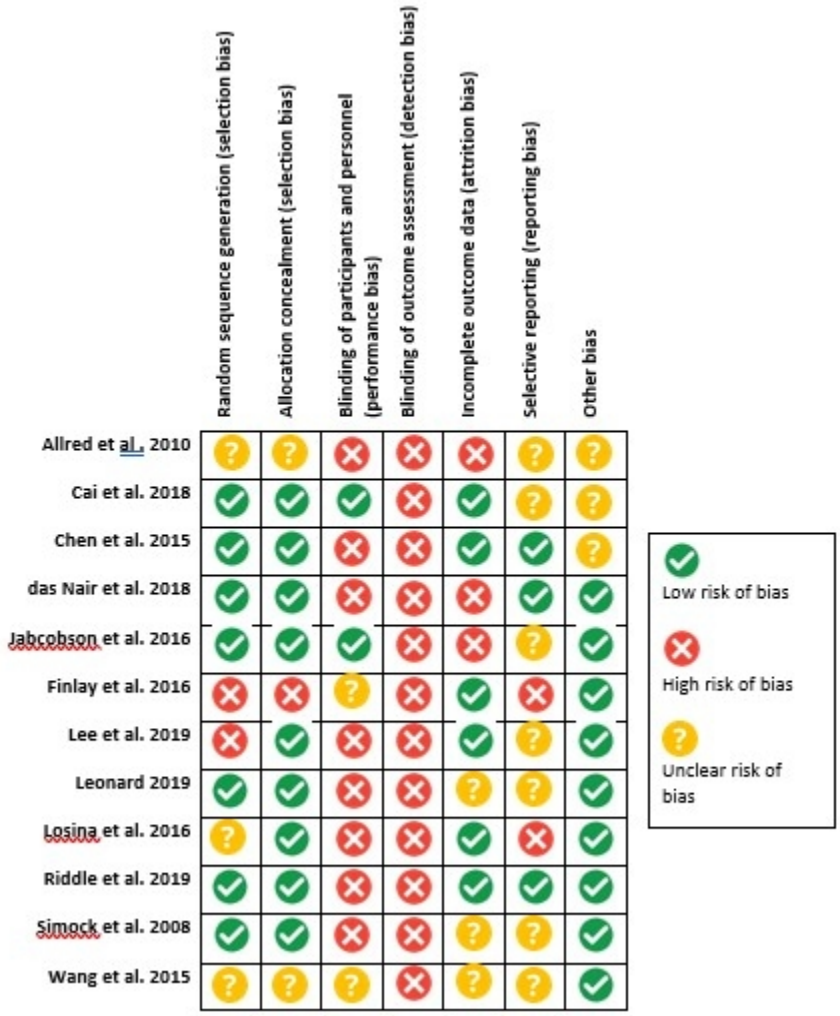

118x134mm (96 x 96 DPI)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3, 4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4,5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Figures 2 and 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Appendix 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figures 2 and 3, pages 7-9
9Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10-13
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data; role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 For more information, visit: www.prisma-statement.org.

Appendix 2: Search terms

MEDLINE

Blom et al. 2016

1. Arthroplasty, Replacement, Knee/ or Arthroplasty, Replacement, Hip/

2. exp Arthroplasty, Replacement, Hip/ or exp Hip Prosthesis/ or hip replacement.mp.

3. exp Arthroplasty, Replacement, Knee/ or exp Knee Prosthesis/ or knee replacement.mp.

4. hip prosthesis.mp. or exp Hip Prosthesis/

5. knee prosthesis.mp. or exp Knee Prosthesis/

6. total hip.tw.

7. total knee.tw.

8. hip implant.mp.

9. knee implant.mp.

10. (knee$ adj5 (arthroplast$ or replacement$ or implant$ or prothes$)).mp.

11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10

1. survey.mp. or exp Data Collection/

2. randomized controlled trial.mp. or exp Randomized Controlled Trials/

3. prospective study.mp. or exp Prospective Studies/

4. observational study.mp.

5. Comparative Study/

6. exp EPIDEMIOLOGY/ or epidemiology.mp.

7. longitudinal study.mp. or exp Longitudinal Studies/

8. case control study.mp. or exp Case-Control Studies/

9. evaluation study.mp. or exp Evaluation Studies/

10. follow up study.mp. or exp Follow-Up Studies/

11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or10

Clarke 2016 – Cochrane protocol

24 exp osteoarthritis/ (42129)

25 osteoarthr$.tw. (41807)

26 (degenerative adj2 arthritis).tw. (1122)

27 or/24-26 (58230)

29 exp Psychotherapy/ (148827)

30 Psychotherap*.mp. (67432)

31 psychological intervention*.mp. (2453)

32 (psychological adj3 intervention*).mp. (3319)

33 (psychological adj3 therap*).mp. (1827)

34 (psychological adj3 treatment*).mp. (4155)

35 Psychology intervention*.mp. (42)

36 (psychology adj3 intervention*).mp. (98)

37 (psychology adj3 treatment).mp. (67)

38 (psychology adj3 therapy).mp. (133)

39 Behav* therap*.mp. (32942)

40 (behav* adj3 therap*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (35645)

41 behav* modification.mp. (3055)

42 activity scheduling.mp. (22)

43 assertiveness training.mp. (173)

44 aversion therap*.mp. (172)

45 covert sensitization.mp. (55)

46 behav* contracting.mp. (63)

47 behav* modification.mp. (3055)

48 biofeedback.mp. (8082)

49 feedback.mp. (99202)

50 contingency management.mp. (662)

51 conversion therap*.mp. (59)

52 distraction therap*.mp. (24)

53 exposure therap*.mp. (897)

54 abreaction therap*.mp. (1)

55 systematic desensitization therap*.mp. (11)

56 Eye Movement Desensitization Reprocessing.mp. (83)

57 EMDR.mp. (266)

58 implosive therap*.mp. (597)

59 pleasant events.mp. (73)

60 psychoeducation*.mp. (2540)

61 reciprocal inhibition therap*.mp. (6)

62 exp Mind-Body Therapies/ (40688)

63 relaxation techniques.mp. (773)

64 autogenic training.mp. (1123)

65 distraction.mp. (11204)

66 response cost.mp. (203)

67 guided imagery.mp. (484)

68 sleep phase chronotherap*.mp. (11)

69 social skills training.mp. (670)

70 social effectiveness.mp. (44)

71 cognitive behav* therap*.mp. (7951)

72 cognitive therap*.mp. (16063)

73 exp Cognitive Therapy/ (15383)

74 (cognitive adj3 therap*).mp. (20005)

75 CBT.mp. (4979)

76 Problem solving.mp. (28598)

77 rational emotive therap*.mp. (61)

78 reality therap*.mp. (307)

79 restructuring.mp. (10231)

80 role play.mp. (870)

81 schema*.mp. (9382)

82 self control.mp. (3319)

83 stress management.mp. (2688)

84 third wave therapies.mp. (1)

85 (acceptance adj3 commitment therap*).mp. (215)

86 ACT.mp. (194240)

87 behav* activation.mp. (1125)

88 compassion-focused.mp. (15)

89 dialectical behav* therap*.mp. (350)

90 diffusion.mp. (151584)

91 functional analytic psychotherapy*.mp. (18)

92 metacognitive therap*.tw. (31)

93 mind training.mp. (30)

94 mindfulness.mp. (1780)

95 (psychodynamic adj3 psychotherap*).mp. (824)

96 brief psychotherap*.mp. (413)

97 countertransference.mp. (3190)

98 Freudian.mp. (3387)

99 group therap*.mp. (3675)

100 Psychoanalytic Therapy/ (14142)

101 balint.mp. (496)

102 Jungian.mp. (734)

103 kleinian.mp. (149)

104 object relations.mp. (1049)

105 person centred therap*.mp. (8)

106 client centred therap*.mp. (16)

107 psychoanalytic therap*.mp. (14213)

108 alderian therap*.mp. (0)

109 dream analysis.mp. (32)

110 free association.mp. (635)

111 self analysis.mp. (244)

112 short term psychotherap*.mp. (219)

113 transference.mp. (7091)

114 humanistic therap*.mp. (12)

115 existential therap*.mp. (28)

116 experiential therap*.mp. (36)

117 process experiential.mp. (13)

118 gestalt therap*.mp. (169)

119 expressive therap*.mp. (49)

120 grief work.mp. (98)

121 rogerian.mp. (101)

122 non directive therap*.mp. (13)

123 supportive therap*.mp. (3101)

124 transactional analysis.mp. (361)

125 integrative therap*.mp. (169)

126 cognitive analytical therap*.mp. (3)

127 Counseling/ (27626)

128 counselling.mp. (17759)

129 eclectic therap*.mp. (25)

130 interpersonal therap*.mp. (249)

131 multimodal.mp. (17549)

132 transtheoretical.mp. (1117)

133 psychodynamic interpersonal therap*.mp. (30)

134 systemic therap*.mp. (7938)

135 conjoint therap*.mp. (68)

136 couples therap*.mp. (516)

137 marital therap*.mp. (1478)

138 relationship therap*.mp. (64)

139 emotion focussed therap*.mp. (1)

140 family therap*.mp. (8431)

141 integrative behavio?ral couple therap*.mp. (15)

142 narrative therap*.mp. (96)

143 personal construct.mp. (834)

144 socioenvironmental therap*.mp. (428)

145 solution focused brief therap*.mp. (29)

146 exp Psychology, Applied/ (188274)

147 Counsel*.mp. (89067)

148 directive counsel*.mp. (1340)

149 motivational interviewing.mp. (1791)

150 or/29-149 (934550)

Appendix 3: Overview of study findings

Study	Results summary
Allred et al. 2010	No difference in mean VAS pain score between intervention and control at any time points (p=.337). T1 (20 minutes before first physical therapy session) Intervention: 52.4 (SD 25.2) Control group: 46.4 (SD 25.7) T2 (just before physical therapy) Intervention: 36.5 (SD 23.8) Control group: 36.2 (SD 26.9) T3 (immediately after physical therapy) Intervention: 44.5 (SD 28.2) Control group: 48.0 (SD 27.7) T4 (20 minutes after physical therapy) Intervention: 41.2 (SD 25.8) Control group: 45.1 (SD 31.2)
Cai et al. 2018	Between group effect improvement for mean pain NRS (F 9.089, p=0.003). 4 weeks Intervention: 6.23 (SD 1.03) Control: 6.52 (SD 0.77) 6 months Intervention: 5.63 (SD 0.73) Control: 6.27 (SD 0.86)
Chen et al. 2015	No difference in VAS pain score between intervention and control (p=.29). Intervention: 3.22 (SE 0.22) Control: 3.00 (SE 0.25)

das Nair	Feasibility study. No difference in mean pain scores at 4 or 6 month follow-up (p=0.40). 6 months Intervention: 7.5 (SD 2.3) Control: 6.5 (SD 3.6)
Jacobson et al. 2016	No statistical comparisons of mean WOMAC pain scores between intervention and control group. Day of surgery: Intervention: 7.8 (SD 3.1) Control: 8.2 (SD 3.8) 3 weeks post-operative: Intervention: 6.9 (SD 2.8) Control: 7.1 (SD 2.9) 6 months post-operative: Intervention: 2.7 (SD 3.1) Control: 3.5 (SD 3.3)
Finlay et al. 2016	No differences in NRS or VRS pain score between intervention and control group (no results provided).
Lee et al. 2019	No difference in NRS pain scores between intervention and control groups at 72 hours (HYP vs TAU p=0.188) or at 6 months (HYP vs TAU p=0.134). 72 hours Hypnosis: 1.77 (SD 0.83) Minimal treatment effect: 2.23 (SD 0.72) Treatment as usual: 2.59 (SD 1.47) 6 months Hypnosis: 1.4 (SD 0.89) Minimal treatment effect: 1.73 (SD 1.40) Treatment as usual: 2.23 (SD 1.41)

Leonard 2019	No difference in NRS pain scores between intervention and control group (p=0.63). Time point 1 (2 minutes) Intervention: 4.69 (SD 2.50) Control: 5.91 (SD 2.27) Time point 2 (4 minutes) Intervention: 5.44 (SD 3.20) Control: 5.56 (SD 2.52)
Losina et al. 2016	No differences found in mean WOMAC pain score between intervention and control groups 6 months post-operative Intervention: 11 (95% CI 9, 14) Usual care: 11(95% CI 9, 14)
Riddle et al. 2019	No difference in WOMAC pain score between intervention and control groups for treatment (p=0.60) or group-by-time interaction (p=0.73). 2 months Intervention: 6.4 (5.5 to 7.3) Education: 6.1 (5.2 to 7.0) Usual care: 6.1 (5.3 to 7.0) 6 months Intervention: 4.1 (3.2 to 4.2) Education: 3.8 (2.9 to 4.7) Usual care: 4.4 (3.6 to 5.3) 12 months Intervention: 3.3 (2.5 to 4.2) Education: 3.0 (2.1 to 3.8) Usual care: 2.9 (2.0 to 3.8)

Simock et al. 2008	Intervention group had lower mean VAS pain score at 3 hours (p=0.01) and at 24 hours (p=0.04). 3 hours Intervention: 1.476 (SD 1.39) Control: 3.876 (SD 3.44) 24 hours Intervention: 2.416 (SD 1.67) Control: 4.036 (SD 2.89)
Wang et al. 2015	Intervention group showed significantly lower between group effects for CMP elicited pain score (p<.001). Day 1 morning Intervention: 0.52 (SD 1.58) Control: 2.03 (SD 1.55) Day 1 afternoon Intervention: 0.61 (SD 1.12) Control: 1.67 (SD (1.29) Day 2 morning Intervention: 0.00 (SD 1.39) Control: 0.55 (SD 1.00) Day 2 afternoon Intervention: 0.00 (SD 1.30) Control: 0.73 (SD 1.23) Day 3 morning Intervention: -0.36 (SD 1.39) Control: 0.48 (SD 0.91)

	Day 3 afternoon Intervention: -0.33 (SD 1.02) Control: 0.61 (SD 0.90) Day 4 morning Intervention: -0.55 (SD 1.03) Control: 0.61 (SD 1.00) Day 4 afternoon Intervention: -0.61 (SD 1.02) Control: 0.95 (SD 1.25) Day 5 morning Intervention: -0.29 (SD 1.01) Control: 0.69 (SD 1.03) Day 5 afternoon Intervention: -0.50 (SD 1.07) Control: 0.68 (SD 1.01)

Appendix 4: Harm outcomes and secondary outcomes

	Serious Adverse Events	Function	Health-related quality of life	Psychological wellbeing / status
Allred et al. 2010	✗	✗	✗	✓ Anxiety VAS
Cai et al. 2018	✗	✓ Hospital for special surgery knee rating scale	✗	✗
Chen et al. 2015	✗	✗	✗	✗
das Nair et al. 2018	✗	✓ WOMAC function	✓ ED-5D	✓ Beck anxiety inventory score
Jacobson et al. 2016	✗	✓ WOMAC function	✓ SF-36	✓ SF-36 mental health
Finlay et al. 2016		✗	✗	✓ Profile of mood states
Lee	✗	✗	✗	✓ HADS-A, HADS-D, Pain catastrophizing
Leonard	✗	✗	✗	✗
Losina et al. 2016	✗	✓ WOMAC function	✗	✗
Riddle et al. 2019	✓ Not defined but reported	✓ WOMAC function	✗	✓ Pain catastrophizing
Simock et al. 2008	✗	✗	✗	✗
Wang et al. 2015	✗	✗	✗	✗