

REVIEWING THE EFFECTIVENESS OF BALANCE TRAINING BEFORE AND AFTER TOTAL KNEE AND TOTAL HIP REPLACEMENT: PROTOCOL FOR A SYSTEMATIC REVIEW AND META-ANALYSIS

Background: Traditional rehabilitation after total joint replacement aims to improve the muscle strength of lower limbs, but little attention is given to the balance and proprioceptive training in order to improve balance and activity daily live performance. In some cases, a training and education program before surgery is given to patients to manage expectations and improve their physical condition. In such situations, little is known about the benefits of balance and proprioceptive training and its effects on the rehabilitation and follow-up of patients. Our aim is to evaluate and critically appraise the effects of specific task-oriented proprioceptive and balance training programs when conducted by patients undergoing total knee replacement (TKR) or total hip replacement (THR), both before and after surgery, and compare the outcomes to traditional programs. **Methods:** This is a prospective protocol for future review and has been presented according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA-P). The final work presentation is planned to be carried out in accordance with the Main Item Guidelines that should be reported for systematic reviews and meta-analysis (PRISMA). A systematic search will be made in the following electronic databases: Pubmed, Embase Cochrane Library and Scopus according to PICO's search strategy. The reviewers will critically evaluate randomized controlled trials and will include those which have carried out a balance training program, prior to or after surgery, for THR or TKR, compared to a controlled program. The risk of bias will be assessed by the Cochrane Risk of Bias Tool. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used in order to assign the quality of evidence of all outcomes. **Discussion:** To our knowledge, this is the first study to evaluate balance and proprioceptive training for THR and TKR, both in preoperative and postoperative treatment.

1. INTRODUCTION

1.1. RATIONALE

Joint osteoarthritis (OA) is one of the most common pathologies in old people (1), and the leading cause of pain and disability (2). Symptoms include joint pain, stiffness, limited mobility, functional impairment and proprioceptive deficit. When conservative treatments fail to control these symptoms, a total joint replacement (TJR) is the chosen treatment, mainly because of its efficacy on pain relief (3). These procedures are mostly used on knee and hip joints, referred to as total knee replacement (TKR) and total hip replacement (THR) procedures, respectively. In recent decades, this surgical

procedure has become more common and has also aroused the interest of researchers regarding patient outcomes after surgery.

Despite good reported outcomes for TJRs (we will use this term to refer to both knee and hip replacements), after surgery patients may experience persistent pain (4) and face problems affecting their functionality, stability, walking speed, proprioception, and motor control, and may be at risk of falling. Therefore, their quality of life can be severely affected (5-8). In more than a third of cases, these deficiencies may be experienced after surgery, from between six months to a year (5), when subjects use to achieve the plateau functional values.

Traditional rehabilitation programs have usually focused on improving the muscle strength of the lower limbs as well as functionality, with specific exercises to achieve this purpose, and to a lesser extent, on balance and proprioception exercises. Evidence supports this approach (9). However, task-oriented rehabilitation focusing on balance enhancement may be one of the most important factors for complete rehabilitation (10), since the benefits of proprioceptive and balance training may range from better stability and motor control, improvements in both static and dynamic balance and enhanced functionality (11,12). Indeed, recent studies have shown that the combination of traditional functional rehabilitation together with balance training may help to restore functional deficits to a larger extent than usual therapy, (13) and based on a systematic review published in 2015, sensory-motor training is an acceptable adjunct to usual physiotherapy care (14).

Regarding preoperative training before TJR surgery, these usually have aimed at improving the physical function, but also managing the expectations of the surgery for better recovery (15). There only exists low to moderate evidence regarding the effects of TJR preoperative training programs (9), and some authors have argued that these are too small to be considered clinically relevant (16). In general, preoperative programs for knee and hip usually focus on functional and strengthening exercises. Despite the fact that proprioception is used in clinical practice for the prevention and recovery of many orthopedics injuries, the amount of evidence about the effects of proprioceptive training programs for

knee and hip replacement is not large. Moreover, few works have compared preoperative and postoperative rehabilitation or training programs and evidence has not been systematically reviewed regarding the efficacy of balance and proprioceptive preoperative training programs.

This systematic review will aim to evaluate and critically appraise the effects of specific task-oriented proprioceptive and balance training programs when conducted by patients undergoing TKR or THR, both before and after surgery, and will be compared to traditional programs.

1.2. OBJECTIVES

The study will review the efficacy of balance and proprioceptive trainings before and after total knee and hip replacement for severe osteoarthritis. To this end, this systematic review will look to properly address the following questions:

1. What are the effects of preoperative and postoperative task-oriented balance trainings when conducted by patients undergoing TKR or THR?
2. Are these effects somewhat different from those achieved with the usual functional and traditional strength trainings?
3. Are these effects comparable in the hip and knee?
4. Does task-oriented balance training have any implications in the short and long-term for patient functionality after surgery?
5. And finally, does specific training have any implications for other outcomes such as functional capabilities and quality of life (QoL)?

2. METHODS

2.1. ELIGIBILITY CRITERIA

Study design

To avoid selection bias, studies included in the review will be randomized control trials (RCTs). Pilot studies will be included if they present randomization either at the individual or cluster level. Only studies written in English will be included.

Participants

We will include studies with participants who underwent THR or TKR for OA and conducted a rehabilitation training protocol as proposed in the intervention section. Those patients treated conservatively will be excluded. Not restriction about age of participants will be made.

Interventions

We will include studies with an experimental group working on either preoperative or postoperative rehabilitation or training programs for THR or TKR. The programs have to be task-oriented and based on proprioceptive, balance, stability, neuromuscular or sensory-motor trainings. The intervention should last at least 2 weeks or 6 sessions to be included. The protocol of the intervention has to be well explained.

Comparators

Studies have to compare the experimental group training (as described above) with other type of preoperative or postoperative rehabilitation or training program, such as a usual physiotherapy, strength or high intensity trainings, home-based exercises, educational program, or no intervention. The intervention protocol of the control group has to be well explained.

Outcomes

The studies included should have as their endpoint at least one of the following outcomes:

- **Self-reported functionality:** According to a recent review (17), this outcome may be reported with different scoring systems or scales, such as the Knee Society Score (KSS) (18), the Knee

disability and Osteoarthritis Outcome Score (KOOS) and the Hip disability and Osteoarthritis Outcome Score (HOOS) activity daily live sub-scales (ADL), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) functionality subscale (19, 20). For this reason, these shall be considered with results extracted regarding self-reported functionality. KSS was developed by the Knee Society and aims to rate the patient's functional abilities. Its functional activities module includes questions about walking and standing, standard activities and advanced activities. It has a maximal punctuation of 85 points, reflecting best functionality. The KOOS and HOOS scales are two specific scales for knee and hip osteoarthritis respectively. The ADL sub-scale is one of the five sub-scales of HOOS and KOOS questionnaires, and consists of 17 questions with punctuations from 0 to 4, measuring the limitations in the ADL. 0 means no limitation while 4 means extreme limitation for that activity. WOMAC is also a specific scale for knee and hip osteoarthritis. The ADL sub-scale is the same as that for HOOS and KOOS. All response rates will be calculated from the total number of randomized patients.

- **Balance:** This outcome could be measured with different validated and reliable scales, according to different aspects in terms of balance (21). Hence, results in balance will be considered when the patients' performances are reported with validated scales to assess (I) the overall state of balance, (II) the static and (III) the dynamic balance capabilities, or (IV) as those balance performances measured with a dynamometric platform. Static balance is the ability to keep the center of gravity in the same place when there is not any movement. On the other hand, dynamic balance is the ability to keep the center of gravity in the same place while the subject is moving. The overall state of balance is a combination of different aspects related to balance, including stability, or static and dynamic performances. Results from reliable and valid tests, such as those shown in section 2.5, will be eligible.
- **Physical function:** measured in terms of the joint range of movement (ROM) or muscle strength.

- **Pain:** this outcome may be considered when reported with the visual analogue scale (VAS). Pain subscales of the self-reported outcomes WOMAC, HOOS and KOOS (22) will also be considered.
- **Quality of life:** This outcome will be considered when measured with validated self-reported health-related scales (23), for instance the 36-item short-form health survey (SF-36) or the WOMAC, HOOS, and KOOS quality of life sub-scales, as well as the Euro Quality of Life Five Dimensions (E-Qol-5D).
- **Incidence of falls** (24): Articles reflecting the total number of falls during a specific period of time.

2.2. INFORMATION SOURCES

PUBMED, EMBASE, COCHRANE LIBRARY, and SCOPUS will be the electronic databases used to search for information. Preliminary searches started on the 20th of October 2016. The electronic database search will be supplemented by searching for trial protocols through metaRegister (<http://www.controlled-trials.com/mrct/>). It is planned to contact the authors of the included articles when some information is considered to be missed or may be considered of interest for the review. The literature search will be limited to the English language and human subjects.

2.3. SEARCH STRATEGY

As we only include articles written in English, terms introduced for searching in the databases will be in this language. Those terms will be developed using medical subjects headings (MeSH).

The terms will be divided into four different categories attending to PICO's search strategy (26). Categories were and will be related between them using the Boolean index AND. All terms of the same category were linked using the Boolean index OR. In the databases where it is possible, the symbol * will be used to add all the derivations of the term.

- **Category 1 (Patients):** Total hip replacement, total knee replacement.
- **Category 2: (Intervention):** proprioceptive, balance, functional, sensory-motor, motor control, stability terms as the definition of the protocol, while these will include the descriptor training, protocol, program, intervention, exercises or rehabilitation.
- **Category 3 (Comparators):** control, passive treatment, usual, traditional, functional, home-based, as well as the corresponding descriptors training, intervention, program, exercises, rehabilitation, physiotherapy or protocol.
- **Category 4 (Outcomes):** we will consider those related to functionality, physical function, balance, pain, falls or QoL as was previously explained.
- **Category 5 (Type of Study):** we will only include RCTs.

No restrictions about date of publication will be made. No geographic restrictions will be made. Results are restricted only to human subjects.

Thus, an example of a search strategy used in a database (Pubmed) will be like this:
Search (((total hip replacement OR total knee replacement)) AND (propiocep OR balance OR neuromuscular OR sensory-motor OR functional exercise)) AND (control OR passive treatment OR usual physiotherapy care OR home based exercise OR educational program)) AND (functionality OR balance OR physical function OR pain OR QOL) AND (Clinical Trial [ptyp]).*

The electronic databases search will be supplemented by searching for trial protocols through metaRegister (<http://www.controlled-trials.com/mrct/>). Also a search was made in virtual platforms as Prospero (<http://www.crd.york.ac.uk/prospero/>) or Clinical trials (<https://clinicaltrials.gov>) to check if this protocol or review, or someone similar, was already ongoing.

2.4. STUDY RECORDS

Data management

Literature search results will be saved at Excel spreadsheet. Thus, duplicate articles will be removed. Zotero program (<https://www.zotero.org>) will be used to cite the reports.

Selection process

Two independent reviewers will screen the databases using the search strategies before mentioned. In a first stage, articles that, based on the title and abstract, seems to meet inclusion criteria, will be pre-included and their full text version will be get. With the full text version, all the articles will be checked again and those that do not meet inclusion criteria will be excluded. Once this stage is finished, the reviewers will put in common and discuss the results. In case of disagreement, a third author will be consulted.

Data selection process

The articles finally considered to be included will be collected in a common Excel spreadsheet. Relevant information about article will be shown in that document and all the authors of the review will be able to both consult and edit the document. In case of some relevant information of an article is missing, the author of the study will be contacted to resolve the questions and complete the missing information.

2.5. DATA ITEMS

Generic information of every article, such us title, authors and date of publication, will be registered. Also relevant information will be saved. We understand by relevant information the following items: number of participants, groups of participants, blinding, interventions, time of intervention and follow-up, time of measurements and results. All the results related to that outcomes will be drawn as mean and standard deviation, and in case of they will be marked as risk or odds ratios, they will be drawn as well like this.

Outcomes will be extracted when assessed with validated and usual scales used for reporting outcomes in TJR trials. For instance, and according to Theodoulou *et al.* (2016), self-reported functionality will be extracted when measured with the Knee Society Scoring System (18), Knee disability and Osteoarthritis Outcome Score, Hip disability and Osteoarthritis Outcome Score and Western Ontario and McMaster Universities Osteoarthritis Index functionality subscales (19, 20). Balance will be extracted from validated tests and scales as measured as the overall state of balance of the patient (i.e. Berg Balance Scale) (27), the static balance (i.e. Single leg stance balance) (28), the dynamic balance (i.e. Time up and go) (29, 30) or those balance performances registered in a dynamometric platform. Physical function will be considered when measured as the joint ROM or muscle strength. Pain is measured in terms of the VAS as well as the WOMAC, HOOS or KOOS pain sub-scales (22). Quality of life will be extracted when measured with validated self-reported health-related scales (23), for instance the short form SF-36 questionnaire or the WOMAC, HOOS or KOOS quality of life sub-scales, and the Euro-Qol-5D. Finally, the incidence of falls and the risk of falling (24) will be used when articles reflect the total numbers of falls during a specific period of time.

2.6. OUTCOMES AND PRIORITIZATION

Primary outcomes:

When a TJR surgery is conducted, one of the main objectives is to reduce pain and restore the patient's knee functionality. Functionality is widely used to assess the achievement of complete rehabilitation (5), as well as an important predictor (31), especially taking into account the high percentage of patients showing functional impairments after surgery, as explained before (32, 5). In trials related to TJR, self-reported functionality was established as the primary outcome (17). However, and taking into consideration that this review is focused on looking for the effectiveness of proprioceptive and balance trainings, we will consider balance as an additional primary outcome measure. Indeed, some authors have suggested that balance may be an important predictive factor for quality of life after

surgery (10) as it has been reported to be related to physical function. Moreover, it is also necessary to consider that one of the review objectives is to appraise the possible relation between the effects of balance training and patients' balance and functional outcomes. For this reason, we decided to include both functionality and balance as the primary outcomes.

Secondary outcomes:

Secondary outcomes that may be considered include Physical function, Pain, Quality of life, and Incidence of falls. Details of the way we assess these outcomes have been detailed in previous sections.

In the case of the absence of results of some parameter, it must be reflected in the articles and with the reason explained. Parameters used to assess the outcomes will be critically evaluated by the two authors independently, considering that there exists evidence to support their validity and reliability. It is required for any outcome that the studies included in the review assessed those measures at least at two different times (baseline and endpoint). Results must have a comparison between the different groups and the differences expressed by p values.

2.7. RISK OF BIAS IN INDIVIDUAL STUDIES

To facilitate the assessment of possible risk of bias in individual studies we will use the Cochrane Risk of Bias Tool (<http://methods.cochrane.org/bias/assessing-risk-bias-included-studies>) (33, 18). The sources of bias assessed by this tool are: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. A result table with the rationale and criteria for judgement will be reported or included in appendix. Studies will be catalogued as high, low or unclear risk of bias. These judgement will be made independently by the two investigators, while a third investigator will be asked in case of disagreement. The purpose of that is to ensure the maximal internal validity.

2.8. DATA SYNTHESIS

Random-effects meta-analysis will be used in case of homogeneity in the studies in terms of design and comparators. Once we will consider that data are appropriated for synthesis, we will use I^2 to analyze the results. All variables will be analyzed using weighted mean differences (95% confidence interval). Pooled estimates also will be calculated for each outcome. The strength of effect sizes will be interpreted as follows: values less than 0.4 will be considered weak, values from 0.41 to 0.7 will be considered moderate, and values greater than 0.7 will be considered strong. For the dichotomous outcomes, we will calculate risk ratios. We will do it following the guidelines of Cochrane Handbook for Systematic Reviews of Interventions, and because we will assume that in all the articles there is control group to compare, due to it was one of the inclusion criteria of the review. For the continuous outcomes we will use the mean differences and standardized mean differences depending on they use the same or different scale respectively.

2.9. META-BIAS (ES)

In order to explore publication bias, different actions will be made. For the studies published after July 1st 2005, we will screen the Clinical Trial Register at the International Clinical Trial Registry Platform of the World Health Organization (<http://apps.who.int/trialsearch/>). Also searches in grey literature will be made to reduce risk of publication bias. Funnel plots will be also done to ensure no restriction bias. Thus, an estimate of an underlying quantity is plotted against an interpretable measure of its precision. If there is no enough relative symmetry and distributions of comparisons, the study involved will be excluded due to risk of bias. Funnel plots are flexible, attractively simple and avoid spurious ranking of institutions into league tables (34).

2.10. CONFIDENCE IN CUMULATIVE ESTIMATE

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used in order to assign the quality of evidence of all outcomes (35). When results will be

displayed, we will judge them fit in one of the four grade scores reflecting the quality of the evidence: high, moderate, low or very low-quality evidence (36). The factors used to assign in one of that four grades will be: risk of bias, indirectness of evidence, inconsistency, imprecision of effect estimates and potential publication bias (37).

3. DISCUSSION

3.1. ABOUT THE WORKS ANALYZED

The results obtained from the selected works will be analyzed to extract conclusions that answer the questions formulated of the introductory section.

3.2 COMPARISON WITH OTHER REVIEWS

Once the results are analyzed, they will be compared to similar studies in terms of findings agreement and disagreement. Differences will be explained and discussed.

3.3 STRENGTHS AND WEAKNESSES

The aspects of the study that may contribute with more reliability and validity will be reported. By the other side, those aspects that may be source of bias, will be also reported.

3.4 CONSIDERATIONS FOR CLINICAL APPLICATION

Based on the evidence obtained from the analyses results, new recommendations for clinical application are planned to be drawn.

Ethics and funding: As it is a review of the existing literature, the informed consent of the participants is not required. The authors certify that they have no financial connection or commitment in any organization or entity with a direct economic interest in the matter addressed in the article.

Protocol Modification: Any substantial modification that occur in this protocol will be registered in PROSPERO and will be documented in the final publication

Authors' work: FD participated in the original idea, carrying out selection criteria and data extraction process, as well as drafting the manuscript. JMB also participated in the original idea, carrying out selection criteria and data extraction process, furthermore, he designed the methodological quality assessment strategy and risk of bias assessment. CI provided her experience in physiotherapy of aging processes for acceptance of the original idea, background and discussion, including interpretation of results, as well as methodological criteria. All authors read, corrected and approved the final protocol manuscript.