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.

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Institution: Universidad de Jaén

NCT number: Not available

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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 (□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 □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.

		Total duration			
	Intervention				
	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.

INFORMED CONSENT FORM

INFORMED CONSENT FORM – PATIENT INFORMATION

Before signing this informed consent form, please carefully read the information provided below and ask any questions you may consider appropriate.

Nature:

Principal Investigators:
Irene María Lopera Pareja (1); Antonio Martínez Amat (1); Alexander Achalandabaso Ochoa (1); Juan Ramón Cano Porras (2)

Institution:
(1) University of Jaén; (2) Costa del Sol Hospital (Marbella)

Department:
(1) Health Sciences; (2) Orthopaedic Surgery and Traumatology

Field of Knowledge:
Human Anatomy and Embryology

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Title of the Study:
Effectiveness of a prehabilitation program on clinical, functional, and psychological variables in candidates for hip or knee arthroplasty surgery.

• Measurements and data collection will take place at the Estepona High Resolution Hospital and at the Costa del Sol Hospital (Marbella).

• Research line: Chronicity, dependency, and community health. Evaluation of the effect of a prehabilitation program on clinical and psychological variables in patients awaiting hip or knee arthroplasty.

Importance of the Study:

The objective of this study is to achieve, following participation in the prehabilitation program, an improvement in quality of life, a reduction of symptoms prior to surgery, and enhanced recovery after surgery.

Implications for the participant/patient:

• Participation is entirely voluntary.
• The participant may withdraw from the study at any time, without providing any explanation and without this affecting their medical care.
• All personal data obtained in this study will be confidential and processed in accordance

with Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights.
• The information obtained will be used exclusively for the specific purposes of this study.

Risks of the research:

Data will be collected through non-invasive and painless tests that do not involve any associated risk for participants.

For additional information, you may contact the research staff at the Costa del Sol Hospital by telephone at 951 97 68 48 or by email at:
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INFORMED CONSENT FORM – WRITTEN CONSENT OF THE PATIENT

"Effectiveness of a prehabilitation program on clinical, functional, and psychological variables in candidates for hip or knee arthroplasty surgery."

I (Full name): .....

• I have read the information sheet accompanying this consent form (Patient Information).
• I have had the opportunity to ask questions about the study.
• I have received sufficient information about the study and have spoken with the healthcare professional providing the information: .....

• I understand that my participation is voluntary and that I am free to decide whether or not to participate.
• I have been informed that all data obtained in this study will be confidential and processed in accordance with Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights.
• I have been informed that the information obtained will be used exclusively for the specific purposes of the study.
• I wish to be informed of any genetic or personal data obtained during the research, including any unexpected findings, provided that such information is necessary to prevent serious harm to my health or that of my biological relatives.

Yes No

I understand that I may withdraw from the study:
• At any time
• Without providing any explanation
• Without this affecting my medical care

I freely give my consent to participate in the project entitled "Effectiveness of a prehabilitation program on clinical, functional, and psychological variables in candidates for hip or knee arthroplasty surgery."

Patient's signature (or legal representative, if applicable) Signature of the informing healthcare professional

Full name: ..... Full name: .....
Date: ..... Date: .....

INFORMED CONSENT FORM – PATIENT INFORMATION

Intervention

1) The prehabilitation program consists of two components: a supervised exercise program carried out in a clinical setting and a home-based exercise program. The supervised exercise program will include: warm-up (5 minutes), strength exercises (20–30 minutes), cardiovascular exercise (stationary bicycle) (10 minutes), and cool-down (5 minutes). The home-based exercise program will consist of stretching and joint mobility exercises (20–30 minutes). Elastic bands, dumbbells, parallel bars, and other equipment will be used. All activities will be performed in a safe and appropriately equipped environment (physiotherapy room and other designated facilities) and supervised by the responsible physiotherapist. Following surgery, participants will follow the same rehabilitation program proposed for the control group.

2) If assigned to the control group, participants will perform a post-operative physiotherapy program in addition to a home-based exercise program, which will be demonstrated by the physiotherapist prior to hospital discharge.

• Duration: The exercise program will last six weeks with a frequency of three sessions per week. All measurements will be performed four times: immediately before and after the exercise program, and at three and six months following arthroplasty surgery. Each session will last approximately 30–45 minutes, including warm-up and cool-down phases. The home-based exercise program will also last six weeks, with a frequency of seven times per week and a duration of approximately 20–30 minutes per session.

The duration of the tests to obtain the study variables will be approximately 15–20 minutes in total, while the estimated time to complete the questionnaires and sociodemographic data will be approximately 20 minutes.

• Brief description of data collection procedures: All measurements are non-invasive. Quality of life will be assessed using the SF-12 Health Survey. Functional capacity will be evaluated using the Timed Up and Go (TUG) test, the Sit-to-Stand Test (STS), and the 6-Minute Walk Test (6MWT) to assess aerobic capacity. Muscle strength will be measured using a hand-held dynamometer. Pain will be assessed using the Numerical Rating Scale

(NRS). Psychological symptoms will be evaluated using the Beck Anxiety Inventory (BAI), the Beck Depression Inventory II (BDI-II), and the Pittsburgh Sleep Quality Index (PSQI).