STUDY PROTOCOL

Title:

Effectiveness of a prehabilitation programme on clinical, functional, and psychological variables in candidates for hip or knee arthroplasty surgery. A randomized controlled trial.

Principal Investigator/ Study Coordinator: Irene María Lopera Pareja

Institution: Universidad de Jaén

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INTERVENTION PROTOCOL

1. Prehabilitation Program

The experimental group will receive a 6-week prehabilitation program for total hip/knee replacement surgery. Once the surgery is complete, these patients will follow the same rehabilitation program proposed for the control group.

The control group will undergo a post-operative physiotherapy program in addition to a home exercise program that will be shown and explained by the physiotherapist before discharge from hospital.

The application of a prehabilitation program supervised by a physiotherapist in the ward is proposed, with a frequency of 3 sessions per week planned on alternate days, with each patient receiving a total of 18 sessions. Each session lasts 30-45 minutes. In addition to the supervised program in the ward, a home exercise program is added with a frequency of seven sessions per week (one session per day).

The **prehabilitation program** is organized as follows:

1- **Warm-up and activation:** General joint mobility exercises to prepare for the main exercise block. Approximate duration of 5 minutes.

2- **Strength training with progressive loads**: It has an approximate duration of 20-30 minutes and is the main work block of the program. A series of exercises will be performed with work loads/intensities between 40-60% of the patient's RM. The planning of the weekly work percentages is planned as follows:

  o Weeks 1-2 work at 40% of the RM. 4 sets of 12 repetitions. 1 minute rest between sets

  o Week 3-4 work at 50% of RM. 4 sets of 10 repetitions. 1 minute rest between sets

  o Week 5-6 work at 60% of RM. 4 sets of 8 repetitions. 1 minute rest between sets

The main exercises in this block are:

- 90º squats with load

- Monster Walker or lateral march

- Loaded quadriceps work (concentric quadriceps or knee extension for 1 second and eccentric quadriceps lowering for 3 seconds)

- Deadlift

- Loaded step ups (Step up)

The workload percentages were estimated from the 1RM of each exercise proposed. These estimates were made in the initial evaluation of the prehabilitation program for its subsequent weekly adjustment. However, the workload is not increased if post-exercise pain greater than or equal to 5 appears on the numerical pain scale. In the opposite case of non-appearance of symptoms (pain less than 5 on the numerical pain scale), post-exercise complications and the possibility of completing each cycle, the work percentages will be increased as indicated above.

3-   **Cardiovascular training:** 10 minutes of aerobic exercise (on a stationary bike) will be performed in 5-minute sets at low-moderate intensity (40-60% of the FCRmax). The intensity of the work was established between values 4-5 on the modified Borg scale.

4-   **Cool down:** Relaxation exercises such as diaphragmatic breathing and gentle stretching for 5 minutes.

As mentioned above, a **complementary home program** of flexibility and proprioception exercises will be added. It will consist of daily sessions lasting 20-30 minutes.

The planned exercises were:

-    Hamstring and triceps surae stretches: 3-4 sets with 15 seconds of maintaining tension with 1 second of rest between sets.

To determine the intensity of the stretch, it will be assessed whether the subject is able to withstand the movement up to the final range of the same without exceeding values of 5 points on the numerical pain scale.

-    Active or self-assisted knee mobilizations (flexo-extension): 3-4 sets of 10 repetitions. 1 minute rest between sets.

-    Active hip mobilizations: 3-4 sets of 10 repetitions. 1 minute rest between sets.

-    Monopodal support: 3-4 sets with 15 seconds of monopodal support. 1 minute rest between sets.

The prehabilitation program is the same for patients with OA of the hip and/or knee who are awaiting arthroplasty surgery, without making distinctions between intensities, percentages of work or type of exercise.

2. Data collection and analysis

The independent variables will be collected at the beginning of the study during the interview with the patient. For the general analytical and biochemical parameters, data will be extracted from the pre-surgical and post-surgical control analyses carried out by the Orthopaedic Surgery and Traumatology service.

In general, the dependent variables will be collected before the start of the intervention after the intervention or at 6 weeks, immediately postoperatively (24/48 hours), at 3 weeks postoperatively and 6 months postoperatively. Figure 1 specifies the time planning for the measurement of the dependent and independent variables since not all questionnaires, scales or tests will follow the same collection pattern.

Regarding the data analysis, data regarding continuous variables will be described by means and standard deviations, while data regarding categorical variables will be described by frequencies and percentages.

The evaluation of normality and homoscedasticity of continuous variables will be carried out through the Kolmogorov-Smirnov and Levene tests respectively. The t-Student and Chi-square tests will be used to evaluate possible differences in baseline between groups, thus ensuring comparability between groups for each of the study variables.

In the evaluation of the effect of the pre-habilitation program over time (T0, T1, T2 T3, T4) compared to the control group, a 2x4 mixed model of repeated measures analysis of variance will be used, where the hypothesis of interest was the interaction between time and group. To determine the effect size (ES) of the interaction between time and group, the Eta-squared coefficient (η^2) will be used, which can be interpreted as the proportion of the differences between groups due to the effect of the different treatments. Thus, an ES can be considered insignificant if the value of η^2 is less than 0.02, small if it is between 0.02 and 0.15, medium if it is between 0.15 and 0.35, and large if it is greater than 0.35.

In addition, the Student t-test will be used for the change scores in order to check the differences between the groups at each assessment time point (T1, T2, T3, and T4), as well as a paired samples t-test to evaluate the differences within each of the groups over

the three assessment time points. In this case, Cohen's coefficient was used as an estimator of the TE, considering it irrelevant for values lower than 0.19, small when it is between 0.2 and 0.49, medium between 0.5 and 0.79 and large when the values are higher than 0.8.

	Intervention		Total duration		
	Week 1	Week 6	24/48h	Week 9	Week 24
	Pre-surgery		Post-surgery		
Age	■				
Sex	■				
Size	■				
Weigth	■	■		■	■
IMC	■	■		■	■
NPRS	■	■		■	■
TUG	■	■		■	■
STS	■	■		■	■
SF-12	■				■
Dynamometry	■	■		■	■
1RM	■	■		■	■
ICSP	■				■
GADS	■	■			■
Activity/Pharmacological Diary		■			
NHP			■		

Figure 1. Flowchart of the variable measurements. BMI: Body Mass Index / NPRS: Numeric Pain Rating Scale / TUG: Time Up and Go Test / STS: Sit to Stand Test / SF-12: SF-12 Health Questionnaire / RM: Maximum Repetition / ICSP: Pittsburgh Scale / GADS: Goldberg Anxiety and Depression Scale / NHP: Nottingham Health Profile Prepared by the authors.