

Psychological therapies for improving outcomes after total hip or knee replacement in people with osteoarthritis and rheumatoid arthritis (Protocol)

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[Intervention Protocol]

# Psychological therapies for improving outcomes after total hip or knee replacement in people with osteoarthritis and rheumatoid arthritis

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### ABSTRACT

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

To assess the effectiveness of psychological therapies on post-surgical outcomes following knee or hip joint replacement surgery in people with osteoarthritis. Secondary questions are whether some psychological therapies confer more benefits than others, and whether effectiveness differs with type of arthritis and site of surgery.

### BACKGROUND

### **Description of the condition**

Arthritis is a disease of the musculoskeletal system that causes pain and inflammation in the joints. The two most common arthritic conditions are osteoarthritis (OA) and rheumatoid arthritis (RA). Osteoarthritis is a musculoskeletal disorder characterised by joint damage, pain, and inflammation in the surrounding tissue (Ea 2010). Osteoarthritis is one of the main causes of disability in older adults, and affects millions of people worldwide (Brooks 2002). Pain is the most commonly reported problem in people with OA, which can be persistent and debilitating (Dieppe 2005). Osteoarthritis is also associated with physical disability, poor quality of life, mood disorders, and high healthcare costs (Lane 2011). Rheumatoid arthritis is a chronic inflammatory disease characterised by joint swelling, joint tenderness, and destruction of synovial joints, leading to severe disability and premature mortality (Aletaha 2010). Pain and psychological distress (depression and anxiety) are experiences commonly associated with RA (Theis 2007).

Total knee arthroplasty (TKA) and total hip arthroplasty (THA; both terms are also known as joint replacement surgery) are common and relatively uncomplicated elective procedures for the management of chronic pain in people with arthritis in the knee or hip (National Joint Registry 2010). Whilst most of these patients experience a steady reduction in pain, and return to normal ac-

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tivities within a few weeks of the operation, some will experience chronic post-surgical pain (Burns 2011). Chronic, or persistent, pain is defined as pain that lasts longer than three months following surgery; the incidence ranges from 10% to 50% of surgical procedures (Kehlet 2006). Chronic post-surgical pain is associated with worse quality of life, greater healthcare costs, and delayed return to meaningful daily activities (Berger 2011; Becker 2011; Bonnin 2011; Brander 2003; Brander 2007). Uncontrollable pain in the short term after surgery is one of the main risk factors for the development of chronic pain (Katz 2009), and is associated with psychological variables such as depression and anxiety (Burns 2011; Faller 2003). Studies have shown that preoperative depression and anxiety were associated with high levels of pain three to twelve months after total knee arthroplasty (Brander 2003; Faller 2003; Lingard 2007); preoperative pain and lower mental health scores were also predictive of worse postoperative pain outcomes (Lingard 2007). Studies with older patients have found negative effects of psychological distress on functional outcomes and role limitations even a year after TKA (Faller 2003). Taken together, these studies implicate the role of psychological factors in the development of chronic postsurgical pain in people with arthritis.

### **Description of the intervention**

Psychological therapies for arthritis use psychological theory to develop treatments that focus on psychological processes and constructs associated with the primary difficulty or health problem (Williams 2012). A plethora of therapies can be described as psychological, many of which have very different theoretical or conceptual underpinnings (Pilgrim 2002). Therapies vary in intensity and duration, and can be delivered in individual and group formats, and via psychologically-based media applications (Hunot 2010). Therapies can be standardised according to a singular theoretical approach, can integrate different theoretical approaches under one treatment model, can use a stand alone set of strategies or approaches, or can be integrated into a multidisciplinary treatment package (Williams 2012).

According to the framework used by Cochrane Common Mental Disorders (CMD), psychological therapies can be categorised into the following approaches, based on their theoretical underpinnings: behaviour therapy or modification; cognitive behavioural therapy (CBT), third-wave CBT, psychodynamic psychotherapy, humanistic therapy, integrative therapy, and systemic therapy.

### How the intervention might work

Each of the seven categories of psychological therapies identified above have different suggested mechanisms for action:

#### I. Behaviour therapies

Behaviour therapy is primarily based upon the work of BF Skinner, and suggests that environmental stimuli serve to either reward or punish particular behaviours, which then become reinforced over time through the individual's learning history (Kazdin 2013; Skinner 1974). Therapeutic change involves identifying the function of environmental reinforcers, and developing alternative behavioural change programmes, based on the reinforcement of reward stimuli (Dawson 2015).

### 2. Cognitive behavioural therapy (CBT)

In broad terms, CBT is underpinned by an information processing model of human cognition, in which the individual's appraisal of an environmental trigger determines their subsequent adjustment (Beck 1976). Biased cognitive processing, based on the original appraisal, is then reinforced by behavioural avoidance (termed safety behaviours; Hawton 1989). Therapeutic change involves developing a set of rational and behavioural techniques that are focused on correcting errors and biases in cognitive processing (Moghaddam 2015).

### 3. Third-wave CBT

So-called 'third-wave CBT' are a group of therapies that have evolved from behaviour therapy and CBT that include: dialectical behavior therapy (DBT), acceptance commitment therapy (ACT), compassion-focused therapy (CFT), and mindfulness-based cognitive therapy (MCT), which all share a common focus on mindfulness, acceptance, context, the patient's core life values and relationships, and a focus on the client-therapist relationship (Hayes 2004). Although the therapies labelled third-wave CBT often have different theoretical underpinnings, suggested common mechanisms of action include acceptance and mindful focus on the present, i.e. changing the function of psychological events that people experience, rather than changing or modifying the events themselves (Hofmann 2010).

#### 4. Psychodynamic therapy

Psychodynamic psychotherapy is based on the work of Sigmund Freud, and postulates a structural view of human personality, in which psychopathology originates in unresolved unconscious conflict from early developmental life stages (Frosh 2012; Leiper 2004). The role of the therapist is to facilitate a process of insight, whereby the client can become aware of the unconscious conflict, and work through it (Malan 2005). The hypothesised core mechanisms of action are considered to be insight (the client becoming aware of unconscious material), affect (the therapeutic focus on the client's emotions), and alliance (the therapist's attention to the therapeutic relationship (Messer 2013)).

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### 5. Humanistic therapy

Humanistic therapies are based on the work of Carl Rogers (Rogers 1961). Humanistic therapists argue that people are inherently motivated towards growth, and the degree to which they are able to reach their full potential depends on how their psychological needs have been met throughout their life course (Murphy 2015). The mechanisms of change are hypothesised to be what is called the 'self-actualising tendency' or the 'organismic valuing process', the individual's self-directed potential for growth, which is facilitated by the therapist's non-directive approach (Cain 2001).

#### 6. Integrative therapies

The term 'integrative therapies' can either refer to approaches that have explicitly integrated different theoretical models and techniques into one standardised approach (e.g. cognitive analytic therapy (Ryle 1995) or schema therapy (Young 2003)), or to practices that use elements of different therapeutic approaches on a more ad-hoc basis (Braham 2015). Therefore, it is difficult to specify one supposed mechanisms of action that is common to all integrative therapies, as the proposed mechanisms will largely depend upon which models are being integrated. However, integrative therapies often take a transtheoretical approach to therapeutic change, in which the evidenced-based factors common to all therapeutic approaches are considered to be the main mechanisms of change, particularly the role of the therapeutic alliance (Norcross 2011).

### 7. Systemic therapy

Systemic therapies (often referred to as 'family therapy') are based on a range of theoretical developments in cybernetics, systems theory, communication theory, postmodernism, and poststructuralism (Carr 2006). The suggested main mechanisms of action are located in the individual's unique social and cultural context (Winek 2010). Change is mediated primarily through interventions aimed at the family or wider system, either in terms of changing how members relate to one another within the family or organisational structure, or by altering negative communication patterns (Dallos 2010).

### Why it is important to do this review

Psychological therapies are commonly delivered to people with a variety of types of pain and musculoskeletal disorders, including osteoarthritis (OA) and rheumatoid arthritis (RA). Psychological therapies are often used in these conditions to assist with the management of pain and pain-related mood difficulties. High rates of mood difficulties have been documented in people with OA and RA (Theis 2007). Evidence suggests that there is an association between mood and pain in these conditions (Dekker 1992). There is also an association between psychological factors and surgical outcomes, including wound repair and postoperative complications

(Mavros 2011). Previous systematic reviews have found psychological therapies generally effective for pain management in people with arthritis (e.g. Dixon 2007), and for depression associated with OA (Yohannes 2010).

It would follow then, that psychological therapies for mood and pain, either preoperatively in terms of psychological preparation, or postoperatively during rehabilitation, may have an impact on surgical outcomes, including postoperative recovery rates. However, there have been no previous reviews of psychological therapies for people with arthritis who are undergoing joint replacement surgery. Although Wallis 2011 conducted a systematic review and meta-analysis investigating presurgical therapies to improve postoperative outcomes (non-pharmacological and non-surgical), they did not identify any psychological therapies. However, as the focus of their review was on all non-pharmacological therapies, and not on psychological therapies specifically, their search strategy did not incorporate the names of all the various types of psychological therapies. Thus, their search strategy may not have been sensitive enough to capture all studies on psychological therapies for arthritis. Therefore, there appears to be a need for a systematic review of psychological therapies for improving surgical outcomes in people with arthritis.

To summarise, psychological therapies are commonly used as treatment approaches for pain and mood, and there is good evidence for their effectiveness in a number of health conditions. However, the value of psychological therapies in improving outcomes for patients with OA or RA who have had total knee or hip arthroplasty is unclear. This review will summarise and evaluate the available evidence in order to determine the benefits and harms of these therapies with this population. We hope that the results of the review will help guide clinical practice and decision-making, and help identify future research priorities for people with OA and RA.

### OBJECTIVES

To assess the effectiveness of psychological therapies on post-surgical outcomes following knee or hip joint replacement surgery in people with osteoarthritis. Secondary questions are whether some psychological therapies confer more benefits than others, and whether effectiveness differs with type of arthritis and site of surgery.

### METHODS

Criteria for considering studies for this review

### Types of studies

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We will include studies of psychological therapies that are delivered before or after total knee or hip arthroplasty. We will include studies if the design is a randomised controlled trial (RCT), a trial with quasi-randomised methods of allocating participants to treatment, or a cluster RCT. We will exclude cross-over trials.

### **Types of participants**

We will consider studies that have included participants with a diagnosis of OA or RA, who have been scheduled for, or just completed surgery for total knee or hip arthroplasty. We will accept all diagnostic definitions of OA and RA (e.g. radiographic, physician diagnosis, etc.).

### **Types of interventions**

We will follow the Cochrane Common Mental Disorders' (CMD) classification of psychological therapies (see Appendix 1) in order to include suitable studies. We will include studies that examine therapies in any of the following categories:

- 1. Behavioural therapy or behaviour modification;
- 2. Cognitive behavioural therapy;
- 3. Third wave cognitive behavioural therapies;
- 4. Psychodynamic therapies;
- 5. Humanistic therapies;
- 6. Integrative therapies;
- 7. Systemic therapies.

According to CMD, psychological approaches can be broken down into eight classifications, based on therapeutic modality. We will not include therapies under the eighth heading 'Other psychologically-orientated therapies', as this class of intervention includes approaches that are not traditional psychological therapies (e.g. art therapy). If the authors do not explicitly state which type of psychological therapy they are using, we will determine this by reviewing the description of the intervention provided by the author.

Despite the apparent variability in therapeutic modality, psychological therapies are relatively homogenous, and the underlying core therapeutic mechanisms are assumed to be the same across all classes (Weinberger 2007). Therefore, for the primary analysis, we will look at the overall effectiveness of all psychological therapies versus a common comparator. If there are enough studies, we will perform secondary analyses to stratify therapies by class. Comparators will include:

- placebo
- active control (e.g. attention control)
- passive control (e.g. waiting list control, usual care)
- one psychological intervention versus another psychological intervention
  - other active therapies

### Types of outcome measures

We will consider a variety of outcome measures, listed below. We have specified outcome measurement tools in the Data extraction and management section below. Please see Unit of analysis issues for an outline of the primary time points of interest, and how we will deal with multiple time points.

### Major outcomes:

- 1. Pain
- 2. Mood
- 3. Total adverse events (infection, thrombosis, other serious adverse events).
- 4. Reoperation rate
- 5. Health-related quality of life
- 6. Physical function
- 7. Patient global assessment of functioning

8. Drop-out rate

- Time points:
  - 1. Baseline
  - 2. Post-treatment
  - 3. Follow-up

### Search methods for identification of studies

#### **Electronic searches**

We will identify studies of psychological therapies for people with OA and RA who have undergone total hip or knee replacement by searching these electronic databases from their inception to the present: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE Ovid, Embase Ovid, CINAHL EB-SCO (Cumulative Index to Nursing and Allied Health Literature), PsycINFO Ovid, AMED Ovid (Allied and Complimentary Medicine), British Nursing Index and Archive Ovid, Global Health Archive Ovid, and International Pharmaceutical Abstracts Ovid. We will impose no restriction on language of publication. We will search ClinicalTrials.gov and the WHO trials portal for on-going trials. See Appendix 2 for the MEDLINE search strategy. We will add the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE (Lefebvre 2011). We will adapt the MEDLINE search strategy for each database.

#### Searching other resources

We will search the reference lists of papers for studies that meet the inclusion criteria for the review in order to identify additional studies. We will also conduct a forward search to identify eligible studies reported in articles citing relevant papers that meet the inclusion criteria of the review.

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### Data collection and analysis

### Selection of studies

Two review authors (SC and NM) will independently select studies for the review. They will compare their decisions and resolve discrepancies through discussion. If they are not able to reach consensus, they will approach a third researcher (RdN) to arbitrate. They will follow these steps in order:

1. conduct an initial review of titles and abstracts

2. assess the full text of articles that appear to meet the criteria, or for which there is a doubt; final decisions will be based on the review of the full text

3. exclude studies that fail to meet the inclusion criteria

### Data extraction and management

One researcher (SC) will extract data, using a standardised data extraction form; a second researcher (NM) will check the data extraction (see Appendix 3). If there are disagreements, a third researcher who was not involved in the initial extraction process (RdN) will check the data. The following data will be extracted:

• General trial information: date, authors, publication, setting, country, study design, proportion of participants initially screened who were eligible for the treatment, number of patients recruited, withdrawals, major and minor outcomes.

• Intervention and Control: intervention model, components of intervention, delivery of intervention (e.g. duration, when, by whom, how, etc.), adherence to treatment model (including how this was assessed).

• Demographic information: age (mean, standard deviation), per cent who are female

• Recruitment information: number recruited at baseline, number of withdrawals

• Outcomes and results: pain, adverse effects, reoperation rate, health-related quality of life, function, global assessment (patient), drop-out rate, and mood. Where available, we will report exact statistics. For continuous outcomes, we will extract the mean and standard deviation and number of participants per treatment arm. We will extract the number of events and number of participants per treatment group for dichotomous outcomes. We will extract outcomes at two time points, e.g. at completion of therapy and at the earliest post-treatment follow-up.

We will use the Cochrane Musculoskeletal Review Group's (CMSG) 11-level hierarchy of measures of pain for people with OA. If more than one measure is reported, we will use results from the measure that is highest on the list.

- 1. Pain overall
- 2. Pain on walking
- 3. WOMAC pain subscale (Bellamy 2002)
- 4. Pain on activities other than walking
- 5. WOMAC global scale (Bellamy 2002)

- 6. Lequesne osteoarthritis index global score (Lequesne 1997)
- 7. Other algofunctional scale
- 8. Patient's global assessment of pain?
- 9. Physician's global assessment
- 10. Other outcome

We will use the CMSG's 8-level hierarchy for physical functioning in OA. If more than one outcome is reported, we will use results from the outcome that is highest on the list.

- 1. Global disability score
- 2. Walking disability
- 3. WOMAC disability subscore (Bellamy 2002)
- 4. Composite disability scores other than WOMAC
- 5. Disability other than walking
- 6. WOMAC global scale (Bellamy 2002)
- 7. Lequesne osteoarthritis index global score (Lequesne 1997)
- 8. Other algofunctional scale

We will use the following hierarchy for quality of life measures, as suggested by the CSMG. If more than one outcome is reported, we will use results from the outcome that is highest on the list.

- 1. SF-36 (Ware 1992)
- 2. EuroQol (The EuroQol Group 1990)
- 3. Sickness Impact Profile (SIP; Bergner 1981)
- 4. Nottingham Health Profile (NHP; Hunt 1980)
- 5. Other instruments

We will use a hierarchy of measures for mood, based on the psychometric properties of the measure and recommended guidelines for research in rheumatology (Schiaffino 2003; Smarr 2011). If more than one outcome is reported, we will use results from the outcome that is highest on the list.

1. Center for Epidemiologic Studies Depression Scale (CES-D; Radloff 1977)

2. General Health Questionnaire-12 (GHQ-12; Goldberg 1979)

3. Geriatric Depression Scale (GDS; Yesavage 1983)

4. Beck Depression Index-II (BD-II; Beck 1996)

5. Hospital Anxiety and Depression Scale (HADS; Zigmond 1983)

- 6. Patient Health Questionnaire-9 (PHQ-9; Spitzer 1999)
- 7. State-Trait Anxiety Index (STAI; Spielberger 1983)

8. Other measures (e.g. Beck Anxiety Inventory (Beck 1993)) In the event of multiple outcome reporting, we will apply the following decision rules:

 If both final values and change from baseline values are reported for the same outcome, we will extract final values.

• If both unadjusted and adjusted values for the same outcome are reported, we will extract the adjusted values.

• If data analyses are based on an intention-to-treat (ITT) sample and another sample (e.g. per-protocol, as-treated), we will extract data from the ITT analyses for outcomes assessing benefits and outcomes assessing risk of harm.

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#### Main planned comparisons

For the main intervention (psychological therapy), we will pool data across different therapies to form one main intervention class for the primary analyses. The following comparisons will be examined:

• Psychological therapy versus placebo

• Psychological therapy versus active control (e.g. attention control)

- Psychological therapy versus passive control (e.g. usual care)
- Psychological therapy versus other psychological therapy
- Psychological therapy versus other therapies

#### Assessment of risk of bias in included studies

We will assess for risk of bias using the recommended Cochrane guidance from Section 8.8.3 of the *Cochrane Handbook of System-atic Reviews* (Higgins 2011b). We will assess selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias not specifically outlined by the previous domains. We will assess detection bias separately for self-reported subjective outcomes (pain, function, global assessment, mood) and objective outcomes (e.g. adverse events).

We will also use a quality tool developed specifically for psychological trials in chronic pain (Yates 2005), as this tool was used in a systematic review of psychological trials for chronic pain (Williams 2012). The first four 'risk of bias' domains from the Cochrane tool are replicated in the design section of the Yates 2005 scale (see Appendix 4). We will describe whether the studies met each of the 35 criteria from the Yates scale and report the results in an additional table (see Appendix 4).

### **Measures of treatment effect**

We will summarise ordinal and interval scales (e.g. pain or mood) using methods for continuous data. We will express the intervention effect as a mean difference (MD) when the same scales are used across studies, and a standardised mean difference (SMD) when different scales are used to measure the same outcome, with the corresponding 95% confidence interval (CI). We will also backtranslate SMD to a typical scale (e.g. 0 to 10 for pain) by multiplying the SMD by a typical among-person standard deviation (e.g. the standard deviation of the control group at baseline from the most representative trial) as suggested in Chapter 12 of the *Cochrane Handbook of Systematic Reviews* (Schünemann 2011b). For dichotomous variables, we will calculate the relative risks (RRs) with 95% CI.

### Unit of analysis issues

We will analyse two time points where possible: early post-treatment and follow-up. 'Post-treatment' is defined as the assessment at the completion of therapy, whilst follow-up is usually captured at 6 or 12 months following randomisation. If more than one follow-up time point is used, we will use the earlier follow-up time point. While the later follow-up time point may be better for assessing the long-term benefits of rehabilitation, all trials will have one post-randomisation time-point. Therefore, the earlier time point is more likely to be consistent across trials.

If studies include more than two psychological interventions or classes of therapies as separate treatment arms, a separate analysis will be conducted for each psychological intervention versus the comparator.

#### Dealing with missing data

We will contact the authors in the event of any missing data. Where possible, missing standard deviations will be computed from other statistics, such as standard errors, confidence intervals or P values (Higgins 2011a). We will not impute standard deviations if the majority of studies do not report these data. If a small proportion of studies are missing standard deviations, and we cannot calculate the values, we will impute values according to the recommendations of Section 16.1.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c).

#### Assessment of heterogeneity

We will assess heterogeneity between trial results by using I<sup>2</sup> estimates, as suggested in Section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). We will use the recommended template for the interpretation of I<sup>2</sup> estimates from Section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011), which suggests:

• The interpretation of an I<sup>2</sup> value of 0% to 40% might 'not be important';

- 30% to 60% may represent 'moderate' heterogeneity;
- 50% to 90% may represent 'substantial' heterogeneity;
- 75% to 100% represents 'considerable' heterogeneity.

### Assessment of reporting biases

We will examine funnel plots for evidence of reporting bias when 10 studies or more are available, as advised in Section 10.4.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2011). Alongside inspection of the funnel plots for asymmetry, we will examine the association between estimated intervention effects and the study size, in order to assess whether the effect is greater than might be expected to occur by chance.

To assess outcome reporting bias, we will check trial protocols against published reports. For studies published after 1 July 2005, we will screen the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organization ( apps.who.int/trialssearch) for the trial protocol. We will compare outcomes to evaluate whether selective reporting is present.

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### Data synthesis

For for all outcomes of the primary analyses, the main comparison will be the intervention (all classes of psychological therapy grouped) versus placebo, active control (e.g. attention control), passive control (e.g. usual care, waiting list control), another psychological intervention, or a non-psychological intervention. We will conduct subgroup analyses for all outcomes with psychological therapies stratified according to class of psychological intervention (e.g. behavioural, cognitive behavioural), using the same four comparators as the primary analyses. As we are including different populations (i.e. knee replacement or hip replacement and OA or RA), it is more likely that there will be underlying heterogeneity. Therefore, we will conduct the meta-analyses using a random-effects model in RevMan (RevMan 2014).

### 'Summary of findings' tables

We will produce five 'summary of findings' tables, for each of the five comparisons, using GRADEpro GDT software ( GRADEproGDT 2015).

1. Psychological therapy versus placebo

2. Psychological therapy versus active control (e.g. attention control)

3. Psychological therapy versus passive control (e.g. usual care)

4. Psychological therapy versus other psychological therapy

5. Psychological therapy versus other therapies

We will classify the quality of the evidence according to the GRADE approach outlined in Section 12.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011a). We will use these five factors to determine whether the quality of the evidence should be decreased:

1. Limitations in the design and implementation of available studies suggest high likelihood of bias.

2. Indirectness of evidence (indirect population, intervention, control, outcomes).

3. Unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses).

4. Imprecision of results (wide confidence intervals).

5. High probability of publication bias.

In the 'comments' column of the 'Summary of findings' table, we will provide the absolute percentage difference, the relative percentage change from baseline, and the number needed to treat for an additional beneficial outcome (NNTB); we will only provide the NNTB when the outcome shows a statistically significant difference.

For dichotomous outcomes, such as serious adverse events, we will calculate the number needed to treat for an additional harmful outcome (NNTH) from the control group event rate and the relative risk, using the Visual Rx NNT calculator (Cates 2008). The NNTH for continuous measures will be calculated using the Wells calculator (available from the CSMG website ( musculoskeletal.cochrane.org/)).

For dichotomous outcomes, we will calculate the absolute risk difference using the 'risk difference' statistic in RevMan, and express the result as a percentage. For continuous outcomes, we will calculate the absolute benefit as the improvement in the intervention group minus the improvement in the control group (mean difference), in the original units, and express the results as a percentage. We will calculate the relative percentage change for dichotomous data as the Risk Ratio - 1 and express the results as a percentage. For continuous outcomes, we will calculate the relative difference in the change from baseline as the absolute benefit divided by the baseline mean of the control group, and express the results as a percentage.

### Subgroup analysis and investigation of heterogeneity

If there are enough studies, we will conduct a subgroup analysis for each of the seven classifications of psychological therapies. We will conduct the analyses for the four main planned comparisons, and for all outcomes.

If sufficient data are available, we will conduct subgroup analyses to determine whether pain differed between site of surgery (hip or knee). Due to significant differences in patient demographics (e.g. age at which condition starts), underlying causal factors, disease progression, prognosis, and clinical presentation, we will also conduct subgroup analyses to determine if pain differed between type of arthritis (RA, OA).

We will calculate subgroup differences using a random-effects model, as suggested in Section 9.6.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

### Sensitivity analysis

We will conduct sensitivity analyses to determine if the risk of bias in trials had an impact on pain outcomes. We will exclude trials with inadequate or unclear allocation concealment, and trials with unclear or inadequate blinding of outcome assessor. As highlighted in Section 9.7 of the *Cochrane Handbook for Systematic Reviews of Interventions*, many of the issues suitable for sensitivity analysis are not always apparent at the protocol stage, and are only identified during the review process and (Deeks 2011). Therefore, we may identify other sensitivity analysis during the review, and present the results in an additional table.

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\* Indicates the major publication for the study

### APPENDICES

### Appendix I. Cochrane Common Mental Disorders - classification of psychological therapies

1. Behaviour therapy and behaviour modification:

- Activity scheduling
- Assertiveness training
- Aversion therapy
  - Covert sensitization
  - Behavior contracting
- Behavior modification
- Biofeedback, psychology
- Feedback, sensory
- Contingency management
- Conversion therapy
- Distraction therapy
- Exposure therapy
  - $\circ$  Abreaction therapy
  - Sensitivity training
  - Systematic desensitization therapy
    - ♦ Eye movement desensitization reprocessing
  - Implosive therapy
- Pleasant events
- Psychoeducation
- Problem-focused
- Reciprocal inhibition therapy
- Relaxation techniques

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- Autogenic training
- Distraction
- $\circ \ \ Guided \ imagery$
- Response cost
- Sleep phase chronotherapy
- Social skills training
  - Social effectiveness

### 2. Cognitive behavioral therapy:

- Problem solving
- Rational emotive therapy
- Reality therapy
- Restructuring
- Role play
- Schemas
- Self-control
- Stress management

### 3. Third wave cognitive behavioral therapies:

- Acceptance and commitment therapy
- Behavioral activation
- Cognitive behavioral analysis system of psychotherapy
- Compassion-focused
- Dialectical behavior therapy
- Diffusion
- Functional analytic psychotherapy
- Metacognitive therapy
- Mind training
- Mindfulness

### 4. Psychodynamic therapies:

- Brief psychotherapy
- Countertransference
- Freudian
- Group therapy
- Balint group therapy
- Insight oriented therapy
- Jungian
- Kleinian
- Object relations
- Person centred therapy, client-centred therapy
- Psychoanalytic therapy
  - Alderian therapy
  - Dream analysis
  - Free association
  - $\circ$  Self analysis
- Short-term psychotherapy
- Transference

### 5. Humanistic therapies:

- Existential therapy
- Experiential therapy
- Process-experiential
- Gestalt therapy
- Expressive therapy

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- Griefwork
- Rogerian
- Non-directive therapy
- Supportive therapy
- Transactional analysis

### 6. Integrative therapies:

- Cognitive analytical therapy
- Counselling
- Eclectic therapy
- Interpersonal therapy
  - Psychodynamic interpersonal therapy
- Multimodal
- Transtheoretical

### 7. Systemic therapies:

- Conjoint therapy
- Couples, marital or relationship therapy
- Emotion focussed therapy
- Family therapy
- Integrative behavioral couple therapy
- Narrative therapy
- Personal construct
- Socioenvironmental therapy
  - Milieu therapy
  - Therapeutic community
- Solution focused brief therapy

### **Appendix 2. MEDLINE Search Strategy**

We developed this search strategy for MEDLINE, which will be adapted for each database. The databases in MEDLINE include: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

-----

1 exp Arthroplasty, Replacement, Knee/ (12202) 2 (knee\$ adj4 (replace\$ or arthroplast\$ or prosthe\$ or endoprosthe\$ or implant\$)).tw. (19522) 3 (tka or tkr).tw. (5069) 4 Knee Prosthesis/ (8419) 5 or/1-4 (23038) 6 knee/ or knee joint/ (46227) 7 knee\$.tw. (91839) 8 exp Arthroplasty, Replacement/ or exp Arthroplasty/ (38358) 9 Knee Prosthesis/ or "Prostheses and Implants"/ (44183) 10 (6 or 7) and (8 or 9) (18993) 11 5 or 10 (25523) 12 exp Arthroplasty, Replacement, Hip/ (16231) 13 (hip\$ adj4 (replace\$ or arthroplast\$ or prosthe\$ or endoprosthe\$ or implant\$)).tw. (28609) 14 (tha or thr).tw. (25130) 15 Hip Prosthesis/ (18235) 16 or/12-15 (56876) 17 hip/ or hip joint/ (28398) 18 hip\$.tw. (227619) 19 exp Arthroplasty, Replacement/ or exp Arthroplasty/ (38358) 20 Hip Prosthesis/ or "Prostheses and Implants"/ (53896)

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21 (17 or 18) and (19 or 20) (27001) 22 16 or 21 (58257) 23 11 or 22 (77605) 24 exp osteoarthritis/ (42129) 25 osteoarthr\$.tw. (41807) 26 (degenerative adj2 arthritis).tw. (1122) 27 or/24-26 (58230) 28 23 and 27 (10936) 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)

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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)

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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) 151 23 and 150 (1870) 152 randomized controlled trial.pt. (369806) 153 controlled clinical trial.pt. (88072) 154 randomized.ab. (289898) 155 placebo.ab. (152662) 156 clinical trials as topic.sh. (169178) 157 randomly.ab. (210149) 158 trial.ti. (124591) 159 or/152-158 (894174) 160 exp animals/ not humans.sh. (3917953) 161 159 not 160 (825248) 162 151 and 161 (187)

### **Appendix 3. Data Extraction Form**

### **General Information**

Trial ID	Author(s)
Year of publication	Single centre Multi-centre
Setting	Country

Psychological therapies for improving outcomes after total hip or knee replacement in people with osteoarthritis and rheumatoid arthritis (Protocol)

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(Continued)

Study design (please indicate): Randomized Controlled Trial (RCT) Randomized Controlled Trial (RCT) with quasi-randomised methods						
Condition: OA RA		Type of surgery: Knee Hip				
Proportion eligible:		Number of patients recruited:				
Primary outcome:	Secondary outcomes:					

### Interventions

	Intervention 1	Intervention 2	Intervention 3	Control
Intervention model:				
Components:				
Delivery (e.g. duration, when, by whom, how etc.):				
Adherence to treatment model (including how this was assessed):				

### Demographic info and recruitment information

	Intervention 1	Intervention 2	Intervention 3	Control
Age (mean±SD)				
Female%				
Number recruited base- line				
Number of withdrawals				

Observational period: Adverse event (s)

Intervention a/n1 b/n2

### Outcome (and measure): Continuous

Outcome mea- sure and time-	Intervention 1		Intervention 2		Intervention 3		Control	
point (ple specify)	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pain								
Health- related								
Quality of Life (QoL)								
Function								
Global as-								
sessment (patient)								
Mood								
Other 1								
Other 2								

Outcome (and measure): Dichotomous

Total/Yes	Intervention 1	Intervention 2	Intervention 3	Control
	Total/Yes	Total/Yes	Total/Yes	
Reoperation rate				
Other 1				
Other 2				

# Appendix 4. Quality assessment form

# PART 1: TREATMENT QUALITY

Item	Question	Item	Response		
1	Has a clear rationale for the treatment been given and an adequate description of its con- tent?	Treatment content / setting	0	1	2
2	Has the total treat- ment duration been reported? If so: No. sessions Total Duration (hrs)	Treatment duration	0	1	
3 2	Is there a treatment manual that describes	Manualisation	0	1	2
parts the active components of treatment?	Adherence to manual	0	1		
4	Have the ther- apists been appropri- ately trained in the rel- evant procedures for this trial?	Therapist training	0	1	2
5	Is there evidence that the patients have ac- tively engaged in the treatment?	Patient engagement	0	1	

### QUALITY OF STUDY DESIGN AND METHODS

Item #	Question	Item	Response		
1	Are the inclusion and	Sample criteria	0	1	
2	exclusion criteria clearly specified?	Evidence criteria met	0	1	
<b>2</b> 2 parts	Is there evidence that CONSORT guide- lines for reporting at-	Attrition	0	1	2
	trition have been fol- lowed?	Rates of attrition	0	1	
<b>3</b> 2	Is there a good de- scription of the sample	Sample characteristics	0	1	
parts	in the trial?	Group equivalence	0	1	
4	Have adequate steps	Randomisation	0	1	2
4 parts	been taken to min- imise biases?	Allocation Bias	0	1	
		Measurement Bias	0	1	
		Treatment expectations	0	1	
3 3	Are the outcomes that have been chosen jus-	Justification of out- comes	0	1	2
Parts	tified, valid and reli- able?	Validity of outcomes for context	0	1	2
		Reliability and sensi- tivity to change	0	1	2
6	Has there been a mea- sure of any sustainable chance between the treatment and control groups?	Follow up	0	1	
7	Are the statistical anal-	Power calculation	0	1	
5 parts	yses adequate for the trial?	Sufficient sample size	0	1	
		Planned data analysis	0	1	
		Statistics reporting	0	1	

### (Continued)

		Intention to treat anal- ysis	0	1	
8	Has a good, well-matched alterna- tive treatment group been used?	Control Group	0	1	2

# HISTORY

Protocol first published: Issue 12, 2016

Date	Event	Description
20 May 2013	Amended	CMSG ID A097

### CONTRIBUTIONS OF AUTHORS

Draft the protocol	Clarke, Moghaddam, das Nair, Walsh, Scammell
Develop a search strategy	Clarke, das Nair
Search for trials (usually 2 people)	Clarke, Moghaddam
Obtain copies of trials	Clarke, Moghaddam
Select which trials to include (2 + 1 arbiter)	Clarke, Moghaddam, das Nair
Extract data from trials (2 people)	Clarke, Moghaddam
Enter data into RevMan	Clarke
Carry out the analysis	Clarke, Moghaddam, das Nair, Walsh
Interpret the analysis	Clarke, Moghaddam, das Nair, Walsh, Scammell
Draft the final review	Clarke, Moghaddam, das Nair, Walsh, Scammell
Update the review	Clarke, Moghaddam

Psychological therapies for improving outcomes after total hip or knee replacement in people with osteoarthritis and rheumatoid arthritis (Protocol)

### DECLARATIONS OF INTEREST

Dr Clarke is seconded to the Arthritis Research UK Pain Centre at the University of Nottingham and is performing this review as a nonsalaried associate member of staff, and is a co-applicant on Research for Patient Benefit (RfPB) grant 'Assessing surgical outcomes for osteoarthritis of the knee following short-term psychological therapy'

Professor Walsh declares professional interests in the review regarding his paid academic and clinical practices at the University of Nottingham and Sherwood Forest Hospitals NHS Foundation Trust. His employing institution is in receipt of funding related to his research on arthritis pain from Arthritis Research UK and NIHR. Professor Walsh has also undertaken investigator-initiated research funded by Pfizer Ltd, and consultancy for GSK unrelated to the topic in this review.

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