PHYSICAL EXERCISE GUIDED BY ACTIVE VIDEO GAMES FOR OPTIMIZING CLINICAL AND PSYCHOSOCIAL OUTCOMES IN OLDER ADULTS WITH KNEE AND/OR HIP OSTEOARTHRITIS UNDER A COMMUNITY-BASED REHABILITATION MODEL.

Date: November 28th, 2022

Study documents

1. GENERAL INFORMATION.

- **Unique Protocol ID**: UNAB-FCR-KINE2023B
- **Brief Title:** Active Video Games for Older Adults With Knee and/or Hip Osteoarthritis.
- **Official Title**: Physical Exercise Guided by Active Video Games for Optimizing Clinical and Psychosocial Outcomes in Older Adults With Knee and/or Hip Osteoarthritis Under a Community-based Rehabilitation Model.
- **Study Type:** Interventional
- **Number of Arms:** 2

2. SCIENTIFIC BACKGROUND.

Osteoarthritis (OA) is highly prevalent, and its incidence increases with aging populations (1). OA is characterized by articular cartilage degeneration, stiffness, inflammation, and musculoskeletal pain (2). In addition, the associated deterioration of health-related quality of life may influence therapeutic adherence and progression to future joint replacement (3,4). It appears that symptoms rather than structural impairment determine the risk of falling in older people with OA (5), so pain, loss of strength, and postural balance are underlying mechanisms for both falls and the clinical picture of OA itself (6). Moreover, the psychosocial sequelae are often underestimated because OA and pain are usually considered benign and unavoidable consequences of aging (7).

Physical exercise in people with knee and hip OA improves clinical aspects and psychosocial aspects such as self-efficacy, social function, and reduction of depression and isolation, among others (8,9). Adherence to exercise is fundamental and is closely related to user satisfaction (10,11). There are several barriers to physical exercise by older adults, such as lack of social support, transportation problems, and prioritization of basic needs; however, a determining factor is lack of motivation (12). In this regard, a study indicates that in Latin America, lack of motivation is among the main reasons for abandoning physical exercise (13).

The technological development of the last decades has allowed the incorporation of virtual reality into the healthcare field, favoring user motivation (14,15). Virtual reality is an experience based on the interactive digital simulation of environments and objects (14,16). These systems are categorized as non-immersive, semi-immersive, and immersive. Non-immersive systems use monitors or television screens, semi-immersive

systems use panoramic screens to enhance the immersive experience, and immersive systems use head-mounted displays or multi-projected environments that generate a strong sense of immersion (17). It has been posited that the cost and expertise required to operate immersive systems may hinder their widespread use in clinical settings (18). In addition, the immersive sensation could produce symptoms such as visual fatigue and dizziness (cybersickness). On the other hand, non-immersive systems using commercially available home consoles are now considered an attractive and more accessible alternative to more sophisticated immersive systems (19,20).

Unlike traditional video games that use a standard command or joystick, active video games (AVGs) (also called exergames) use motion monitoring systems such as accelerometers, gyroscopes, haptic technology, and video capture (16). AVGs have been defined as a "combination of video game technologies and exercise routines to motivate physical activity among individuals or groups," recognizing that exercise in older people requires a greater understanding of the complexity of interaction with computer systems (21).

Conventional physical rehabilitation (CPR) consists of traditional physical exercises that improve functional capacity (22,23). Over the past few years, it has been suggested that incorporating AVGs into CPR can optimize clinical and psychosocial outcomes in the elderly (24-26). AVGs have been reported to promote improvements in functional mobility, coordination, muscle strength, and cognitive function in older people (27-29). In addition, AVGs improve walking ability (30) and postural balance (31), as well as social well-being (perception of loneliness, social connectedness, and positive attitudes) (24). However, this research has focused on healthy elderly (30-33) and patients with neurocognitive pathologies (29,34-37). On the other hand, little information is available on older people with musculoskeletal conditions such as OA (38-40). In this regard, a systematic review conducted in patients with knee and/or hip OA indicates that the evidence is insufficient and inconclusive regarding the effectiveness of AVGs (38). Moreover, one study concludes that AVGs are a feasible and acceptable intervention for patients with knee OA (39). Interestingly, both studies raise the benefits and potential of AVGs in this population, urging further clinical trials (38,39).

3. RESEARCH QUESTION AND HYPOTHESIS.

- **Research question:** In older adults with knee and/or hip OA. Is AVG-guided physical exercise adjunct to CPR more effective than CPR alone in improving clinical and psychosocial outcomes?
- **Working hypothesis:** In older adults with knee and/or hip OA, AVG-guided physical exercise adjunct to CPR is more effective than CPR alone in improving clinical and psychosocial outcomes.

4. OBJECTIVES.

General objective: To determine the effects of an AVG-guided physical exercise program adjunct to CPR on clinical and psychosocial outcomes in older adults with knee and/or hip OA attended at a community-based family health center.

Specific objectives:

1. To characterize the study sample from sociodemographic, anthropometric, clinical, and psychosocial perspectives.
2. To compare the results of the primary outcome (functional mobility) and secondary outcomes between the study groups (experimental and control) in the different instances of outcome measurement.
3. To evaluate the clinical significance of the interventions and the clinical relevance of the interventions as perceived by the participants.

5. METHODS.

Study design and setting.

The design is a two-arm parallel randomized clinical trial (RCT) and will be conducted according to the CONSORT statement. A control group (CG) will perform CPR, and an experimental group (EG) will perform AVG adjunct to CPR. Subjects will be invited to participate upon admission to the rehabilitation unit of a family health center. All study requirements will be explained, and all subjects will be required to sign an informed consent form.

Sample calculation.

The a priori calculated sample size using G*Power yielded 50 subjects. Statistical power (1-β)=0.8 and significance (α)=0.05 were considered. In addition, a moderate effect size (ES)=0.51 was considered for the TUG test (functional mobility) to

detect a minimum clinically important difference (MCID) of 1.4 seconds. Ten subjects will be added for a potential dropout of 20%, finally estimating a sample of 60 subjects (CG=30; EG=30).

Participation criteria.

- Inclusion criteria: Age ≥60 and ≤84 years; Diagnosis of mild or moderate OA of the knee and/or hip; Independent walking capacity of at least 15 meters
- Exclusion criteria: Inability to interact with active video games; Undergoing treatment with opioids or other medications with a potential influence on the outcomes of interest; <13 points in the abbreviated version of the Mini-Mental State Examination (MMSE-EFAM); OA associated with infectious, autoimmune, fractures or surgery; Participate or have participated in another physical-cognitive rehabilitation program during the last 3 months.

Randomization and allocation concealment.

A stratified randomization will be applied to balance the two study groups according to "age" (60-69, 70-79, 80-84 years) and "sex" (male, female). Allocation concealment will be ensured through sealed and consecutively numbered opaque envelopes.

Sample characterization.

Sociodemographic (age, sex, and education) and clinical characteristics (diagnosis of OA, comorbidity, history of falls, technical aids, and pharmacotherapy) will be collected by interview. In addition, height, body weight, and body mass index will be measured.

Study outcomes.

An experienced physical rehabilitation professional will perform the measurements in a blinded manner.

a) Primary outcome measure:

- Functional mobility. Timed Up and Go (TUG). Number of seconds required to get up from seated position, walk 3 m, turn, and return to seated position on chair. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.

b) Secondary outcome measures:

- Lower body strength: 30-s chair stand. Number of full stands in 30 s with arms folded across chest. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Upper body strength. 30-s arm curl. Number of bicep curls in 30 s holding hand weight (women 5 lb; men 8 lb). Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Aerobic endurance. 2-min step test. Number of full steps completed in 2 min, raising each knee to point midway between patella and iliac crest (score is number of times right knee reaches target). Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Lower body flexibility. Chair sit-and-reach. From sitting position at front of chair, with leg extended and hands reaching toward toes, number of inches (+or −) from extended fingers to tip of toe. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Upper body flexibility. Back scratch. With one hand reaching over shoulder and one up middle of back, number of inches between extended middle fingers (+ or −). Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Hand grip strength. Number of kg measured with a Jamar dynamometer. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.

- Functional disability. Western Ontario McMaster Osteoarthritis Index (WOMAC) questionnaire. Score obtained on the scale of items grouped into 3 dimensions: pain, stiffness, and difficulty in performing tasks. Scores range from 0 to 96, where 0 represents the best health status and 96 the worst possible status. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Cognitive performance. Montreal Cognitive Assessment (MoCA) test. Score obtained in the development of the tests. It considers executive functions, attention, abstraction, memory, language, viso-constructive abilities, calculation, and orientation. MoCA scores range from 0 to 30; higher scores indicate a better cognitive performance. Time Frame: Three-time points. Baseline (pre-intervention); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Pain intensity. Visual Analog Scale (VAS). 100 mm straight line with two labels ("no pain" and "worst possible pain") at each end. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Pressure pain threshold. Wagner® FPX-25 algometer. It is expressed in kilogram/cm2. Time Frame: Five-time points. Baseline (pre-intervention); at week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Health-related quality of life. SF-12v2 Chile-Spanish Questionnaire. Score from 0-100 points. Assessment of 8 dimensions (physical functioning [PF], role-physical [RP], bodily pain [BP], general health [GH], vitality [VT], social functioning [SF], role-emotional [RE], and mental health [MH]), and two summary scores (physical component summary [PCS] and mental component summary [MCS]). Time Frame: Three-time points. Baseline (pre-intervention); and week 10 (after 30 sessions from baseline). In addition, four weeks after the completion of the intervention.
- Adherence to treatment. Number of effective assistances at the end of treatment. A participant with an attendance ≥2/3 of the total (30 sessions) is considered "adherent"

(≥20 sessions). Time Frame: One-time point. At week 10 (after 30 sessions from baseline).

- User satisfaction. The average score of 3 questions (overall level of satisfaction, expectation fulfillment, and recommendations to others) using a scale of 1 to 7 points, where 1 is the worst evaluation, and 7 is the best evaluation. Time Frame: Three-time points. At week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline).
- Therapeutic alliance. Subscale of the Pain Rehabilitation Expectations Scale (PRES). The score ranges from 1 to 44; a higher score is a higher therapeutic alliance. Time Frame: Three-time points. At week 4 (after ten sessions from baseline); at week 7 (after 20 sessions from baseline); and week 10 (after 30 sessions from baseline).

Interventions.

Two experienced physiotherapists will perform the interventions. For both groups, the duration will be ten weeks with a frequency of 3 sessions per week (30 sessions). The intensity of the interventions in both groups will be controlled using a scale of 0 to 10 points, adjusting individually as "light" (effort <5) and "moderate" (effort 5 to 6). For the progression of intensity, it is considered: i) Session 1 to 10 "light" 70% and "moderate" 30% of the session time; ii) Session 11 to 20 "light" 50% and "moderate" 50% of the session time; iii) Session 21 to 30 "light" 30% and "moderate" 70% of the session time. Adverse events, medications, and general health status will be monitored throughout the experimental period. The interventions are described below:

- Control Group (CG): Will receive a routine of four blocks of conventional exercises (50 minutes per session): Aerobic, muscle strengthening, postural balance, and flexibility. A warm-up phase will be performed before the exercise routine and a cool-down phase after the routine. In addition, before and after the session, physical agents will be applied in a standardized manner (electrotherapy and thermotherapy).
- Experimental group (EG): Will perform the same procedures as the CG, although the conventional exercise routine will last 30 minutes. Then, this group will perform an AVG intervention for 20 minutes so that the exercise time will be the same in both groups (50 minutes per session). The week before the interventions start, this group's participants will have a familiarization session with the AVGs. The AVG routine will be performed using a set of selected exercises and dynamic activities from the "Ring fit adventure" video game available for the Nintendo Switch® console.

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STATISTICAL ANALYSIS PLAN (SAP)

The description of quantitative indicators (continuous or discrete) will be done using measures of central tendency (mean or median) and dispersion (standard deviation, interquartile ranges, and confidence intervals) according to their normality distribution. For the description of categorical variables (nominal and ordinal), absolute and relative frequency measures will be used. The R v.4.1.2 software will be used for the analyses ($p<0.05$). The assumptions of normality and homoscedasticity will be verified using the Shapiro-Wilk and Levene tests, respectively. For variables that do not meet the assumption of normality, a two-step rank transformation will be applied. A two-way, repeated measures ANOVA will be used to determine intragroup and intergroup differences. Model effects are Group, Time, and their interaction over time (Group x Time). Tukey's post hoc test will be used for variables with Group × Time interaction. The statistical analyst will be blinded for the intervention groups, and in addition, an intention-to-treat analysis (multiple imputation method) will be considered for handling potential incomplete data. Clinical significance (ES) of interventions will be determined using Cohen's "d" (<0.2=negligible, 0.2-0.49=small, 0.5-0.79=moderate; ≥0.8=large). Additionally, at the end of the intervention, patients will be asked to rate their overall change in clinical status (pain and functionality) using a 15-point scale. The global rating of change ranges from +7 (“a very great deal better”) to 0 (“about the same”) to –7 (“a very great deal worse”). The interpretation of changes is: 1-3 points=small, 4-5=moderate, and 6-7=large.